



DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year
2011

Public Health and Social
Services Emergency Fund

*Justification of
Estimates for
Appropriations Committees*



We are pleased to present the FY 2011 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). This budget request directly supports the Nation's ability to prepare for, respond to, and recover from the health consequences of naturally occurring and manmade threats. The

PHSSEF submission includes the FY 2011 budget justifications for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Pandemic Influenza, Cyber-Security in the Office of the Assistant Secretary for Administration (ASA), the Medical Reserve Corps in the Office of Public Health and Science (OPHS), and the Office of Security and Strategic Information (OSSI).

This justification includes the FY 2011 Annual Performance Plan and the FY 2009 Annual Performance Report as required by the Government Performance and Results Act of 1993. Efforts to measure and report on results-oriented performance provide information to stakeholders on progress toward achieving established goals and objectives.

Today, we face a wide range of both natural and man-made threats that can have an impact on the public health of our Nation. We must be prepared for all contingencies – whether an anthrax attack, a dirty bomb, or another new flu strain for which we have limited immunity. Appropriate preparedness and timely response to public health events are critical to mitigate the consequences of such an event. Responses to these challenges call on every aspect of our healthcare infrastructure – from our first responders to our partners in industry developing new countermeasures – and demand our most robust efforts. The FY 2011 request includes a total of \$1.1 billion for ASPR, an increase of +\$162 million. These funds represent critical investments in our Nation's security and include advanced development of medical countermeasures for chemical, biological, radiological and nuclear (CBRN) threats; strategic planning and operational coordination; and improved preparedness, response, and resiliency for Federal, State, and local entities.

In December 2009, Secretary Sebelius announced a review of the public health countermeasures enterprise with the goal of improving our ability to prepare for, respond to, and recover from public health threats. Improving this system is an iterative process and represents a long-term commitment to preparedness. However, there are steps we can take now to make progress in critical areas. We need to look to the fastest ways to move to new technologies that will let us quickly produce countermeasures that are more dependable and more robust. As such, this budget includes \$476 million for advanced development and the authority to allocate additional funds for this purpose. This flexibility would enable ASPR to target resources to the most promising countermeasure candidates whether through advanced development or through a Project BioShield procurement.

The FY 2011 President's Budget also requests \$66 million for on-going activities in the Office of the Secretary to address Pandemic Influenza preparedness. These funds support international in-country advanced development and industrialization of human pandemic influenza vaccine production, and the development of point-of-care diagnostic devices.

The HHS IT Security Program ensures that the appropriate levels of security are in place to protect the sensitive information systems and data that support the mission and functions of

HHS. The FY 2011 request of \$37 million will implement security upgrades and reconfiguration of the Department's network infrastructure. This will provide additional layers of security protections needed to prevent IT system compromises and the loss of sensitive data. The program will also continue to enhance enterprise-wide capabilities to continuously monitor the Department's computers and networks for security incidents and attacks.

A total of \$13 million is included in the FY 2011 President's Budget for the Medical Reserve Corps. The Medical Reserve Corps is comprised of organized medical and public health professionals who serve as volunteers to respond to natural disasters and emergencies. These volunteers assist communities nationwide during emergencies and with ongoing efforts in public health. Medical Reserve Corps units represent those at the local level, as they are responsible for implementing volunteer capabilities for emergency medical response and public health initiatives to match specific community needs.

The President's Budget includes \$6.5 million for the Office of Security and Strategic Information (OSSI). OSSI serves as a representative of and principal advisor to the Secretary and Deputy Secretary on issues concerning national security, strategic information, intelligence, physical and personnel security policy, security awareness, classified information communications security, and related medical, public health, and biomedical information matters. OSSI has Department-wide responsibility for coordination, convergence, and oversight of all aspects of integrating national security information including classified and unclassified intelligence and is the Original Classification authority for the Department. OSSI also conducts other operations that are classified and cannot be fully described here.



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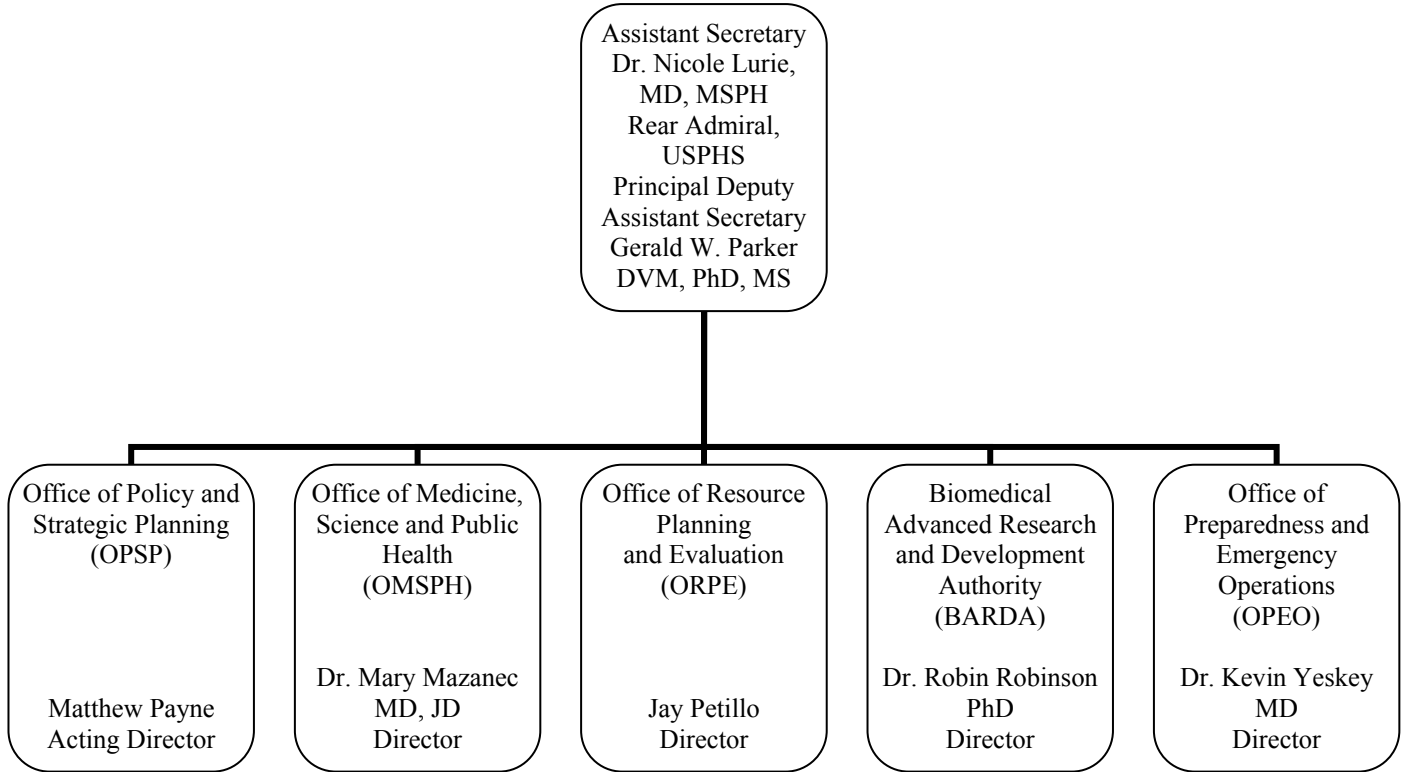
RADM Arthur J. Lawrence, Ph.D.
**Director of the Office of Security and
Strategic Information**

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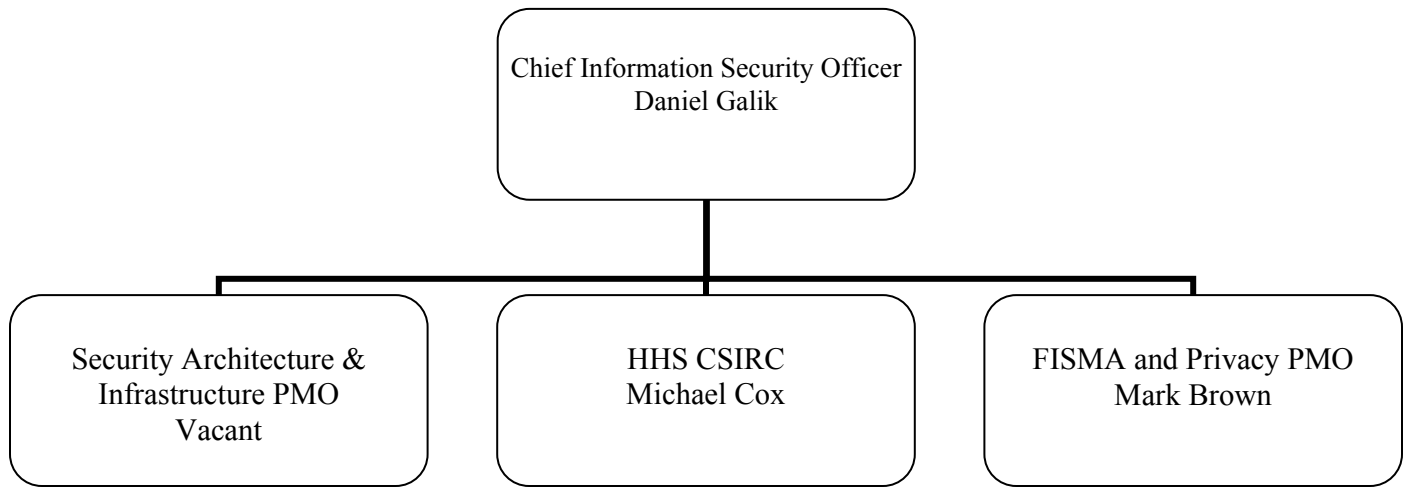
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Organizational Charts

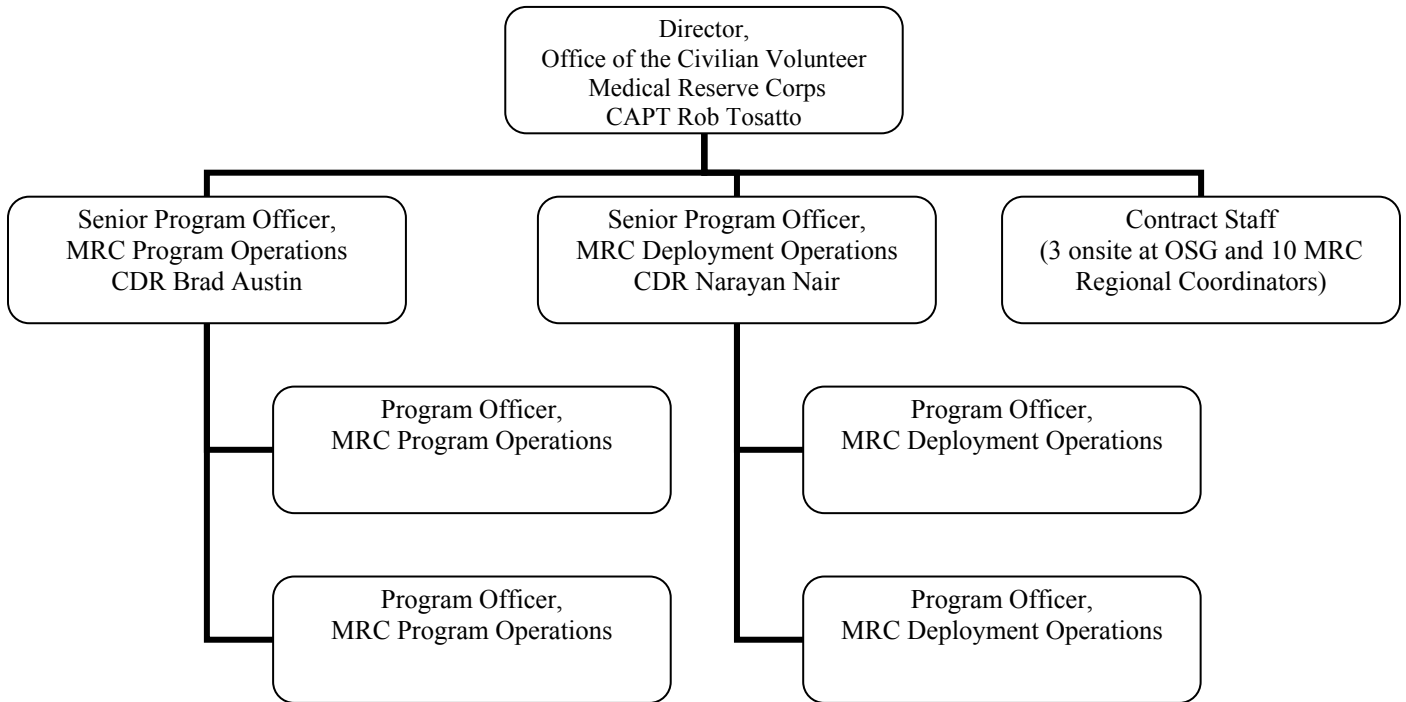
Office of the Assistant Secretary for Preparedness and Response (ASPR)



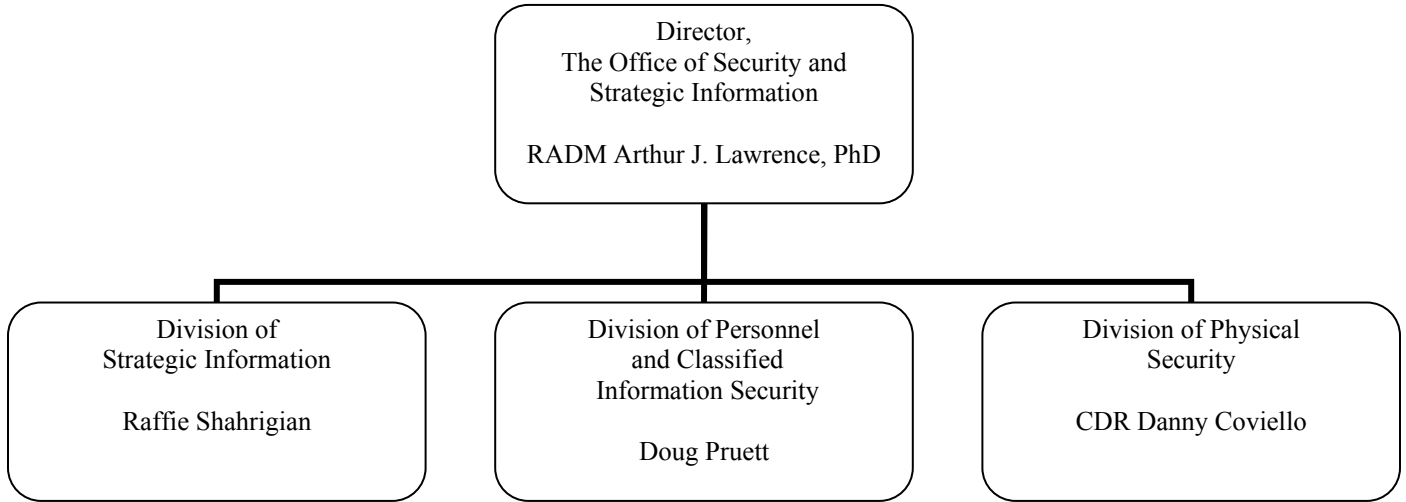
Office of IT Security



OSG/Office of the Civilian Volunteer Medical Reserve Corps



Office of Security and Strategic Information



Executive Summary

The FY 2011 Program Level request for the Public Health and Social Services Emergency Fund (PHSSEF) is \$1,540,506,000, an increase of \$193,812,000 and +91 FTE above the FY 2010 enacted level. These funds will provide the necessary resources to:

- Support a more comprehensive program to prepare for the health and medical consequences of bioterrorism and other public health emergencies;
- Build on the Department's cyber-security efforts; and,
- Support the Department's security activities.

The budget justification includes funds requested within the Office of the Secretary (OS) for the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Assistant Secretary for Administration (ASA), and the Office of Public Health and Science (OPHS). This justification also requests funding for the Office of Security and Strategic Information (OSSI), the Department's Pandemic Influenza Initiative, and the Parklawn lease replacement.

Programmatic Increases:

- Assistant Secretary for Preparedness and Response (+\$162 million) to expand support for advanced development of medical countermeasures, plan and prepare for National Security Special Events, improve regional hospital emergency care, and improve its ability to provide expert advice to the Secretary and others during public health emergencies.
- Cyber Security (+\$10 million) to build on work started in FY 2009 with the \$50 million for IT Security in HHS provided by the Recovery Act. These funds will enable HHS to implement security architecture upgrade plans and strategies that will ensure that the most critical data and systems are appropriately protected utilizing a cost effective, risk-based approach to security.
- Office of Security and Strategic Information (+\$1.6 million) to secure, enhance and strengthen HHS critical assets, fulfill numerous presidential directives, ensure processing of an increasing number of security clearances and analyze/disseminate sensitive information.
- Pandemic Influenza (+55 million) to enhance the Nation's preparedness for a future pandemic by increasing vaccine production capacity, developing new classes of antiviral drugs, and supporting the development and testing of rapid diagnostics.

Programmatic Decreases:

- Parklawn Replacement (-\$35 million) to support build-out costs for the Parklawn Building replacement as it relates to relocation expenses, as well as repositioning HHS within the Parklawn Building under a short term lease extension.

Public Health and Social Services Emergency Fund
(Dollars in thousands)

	FY 2009	FY 2009	FY 2010	FY 2011
	<u>Appropriation</u>	<u>Recovery Act</u>	<u>Appropriation</u>	<u>President's Budget Request</u>
Assistant Secretary for Preparedness and Response				
Preparedness and Emergency Operations.....	\$22,225	--	\$33,065	\$44,153
National Disaster Medical System.....	49,500	--	56,037	56,540
Hospital Preparedness.....	393,585	--	426,000	426,000
Medical Countermeasure Dispensing.....	--	--	10,000	10,000
Biomedical Advanced Research and Development....	306,052	--	340,531	476,194
Medicine, Science, and Public Health.....	8,690	--	8,748	10,000
Policy, Strategic Planning, and Communications.....	4,292	--	4,367	8,000
Operations.....	12,847	--	12,847	12,847
Co-Located Office Facility.....	--	--	--	10,000
<i>Subtotal, ASPR Program Level.....</i>	797,191	--	891,595	1,053,734
Assistant Secretary for Administration				
CyberSecurity.....	8,906	50,000	27,040	37,040
Office of Public Health and Science				
Medical Reserve Corps	12,344	--	12,581	12,694
Office of the Secretary				
Office of Security and Strategic Information.....	3,263	--	4,893	6,460
Pandemic Influenza.....	8,026,091	--	341,000	395,578
Parklawn Replacement.....	--	--	69,585	35,000
BioShield.....	1,763,000	--	--	--
Total, PHSSEF Program Level.....	\$10,610,795	\$50,000	\$1,346,694	\$1,540,506
Less funds from other Sources				
Pandemic Influenza FY 2009 Supplemental Balances	--	--	--	(330,000)
Shift of BioShield balances to other purposes.....	--	--	(609,000)	(476,194)
Total, PHSSEF Budget Authority.....	\$10,610,795	\$50,000	\$737,694	\$734,312

FY 2011 Proposed Appropriations Language

For expenses necessary to support activities related to countering potential biological, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies [and to pay the costs described in section 319F-2(c)(7)(B) of the Public Health Service Act ("PHS Act"), \$617,942,000], \$623,734,000; of which [\$33,065,000] \$44,153,000 shall be to support preparedness and emergency operations, of which [\$5,000,000] \$15,000,000, to support expenses due to response efforts, shall remain available [through September 30, 2011] *until expended*; and of which \$10,000,000, to remain available through September 30, [2011] 2012, shall be to support the delivery of medical countermeasures: Provided, That of the amount made available herein for the delivery of medical countermeasures, up to \$8,000,000 may be transferred to the U.S. Postal Service to support delivery of medical countermeasures.

[For] *From funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to \$476,194,000 shall be available for expenses necessary to support advanced research and development pursuant to section 319L of the [PHS] Public Health Service Act ("PHS Act"), [\$305,000,000, to be derived by transfer from funds appropriated under the heading "Biodefense Countermeasures" in the Department of Homeland Security Appropriations Act, 2004, to remain available through September 30, 2011] and other administrative expenses of the Biomedical Advanced Research and Development Authority: Provided, That the Secretary may increase this limitation 15 days after notifying the Committees on Appropriations of the House of Representatives and the Senate of the intent to do so to support additional advanced research and development pursuant to section 319L of the PHS Act.*

For expenses necessary to prepare for and respond to an influenza pandemic, [\$354,167,000, of which \$276,000,000 shall be available until expended, for activities including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools: Provided, That products purchased with these funds may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F-2(a) of the PHS Act: Provided further, That notwithstanding section 496(b) of the PHS Act, funds may be used for the construction or renovation of privately owned facilities for the production of pandemic influenza vaccines and other biologics, if the Secretary finds such construction or renovation necessary to secure sufficient supplies of such vaccines or biologics: Provided further, That funds appropriated herein may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this paragraph] \$65,578,000.

[All remaining balances from funds appropriated under the heading "Biodefense Countermeasures" in the Department of Homeland Security Appropriations Act, 2004, shall be transferred to this account, and shall remain available for obligation through September 30, 2013, for the procurement of medical countermeasures pursuant to section 319F-2(c) of the PHS Act: Provided, That products purchased with these funds shall be deposited in the Strategic National Stockpile under section 319F-2(a) of the PHS Act.]

For expenses necessary for fit-out and other costs related to a competitive lease procurement to renovate or replace the existing headquarters building for Public Health Service agencies and other components of the Department of Health and Human Services, [\$69,585,000] \$35,000,000, to remain available until expended; *and, in addition, for fit-out and other costs*

related to the consolidation of office space for the Office of the Assistant Secretary for Preparedness and Response, \$10,000,000, to remain available until expended.

Language Analysis

Language Provision

“From funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to \$476,194,000 shall be available for expenses necessary to support advanced research and development pursuant to section 319L of the Public Health Service Act (“PHS Act”) and other administrative expenses of the Biomedical Advanced Research and Development Authority”

“Provided, That the Secretary may increase this limitation 15 days after notifying the Committees on Appropriations of the House of Representatives and the Senate of the intent to do so to support additional advanced research and development pursuant to section 319L of the PHS Act.”

“and, in addition, for fit-out and other costs related to the consolidation of office space for the Office of the Assistant Secretary for Preparedness and Response, \$10,000,000, to remain available until expended.”

Explanation

This language will allow HHS to use up to \$476 million in current BioShield balances for either BioShield procurements or for advanced research and development activities. Funds will retain their original period of availability. Language will also make funds available for management of BARDA, Project BioShield, and ASPR’s pandemic influenza activities.

This language gives the Secretary the authority to make addition funds, beyond the \$476 million provided in the previous provision, from BioShield balances available for advanced development activities after notification of Congress.

This language provides no-year funding for the leasing and fit-out costs to relocate the staff of the Office of the Assistant Secretary for Preparedness and Response from five locations to two locations.

Amounts Available for Obligation¹

	FY 2009 <u>Enacted</u>	FY 2010 <u>Enacted</u>	FY 2011 <u>President's Budget</u>
Annual Appropriation	\$585,795,000	\$681,109,000	\$664,312,000
Multi-Year Appropriation	305,000,000	2,744,000,000	10,000,000
Supplemental (P.L. 111-5)	<u>50,000,000</u>		
Subtotal Multi-Year Appropriations	355,000,000	2,744,000,000	10,000,000
No-Year Appropriation	507,000,000	345,585,000	60,000,000
Supplemental (P.L. 111-32)	<u>7,450,000,000</u>		
Subtotal Multi-Year Appropriations	7,957,000,000	345,585,000	60,000,000
Total, adjusted budget authority	8,897,795,000	3,770,694,000	734,312,000
Unobligated balance, start of year	1,140,784,000	7,109,303,592	7,811,832,300
Unobligated balance, end of year	7,109,303,592	7,811,832,300	7,144,438,310
Unobligated balance lapsing	--	--	--
Total obligations	2,929,275,408	3,068,165,292	1,401,705,990
Obligations less ARRA	\$2,921,169,350	\$3,026,271,350	\$1,401,705,990

¹ Excludes reimbursable activities carried out by this account and evaluation fund transfers.

Summary of Changes

2010 Comparable Enacted Level	
Total estimated budget authority	\$737,694,000
2011 President's Budget	
Total estimated budget authority	\$734,312,000
Net change	(\$3,382,000)

	2010 Enacted		Change from Base	
	<u>Budget Base</u>		<u>Change from Base</u>	
	<u>(FTE)</u>	<u>Budget Authority</u>	<u>(FTE)</u>	<u>Budget Authority</u>
<u>Increases:</u>				
Cyber-Security		\$27,040,000		+\$10,000,000
Office of Security and Strategic Information (OSSI)		\$4,893,000		+\$1,567,000
Medical Reserve Corps		<u>\$12,581,000</u>		<u>+\$113,000</u>
Total Increases	580	\$44,514,000	+91	+\$11,680,000
<u>Decreases:</u>				
Assistant Secretary for Preparedness and Response		\$586,595,000		(\$9,055,000)
Pandemic Influenza		\$341,000,000		(\$275,422,000)
Parklawn Replacement		<u>\$69,585,000</u>		<u>(\$34,585,000)</u>
Total Decreases		\$997,180,000		(\$319,062,000)
Net Change			+91	(\$307,382,000)

Budget Authority by Activity
(Dollars in thousands)

	FY 2009		FY 2009		FY 2010		FY 2011	
	<u>Actual</u>		<u>Recovery Act</u>		<u>Enacted</u>		<u>President's Budget</u>	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
Bioterrorism	457	\$821,704	--	\$50,000	572	\$327,109	663	\$623,734
Pandemic Influenza	8	8,026,091	--	--	8	341,000	8	395,578
Buildings and Facilities	--	--	--	--	--	69,585	--	45,000
TOTAL	465	\$8,847,795	--	\$50,000	580	\$737,694	671	\$1,064,312

Authorizing Legislation

	FY 2010		FY 2011	
	<u>Amount Authorized</u>	<u>Enacted</u>	<u>Amount Authorized</u>	<u>President's Budget</u>
Pandemic and All-Hazards Preparedness Act, 2006 and the Public Health Security and Bioterrorism Preparedness and Response Act, 2002	} } }		\$1,346,694,000	\$1,540,506,000

Appropriations History (Non-Comparable)

	<u>Budget Estimate to Congress</u>	<u>House Allowance</u>	<u>Senate Allowance</u>	<u>Appropriation</u>
<u>FY 2002</u>				
Appropriation	250,619,000	300,619,000	250,619,000	2,429,490,000
Defense Approp				2,644,315,500
Rescission				-1,396,000
<u>FY 2003</u>				
Appropriation	1,806,180,000	2,507,184,000	2,306,580,000	2,246,680,000
Rescission				-14,604,000
Transfer to Dept of Homeland Security (DHS)				-427,638,000
Supplemental Appropriation				142,000,000
<u>FY 2004</u>				
Appropriation	1,896,149,000	1,776,846,000	1,856,040,000	1,776,846,000
Rescission				-10,483,000
Transfer from DHS				397,640,000
<u>FY 2005</u>				
Appropriation	61,456,000	61,456,000	61,456,000	161,456,000
Rescissions				-1,389,984
Supplemental Appropriation				60,000,000
<u>FY 2006</u>				
Appropriation	203,589,000	60,633,000	60,633,000	63,589,000
Rescissions				-635,890
Transfer to CMS				-43,245
Supplemental Appropriation				5,570,000,000
<u>FY 2007</u>				
Appropriation	218,413,000	160,475,000	166,907,000	602,200,000
Supplemental Appropriation				99,000,000
<u>FY 2008</u>				
Appropriation	1,729,211,000	1,705,382,000	1,674,556,000	729,295,000

	<u>Budget Estimate to Congress</u>	<u>House Allowance</u>	<u>Senate Allowance</u>	<u>Appropriation</u>
<u>FY 2009</u>				
Appropriation	2,300,831,000	1,443,827,000	1,251,758,000	3,160,795,000
Supplemental				
Appropriation (PL 111-5)		900,000,000	870,000,000	50,000,000
Appropriation (P.L. 111-32)				7,650,000,000
Transfer to CDC				-200,000,000
 <u>FY 2010</u>				
Appropriation	2,678,569,000	\$2,100,659,000	\$2,621,154,000	\$3,770,694,000
 <u>FY 2011</u>				
Estimate	\$734,312,000			

Office of the Assistant Secretary for Preparedness and Response Summary of Request

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Program Level	\$797,191,000	\$891,595,000	\$1,053,734,000	+\$162,139,000
<i>Budget Authority (non-add)</i>	\$522,191,000	\$586,595,000	\$577,540,000	-\$9,055,000
<i>Other Sources (non-add)*</i>	\$275,000,000	\$305,000,000	\$476,194,000	+171,194,000
FTE	427	515	598	+83

NOTE: Comparable adjustments for funding and FTE have been made for the consolidation of BARDA funding sources, including Pandemic Influenza management, proposed in FY 2011.

** The President's Budget proposes to make funds from the Project BioShield Special Reserve Fund available for BARDA advanced development and other activities.*

The mission of the Office of the Assistant Secretary for Preparedness and Response (ASPR) – to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters – and its vision – a Nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters – reflect the essential role ASPR plays within the Nation's public health preparedness and emergency response arena. ASPR focuses its efforts on promoting community preparedness and prevention; building public health partnerships with Federal departments and agencies, academic institutions and private sector partners; and coordinating Federal public health and medical response capability.

In FY 2011 the total request is \$1,053,734,000, which includes \$476,194,000 made available from the Project BioShield Special Reserve Fund, an increase of +\$162,139,000 above FY 2010. The request consolidates funding sources supporting ASPR's Biomedical Advanced Research and Development Authority (BARDA) operations, including Pandemic Influenza management funding which has previously been provided as part of the Office of the Secretary Pandemic Influenza funding.

The request includes:

- \$40.8 million, an increase of +\$14.9 million over FY 2010, to support ASPR strategic oversight and operational coordination for preparedness and response activities. Increases will support development of a research agenda to achieve National Health Security Strategy (NHSS) activities and analysis of the impact of the NHSS, and expanded biosecurity and biosafety activities. Also, \$10 million is requested to improve operational efficiency by co-locating approximately 90% of ASPR staff in a single facility.
- \$536.7 million, an increase of +\$11.6 million over FY 2010, to improve Federal, State and local capacity and capabilities in emergencies. Also, a total of \$15 million, an increase of +\$5 million will support responses to National Special Security Events (NSSEs) and other planned and unplanned emergencies.

- \$476.2 million, an increase of +\$135.7 million, to the Biomedical Advanced Research and Development Authority to fund advanced development projects including anthrax vaccines and antitoxins, countermeasures for acute radiation syndrome, and broad-spectrum antibiotics. The request is financed by making funds from the Project BioShield Special Reserve Fund available for BARDA advanced development and other activities. These funds support oversight and management of all BARDA programs including Project BioShield (over \$2 billion awarded to date) and Pandemic Influenza (over \$5 billion awarded to date). The request also proposes to allow additional Project BioShield funding to support advanced research and development, following Congressional notification. This flexibility would enable ASPR to target resources to the most promising candidates through either advanced research and development or Project BioShield.

**Office of the Assistant Secretary for Preparedness and Response
Preparedness and Emergency Operations**

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$22,225,000	\$33,065,000	\$44,153,000	+ \$11,088,000
<i>NSSE/Public Health Emergencies(non-add)</i>	--	<i>\$10,000,000</i>	<i>\$15,000,000</i>	<i>+\$5,000,000</i>
FTE	85	90	98	+8

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

HHS serves as the primary agency for Emergency Support Function (ESF) #8 – preparedness for and response to the public health and medical consequences of disasters, including terrorist incidents involving weapons of mass destruction – under the National Response Framework (NRF). ASPR is the lead for all activations of ESF #8 and independent authorities under which HHS is responsible, such as Sections 311 and 319 of the Public Health Service Act regarding Secretarial declarations of public health emergencies, Federal-State cooperation, and temporary assistance to States. As such, ASPR is required to maintain an effective planning, coordination, and response capability, including significant logistics capabilities, for public health and medical emergencies. Through the Secretary's Operations Center (SOC), the Incident Response Coordination Team (IRCT), the National Disaster Medical System (NDMS), and OPEO's Regional Emergency Coordinators, ASPR directs and coordinates all public health and medical assets associated with an ESF #8 response. ASPR's Office of Preparedness and Emergency Operations (OPEO) manages the continued planning for capabilities to meet public health and medical response missions on a day-to-day basis and in response to threatening or emergent public health situations and maintains a regional preparedness and response capability.

Funding requested for Preparedness and Emergency Operations supports overall planning and response coordination including with State, local and federal partners. This includes having the right information to deliver the right assets – human and materiel – at the right time during a disaster or public health emergency. It also includes support for the Regional Emergency Coordinators who work with States and other partners to understand the specific needs of cities, regions, States, territories, and Tribes, and to plan for responses to emergencies.

Preparedness, Response Operations, and Logistics

ASPR leads HHS's integrated preparedness planning, response and regional logistics support that require public health, medical, human services and recovery support under ESF #8, ESF #6 (Mass Care, Emergency Assistance, Housing, and Human Services), and ESF #14 (Long-Term Community Recovery). During 2009, ASPR responded to several events including, but not limited to: the G-20 summit, the Presidential Inauguration, the crash of Continental Flight 3407 in Buffalo, New York, and the 2009-H1N1 influenza outbreak.

ASPR is building a regional response capability by consolidating warehousing and equipment/supply caches within the regions and engaging ASPR's 35 Regional Emergency

Coordinators in conducting integrated planning with State/local entities to include detailed analyses of potential gaps in State/local capabilities that may require federal support during disaster response. Exercises based on departmental and national plans have allowed HHS to make necessary revisions to expand response capabilities based on “lessons learned.”

Exercises

ASPR leads training and exercise activities within the Department under ESF #8. This includes ensuring that preparedness and response personnel are National Incident Management System (NIMS) compliant and have completed both Incident Command System (ICS) 300 and 400, and that the IRCT A has advanced and ongoing training. These activities include the development of Presidential level exercises, Secretary’s quarterly exercises, as well as those meant to enhance the abilities of our Emergency Management Group (EMG) to lead response operations during an event.

National Special Security Events (NSSEs)

ASPR’s Regional Emergency Coordinators are the lead in working with State and local entities and OPEO preparedness and operations offices to plan for National Special Security Events (NSSEs) and other planned and unplanned events. The OPEO Operations section leads the OPEO Special Event Working Group that focuses on tactics and resources to meet the goals and objectives for each of these events. Activities include building a capabilities based assessment, developing preparedness plans in collaboration with all stakeholders, development of interagency concepts of operations, resource typing of these capabilities, event planning, travel/meeting attendance, deployment of teams, and required logistical, travel, and equipment support. These planning and response activities focus on four overarching goals: to save and sustain lives, protect the public health and medical infrastructure, maintain situational awareness, and assure the safety of deployed personnel. The majority of NSSEs and other mass gathering special events that ASPR is asked to support occur in the National Capitol Region, although support is provided as requested to other events such as the Democratic National Convention, Republican National Convention, and Super Bowl. Historically ASPR has supported multiple events annually including some events which are unforeseen, such as a State Funeral or the re-entry of a U.S. satellite into the Earth’s atmosphere in February, 2008. In FY 2009, ASPR responded to two NSSEs, the Presidential Inauguration and the President’s Address to Joint Session of Congress. Other events ASPR provided support for include the Lincoln Memorial re-dedication, the Police-Peace Memorial ceremony, Independence Day ceremonies in Washington DC, the annual Cherry Blossom Festival, and the 2009 World Police and Fire Games, which provided operational concepts testing for the 2010 Winter Olympics.

Mass Casualty Care

ASPR leads planning activities required to fulfill OPEO mass casualty care responsibilities under ESF #8 of the NRF and Homeland Security Presidential Directives (HSPDs) -10 and -21. This includes regional planning for pre-staging Federal Medical Stations (FMS) especially in high risk areas of the country. The FMS project supports ASPR/OPEO, working with CDC, in fulfilling the responsibility under mandates noted above to develop a federal asset to provide over 30,000 patient beds. ASPR is also building mass casualty care capability by 1) developing evidence-based, threat-specific operational plans (known as playbooks), 2) creating web-based tools and guidelines to enhance national preparedness, 3) establishing logistics mechanisms for rapidly

deploying Federal and civilian medical personnel and medical materiel, and 4) building a cadre of surge personnel with specialized skills anticipated to be in short supply during disasters. OPEO has included significant field expertise from the NDMS Team Commanders to support and enhance response preparedness posture. The ASPR/OPEO mass casualty care initiative also works to mobilize emergency medical personnel by developing protocols for coordinating with ESAR-VHP and the Medical Reserve Corps. Other mass casualty preparedness planning activities include initiatives to promote development of subject matter expertise and decision support tools for chemical, biological, radiological and nuclear (CBRN) incidents.

Planning, preparedness and response for mass casualty events, particularly some which have heretofore not been approached in the civilian sector, requires ASPR to continually create new strategies and address the toughest issues including decision-making and triage under scarce resource conditions, developing response plans that seamlessly link government and non-government responders at the national level and development of medical countermeasures and distribution schemes to save as many lives as possible.

Situational Awareness, Analysis, and Decision Support

ASPR has successfully responded to tropical storms, food safety concerns such as salmonella and *E. coli* outbreaks, NSSEs, and other threats throughout the past year. These responses have provided ASPR and HHS the opportunity to strengthen their situational awareness, analysis and decision support capabilities, and mature their response management. ASPR is building its ability to manage information by outlining the existing information management processes between its internal and external stakeholders and by improving the definition of the Department's core capabilities to ensure essential elements of information are collected.

One project under development is MedMap, a mapping and information system, which when fully operational, will provide situational awareness capability using electronic inputs from various streams. Sources of streams include those maintained by ESF-8 partners (e.g. NDMS Electronic Medical Record system), the U.S. Census Bureau, commercial health and medical data repositories, open source news pushes (free and commercial), as well as State/local syndromic surveillance data. In order for MedMap to maintain the most accurate information about local and State health environments to include hospitals, nursing homes, assisted living facilities, as well as to have accurate assessments of those facilities, it will need to be integrated with State- and local-based systems. This would require making the appropriate links between IT systems at various levels of government so that the translation of data between groups is seamless. This is something that MedMap will also continue to work on among HHS OPDIVs and STAFFDIVs, as well as with other federal partners.

ASPR continues to develop prospective and retrospective decision-support, information, and analysis capabilities that support both planning and operations and that provide senior leaders with situational awareness data elements in tools such as MedMap. These tools are designed to access and analyze data available through multiple sources (e.g. web, published reports, medical record information, internal documents, etc.) and synthesize the information to detect patterns, make links, and possible associations that support decision making by senior leadership. ASPR refers to this combinatorial process as "fusion." Data fusion involves the exchange of information from many sources and when combined with appropriate analysis, it can result in

meaningful and actionable information. Within ASPR this process requires close coordination with multiple stakeholders within and outside the agency. Data fusion supports the implementation of risk-based, information-driven prevention, response and consequence management programs and decision support. At the same time, it supports efforts to address immediate or emerging threat-related circumstances or events.

Continuity of Operations and Critical Infrastructure Protection

ASPR also has lead responsibility for ensuring that all of HHS complies with all Continuity of Operations (COOP) and Continuity of Government (COG) requirements. This includes planning for the continuation of the Department's essential functions and leadership during emergencies, and providing direction and guidance to all HHS OPDIVs, STAFFDIVs, and regional offices concerning COOP programmatic activities. The COOP Program successfully participated in National Level Exercise 2-08 "Eagle Horizon" by fully activating one of the alternate facilities, exercising the HHS Orders of Succession, and training senior HHS leadership in their roles and responsibilities when acting from the alternate facility during disasters. ASPR also participated in and evaluated several tabletop, functional, and full scale exercises such as TOPOFF 4, hurricane scenarios, and the Democratic and Republican National Conventions.

ASPR serves as the lead Sector Specific Agency under HSPD-7 *Critical Infrastructure Identification, Prioritization, and Protection* for the Healthcare and Public Health (HPH) Sector. The HPH Sector provides a diverse array of goods and services that are distributed widely across the country. It includes not only acute hospital and ambulatory healthcare but also the vast and complex public-private systems that finance that care. It includes population-based care provided by health agencies at the local, State, and federal levels. It also includes a large system of private sector enterprises that manufacture, distribute, and sell drugs, biologics, and medical devices. This is all done within a complex environment of science, regulation, finance, and public policy. In FY 2009, ASPR initiated and completed a number of efforts to significantly enhance the public-private partnership among HPH sector partners. Initiatives included the development of an on-line information sharing portal for public and private sector partners and a new liaison program permitting private sector partners to engage in ESF #8 operations at the federal level. In addition to the two existing governing bodies and workgroups, the Critical Infrastructure Protection (CIP) program expanded the number of collaborative workgroups involving public and private sector partners to address issues such as information sharing and risk assessment. The on-line portal system will enroll thousands of State, local, Tribal, territorial and private sector partners in a secure forum to share information related to healthcare and public health preparedness, mitigation and response.

At Risk, Behavioral Health and Human Services

In its role of coordinating efforts to address mental health and needs of "at-risk individuals," ASPR has undertaken several significant initiatives. In FY 2009, working with the Disaster Mental Health Subcommittee of the National Biodefense Science Board (NBSB), ASPR worked to develop a federal strategy to address behavioral health and began implementation of the action items. In FY 2009, efforts focused on integrating attention to at-risk/special-needs individuals into preparedness and response activities, as mandated by PAHPA. ASPR has also established a new program to improve federal coordination of in-hospital emergency medical care activities and to promote programs and resources that improve the delivery of daily emergency medical

and mental health care. This is a multi-level collaboration that will result in a coalition comprised of subject-matter experts from various organizations who will provide strategic and operational policy guidance and facilitate agencies involvement.

Funding History:

FY 2006	\$14,942,000
FY 2007	\$13,564,000
FY 2008	\$17,275,000
FY 2009	\$22,225,000
FY 2010	\$33,065,000

Budget Request:

The FY 2011 request for Preparedness and Emergency Operations is \$44,153,000, an increase of +\$11,088,000 above the FY 2010 level. The increase includes an additional +\$5,000,000, \$15,000,000 total requested as no-year funding, to prepare for and respond to non-Stafford Act National Special Security Events (NSSEs) and other planned and unplanned events, including other mass gathering events and public health emergencies. Funding for this activity was first requested in FY 2010, and it is expected to support response to planned (e.g. State of the Union, 2010 Olympics) and unplanned events (e.g. State Funeral or dignitary visit). The emergence of 2009 H1N1 influenza demonstrates how immediate access to funding to prepare for and respond to unplanned events with the flexibility of no expiration is necessary.

OPEO will improve the quality and availability of data used to prepare for and respond to public health emergencies. Programs will target analysis of State and local public health and medical preparedness that results in the creation of integrated preparedness plans across all the tiers of response (local/State/Tribal/federal/territorial). The enhanced regional presence will assist in testing of the integrated plans with State/local/Tribal/territorial partners to create strategic partnerships for preparedness. Past experience in real events, along with exercises and studies, will form the foundation of corrective action planning that includes advanced data systems to track preparedness. OPEO will continue its campaign to enhance situational awareness and information sharing among all levels of government and the private sector, in both the classified and unclassified domains. Greater emphasis will be placed on Continuity of Operations (COOP) program in FY 2011, including development of a COOP HHS Quality Assurance program.

Funds support regional and interagency coordination for ESF #8, Federal response capabilities, and to address the special needs of at-risk populations. These activities culminate in direct support for the Nation at the most basic level, the local community. The request includes funding for deployment support and cache management to maintain regional readiness capability as well as preparedness planning activities, such as national-level gap analyses, conducting integrated planning processes, performing regional readiness exercises, developing regional playbooks and web-based training modules addressing multiple scenarios and disciplines. Funding will be directed to preparedness planning and response operations to continue to identify requirements for the public health and medical needs of the National Planning Scenarios and help quantify the assets and other capabilities needed to meet ASPR's preparedness and response mission as the lead for ESF #8.

Also, the funds will permit continued efforts to coordinate and provide services specifically aimed at assisting at-risk individuals, including developing training for responders. ASPR will advance the integration of at-risk individuals and behavioral health into public health emergency planning and response to address functional needs that otherwise would prevent at-risk populations from seeking or receiving care. The outreach will include development and distribution of targeted education, training, and locally based activities aimed at increasing knowledge regarding how to serve these populations in emergencies. Funding also will support training and exercises including Tier 1 National Level Exercises, regional exercises (focuses on validating ASPR's response capabilities), Secretary's Quarterly Readiness Exercises, and Senior Action Officer Exercises (focused on senior decision makers and policymakers), and tabletop exercises. Funding will also support the Emergency Management Group (EMG)/Secretary's Operations Center (SOC) activities and operations, including information technology and communication systems upgrades and infrastructure enhancements in the SOC, which are necessary to maintain situational awareness and the ability to share information with federal, State, and local partners during an incident. Together, these investments will maintain HHS's capabilities to deploy, coordinate, and communicate effectively during a response and to strengthen preparedness and response based on the findings of the White House report, *Federal Response to Hurricane Katrina: Lessons Learned* and the requirements outlined in PAHPA and HSPD-21.

Outcomes and Outputs:

Long Term Objective: Improve DHHS response assets to support municipalities and States.

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
<p>2.4.1: Improve ESF #8 preparedness planning and response capability. <i>(Outcome)</i></p>	<p>FY 2009: Regional Emergency Care Coordinators (REC) worked directly with State, local and Tribal agencies to enhance response capabilities expanding. REC continued integrated planning efforts to identify capability gaps for hurricane responses. IRCT advanced training provided at ESF 8 Summit. First draft of the Field Operations Guide completed. 14 playbooks completed out of 15 National Planning Scenarios. Exercises conducted annually on hurricane preparedness. Additional exercises focused on anthrax, and continuity of government, and continuity of operations for the transition to the new Administration. The fusion cell is developing situational awareness tools such as MedMap. Tools and guidelines are available such as Radiation Event Medical Management that is now available in a PDA version and Chemical Event Medical Management is under development. (Target Met)</p>	<p>Complete cache regionalization to improve response and team deployment. Be able to fully deploy teams with the appropriate support cache within 24 hours of activation within the continental US. Exercise participation will include partners to affect optimum response.</p>	<p>All equipment caches capable of sustaining deployed medical personnel for 48 hours and full fielding of the Disaster Medical Information Suite (DMIS) electronic medical record, patient tracking system and Health Information Repository (HIR). Build a capabilities based assessment, developing preparedness plans to include interagency concepts of operations, resource typing and team deployment logistical/ travel/ equipment support.</p>	<p>N/A</p>

**Office of the Assistant Secretary for Preparedness and Response
National Disaster Medical System**

	<u>FY 2009 Appropriation</u>	<u>FY 2010 Appropriation</u>	<u>FY 2011 President's Budget Request</u>	<u>FY 2011 +/- FY 2010</u>
Budget Authority	\$49,500,000	\$56,037,000	\$56,540,000	+ \$503,000
FTE	102	102	102	--

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

The National Disaster Medical System (NDMS) is a cooperative, asset-sharing partnership with the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Department of Homeland Security (DHS) that leverages federal and non-Federal resources to care for large numbers of casualties resulting from a disaster. NDMS consists of three key functions:

- Medical response which includes assessments of health and medical needs, primary and emergency medical care, health and medical equipment and supplies, victim identification and mortuary services, veterinary services, and other auxiliary services at the site of an emergency through NDMS response teams.
- Patient evacuation from a mobilization center near the disaster site to facilities where patients can receive definitive medical care. This includes communication with federal, State, and local authorities; transportation; and medical care during evacuation.
- Definitive medical care consisting of medical treatment or services beyond emergency medical care provided after admission to an NDMS partner hospital or other healthcare facility. Care can be provided for injuries or illnesses resulting directly from a specified public health emergency, or for injuries, illnesses and conditions requiring non-deferrable medical treatment or services to maintain health when such medical treatment and services are temporarily not available as a result of the public health emergency.

Definitive care is rendered by a nationwide network of voluntarily participating, pre-identified, non-Federal healthcare facilities. The network includes an ability to track available beds by medical specialty. In a public health emergency, these services provide definitive medical care for victims. In a military health emergency, NDMS non-federal hospitals provide backup to the available military and VA medical services for military beneficiaries.

NDMS teams have been successfully deployed to a variety of missions, including: the G-20 Summit, the Presidential Inauguration, and the crash of Continental Flight 3407 in Buffalo, New York. The ESF-8 Integrated Training Summit (formerly NDMS Training Summit) was held in Dallas, Texas, in April 2009, and attendance exceeded 3,200 participants. The Summit included the Medical Reserve Corps and the Emergency System for the Advance Registration of Volunteer Health Professionals (ESAR-VHP) programs and incorporated specialized trainings for Incident Response Coordination Team (IRCT) -A personnel, ASPR logistics and the DoD for aero-medical evacuation. Also, in FY 2009, all equipment caches were inventoried, and

additional equipment caches are being developed to meet expanded mission types. Existing caches are being modified, upgraded, and re-supplied.

Funding History:

FY 2006	approx. \$46,605,000
FY 2007	\$46,605,000
FY 2008	\$45,999,000
FY 2009	\$49,500,000
FY 2010	\$56,037,000

Budget Request:

The FY 2011 request for the National Disaster Medical System is \$56,540,000, an increase of +\$503,000 above the FY 2010 level. Funding will support central headquarters operations, regional emergency coordination, as well as medical response assets, including teams, supplies, and equipment including continued standardization and regionalization of equipment caches. NDMS is a unique capability, supported by the partnership of four Federal agencies (HHS, DHS, DoD, and VA). The NDMS mission has grown substantially since 2005. NDMS remains the only system able to mesh federal response with civilian infrastructure and human capital assets.

FY 2011 funding includes logistics support for cache maintenance including medical and pharmaceutical supplies, IT and communications capabilities to ensure all equipment caches will sustain deployed medical personnel throughout the full range of emergent care in the field. Funding will support the Disaster Medical Information Suite (DMIS), which is the NDMS electronic medical record and patient tracking system.

The NDMS structure is being streamlined to maximize critical skill sets, share overhead cost and increase response capacity. The program will improve capability by reorganizing the National Medical Response Teams (NMRT) - the component of the NDMS trained to respond to weapons of mass destruction attacks - redesigning the Burn, Nurse, Pharmacy, and Mental Health specialty teams, and reformulating and expanding of the International Medical/Surgical Response Teams (IMSURT) to meet both current and future mission requirements.

FY 2011 activities will include development of policies and procedures related to training standards, objectives and cycles, with emphasis on regional training and exercises for more than 100 NDMS Response Teams. Teams include: Disaster Medical Assistance Teams (DMAT), Disaster Mortuary Operational Response Teams (DMORT), National Veterinary Response Teams (NVRT), and other NDMS Specialty Teams located across the country.

Funding will be used to continue improvements to planning and preparedness activities associated with the development of an integrated ESF #8 National Strategy for Fatality Management, as outlined in the ESF #8 concept of operations. Funding will support the operational needs of the Regional Emergency Coordinators, in addition to the development, training, and deployment, of six IRCT-A teams and three Logistical Response Assistance Teams (LRAT).

FY 2011 efforts will target improvements to the definitive care reimbursement program, augmentation to patient movement capabilities, enhancements to hospital recruitment, and expanded training and evaluation in conjunction with the federal Coordinating Centers.

Outcomes and Outputs:

See Preparedness and Emergency Operations.

**Office of the Assistant Secretary for Preparedness and Response
Hospital Preparedness**

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$393,585,000	\$426,000,000	\$426,000,000	--
<i>Hospital Preparedness (non-add)</i>	\$387,585,000	\$420,000,000	\$420,000,000	--
<i>ESAR-VHP (non-add)</i>	\$6,000,000	\$6,000,000	\$6,000,000	--
FTE	39	51	55	+4

Allocation Method: Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments:

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) transferred responsibility for the Hospital Preparedness Program from the Health Resources and Services Administration (HRSA) to ASPR. Consistent with the legislation, the program has continued to develop stronger State, territorial and regional partnerships to improve overall surge capacity and capability and enhance hospital preparedness. The program’s focus is on strengthening the capability of hospitals and healthcare systems to plan for, respond to and recover from all-hazard events. These capabilities include, but are not limited to, interoperable communications, bed and resource tracking systems, development and operation of Emergency System for the Advance Registration of Volunteer Health Professionals (ESAR-VHP) systems, fatality management and evacuation planning, partnership/coalition development, and supporting training and exercises to promote seamless preparedness integration across the local, State, regional, and federal tiers of health care asset management. The program also supports the activities of the Critical Infrastructure Protection program for the Healthcare and Public Health Sector in meeting the requirements of the National Infrastructure Protection Program (NIPP) in building partnerships with local, State, and regional stakeholders under the NIPP framework.

The program developed new evidenced-based performance measures for grantees in FY 2008 that reflect the requirements of PAHPA, and continues to refine those measures for FY 2010 and beyond to provide a more accurate picture of the direction and focus of healthcare system preparedness efforts. During 2008 and 2009 ASPR undertook an internal program assessment review. Staff clarified measures, analyzed data, and developed reports of States’ accomplishments. The internal review demonstrated that significant progress has been made. Measures of healthcare system preparedness were more clearly defined and the procedures for collecting and analyzing data that have been standardized will continue to evolve. Independent reports from the Government Accountability Office and the Center for Biosecurity at the University of Pittsburgh, indicate that the Nation’s health care system is more prepared to respond to disasters because of the funding that has been provided through this cooperative agreement program.

One of the FY 2009 performance targets was that 80 percent of States be able to demonstrate the ability to report hospital bed data using the Hospital Available Beds in Emergencies and Disasters (HAvBED) System in at least one drill, exercise, or real life event. Progress on this target was validated in March 2009 during a test of the HAvBED system when 74 percent of

States were able to report their available beds without difficulty. Additional validation came in response to the fall 2009 H1N1 event, where an even greater percentage of States consistently reported bed status to the HHS Secretary's Operation Center. Another FY 2009 performance target was that 95 percent of States be able to demonstrate through reporting or exercises the use of interoperable communications systems with multiple communications technologies that would ensure connectivity and operability in a public health emergency. Because of the enhanced data collection and reporting procedures that were put in place, FY 2007 end of year data has been finalized, and new FY 2008 data submitted by the States is currently being analyzed. As reported by the States through FY 2007, 91 percent were able to demonstrate interoperable communications during exercises, and preliminary FY 2008 data suggests that percentage will increase.

In FY 2008, the HPP programmatically institutionalized the Homeland Security Exercise and Evaluation Program (HSEEP) methodology, and implemented an execution strategy for awardees and sub-recipient healthcare systems in accordance with the Department of Homeland Security (DHS) initiative. HSEEP is a capabilities and performance based exercise program that provides a standardized methodology and terminology for exercise design, development, conduct, evaluation, and improvement planning. The HSEEP constitutes a national standard for all exercises. Through exercises, the National Exercise Program (NEP) supports organizations to achieve objective assessments of their capabilities, so that strengths and areas for improvement are identified, corrected, and shared prior to a real incident. The HPP goal is to ensure State and territory departments of public health awardees and sub-recipient healthcare systems engage appropriately in this enterprise. HSEEP implementation has resulted in a program shift, starting in FY 2008, from increasing and measuring the number of hospital-based drills and exercises, to ensuring fewer, but more comprehensive, multidisciplinary regional and statewide exercises with hospital participation.

The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is a national program intended to help health professionals volunteer in public health emergencies and disasters. The ESAR-VHP program is working to establish a national network of systems. Each system is maintained by a State or group of States for the purpose of verifying the credentials, certifications, licenses, and hospital privileges of health care professionals. Each State's ESAR-VHP system is built to standards that will allow quick and easy exchange of health professionals with other States thereby maximizing the size of the population able to receive services during a time of a declared disaster or public health emergency. The ESAR-VHP program has established requirements to ensure the electronic and operational compliance of each State. The ESAR-VHP program provides technical assistance and guidance for recruitment, registration, credentials verification, classification according to verified professional credentials, legal and regulatory issues, and policy for the use of volunteers.

PAHPA transferred responsibility for the ESAR-VHP program from HRSA to ASPR. PAHPA mandates that States are not eligible to receive the ASPR Hospital Preparedness Program and CDC Public Health Emergency Preparedness Program funding unless they participate in ESAR-VHP. Forty-nine States have fully operational ESAR-VHP systems, and the remaining State is working to become fully operational. There are over 147,600 registered ESAR-VHP volunteers.

In FY 2009, ASPR launched a new grants program to support and sustain State and territorial ESAR-VHP programs. The focus of the grants was to meet compliance requirements, adopt and implement guidelines, and support activities related to the integration of local Medical Reserve (MRC) volunteer resources and State ESAR-VHP programs. The ESAR-VHP program continued to provide State access to national data sources, such as the American Board of Medical Specialties (ABMS), Federation of State Medical Boards (FSMB), American Osteopathic Information Association (AOIA), and the Drug Enforcement Administration (DEA). The ESAR-VHP program partnered with the National Disaster Medical System (NDMS), the Office of Public Health and Science (OPHS), the Office of Force Readiness and Deployment (OFRD), and the Medical Reserve Corps (MRC) to conduct the first Integrated Medical, Public Health, Preparedness and Response Training Summit. The Summit was attended by over 3,200 participants. In addition to ESAR-VHP specific sessions and regional breakouts, the Summit provided a forum for training, discussion, information sharing, and networking with public health and response partner organizations. During the initial H1N1 influenza outbreak in the spring of 2009, ESAR-VHP collaborated with HHS and ASPR programs to revise the federal protocol to plan for the potential use of civilian volunteer health professionals in a federally coordinated response to this event.

During FY 2010, the ESAR-VHP program will work with State representatives, stakeholders, and subject matter experts to develop a series of documents that will define and clarify policies and procedures required of State and territorial ESAR-VHP programs, including activation and deployment protocols, training, collaboration with other volunteer and ESF #8 entities and sustainability. The program will continue efforts to identify an approach and the requirements to meet Section 303 of PAHPA to link existing State systems to maintain a single national interoperable network of systems. In FY 2010, ESAR-VHP will convene an expert panel for a strategic visioning meeting to discuss and chart the strategic direction of the program. The meeting outcomes will be used to inform current ESAR-VHP projects and serve as building blocks for strategic planning. Priorities for the FY 2010 grants are partnership building and exercises. ESAR-VHP will continue its partnership with NDMS, OFRD, and MRC to conduct 2010 Integrated Training Summit and will support the attendance of up to 125 State and territorial ESAR-VHP participants. Federal and State ESAR-VHP programs will participate in 2010 National Level Exercise. In FY 2010, an evaluation of the State ESAR-VHP programs is planned to assess their progress. The program will conduct outreach activities to raise public awareness of the national ESAR-VHP program and State registries and recruit and direct potential health professional volunteers to the State ESAR-VHP web sites to register to become volunteers.

Funding History:

FY 2006	\$473,882,000
FY 2007	\$474,030,000
FY 2008	\$423,399,000
FY 2009	\$393,585,000
FY 2010	\$426,000,000

Budget Request:

The FY 2011 request for Hospital Preparedness is \$426,000,000, maintaining the FY 2010 enacted level. Funding will be provided to the existing cooperative agreement awards to further enhance surge capacity. In addition funding will support program management and administrative costs, evaluation and technical support. Specifically awards will improve preparedness plans for all-hazards, increase the ability of hospitals and other healthcare entities to provide needed beds, engage with other responders through interoperable communication systems, and track bed and resource availability using electronic systems. Also, funding will support the development of ESAR-VHP systems, protection of healthcare workers with proper equipment, decontamination of patients, enable partnerships and coalitions, educate and train healthcare workers, enhance fatality management and hospital evacuation/shelter in place plans, and enable healthcare system coordination within regional exercises.

In FY 2011, consistent with directions identified in PAHPA, the program will continue to focus on aspects of medical surge planning including fatality management and evacuation planning, incorporating the needs of at-risk individuals, maximizing the interactions of public/private partnerships and utilizing exercises as a major component of the evaluation of the program. To the extent practical, exercises will be integrated with the other preparedness grant programs (e.g. CDC and DHS) and will test the target capabilities that are identified as part of the National Preparedness Goal. There will be ongoing requirements for the States, health-care systems and facilities to report available assets in support of seamless preparedness and response across the tiers of health care asset management. Funding also supports evaluation activities, such as review and revision of current performance measures, development of profiles of State health care system preparedness, implementation of a management information system to improve and simplify the process of data collection for grantees, continued development of exercise evaluation guidelines to standardize the methodology for reporting exercise results, continued development of guidelines for States on allocation of scarce resources during catastrophic events and modeling of the resiliency of the health care system's ability to respond when the infrastructure surrounding the health care system has been damaged. The data information systems under development will allow for more rigorous data analysis and program evaluation.

Within the total, \$1,020,000 will support the activities of the Critical Infrastructure Protection program for the Healthcare and Public Health Sector. This includes collaboration with federal, State, local, territorial, tribal, and private sector stakeholders on a range of activities from information sharing to threat risk assessments, to participation in exercises to enhance the resiliency of the sector.

The FY 2011 request also includes \$6,000,000 for ESAR-VHP, maintaining the FY 2010 level. Funding will be used to continue grant support to State and territorial ESAR-VHP programs, State access to national data sources for credentials verification, and the participation of State and territorial ESAR-VHP personnel in the Integrated Training Summit. The National Level Exercise 2011 will provide an opportunity to exercise the federal protocol for mobilizing civilian volunteers, test and improve the capability of State ESAR-VHP programs to respond to disasters and public health emergencies, and improve federal and State coordination. In FY 2011, the ESAR-VHP program will begin the implementation of the approach identified during FY 2010 to link existing State systems to maintain a single national interoperable network of systems and

meet the requirements of PAHPA. In FY 2011, funding for ESAR-VHP will also be used to support contracts which provide technical assistance to the state and territorial ESAR-VHP programs.

Outcomes and Outputs:

Long Term Objective: Enhance State and Local Preparedness

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.2: Improve surge capacity and enhance community and hospital preparedness for public health emergencies through:				
A: % of States demonstrating ability to report hospital bed data (Outcome)	FY 2007: 74% (Target Exceeded)	90%	100%	+10
B: % of States demonstrating use of Interoperable Communications Systems (Outcome)	FY 2007: 91% (Target Exceeded)	98%	100%	+2
C: % of States demonstrating development of Fatality Management Plans (Outcome)	FY 2007: 64% (Target Exceeded)	85%	100%	+15
D: % of States demonstrating development of Hospital Evacuation Plans (Outcome)	FY 2007: 79% (Target Exceeded)	90%	100%	+10
E: % of States demonstrating development of fully operational and compliant ESAR-VHP programs (Outcome)	FY 2009: 98% (Target Exceeded)	100%	100%	Maintain
2.4.3: Increase the ratio of preparedness exercises and drills per total program (Coop. Agreement) dollar by 50% each year. (Approved by OMB.) (Outcome)	FY 2007: 7.1 per million dollars (Target Not Met)	34.0 per million dollars	51.1 per million dollars	N/A

Grant Awards Table:

Hospital Preparedness:

(whole dollars)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate
Number of Awards	62	62	62
Average Award	\$5,839,000	\$6,304,968	\$6,304,968
Range of Awards	\$271,559 to \$29,486,456	\$273,431 to \$32,002,981	\$273,431 to \$32,002,981

ESAR-VHP:

(whole dollars)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate
Number of Awards	53	62	62
Average Award	\$58,781	\$59,225	\$56,806
Range of Awards	\$50,000 to \$60,000	\$59,225	\$56,806

FY 2011 Mandatory (or Discretionary) State/Formula Grants

National Bioterrorism Hospital Preparedness Program (HPP)

STATE/TERRITORY	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	Difference +/- 2010
Alabama	\$5,528,753	\$5,959,110	\$5,959,110	\$0
Alaska	\$1,232,661	\$1,294,916	\$1,294,916	\$0
Arizona	\$7,242,486	\$7,819,680	\$7,819,680	\$0
Arkansas	\$3,573,514	\$3,836,340	\$3,836,340	\$0
California	\$29,486,456	\$31,969,579	\$31,969,579	\$0
<i>City of Chicago</i>	\$3,608,117	\$3,873,907	\$3,873,907	\$0
Colorado	\$5,697,522	\$6,142,339	\$6,142,339	\$0
Connecticut	\$4,332,291	\$4,660,131	\$4,660,131	\$0
Delaware	\$1,433,223	\$1,512,663	\$1,512,663	\$0
District of Columbia	\$1,589,577	\$1,682,413	\$1,682,413	\$0
Florida	\$20,280,168	\$21,974,470	\$21,974,470	\$0
Georgia	\$10,738,888	\$11,615,664	\$11,615,664	\$0
Hawaii	\$1,905,612	\$2,025,528	\$2,025,528	\$0
Idaho	\$2,103,488	\$2,240,358	\$2,240,358	\$0
Illinois	\$11,422,845	\$12,358,225	\$12,358,225	\$0
Indiana	\$7,403,442	\$7,994,427	\$7,994,427	\$0
Iowa	\$3,760,725	\$4,039,591	\$4,039,591	\$0
Kansas	\$3,522,344	\$3,780,786	\$3,780,786	\$0
Kentucky	\$5,099,081	\$5,492,621	\$5,492,621	\$0
<i>LA County</i>	\$11,377,608	\$12,309,112	\$12,309,112	\$0
Louisiana	\$5,188,408	\$5,589,603	\$5,589,603	\$0
Maine	\$1,945,059	\$2,068,354	\$2,068,354	\$0
Maryland	\$6,640,448	\$7,166,059	\$7,166,059	\$0
Massachusetts	\$7,538,670	\$8,141,243	\$8,141,243	\$0
Michigan	\$11,538,958	\$12,484,287	\$12,484,287	\$0
Minnesota	\$6,149,904	\$6,633,482	\$6,633,482	\$0
Mississippi	\$3,682,495	\$3,954,658	\$3,954,658	\$0

STATE/TERRITORY	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	Difference +/- 2010
Missouri	\$6,888,644	\$7,435,519	\$7,435,519	\$0
Montana	\$1,532,896	\$1,620,876	\$1,620,876	\$0
Nebraska	\$2,433,560	\$2,598,712	\$2,598,712	\$0
Nevada	\$3,228,706	\$3,461,988	\$3,461,988	\$0
New Hampshire	\$1,937,756	\$2,060,425	\$2,060,425	\$0
New Jersey	\$10,039,764	\$10,856,638	\$10,856,638	\$0
New Mexico	\$2,637,233	\$2,819,835	\$2,819,835	\$0
New York	\$12,628,147	\$13,666,801	\$13,666,801	\$0
<i>New York City</i>	\$9,481,964	\$10,251,044	\$10,251,044	\$0
North Carolina	\$10,184,038	\$11,013,273	\$11,013,273	\$0
North Dakota	\$1,195,281	\$1,254,332	\$1,254,332	\$0
Ohio	\$13,050,486	\$14,125,327	\$14,125,327	\$0
Oklahoma	\$4,413,646	\$4,748,457	\$4,748,457	\$0
Oregon	\$4,546,549	\$4,892,747	\$4,892,747	\$0
Pennsylvania	\$14,103,046	\$15,268,074	\$15,268,074	\$0
Rhode Island	\$1,667,365	\$1,766,867	\$1,766,867	\$0
South Carolina	\$5,225,017	\$5,629,348	\$5,629,348	\$0
South Dakota	\$1,354,980	\$1,427,715	\$1,427,715	\$0
Tennessee	\$7,103,056	\$7,668,303	\$7,668,303	\$0
Texas	\$26,204,300	\$28,406,199	\$28,406,199	\$0
Utah	\$3,288,335	\$3,526,726	\$3,526,726	\$0
Vermont	\$1,182,205	\$1,240,136	\$1,240,136	\$0
Virginia	\$8,857,019	\$9,572,550	\$9,572,550	\$0
Washington	\$7,493,408	\$8,092,101	\$8,092,101	\$0
West Virginia	\$2,488,384	\$2,658,233	\$2,658,233	\$0
Wisconsin	\$6,575,694	\$7,095,755	\$7,095,755	\$0
Wyoming	\$1,063,125	\$1,110,853	\$1,110,853	\$0
Subtotal	\$354,827,345	\$382,888,381	\$382,888,381	\$0
Indian Tribes	\$0	\$0	\$0	\$0
Migrant Program	\$0	\$0	\$0	\$0
American Samoa	\$313,249	\$318,407	\$318,407	\$0
Guam	\$428,879	\$443,945	\$443,945	\$0

STATE/TERRITORY	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	Difference +/- 2010
Marshall Islands	\$311,702	\$316,727	\$316,727	\$0
Micronesia	\$368,248	\$378,119	\$378,119	\$0
Northern Mariana Islands	\$333,242	\$340,114	\$340,114	\$0
Palau	\$271,559	\$273,146	\$273,146	\$0
Puerto Rico	\$4,794,779	\$5,162,246	\$5,162,246	\$0
Virgin Islands	\$368,981	\$378,915	\$378,915	\$0
Subtotal	\$7,190,639	\$7,611,619	\$7,611,619	\$0
Total States/Territories	\$362,017,984	\$390,500,000	\$390,500,000	\$0
Technical Assistance	\$0	\$0	\$0	\$0
State Penalties	\$0	\$0	\$0	\$0
Contingency Fund	\$0	\$0	\$0	\$0
Other Adjustments (specify)	\$0	\$0	\$0	\$0
Subtotal Adjustments	\$0	\$0	\$0	\$0
Total Resources	\$362,017,984	\$390,500,000	\$390,500,000	\$0

FY 2011 Mandatory (or Discretionary) State/Formula Grants

**Emergency System for Advance Registration of Volunteer Health Professionals
(ESAR-VHP)**

STATE/TERRITORY	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	Difference +/- 2010
Alabama	\$0	\$59,225	\$56,806	-\$2,419
Alaska	\$60,000	\$59,225	\$56,806	-\$2,419
Arizona	\$0	\$59,225	\$56,806	-\$2,419
Arkansas	\$50,266	\$59,225	\$56,806	-\$2,419
California	\$60,000	\$59,225	\$56,806	-\$2,419
<i>Los Angeles County</i>	\$60,000	\$59,225	\$56,806	-\$2,419
Colorado	\$58,949	\$59,225	\$56,806	-\$2,419
Connecticut	\$60,000	\$59,225	\$56,806	-\$2,419
Delaware	\$60,000	\$59,225	\$56,806	-\$2,419
<i>District of Columbia</i>	\$60,000	\$59,225	\$56,806	-\$2,419
Florida	\$60,000	\$59,225	\$56,806	-\$2,419
Georgia	\$60,000	\$59,225	\$56,806	-\$2,419
Hawaii	\$59,920	\$59,225	\$56,806	-\$2,419
Idaho	\$56,225	\$59,225	\$56,806	-\$2,419
Illinois	\$60,000	\$59,225	\$56,806	-\$2,419
<i>Chicago</i>	\$0	\$59,225	\$56,806	-\$2,419
Indiana	\$60,000	\$59,225	\$56,806	-\$2,419
Iowa	\$60,000	\$59,225	\$56,806	-\$2,419
Kansas	\$59,486	\$59,225	\$56,806	-\$2,419
Kentucky	\$60,000	\$59,225	\$56,806	-\$2,419
Louisiana	\$60,000	\$59,225	\$56,806	-\$2,419
Maine	\$60,000	\$59,225	\$56,806	-\$2,419
Maryland	\$60,000	\$59,225	\$56,806	-\$2,419
Massachusetts	\$60,000	\$59,225	\$56,806	-\$2,419
Michigan	\$60,000	\$59,225	\$56,806	-\$2,419
Minnesota	\$60,000	\$59,225	\$56,806	-\$2,419
Mississippi	\$60,000	\$59,225	\$56,806	-\$2,419

STATE/TERRITORY	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	Difference +/- 2010
Missouri	\$60,000	\$59,225	\$56,806	-\$2,419
Montana	\$51,315	\$59,225	\$56,806	-\$2,419
Nebraska	\$51,914	\$59,225	\$56,806	-\$2,419
Nevada	\$56,379	\$59,225	\$56,806	-\$2,419
New Hampshire	\$60,000	\$59,225	\$56,806	-\$2,419
New Jersey	\$0	\$59,225	\$56,806	-\$2,419
New Mexico	\$60,000	\$59,225	\$56,806	-\$2,419
New York	\$60,000	\$59,225	\$56,806	-\$2,419
<i>New York City</i>	\$60,000	\$59,225	\$56,806	-\$2,419
North Carolina	\$59,950	\$59,225	\$56,806	-\$2,419
North Dakota	\$51,000	\$59,225	\$56,806	-\$2,419
Ohio	\$60,000	\$59,225	\$56,806	-\$2,419
Oklahoma	\$60,000	\$59,225	\$56,806	-\$2,419
Oregon	\$60,000	\$59,225	\$56,806	-\$2,419
Pennsylvania	\$60,000	\$59,225	\$56,806	-\$2,419
Rhode Island	\$59,983	\$59,225	\$56,806	-\$2,419
South Carolina	\$60,000	\$59,225	\$56,806	-\$2,419
South Dakota	\$0	\$59,225	\$56,806	-\$2,419
Tennessee	\$60,000	\$59,225	\$56,806	-\$2,419
Texas	\$60,000	\$59,225	\$56,806	-\$2,419
Utah	\$60,000	\$59,225	\$56,806	-\$2,419
Vermont	\$0	\$59,225	\$56,806	-\$2,419
Virginia	\$60,000	\$59,225	\$56,806	-\$2,419
Washington	\$60,000	\$59,225	\$56,806	-\$2,419
West Virginia	\$0	\$59,225	\$56,806	-\$2,419
Wisconsin	\$60,000	\$59,225	\$56,806	-\$2,419
Wyoming	\$60,000	\$59,225	\$56,806	-\$2,419
Subtotal	\$2,775,387	\$3,198,150	\$3,067,524	-\$130,626
Indian Tribes	\$0	\$0	\$0	\$0
Migrant Program	\$0	\$0	\$0	\$0
American Samoa	\$50,000	\$59,225	\$56,806	-\$2,419
Guam	\$60,000	\$59,225	\$56,806	-\$2,419

STATE/TERRITORY	FY 2009 Actual	FY 2010 Estimate	FY 2011 Estimate	Difference +/- 2010
Marshall Islands	\$50,002	\$59,225	\$56,806	-\$2,419
Micronesia	\$60,000	\$59,225	\$56,806	-\$2,419
Northern Mariana Islands	\$0	\$59,225	\$56,806	-\$2,419
Palau	\$60,000	\$59,225	\$56,806	-\$2,419
Puerto Rico	\$60,000	\$59,225	\$56,806	-\$2,419
Virgin Islands	\$0	\$59,225	\$56,806	-\$2,419
Subtotal	\$340,002	\$473,800	\$454,488	-\$19,352
Total States/Territories	\$3,115,389	\$3,671,950	\$3,522,012	-\$149,978
Technical Assistance	\$0	\$0	\$0	\$0
State Penalties	\$0	\$0	\$0	\$0
Contingency Fund	\$0	\$0	\$0	\$0
Other Adjustments (specify)	\$0	\$0	\$0	\$0
Subtotal Adjustments	\$0	\$0	\$0	\$0
Total Resources	\$3,115,389	\$3,671,950	\$3,522,012	-\$149,978

**Office of the Assistant Secretary for Preparedness and Response
Medical Countermeasure Dispensing**

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	--	\$10,000,000	\$10,000,000	--
FTE	--	3	3	--

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

In 2004 the Department of Health and Human Services established the Cities Readiness Initiative (CRI) to prepare major U.S. cities and metropolitan areas to effectively respond to a large-scale bioterrorist event by dispensing antibiotics to the entire identified population within 48 hours of a decision to do so.

The initial effort was established through a Memorandum of Agreement signed in February 2004, by the Secretaries of HHS and Homeland Security (DHS) and the Postmaster General. The agreement covered the delivery of antibiotics during a catastrophic incident using the personnel and assets of the U.S. Postal Service (USPS). The agreement specifically addressed:

- The general procedures and authorities;
- Reimbursement;
- Federal activation;
- Delivery of medications only;
- Employee volunteers;
- Security for volunteers; and,
- Safety for volunteers and family members.

Recognizing the challenges of distributing and dispensing antibiotics to a large population within 48 hours, HHS and USPS have systematically developed a concept of a Federal capability to provide for direct residential delivery of medical countermeasures. Proof of principle was demonstrated through large-scale day-long drills that involved tens of thousands of households and were conducted in concert with local public health and law enforcement entities. Currently, an initial operational capability has been developed in the Minneapolis-St. Paul metropolitan statistical area. This activity, which is a component of CRI, has become known as the “Postal Module.”

On December 30, 2009, the President issued Executive Order 13527 making it the policy of the Federal government to plan and prepare for the timely provision of medical countermeasures to the American people in the event of a biological attack through a rapid federal response in coordination with State, local, territorial, and Tribal governments. The goal is to mitigate illness and prevent death, sustain critical infrastructure, and complement and supplement State, local, territorial, and Tribal government medical countermeasure distribution capacity.

Funding History:

FY 2006	--
FY 2007	--
FY 2008	--
FY 2009	--
FY 2010	\$10,000,000

Budget Request:

The FY 2011 request for the Medical Countermeasure Dispensing program is \$10,000,000, maintaining the FY 2010 level. Funding continues to be requested with two-year availability. Of this total, up to \$8,000,000 may be transferred to the USPS. Funds requested will seek to continue to expand the initial conceptual program to develop a Federal capability for direct residential delivery of medical countermeasures using the USPS. This postal capability is envisioned as the heart of the initial mass dispensing of antibiotics throughout a large metropolitan area during a catastrophic incident, specifically the outdoor release of a biological agent such as the anthrax germ. The overall objective achieved by the USPS component of the CRI would be to begin the development of a capability that can dispense and deliver antibiotics in designated zip codes in up to four CRI metropolitan statistical areas per year. The presence of a carrier volunteer strike capability would allow dispensing and delivery to be initiated within hours of a notification of an aerosolized anthrax attack and in advance of the points of dispensing (PODs) providing inventory from the Strategic National Stockpile (SNS) to broader exposed populations.

Funding is required for personnel costs of those participating in processing recruitment, training and exercises, delivery zone, design planning, medical and safety screening of the USPS volunteers and their families, safety screenings for PPE requirements of carrier volunteers, provision of antimicrobial and kit materiel, and disposable carrier uniforms as well as for IT support and program development, support and management. In addition, funds will be used to provide initial fit-testing and respiratory protection to the volunteer carriers. While some funds may be necessary to support capabilities developed in FY 2010 (e.g. screening of new USPS volunteers if initial volunteers do not continue with the program), the majority of new funding will support new sites in FY 2011.

Outcomes and Outputs:

Long Term Objective: Enhance State and Local Preparedness

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.10: Expansion of the Cities Readiness Initiative USPS Strike Teams in up to 15 cities (Outcome)	N/A	4 cities	8 total cities	+4 cities

**Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority**

	FY 2009	FY 2010	FY 2011 President's	FY 2011 +/-
	<u>Appropriation</u>	<u>Appropriation</u>	<u>Budget Request</u>	<u>FY 2010</u>
Program Level	\$306,052,000	\$340,531,000	\$476,194,000	+\$135,663,000
<i>Advance Development (non-add)</i>	\$240,163,000	\$269,851,000	\$403,194,000	+\$133,343,000
<i>BARDA Operations (non-add)</i>	\$65,889,000	\$70,680,000	\$73,000,000	+\$2,320,000
FTE	133	184	240	+56

Note: Funding requested for the Biomedical Advanced Research and Development Authority consolidates funding previously requested separately for Advanced Research and Development including management activities, BioShield Management, and Pandemic Influenza management.

Allocation Method: Direct Federal/intramural; contracts; grants

Program Description and Accomplishments:

The Office of Biomedical Advanced Research and Development Authority (BARDA), was established in April 2007 to develop and procure countermeasures to mitigate the medical consequences of man-made and natural threats. BARDA is charged with implementation of new authorities provided in the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA), as well as all of the previous responsibilities for the medical countermeasure (MCM) requirement setting, product innovation, advanced research and development, product acquisition and manufacturing infrastructure building and surge capacity to mitigate the medical consequences of pandemic influenza, and chemical, biological, radiological, and nuclear (CBRN) threats. Under these authorities, BARDA continues to broaden its focused advanced development product portfolio approach initiated successfully for pandemic influenza preparedness in FY 2006 to promising medical countermeasure candidates for CBRN threats. BARDA balances investments across the medical countermeasure development pipeline to mitigate the medical consequences of these threats by supporting advanced research development, stockpiling acquisition, building manufacturing infrastructure, and innovating product efficacy, manufacturing and testing.

BARDA facilitates collaboration among stakeholders in Federal, State, and local governments, industry, and academia; supports the advanced research and development of medical countermeasures; and promotes innovation to reduce time and costs of medical countermeasures development and production. Consistent with the requirements established by PAHPA and the roles and responsibilities identified in Homeland Security Presidential Directive (HSPD) -18, the *National Strategy for Medical Countermeasures against Weapons of Mass Destruction*, ASPR assists in the management of the *Public Health Emergency Medical Countermeasures (PHEMC) Enterprise*. ASPR is responsible for coordinating medical countermeasure research and development and acquisition programs across HHS and with interagency partners, particularly the Department of Defense.

In March 2007, the *PHEMC Enterprise* released the *Public Health Emergency Medical Countermeasures Enterprise Strategy for CBRN Threats (PHEMCE Strategy)*. In April 2007, the *PHEMC Enterprise* (led by ASPR) identified top priorities for the advanced development and acquisition of medical countermeasures for CBRN threats based on principles established in

HSPD-18 and the goals and framework for priority-setting detailed in the *PHEMCE Strategy*. In 2009, a second assessment of the PHEMCE strategic plan commenced with results expected in early 2010, commensurate with the HHS Secretary's call for a Countermeasure Review led by the ASPR.

Broad agency announcements (BAA) were issued in FY 2008 in partnership with the National Institute of Allergy and Infectious Diseases (NIAID) at NIH to solicit proposals to develop products in the following areas: anthrax vaccine enhancement, filovirus vaccines, and broad spectrum antibiotics and antivirals. Contract awards were made under vaccine enhancement and broad spectrum antivirals solicitations in September 2008. Additionally, BARDA supported several existing NIAID contracts that were consistent with the *PHEMCE Implementation Plan*.

Also in FY 2008, to ameliorate the many illnesses associated with the threat of radiation, BARDA awarded seven contracts for Acute Radiation Syndrome (ARS) medical countermeasures, one contract to support a radionuclide facility support services certified under good laboratory practices (GLP), and eight contracts for radiation-induced cutaneous and lung injuries. Additionally, funding on three contracts for oral DTPA (diethylene triamine pentaacetic acid) was continued in FY 2008. In FY 2009, a BAA was issued for development of biodosimetry devices and a request for proposals (RFP) was posted for neutropenia associated with ARS. Multiple awards are anticipated for each solicitation.

Funding was continued on several broad spectrum antimicrobial agent projects in FY 2008. Further, BARDA continued to fund inhalational gentamicin studies, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) antimicrobial drug screening program, and the development of smallpox antiviral drug product. Additionally, a new contract was awarded for the development of an alternate formulation of a smallpox antiviral drug for morbidly ill and post-exposure prophylaxis indication.

In FY 2009, BARDA published a BAA for CBRN medical countermeasures to support the advanced research and development of products for priority threats. Special instructions were issued for anthrax vaccines and anthrax antitoxins with numerous awards anticipated. Additional special instructions are being prepared for publication to address other threats to increase the number of products under advanced research and development.

Regarding advanced research and development of countermeasures to CBRN threats, BARDA awarded contracts in December 2009 for nine new projects to develop biomarkers and biodosimetry devices to measure radiation exposures and one existing project to continue development of a therapeutic monoclonal antibody to treat anthrax.

BARDA also manages Project BioShield acquisitions. The purpose of Project BioShield is to accelerate the research, development, purchase and availability of effective medical countermeasures against CBRN agents. In FY 2004, Congress appropriated a total of \$5.6 billion to the Special Reserve Fund to support late-stage development and acquisitions of CBRN medical countermeasures. To date, contracts have been awarded for medical countermeasures for anthrax, botulism, smallpox, and radiological/nuclear exposure. BARDA

continues to manage these contracts and the deliveries of products to the Strategic National Stockpile.

BARDA also manages Pandemic Influenza activities, including H1N1 activities. Funding for Pandemic Influenza acquisitions and other programmatic activities is requested separately.

Funding History:

FY 2006	\$66,734,000
FY 2007	\$119,741,000
FY 2008	\$131,419,000
FY 2009	\$306,052,000
FY 2010	\$340,531,000

Budget Request:

The request for the Biomedical Advanced Research and Development Authority in FY 2011 is \$476,194,000, an increase of +\$135,663,000 above the FY 2010 level. The request is financed by making funds from the Project BioShield Special Reserve Fund available for both BioShield procurements, and advanced development contracts. The President's Budget also proposes to allow additional Project BioShield funding to support advanced research and development, following Congressional notification. This flexibility would enable ASPR to target resources to the most promising candidates, be it through advanced research and development or Project BioShield. This proposal also aligns with the Secretary's call to review the MCM enterprise, which has a goal of a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices. BARDA's statutory mandate for preparedness includes chemical, biological, radiological, and nuclear bioterror threats, and pandemic influenza under the Pandemic and All-Hazards Preparedness Act. Funding in FY 2011 will be used to support efforts to develop and evaluate candidate medical countermeasures with the long-term potential to qualify for acquisition as medical countermeasures for the Strategic National Stockpile (SNS) and utilization prior to, during, and after CBRN threat events. Funds will support the advanced development of the highest priority medical countermeasures among the twelve biological threat agents and radiological/nuclear threats identified in the *PHEMCE Strategy and Implementation Plans*.

BARDA will manage the advanced research and development of certain products from proof-of-concept Phase 1 clinical studies and scale-up process manufacturing development and validation through Phase 2 and 3 human safety clinical studies and animal challenge and efficacy studies, to become eligible for consideration in an emergency and towards FDA approval.

Specifically, funding requested at this level is for continued advanced development of anthrax vaccine candidates and anthrax polyclonal and monoclonal antitoxins on new and existing BARDA contracts. This support will augment anthrax vaccines and therapeutics under development and progress these candidates forward for their potential use during a declared emergency and ultimately toward licensure, increasing preparedness for a high priority threat. In addition, funding is being requested to build infrastructure for the current licensed vaccine to

increase manufacturing capacity, bringing the federal government closer to the goal of acquiring enough anthrax vaccine to protect 25 million people.

Additionally, funding will support the advanced development of therapeutics under existing BARDA contracts to address illnesses associated with acute radiation syndrome. These funds will afford additional development of some, but not all, therapeutic candidate products in BARDA's widely-diverse product pipeline for the six illnesses resulting from radiological and/or nuclear event injury. Funds will also allow for development of physical biodosimetry devices to measure radiation exposure during an event. Finally the funds would be used to expand the indication for Prussian Blue, a treatment for radiological exposure, to the pediatric population.

For another high-priority need, funding is also requested for development of broad spectrum antimicrobial drugs to treat infections resulting from biothreats such as anthrax, plague, and tularemia, especially enhanced antibiotic resistant forms of these bacterial threat agents. This support will address another high priority need to support further product development of antibiotic candidates primarily under existing NIH, National Institute of Allergies and Infectious Diseases, Department of Defense, or BARDA contracts. Funds will also be utilized to initiate development of broad spectrum antiviral agents. An increase in funding will allow for development of more candidates as well as continued funding for those identified in FY 2010, which will have increased costs associated with advanced development in the out years.

Further, funding will continue support for the BARDA-sponsored innovation program to enhance late-stage or existing All-Hazards medical countermeasures and diagnostics, improve the manufacturing processes of these products, or the testing of the products during manufacturing or clinical study analysis.

The request also includes support for management and administrative support of the multi-billion dollar BARDA portfolio, including advanced research and development projects, Project BioShield awards, and Pandemic Influenza activities. (The FY 2011 request consolidates funding for advanced research and development, including management costs, Project BioShield management, and management of pandemic influenza activities. Comparable adjustments have been made consistent with this proposal.) The FY 2011 request includes \$73,000,000, an increase of +\$2,320,000 for BARDA operations.

Funding will support program management, clinical development, regulatory affairs, program protection and quality assurance staff to oversee both product development and implementation of internal controls and quality assurance programs, including on-site oversight of contract manufacturers, pre-award audits, and legal and subject matter experts. This includes management of pandemic influenza extramural contracts and grants that support the development, stockpiling acquisition and infrastructure building of medical countermeasures and non-pharmaceutical medical supplies and devices, including vaccines, antiviral drugs and therapeutics, rapid diagnostic coordination with CDC, masks, respirators and ventilators. Staff will be responsible for monitoring previous contracts as well as for new efforts planned in FY 2010 and FY 2011 including initiation of pivotal clinical trials for licensure of the Modified Vaccinia Ankara smallpox vaccine, licensure of botulinum antitoxin, and submission of data to FDA in support of licensure for anthrax therapeutic (Raxibacumab), support studies for label

extension for current licensed anthrax vaccine AVA for post exposure prophylaxis, and support development of rPA and smallpox antiviral candidates (manufacturing, non-clinical and clinical oversight). These investments in internal capacity will improve results. For example, support for manufacturing, regulatory, and clinical professional staff will facilitate product development, regulatory filings, and clinical protocol and data evaluation. This will result in proper oversight by the federal government and ensure that contractors are submitting high quality documents to the FDA that will expedite the review process. This in turn will improve in the contractor's ability to maintain adherence to project timelines and facilitate timely delivery of product to the Strategic National Stockpile. Investments in internal capacity will also result in proper programmatic oversight of all contracts by the HHS and allow for the Department to intervene quickly when problems arise and ensure proper risk mitigation and minimal disruption to project timelines.

In addition, funds will support modeling efforts for determining medical countermeasure requirements and assessing response strategies and capacities, as well as maintaining the web-based stakeholder portal (TechWatch) for information management and sharing, professional staff training in medical countermeasure research, development and acquisition, document management, and program management.

In FY 2011, ASPR will continue to support policy and strategic planning to set requirements and acquisition strategies for needed public health emergency medical countermeasures including stakeholder outreach to solicit input from industry, academia, and other interested parties of the planning process. In FY 2011, BARDA will hold the annual Industry Day and PHEMCE Stakeholder's Workshop to facilitate collaboration with all stakeholders and additional workshops on key topics in countermeasure development and management.

Outcomes and Outputs:

Agency Long-Term Objective: Develop and provide safe and effective medical countermeasures to identified chemical, biological, radiation and nuclear (CBRN) threats and emerging infectious diseases through coordination of interagency activities, support of product development and innovation with industry partners and building manufacturing infrastructure and surge capacity to enable product acquisition.

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
<p>2.4.4: Support development and innovation of candidate medical countermeasures for CBRN threats to facilitate their eligibility for procurement under Project BioShield. (Outcome)</p>	<p>FY 2009: BARDA issued BAAs and RFPs in FY09; Offerors submitted white papers (under the BAA) or full proposals (under the RFP) for BARDA consideration. Contracts awarded in 2009. See details below. (Target Met)</p>	<p>Targets, which may be addressed by contract awards in FY10 from BAA for CBRN MCM AD, include anthrax, acute radiation syndrome, and biothreats including enhanced agents such as antibiotic-resistant forms of anthrax, plague, and tularemia.</p>	<p>See specific targets by countermeasure area below.</p>	<p>N/A</p>

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
<p><u>2.4.4A</u>: Anthrax (vaccines, therapeutics, and medkits) (Outcome)</p>	<p>FY 2010: BARDA awarded multiple contracts in FY10 supporting development of third generation anthrax vaccines to prevent anthrax and therapeutic monoclonal antibody to treat anthrax. BARDA expects to award multiple contracts in FY10 for advanced development of new and existing anthrax rPA vaccine candidates and several promising broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and botulism. Additionally, a contract in FY10 is expected to support expanding domestic manufacturing capacity for existing licensed anthrax vaccine production and product testing. (In Progress)</p>	<p>New round of special instructions under the CBRN BAA will be issued for anthrax MCM development. Award contracts for third-generation anthrax vaccine products, anthrax therapeutics or enhancements to current products such as alternative routes of administration. In addition, continue funding for contracts awarded in FY09.</p>	<p>Progress 50% of anthrax therapeutic programs to TRL 7. Advance program to develop increased manufacturing capacity of AVA to TRL 6. Advance anthrax vaccine enhancement program to TRL 5</p>	<p>N/A</p>

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.4B: Radiation (Outcome)	FY 2010: BARDA awarded multiple contracts in FY10 supporting development of biomarker and biodosimetry devices to measure radiation exposure (9 contracts). BARDA expects to award multiple contracts in FY10 for advanced development of therapeutics to treat neutropenia, cutaneous skin afflictions, and pulmonary illnesses associated with acute radiation exposure. (In Progress)	Continue support of (i) ARS MCM ARD contracts awarded in FY08, (ii) for development of MCMs to address ARS-associated neutropenia, and (iii) for development of biodosimetry diagnostic devices and assays for rad/nuc exposure. Issue new special instructions under CBRN BAA, if needed, for ARS MCMs and biodosimetry devices.	Advance 50% of biodosimetry programs to TRL 3. Advance Neutropenia program to TRL 6. Advance Prussian Blue program to TRL 6.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.4C: Broad Spectrum Antimicrobial (BSA) (Outcome)	FY 2010: BARDA expects to award multiple new contracts and support an existing contract (gentamicin) in FY10 for advanced development of several promising broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and botulism. (In Progress)	Continue support of existing BSA ARD contracts awarded in FY09. Issue new special instructions under CBRN BAA in FY10 for development of next generation BSA drugs for treatment of infections resulting from biothreats such as anthrax, plague and tularemia with emphasis focused on enhanced resistant forms of these bacterial pathogens.	Award multiple programs for development of broad spectrum antivirals. Advance BSA programs to the next TRL (will vary by contract). Progress inhalational gentamicin to TRL 6.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.4D: Innovation (Outcome)	FY 2010: BARDA expects to award multiple new contracts for the innovation of products to facilitate measurement of host immune competency for vaccines, to evaluate the effects of several novel adjuvants on the immunogenicity of anthrax vaccines, to evaluate new platform expression systems for commercial scale antigen production, and new rapid diagnostic methods for broad spectrum antimicrobial detection and assessment of drug resistance. Second round of BAA for innovation will be issued in FY10. (In Progress)	Award innovation grants for BAA issued in FY09. Programs have the potential to affect multiple products as platform technologies are developed, improve the manufacturing processes of products and develop new <i>in vitro</i> testing methods to determine a product's efficacy, support assay development. In addition this effort will support development of late stage diagnostics.	Continue to support contracts awarded in FY10. No new starts.	N/A
2.4.4E: Smallpox (Outcome)	FY 2009: BARDA continued to fund existing development contracts. (Target Met)	Continue funding ARD program and ensure no overlap with scope of work for potential SRF award(s).	No new starts.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.4F: Viral Hemorrhagic Fevers (Outcome)	FY 2009: BAA issued, and white paper proposals were under technical review. (Target Met)	No new activity.	No new starts.	N/A
2.4.4G: Botulism (Outcome)	FY 2010: BARDA expects to award multiple new contracts and support an existing contract (gentamicin) in FY10 for advanced development of several promising broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and botulism and diagnostics to detect botulism. (In Progress)	No new activity.	No new starts.	N/A
2.4.4H: Chemical (Outcome)	FY 2010: BARDA expects to award one new contract to support an anticonvulsive drug as a chemical antidote. (In Progress)	No new activity	No new starts.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
2.4.4I: Bioproduction Facility (Outcome)	FY 2010: BARDA expects to issue an RFP to support functional design plans for facilities to develop and manufacture biological products. (In Progress)	Release RFP for concept design for multipurpose use manufacturing facility	No new starts.	N/A

**Office of the Assistant Secretary for Preparedness and Response
Medicine, Science, and Public Health**

	FY 2009	FY 2010	FY 2011 President's	FY 2011 +/-
	<u>Appropriation</u>	<u>Appropriation</u>	<u>Budget Request</u>	<u>FY 2010</u>
Budget Authority	\$8,690,000	\$8,748,000	\$10,000,000	+\$1,252,000
FTE	14	18	24	+6

Allocation Method: Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments:

The health and welfare of Americans is intertwined with the health of other nations' people. In the international realm, HHS's immediate responsibility is to advance and support policies and programs that will help safeguard and protect Americans from global health threats. HHS' actions are frequently conducted in coordination with the World Health Organization (WHO) and other global health partners, and include leading U.S. Government efforts to prepare for and respond to public health emergencies and acute threats. Specific activities include helping to build the capacity to detect both influenza outbreaks that have pandemic potential, and other infectious disease threats overseas. ASPR, in coordination with the Office of Global Health Affairs (OGHA) and under the framework of the WHO's revised International Health Regulations (IHR), continues to strengthen the nation's capabilities to detect public health threats, including emerging infectious diseases, by strengthening infectious disease surveillance and diagnostic capacities and by building emergency preparedness and response capacity in a number of developing countries.

ASPR coordinates and facilitates the development of international preparedness and response capabilities through agreements with the WHO, Ministries of Health and other international organizations, and by leveraging global partnerships to increase preparedness and response capabilities around the world. ASPR provided technical assistance, training and capacity building in Asia and Latin America, as well as the coordination of influenza vaccine production capacity in key developing countries through a global initiative with the WHO. Efforts have also been directed toward improving influenza surveillance and pandemic preparedness for H5N1 avian influenza in select countries of Asia, Africa, and Latin America, thereby strengthening global health security. ASPR also implements a collaborative program among U.S., Mexican and Canadian States and provinces along the U.S. international borders to enhance disease detection capacities. The U.S. Border States Early-Warning Infectious-Diseases Surveillance (EWIDS) Project increased sharing of epidemiological surveillance and lab data, improved participation in international preparedness exercises, and increased health alert communications between border States in the U.S. and Mexico and between U.S. border States and Canadian provinces.

ASPR is engaged in international preparedness and response partnerships, including with the Global Health Security Initiative (GHSI), the North American Leaders' Summit (NALS) [formerly the Security and Prosperity Partnership of North America (SPP)], and the WHO. ASPR coordinated the GHSI 2007 Ministerial Meeting and now leads a GHSI initiative to support the development of a sustainable global infrastructure for medical countermeasures for

CBRN events and pandemic influenza. In this regard, ASPR has organized two successful workshops in 2008 and 2009 attended by international stakeholders. Additionally, ASPR plans to organize and host additional exercises and workshops that the GHSI Working Groups have identified as priority needs, including a scenario on an international public health emergency that requires sharing of medical countermeasures, a workshop on international pandemic influenza response issues, an H1N1 pandemic influenza lessons-learned workshop.

As part of the NALS, ASPR's accomplishments include developing protocols with Canada and Mexico to improve connectivity between each country's Emergency Operations Centers. In FY 2009 ASPR detailed a public health liaison to Canada for a two-year period. ASPR has conducted a pilot program sending a short-term liaison to Mexico to help determine the ideal location for a long-term assignment and is working with the Mexican counterparts on the development of the full-term program.

ASPR has increased its international outreach efforts, in collaboration with the WHO, to implement the revised International Health Regulations (IHR) globally. ASPR led the federal government's effort to implement the revised IHR and monitored IHR compliance on behalf of the Department. ASPR has supported IHR implementation globally by sharing the federal government's best practices regarding IHR implementation and providing technical assistance to 43 countries across all six WHO regions. ASPR works closely with the Pan American Health Organization (PAHO) and U.S. partners to ensure timely information-sharing on significant public health events. ASPR has also collaborated with the Departments of Defense and State to develop a joint engagement strategy for use with countries that host U.S. military personnel. The strategy provides guidance to ensure timely and accurate reporting of infectious disease outbreaks and other public health events involving military personnel.

In addition to these partnership activities, ASPR develops and exercises international response plans. The Pandemic and All-Hazards Preparedness Act (PAHPA) charges the Assistant Secretary for Preparedness and Response to provide leadership for programs, initiatives and policies that deal with international public health and medical emergency preparedness and response. Beginning in FY 2008, ASPR led the Department-wide effort to develop the all-hazards *HHS International Emergency Response Framework* and engaged the federal departments under whose lead HHS might support a coordinated international response. In FY 2009, ASPR developed ten supporting annexes to this framework and assisted the Department of State, the U.S. Agency for International Development, and Department of Defense, to harmonize interagency plans related to international response. In FY 2009, ASPR began leading a Department-wide effort to develop and exercise the plan for how it will assist with international efforts to contain a pandemic outbreak.

ASPR represents HHS in the Interagency Work Group on Foreign Consequence Management (FCM) led by the State Department. The NPSD-17 Annex 6, FCM Preparedness and Response ("The Annex"), tasked the National Security Council to establish an interagency FCM working group to coordinate and oversee interagency FCM activities. As stated in The Annex, FCM is defined as, "U.S. Government activity which assists friends and allies in preparing for and responding to the human casualty effects from a chemical, biological, radiological, or nuclear (CBRN) incident."

ASPR led HHS engagement in the whole-of-government effort to establish a civilian capacity to prevent or prepare for post-conflict situations and help stabilize and reconstruct societies in transition from conflict or civil strife, so they can reach a sustainable path toward peace, democracy, social-well being and a market economy.

Biodefense and biosecurity are national priorities. To address these priorities, ASPR has expanded, intensified, and accelerated its support for critical national security biodefense and biosecurity activities. ASPR led activities related to the Trans-Federal Task Force on Optimizing Biosafety Oversight. The Task Force performed an intensive analysis of the current framework of biosafety and biocontainment oversight of high and maximum containment research on hazardous biological agents and toxins, and delivered a report outlining strategies to address concerns voiced by Congress and the general public.

ASPR chaired the working group (WG) on Strengthening the Biosecurity of the United States, which was established by Executive Order 13486 dated January 9, 2009. The WG reviewed existing policies and practices in place at federal and non-federal facilities that conduct research on; manage clinical or environmental laboratory operations involving; or handle, store or transport biological select agents and toxins (BSAT) and made recommendations for new legislation, regulations, guidance, or practices for security and personnel assurance and options for establishing oversight mechanisms. The WG's findings and recommendations are described in its draft report, which was completed and submitted to the White House by July 9, 2009 as required by EO 13486. ASPR also supports the efforts the Working Group on Optimizing Biological Select Agent and Toxin (BSAT) Security. The group is led by the National Security Council/National Security Staff and the Office of Science and Technology Policy.

ASPR supports the development and implementation of the *National Strategy for Countering Biological Threats*. The *Strategy* outlines the vision for addressing the challenges from proliferation of biological weapons or their use by terrorists. It highlights the beneficial nature of advances in the life sciences and their importance in combating infectious diseases of natural, accidental, and deliberate origin. It also outlines how the risks associated with misuse and potential consequences of a biological attack require tailored actions to prevent biological threats. The *Strategy* emphasizes the need to (1) improve global access to the life sciences to combat infectious disease regardless of its cause; (2) establish and reinforce norms against the misuse of the life sciences; and, (3) institute a suite of coordinated activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences. Through this strategy the Department will work with domestic and international partners to protect against misuse of the life sciences to support biological weapons proliferation and terrorism.

ASPR also supports the Department of State's activities related to the Biological and Toxin Weapons Convention (BWC), UN Security Council resolution 1540 implementation, and the G-8 Bioterrorism Experts Group (BTEX). Also, ASPR is an active participant in the federal effort to address the full spectrum of biological risk under the International BioEngagement sub-IPC (NSS-led) that developed strategies and roadmaps for engagement for Afghanistan, Pakistan,

East Africa, and SE Asia, addressing the ‘nexus’ of federal government goals and activities relevant to international engagement on biosecurity, public health, and science.

ASPR led the Interagency Working Group on Synthetic Nucleic Acid Screening to develop guidance for the gene synthesis industry to minimize the risk that unauthorized individuals will gain unique access to biological agents of concern through the use of nucleic acid synthesis technology.

ASPR serves as a liaison to the National Science Advisory Board for Biosecurity (NSABB) and is a non-voting HHS *ex officio* member of the board. The NSABB’s charge is to “provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biological threat to public health and/or national security.” NSABB advises the federal government on ways to minimize the risks associated with dual-use life sciences research; recommended a comprehensive framework for oversight of dual-use life sciences research; and developed recommendations for addressing the biosecurity concerns related to the synthesis of select agents, and enhancing personnel reliability among individuals with access to biological select agents and toxins. The National Biodefense Science Board (NBSB) is comprised of 13 voting members, individuals selected from among the Nation’s preeminent scientific, public health, and medical experts and 21 non-voting, *ex officio* members from across the federal government.

The inaugural meeting of the NBSB occurred on December 17-18, 2007 in Washington, DC. At that time the NBSB Board voted to establish four working groups. From FY 2008 through FY 2009, the Board convened six public meetings in-person and six public meetings by teleconference. The Board considered and made recommendations regarding the Charter of the Federal Education and Training Interagency Group—critical to the establishment of a Joint Federal Program for Disaster Medicine and Public health; for strengthening the National Disaster Medical System and medical surge capacity; and for improving the Department’s response to the mental health impacts of disasters. The Board made recommendations on the home stockpiling of antibiotics and the collection of data on the implementation of home stockpiling. The Board also provided recommendations on 2009 H1N1 countermeasures, support of the 2009 H1N1 vaccination program, and actions to prevent and mitigate adverse behavioral health outcomes during the 2009 H1N1 public health emergency.

Funding History:

FY 2006	\$8,988,000
FY 2007	\$8,808,000
FY 2008	\$8,690,000
FY 2009	\$8,690,000
FY 2010	\$8,748,000

Budget Request:

The FY 2011 request for Medicine, Science, and Public Health is \$10,000,000, an increase of +\$1,252,000 above the FY 2010 level. Increased funding will support efforts related to the optimization of laboratory biosafety and biosecurity and the creation of an enduring culture of

responsibility. Specifically, this increase will support efforts to:

- Improve biosafety and biocontainment oversight of research activities at high and maximum containment research laboratories in the United States;
- Development and implementation of policies to mitigate risks posed by the misuse of technologies related to the synthesis of nucleic acids;
- Development of policies and program efforts related to help safeguard classified life sciences research;
- Support continuing and new HHS efforts to strengthen pathogen security; and,
- Support communication and outreach related to biosafety and biosecurity.

Also, funding will be used to continue development of public health infrastructure in key regions of the world to further enhance epidemiological surveillance and laboratory capacities, and of associated information technology to foster accurate and prompt reporting of and response to naturally occurring and intentional infectious disease outbreaks. Specifically, funds will be used for programs with an emphasis on increasing capacity for detection, surveillance and response to novel influenza viruses and other emerging infections. Funds will also be used to continue the HHS partnership to enhance the capacity of public health systems along the U.S. border to rapidly detect infectious disease outbreaks. This effort will continue to improve cross-border public health early warning and situational awareness capability by decreasing the time needed to identify health events that could result from terrorism or naturally-occurring events. Funds will also continue to support the World Health Organization's Smallpox Advisory Committee's activities.

Funds will also support ASPR efforts to increase preparedness and response capabilities around the world through continued participation in international partnerships and initiatives, including the Global Health Security Initiative (GHSI), the Security and Prosperity Partnership of North America (SPP), and implementation and management of the International Health Regulations (IHR) program with the WHO. Investment in these activities will: improve international capabilities to detect infectious outbreaks early; foster collaborations with international partners to build a sustainable global infrastructure for medical countermeasures for CBRN events and pandemic influenza; and improve the federal government's abilities to assist and receive assistance from partner countries during public health emergencies. ASPR will also fund the further development and exercise of international all-hazards response plans with the federal government and other international partners. All of these efforts will improve member countries ability to rapidly respond, in a coordinated manner, and to mitigate the medical consequences of domestic and/or international public health emergencies. ASPR aims to continue to foster interagency relationships and collaborative planning, exercises and deployments abroad, as well as the development and implementation of responder readiness training.

Funding also supports the NBSB and its five Working Groups and the Subcommittee on Disaster Mental Health. The NBSB will hold two public meetings as required by the statute and hold public meetings as necessary to include the public in deliberations of the NBSB prior to sending recommendations to the Secretary. In addition to continued NBSB activities, funding will also be used to support the expansion of biosafety and biosecurity efforts within HHS, including implementation of recommendations from several Interagency working groups.

Outcomes and Outputs:

Long Term Objective: Mitigate the adverse public health effects of a terrorist attack.

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
<p>2.4.6: Coordinate and facilitate development of international preparedness and response capabilities. (Outcome)</p>	<p>FY 2009: Collaborated w/ GHSI ctrys & WHO to enhance cap. to prepare for/resp to health threats. ASPR org'd WS led to GHSI ctrys agreeing on specific areas of Emergency MCM collab't'n. Dev. 10 supporting annexes to all-hazards HHS International Emergency Resp Framework; assisted DOS, USAID, & DOD harmonize interagency plans on intl resp. Led HHS in whole-of-gov. effort to establish civilian cap. to prevent/prepare for post-conflict sit's, & help stabilize/reconstruct societies in transition from conflict. Detailed health and humanitarian assistance advisor to the US Army War College Peacekeeping and Stability Operations Instit. w/ focus on dev. doctrine & training on health & medical aspects of DOD stability, security, transition & reconstruction. Sig. improved US Border State cross-border epi infectious disease surveillance cap. to rapidly detect bio-terrorism & infectious disease threats. Assisted MX renovate a BSL-3 laboratory with cap. to diagnose biological threat agents. (Target Met)</p>	<p>Continue to collaborate with HHS Agencies, federal departments, U.S. border States, neighboring countries, other cross-border and international partners (e.g. WHO, foreign governments, NGOs), and with multilateral initiatives to advance domestic and international preparedness and response to all public health emergencies, including CBRN events and emerging infectious disease outbreaks. Continue to support and manage international response exercises and to collaborate with US States/Tribes/Territories and international partners to support universal implementation of the IHR. Continue to build international preparedness and response capabilities and develop plans, specifically in the areas of medical countermeasure development, pandemic influenza, stockpiling and deployment, international responder readiness, and testing/exercising of emergency response plans.</p>	<p>Continue to collaborate with HHS Agencies, federal departments, U.S. border States, neighboring countries, other cross-border and international partners (e.g. WHO, foreign governments, NGOs), and with multilateral initiatives to advance domestic and international preparedness and response to all public health emergencies, including CBRN events and emerging infectious disease outbreaks. Continue to support and manage international response exercises and to collaborate with US States/Tribes/Territories and international partners to support universal implementation of the IHR. Continue to build international preparedness and response capabilities and develop plans, specifically in the areas of medical countermeasure development, pandemic influenza, stockpiling and deployment, international responder readiness, and testing/exercising of emergency response plans.</p>	<p>N/A</p>

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
<p>2.4.7: Provide medical, scientific, and public health subject matter expertise (Outcome)</p>	<p>FY 2010: National Biodefense Science Board held public teleconferences October 2009, and November 2009. Recommendations were submitted to the Secretary following approval of the Board, in October and November 2009 (In Progress)</p>	<p>Conduct two annual meetings of the National Biodefense Science Board. Participate on working groups and Subcommittee. Identify and engage with subject matter experts. Draft policy options papers and reports. Hold an in-person public meeting in November 2009 and June 2010. The six Working Groups will hold over 70 working Group Meetings, and 12 Subcommittee Meetings.</p>	<p>Conduct two annual meetings of the National Biodefense Science Board. Participate on working groups and Subcommittee. Identify and engage with subject matter experts. Draft policy options papers and reports.</p>	<p>N/A</p>

**Office of the Assistant Secretary for Preparedness and Response
Policy, Strategic Planning, and Communications**

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$4,292,000	\$4,367,000	\$8,000,000	+\$3,633,000
FTE	19	22	27	+5

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

As the Department’s lead for emergency preparedness and response activities, there are additional expectations and requirements for the office to enhance its strategic planning, policy assurance, and strategic communication efforts, both within and outside HHS. This includes the development of the ASPR-wide policy agenda, the enhancement of efforts to promote community preparedness and prevention, and the building of public health partnerships with federal departments and agencies. Throughout the activities of the office, ASPR ensures transparency in policy and program development efforts, supporting State and local government preparedness efforts and continuing collaboration with academic institutions and private sector entities.

Internally, ASPR continues to initiate knowledge management tools to enable our stakeholders and partners to learn from the programs, projects and lessons learned. Externally, and in coordination with the Office of the Assistant Secretary for Public Affairs (ASPA), ASPR will continue to enhance public health risk communication. Through paid and free media, and the training and education of journalists and public spokespersons, HHS will develop and deliver messages and strategies that can enhance communications with the public during a public health emergency, including a pandemic influenza outbreak or a terrorist attack.

Planning and development of emergency crisis risk communications products is necessary as part of the response to a pandemic influenza outbreak. Public health communications strategies and messages have been identified, used and shared during both major disasters, such as Hurricanes Gustav and Ike, and training sessions, such as the series of pandemic influenza outbreak response tabletop exercises and the 2009-H1N1 influenza. Ongoing collaboration on crisis and emergency risk communications related to public health emergencies has expanded to include not only federal partners via the Interagency Communications Coordination Committee but also the National Public Health Information Coalition of State and local public health communicators, our North American partners Canada and Mexico, and the entire international health community via the World Health Organization.

The 2009-H1N1 influenza outbreak has driven the need to ensure clear communication of guidance and information to federal, State, local, public, and private partners about the event and mitigation strategies. Additionally, the development efforts around vaccine development and procurement, community mitigation policies, surveillance, laboratory capacity and borders for the 2009-H1N1 influenza outbreak have highlighted the need for ASPR to sustain and improve its Department-wide policy development and coordinating function.

The 2009-H1N1 outbreak has also highlighted the need for more robust information technology infrastructures that could be used during a public health and medical emergencies and responses. These infrastructures will bring consultative capacity into austere and compromised environments and enhance the capture of patient information, tracking, and therapeutic intervention throughout the arc of an event.

On behalf of the Department, ASPR serves as the lead office responsible for the quadrennial development and publication of the National Health Security Strategy (NHSS), as required by the Pandemic and All-Hazards Preparedness Act. The first NHSS was delivered to Congress in December of 2009. An Implementation Guide for the NHSS will be completed by fall of 2010.

Funding History:

FY 2006	\$2,756,000
FY 2007	\$3,116,000
FY 2008	\$4,292,000
FY 2009	\$4,292,000
FY 2010	\$4,367,000

Budget Request:

The FY 2011 request for Policy, Strategic Planning and Communications is \$8,000,000, an increase of +\$3,633,000 over the FY 2010 level. Funds will support the quadrennial development of the NHSS and the development of annual products to support this effort. Increases would be directed to develop and begin implementation of a research agenda to achieve the NHSS priorities and to analyze the impact of the NHSS. Proper objectives and benchmarks for evaluating the success of preparedness are needed, and a research agenda based on federal, State, territorial, local, and Tribal public health priorities will facilitate the achievement of national health security strategy priorities. Funds will be used to evaluate the progress and impact of the strategy using the framework established in the first NHSS. In addition, outreach to stakeholders via webinars or other means will be conducted to gain input on the progress and implementation of the strategy. Addenda to the NHSS implementation plan and updates will be developed.

Funds are requested to enhance the ASPR-wide infrastructure for policy formulation, analysis, coordination, and evaluation of preparedness and response efforts. This includes coordination, analysis and implementation of relevant laws (e.g., PAHPA, Public Readiness and Emergency Preparedness Act), proposed policies, Presidential directives, and regulations.

Activities also include the development of short and long-term policy and strategic objectives and of strategic communication including programming support for the HHS-TV studio which provides 24-hour emergency health preparedness information to the public. Funding will also support the continued development of the NHSS, which is required by PAHPA to be published every four years beginning in 2009. ASPR will conduct regularly scheduled communications meetings internally and externally with key stakeholders and will communicate strategy via web, video, and presentations at major meetings of stakeholders.

Outcomes and Outputs:

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
<p><u>2.4.8:</u> Improve strategic communications effectiveness. (Outcome)</p>	<p>FY 2009: Supported the development and execution of the Department's communication strategy related to the 2009-H1N1 influenza outbreak. Coordinated with GHSAG partners around the international messaging related to the 2009-H1N1 influenza outbreak. (Target Met)</p>	<p>Implement the ASPR strategic communications plan, including initiating a branding and marketing effort of ASPR. Implement ASPR's central infrastructure for public web communications with ESF 8 partners and the public.</p>	<p>Continue to implement the ASPR strategic communications plan. Maintain and improve ASPR's central infrastructure for public web communications and interagency collaboration.</p>	<p>N/A</p>
<p><u>2.4.9:</u> Establish and improve awareness of the ASPR strategy for preparedness and response (Outcome)</p>	<p>FY 2009: Completed draft National Health Security Strategy and Submitted to Congress (Target Met)</p>	<p>Continue to build on current outreach and awareness strategy via web, video, and presentations at major meetings of stakeholders.</p>	<p>Publish the first NHSS Biennial Implementation Plan by December 2010.</p>	<p>N/A</p>

Office of the Assistant Secretary for Preparedness and Response Operations

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$12,847,000	\$12,847,000	\$12,847,000	--
FTE	35	45	49	+4

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) created the Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR directs and coordinates HHS-wide capabilities to prepare for and respond to bioterrorism and other public health and medical emergencies. ASPR also coordinates activities with other departments and agencies as the lead for Emergency Support Function (ESF) #8 of the National Response Framework (NRF). ASPR's mission – to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters – and its vision – a Nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters – reflect the essential role ASPR plays within the Nation's public health preparedness and emergency response arena.

Carrying out HHS' responsibility as the primary agency for medical and public health preparedness requires the diverse and unique skills of scientists, public health experts and health care providers at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Administration for Children and Families (ACF), and the Centers for Medicaid and Medicare Services (CMS). Through its program offices ASPR coordinates the activities of these agencies, develops and coordinates national policies and plans, provides program oversight, and is the Secretary's public health emergency representative to other federal, State territorial, Tribal, and local organizations. The Public Health Emergency Medical Countermeasures Enterprise (PHEMC Enterprise), consisting of ASPR, CDC, FDA and NIH with members from the Departments of Defense, Homeland Security, Veterans Affairs and Agriculture, serves as the overarching coordination for the research, development, procurement, storage, maintenance, deployment and use of medical countermeasures for public health emergencies.

PAHPA provides ASPR with "authority over and responsibility for" the National Disaster Medical System (NDMS) (as of January 1, 2007) and the Hospital Preparedness Program. Additionally, the Act states that ASPR shall "exercise the responsibilities and authorities of the Secretary with respect to the coordination of the Medical Reserve Corps, the Emergency Systems for the Advance Registration of Volunteer Health Professionals (ESAR-VHP), the Strategic National Stockpile (SNS), the Cities Readiness Initiative (CRI) and other duties as the Secretary determines appropriate." The Act also established the Biomedical Advanced Research and Development Authority (BARDA) to facilitate collaboration between HHS and other federal

agencies, relevant industries, academia, and other persons, with respect to advanced research and development of medical countermeasures for chemical, biological, radiological and nuclear (CBRN) threats and pandemic or epidemic threats.

PAHPA also designates the Assistant Secretary for Preparedness and Response the responsibility “to serve as the principal advisor to the Secretary of HHS on all matters related to federal public health and medical preparedness and response to public health emergencies. ASPR Operations includes support for the Immediate Office of the ASPR to fulfill this role through strategic coordination of all HHS preparedness efforts and executive direction of all ASPR programs. Operations funding also supports ASPR-wide efforts to ensure the maximum alignment of resources to strategy. Recent efforts in this area include the development of an in-house budget execution and monitoring function, and an expanded assessment of ASPR’s risk management of business functions consistent with OMB Circular A-123. In addition ASPR has conducted several initiatives to improve workforce development including gauging staff productivity and engagement through a comprehensive all-hands survey, cultivating ASPR’s next generation of leaders through OPM certified 360 assessments and promoting executive development in collaboration with the Annenberg Leadership Institute. Additional progress has been made in monitoring management and program performance through an ASPR scorecard, promoting key competencies for all staff, increasing the utilization of Individual Development Plans and building an ASPR-wide records management program.

Funding History:

FY 2006	\$9,147,000
FY 2007	\$7,626,000
FY 2008	\$10,261,000
FY 2009	\$12,847,000
FY 2010	\$12,847,000

Budget Request:

The FY 2011 request is \$12,847,000, maintaining the FY 2010 level. Funding will continue to support staff salaries including for the Immediate Office of the Assistant Secretary, rent and service charges, equipment costs, travel, telecommunications, training and continued implementation of revised OMB Circular A-123. Funds will also support the continued development of ASPR performance measurement and strategic human capital management.

**Office of the Assistant Secretary for Preparedness and Response
ASPR Facilities Project**

	<u>FY 2009 Appropriation</u>	<u>FY 2010 Appropriation</u>	<u>FY 2011 President's Budget Request</u>	<u>FY 2011 +/- FY 2010</u>
Budget Authority	--	--	\$10,000,000	+\$10,000,000
FTE	--	--	--	--

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

ASPR manages 131,000 sq ft of space in the Southwest Complex, in five different buildings, with over 15 distinct blocks of space in support of approximately 650 total onboard staff and contractors. These disparate locations require separate and often-times duplicate office support staff, equipment and administrative support spaces (conference rooms, break areas, storage rooms, etc.) which lead to a high level of management inefficiency. In addition, these different locations serve as potential barriers to mission execution as communication, collaboration, and coordination are hampered when operating across these distances.

ASPR is seeking funding for costs associated with a large GSA prospectus project that would collocate approximately 90% of ASPR staff in a single facility in the Washington DC area. A collocated facility would include the following: office space for up to 700 staff (in addition to approximately 80 staff that would remain in HHS Humphrey headquarters building), joint use meeting rooms that will double as surge space during emergency responses, and a Secure Compartmentalized Information Facility (SCIF).

Being collocated in two facilities (HHS HQ and one new location) would provide for 1) improved adjacencies to assist in faster response rates to public health emergencies 2) attracting and retaining key talent by allowing staff to have easy access to each other and the appropriate technologies and space for employees to excel and 3) support our unique needs during a national emergency. Through a comprehensive review with the HHS Assistant Secretary for Administration, GSA and its design and architecture partners, ASPR has developed a full facilities program of requirements that will meet these needs.

An ASPR collocation project is essential to improving ASPR’s readiness function and mission accomplishment while improving management efficiencies and optimizing scarce resources. In addition to maintaining ASPR’s present space in the HHS HQ building, the collocation project retains the existing Secretary Operation Center (SOC) so it can continue to support the Department and its stakeholders. Preserving this presence in the HHS Humphrey HQ building ensures that the ASPR can fulfill the responsibility to serve as the HHS Secretary’s principal advisor for public health and medical preparedness and response.

Funding History:

New program proposal in FY 2011.

Budget Request:

The FY 2011 President's Budget requests \$10,000,000 to be used for year one of two year financing for physical moves, IT infrastructure installation, telecom system equipment, design, construction/renovation, project and construction management services and furniture for a new 150,000 square foot facility. These funds are requested with no-year availability. The project also includes ASPR providing temporary space in 2011, for up to 230 ASPR staff required to vacate 50,000 square feet of currently occupied space in the Southwest Complex. It is anticipated that this temporary space will be needed until final move-in for up to 90% of ASPR staff to a co-located facility currently scheduled for 2013.

**Office of the Assistant Secretary for Administration
Cyber Security (IT Security)**

	FY 2009 <u>Appropriation</u>	FY 2009 <u>Recovery Act</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$8,906,000	\$50,000,000	\$27,040,000	\$37,040,000	\$10,000,000
FTE*	--	--	17	17	--

* Of the 17 FTE in FY 2010, 8 are funded through Recovery Act balances.

Allocation method: Contracts and direct Federal/Intramural

Program Description and Accomplishments:

The HHS IT Security Program within the Office of the Chief Information Officer (OCIO), under the Assistant Secretary for Administration, assures that all automated information systems and data throughout HHS are designed, operated, and maintained with the appropriate IT security and privacy safeguards. To maintain public trust and service delivery partnerships, most official activities at the Department require the protection of confidential data such as personally identifiable and proprietary commercial information. Meanwhile, ready access to increasing amounts of public information is necessary to support research and innovation, and provide efficient government services. To ensure data security, every general-purpose computing environment and specific program application is subjected to risk-based security control testing prior to implementation. Post-implementation monitoring occurs continuously to guard against increasingly sophisticated threats.

Secure information systems are needed to support the disbursement of billions of dollars through Medicare and Medicaid, provide critical social services such as Head Start, childcare and child support enforcement, support a life-giving organ transplant system, maintain food and pharmaceutical quality, develop groundbreaking biomedical research, report accurate and timely disease treatment information, and detect disease outbreaks and bioterrorism.

Utilizing a risk-based approach to security, the HHS IT Security Program focuses priority attention on providing an appropriate level of security protections for the most sensitive information systems and data that support the critical mission and functions of HHS. The program also ensures that security policies and processes are in place to support compliance with the requirements of the Federal Information Security Management Act (FISMA), and compliance with OMB and NIST guidance. The program safeguards the information used to support the health of people and communities. HHS information technology balances the security needs with the business needs of our staff and public health partners. The OCIO oversees the HHS IT Security Program with staff funded within the Cyber-Security appropriation in FY 2010 and FY 2011.

The HHS IT Security Program has established the HHS Computer Security Incident Response Center (CSIRC), which will include the security technologies that will provide an enterprise-wide capability to monitor the Department's computers and networks for security incidents and attacks. HHS plans to continue to expand CSIRC capabilities in FY 2010 and FY 2011 to enable the Department to better determine the overall enterprise security risk posture of our operational

IT systems, by deploying additional intrusion detection systems and other security technologies throughout the Department. The CSIRC expansion efforts will include planning and engineering required to support the security requirements associated with the Federal government's Trusted Internet Connections (TIC) initiative. The Department's planning efforts for the TIC initiative respond to the Office of Management and Budget (OMB) Memorandum M-08-05, dated November 20, 2007, as a result of which the Department will adopt a network and security architecture for all external connections to include the Internet and all inter-agency, partner, contractor, educational, health and research connectivity that reduces the total number of Internet connections and complies with the Department of Homeland Security (DHS) requirements. In addition, the Department will continue efforts to develop security architecture plans and strategies at all Operating Divisions, in order to define cost-effective approaches to better secure the Department's network infrastructure, and prevent IT system compromises and the loss of sensitive data.

The HHS IT Security Program also manages the procurement of enterprise licenses for a wide variety of security tools to include tools for the encryption of sensitive information and tools that provide for vulnerability scanning and IT systems and application software security configuration compliance. The program also supports the implementation of more effective computer systems access controls using credentials issued in accordance with Presidential Homeland Security Presidential Directive-12 and federated trust relationships established under the HHSIdentity program.

The American Reinvestment and Recovery Act (Recovery Act) was signed into law by President Obama on February 17, 2009. The Department of Health and Human Services OCIO Information Technology (IT) Security Program has received \$50 million in total Recovery Act funding. More information on these and other Recovery Act programs can be found at www.hhs.gov/recovery.

The IT Security Program initiated an effort in FY 2009 to re-validate and update its inventory of information systems. This corresponded with the issuance of a Department-wide information systems security and privacy policy guidance that brought the Department's policies into compliance with FISMA. In addition, updated security policy guidance was developed and issued to address a number of new or expanded requirements, including guidance for the encryption of sensitive information, IT systems inventory guidance in support of FISMA reporting, and the establishment of consistent processes for security certification and accreditation and security weakness tracking. The Department successfully achieved a number of FISMA milestones and performance measures, to include the timely submission of quarterly and annual FISMA reports to the OMB. Department-wide licenses were also procured providing all OPDIVs with the capability to perform security weakness vulnerability scanning of all computer systems and web sites, using a Security Content Automation Protocol (SCAP) tool that had been validated by the National Institute of Standards and Technology (NIST). The establishment of the Department's CSIRC provides a significant improvement in the Department's ability to more effectively coordinate defensive actions by the OPDIVs in responding to attacks against our computer systems and networks. A security architecture assessment was completed at the NIH that recommended a number of security infrastructure upgrade projects and initiatives. Funding for the NIH high priority security infrastructure upgrade initiatives will begin in FY 2010. FY

2010 funding will also provide for the start of security infrastructure enhancements at CDC and CMS.

Funding History:

FY 2006	\$9,586,000
FY 2007	\$9,482,000
FY 2008	\$8,906,000
FY 2009	\$58,906,000 (includes Recovery Act)
FY 2010	\$27,040,000

Budget Request:

In early FY 2009, HHS embarked on multiple strategic discussions and meetings to define the highest priority efforts and desired security capabilities that would substantially improve the IT security posture of HHS while also addressing the highest priority security risks that are impacting the Department as a whole. This directly resulted in the development of the Recovery Act spend plan for cybersecurity, and the Department level and OPDIV level cybersecurity spend plans for FY 2010 and FY2011. The Recovery Act spend plan and the Department level cybersecurity spend plan complement the efforts of the OPDIVs to address the Department's highest priority security risks. The FY 2011 President's Budget for IT Security is \$37,040,000, an increase of +\$10,000,000 over the FY 2010 enacted level. The FY 2011 request will enable the HHS Office of IT Security (OITS) to continue to provide management and oversight of the Department's IT Program, to ensure compliance with the requirements of FISMA. This includes the continued staffing and operation of the HHS Computer Security Incident Response Center (CSIRC), which serves to provide continuous monitoring and security incident response coordination for the Department's computer systems and networks. The request includes a number of major security projects under the Computing Infrastructure Security Re-design Project which includes funds to support planning and security engineering for the Trusted Internet Connection (TIC) initiative, and funds for Endpoint Protection Security Tools.

FISMA Program Management: The request will allow the HHS IT Security program to continue to perform the functions and processes required to comply with FISMA. This will include efforts to pursue more effective implementation of security weakness remediation in response to recommendations and findings made in connection with the audits and evaluations, including the Department's annual financial statement audits. The Department will continue to enhance the program's security compliance and annual FISMA program review efforts to more effectively measure the Department and OPDIV levels of compliance with the requirements of FISMA. The Department will enhance OPDIV operational IT systems continuous monitoring capability to determine OPDIV compliance with Department policy and standards to include quarterly evaluation of security weakness Plans of Action and Milestones (POA&M), Privacy Impact Assessments (PIA), and system of records notice (SORN) compliance. Support will continue for the activities of the HHS personally identifiable information (PII) Breach Response Team that will enable the Department to evaluate OPDIV breach response assessments to determine the appropriate response to any reported breaches of PII.

Computer Security Incident Response: The CSIRC will continue expansion efforts to achieve

full operational capability (FOC) in FY 2011. A number of significant security technologies will be incrementally fielded throughout FY 2010 and into FY 2011, to include enterprise network intrusion detection and prevention solutions, network traffic analysis tools, security event and information management solutions, and tools to support the forensic analysis of malicious software (malware). The systems engineering and integration efforts associated with these technologies will be demanding, and will also need to be closely aligned with the TIC initiative and other Department of Homeland Security (DHS) efforts to improve the Federal government's ability to counter attacks. These technologies will have a major impact on the Department being able to achieve the continuous security monitoring of our network systems and software applications. FY 2011 efforts to achieve FOC will complete the various projects that were initiated with Recovery Act funds, and will enable the Department to sustain a very robust capability to defend against computer attacks, and also better detect and respond to any attacks.

Computing Infrastructure Security Re-Design Projects: The OIG specifically identified the computing and network infrastructure domains of the OPDIVs as being flawed, and recommended that the Department take action to eliminate the currently flawed designs. This project provides for the reconfiguration of the computing infrastructures at the OPDIVs to enable the computing infrastructure to be re-configured into secure segments and zones, resulting in a significantly improved defense in depth approach to security. This will provide for multiple layers of security controls to protect our most critical HHS information, while also enabling HHS to securely conduct scientific research with our partners. This work continues and builds on work started in FY 2009 with the \$50 million provided for IT Security in HHS provided by the Recovery Act. These funds will enable HHS to implement security architecture upgrade plans and strategies that will ensure that the most critical data and systems are appropriately protected utilizing a cost effective, risk based approach to security. The IT Security Program will coordinate the re-design of OPDIV network infrastructures to establish separate, secure network and data segments for development, testing, and production environments. This will also include the establishment of dedicated hosting environments (hardware, software, VMWare) for development and testing environments, as well as the establishment of segmented environments in which data will be stored based on high, moderate, and low sensitivity.

In addition, upgrades to and the re-architecture of OPDIV environments will be completed to provide enhanced protection for OPDIV database and application servers by establishing multiple security zones within HHS and OPDIV networks. This will include the establishment of an additional level of protection within the HHS and OPDIV network's protected demilitarized zone (DMZ), in order to isolate critical servers while maintaining internal and external accessibility. These re-architecture efforts will directly support the Department's implementation of the Trusted Internet Connections (TIC) initiative. The Department will continue to pursue efforts to significantly enhance the enterprise security program at CMS, to address several gaps identified in OIG audits, to include weaknesses in enterprise risk management capabilities, intrusion detection, security information and event management, and incident response

Endpoint Protection Security Tools: HHS will enhance the IT security at the Operating Divisions by pursuing a number of high impact investments that will address and correct existing security gaps. This includes the implementation of Network Access Control (NAC) security technology and endpoint protection technologies which will provide commercially available access control solutions required to better secure access HHS computers and network resources. This will provide for additional solutions to counter malicious software (malware) and other sophisticated computer viruses and worms that continue to plague government computer systems. The Department will also renew the Department-wide licenses for a number of security technologies including solutions for encryption, enterprise malware and content filtering, data loss prevention, vulnerability scanning software, and automated tools for FISMA reporting, and security weakness tracking.

While the Department has begun addressing these areas via the FY 2009 appropriation and Recovery Act funding, the requested increase in FY 2011 is necessary to ensure these security activities are implemented fully and consistently at all levels of HHS. An effective IT Security program will decrease the number and severity of exploits of sensitive HHS information systems, including compromise of mission critical data. Maintenance and updating of infrastructure will be required Department-wide in order to proactively identify and address vulnerabilities before they are successfully exploited.

Performance Table:

Measure	Most Recent Result	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
1.1 Percentage of desktop computers operating in compliance with Federal Desktop Core Configuration (FDCC) security guidance (windows computers)	99% (FY 2009)	100%	100%	--
1.2 Percentage of HHS laptops and desktops secured with encryption	40% (FY2009)	55%	95%	+40%
1.3 Percentage of HHS enterprise network infrastructure monitored with automated intrusion detection systems	55% (FY2009)	60%	90%	+30%
1.4 Percentage of HHS IT systems protected with advanced Internet content filtering and anti-malware solutions	60% (FY2009)	85%	95%	+10%
Program Level Funding (\$millions)	8.906 (FY2009)	27.04	37.04	37.04
ARRA Level Funding (\$millions)	N/A	50	N/A	N/A

Office of Public Health and Science Medical Reserve Corps

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$12,344,000	\$12,581,000	\$12,694,000	+\$113,000
FTE	9	9	9	--

Authorizing Legislation: Public Health Service Act, Section 2813

Allocation Methods: Direct Federal; contract; and cooperative agreement

Program Description and Accomplishments:

The Medical Reserve Corps (MRC) was developed by the Office of the Surgeon General (OSG), within the HHS Office of Public Health and Science (OPHS), in March 2002. It was subsequently authorized by Congress in the Pandemic and All-Hazards Preparedness Act of 2006.

The Medical Reserve Corps is a national network of local groups of volunteers committed to improving the health, safety and resiliency of their communities. MRC volunteers include medical and public health professionals, as well as others interested in strengthening the public health infrastructure and improving the preparedness and response capabilities of their local jurisdiction. MRC units identify, screen, train and organize the volunteers, and utilize them to support routine public health activities and augment preparedness and response efforts.

The MRC originated as a demonstration project (started in FY 2002 and continued through FY 2006) that provided start-up grants to 166 communities across the U.S. Many other communities have since established MRC units outside of the demonstration project. As of December 2009, there are 865 MRC units in all 50 states, Washington, DC, Guam, Palau, Puerto Rico and the US Virgin Islands, totaling more than 190,000 volunteers.

Many jurisdictions have used the MRC to improve public health and prepare for emergencies in their communities. While the MRC provides volunteers with an opportunity to make a difference in the health and safety of those nearest to them, it also fills gaps in both public health initiatives and local preparedness. This has enabled local communities to achieve a higher degree of resiliency and reduced dependence on States and the Federal government during public health emergencies.

Medical Reserve Corps units are organized locally to meet the needs in their community. They are encouraged to contribute to local public health initiatives, such as those meeting the Surgeon General's priorities for public health: increase disease prevention, eliminate health disparities and improve public health preparedness. As a community-based program, each MRC is responsible for determining its own structure and developing its own policies and procedures. MRC units have been established and implemented by local governmental agencies and non-governmental organizations, each with strong partnerships with local medical, public health, emergency management and other entities vital to their success and sustainability.

The Office of the Civilian Volunteer Medical Reserve Corps (OCVMRC) is housed within the OSG. It functions as a clearinghouse for information and guidance to help communities establish, implement, and maintain MRC units nationwide. Office activities include strategic planning, intra- and interagency coordination, communications, policy development, program operations, grants management, contract oversight, technical assistance, and deployment operations. These activities are carried out by OCVMRC Federal and contract staff.

The OCVMRC undertakes efforts to expand the capacity of MRC units throughout the nation. This work is closely coordinated with the White House/Homeland Security Staff, the Surgeon General, the Assistant Secretary for Health (ASH), the Assistant Secretary for Preparedness and Response (ASPR), Regional Health Administrators and other Federal officials, as well as State MRC coordinators and a variety of other stakeholders. While the vital, ongoing work of the MRC program continues, additional efforts are being made to establish the necessary mechanisms and processes to involve MRC members who are willing, able and approved to deploy with HHS on national-level responses.

In order to accomplish its mission, OCVMRC works with several different partners, using a variety of allocation methods to distribute funds:

- Cooperative agreement with the National Association of County and City Health Officials (NACCHO). This cooperative agreement was initiated in FY 2006 (FY06 - \$8 million; FY07 - \$6 million; FY08 - \$5.3 million) and extended for one year in FY 2009 (\$7.2 million). Activities include providing “Capacity-building Awards” directly to MRC units (FY06 - 491 awards; FY07 - 507 awards; FY08 – 537 awards), providing logistical and other support for regional and national MRC conferences, supporting several national-level MRC work groups, and assisting with MRC communications, outreach and marketing efforts. The capacity-building awards (\$5,000-\$10,000 per eligible/selected MRC unit) are used by MRC units to offset a variety of administrative costs, including personnel, training, travel, supplies and equipment. OCVMRC expects to award a new cooperative agreement in FY 2010.
- Contract with ICF/Z-Tech Corporation for MRC program support. This contract provides a National Technical Assistance Coordinator, Public Information Officer, Junior Communications Specialist, and 10 Regional Coordinators situated in the HHS Regional Health Administrator offices. The Regional Coordinators provide day-to-day connection with the MRC units and conduct annual technical assistance assessments. Z-tech hosts and maintains the MRC website (www.medicalreservecorps.gov), as well as the database of MRC unit profiles. Other activities supported by this contract include the technical assistance materials and resources, MRC promotional materials (i.e. brochures, exhibit booth, information packets), and support for MRC outreach.
- Interagency Agreement with the Centers for Disease Control and Prevention which provides a funding supplement to an existing CDC Cooperative Agreements with the Public Health Foundation (PHF). The funding to PHF supports MRC-Train, a learning management resource offered (free-of-charge) to all MRC units.

The MRC has seen significant growth since its development, both in the number of units and in the number of volunteers:

	New MRC Units	Total Number of MRC Units	Total Number of Volunteers
FY02	42	42	(Inception)
FY03	124	166	10,116
FY04	66	232	34,164
FY05	118	350	62,982
FY06	247	597	112,089
FY07	116	713	146,414
FY08	103	787	168,996
FY09	90	856	189,245
FY10 (to date)	14	865	194,637

The continually increasing number of MRC units indicates the level of acceptance of the MRC concept, mission and purpose within communities and States throughout the nation. The need for a credible and valuable MRC network is clearly demonstrated. There was a larger growth rate in FY 2006 due to increased awareness following Hurricane Katrina and the initial NACCHO Capacity-building Awards. With the implementation of annual Technical Assistance Assessments in 2007, OCVMRC has seen an increase in the number of de-registrations of MRC units, as inactive units are discovered and removed from the list of viable MRC units. Currently, OCVMRC expects to see a 5-10% growth rate.

Funding History:

FY 2006	\$9,748,000
FY 2007	\$9,748,000
FY 2008	\$9,578,000
FY 2009	\$12,344,000
FY 2010	\$12,581,000

Budget Request:

The FY 2011 Request Level is \$12,694,000, an increase of \$113,000 above the FY 2010 President’s Budget. The increase provides funds to continue to support salaries, travel, cooperative agreements, contracts, grants and contract management, technical assistance, outreach, deployment operations and other programmatic activities.

OCVMRC concentrates on achieving the following broad goals:

- Serve as the national voice of the MRC network;
- Promote MRC participation in response efforts at all levels;
- Support the growth and maintenance of the nationwide network of MRC units; and,
- Strengthen our internal capacity to support MRC units.

Twelve strategic objectives have been identified and are grouped using a Balanced Scorecard approach into three perspectives:

- **People and Resources**

This perspective focuses on the core assets of OCVMRC which are people and resources. Our success depends on the effective use of human and capital resources. We seek to become a strength-based organization that pursues strategies to develop our staff and use their talents, abilities, and skills to their fullest potential. Resources and careful stewardship of assets are also necessary in order to achieve our mission and goals.

- **Sound Fiscal Management.** Needs are prioritized, initiatives are developed, spending levels are proposed, and resources are allocated effectively.
- **Competent, Motivated and Engaged Staff Members.** Staff members understand what is expected of them; have the appropriate talents, knowledge, skills, abilities, and attitudes to function well in their assigned roles; and work in a learning and nurturing environment.
- **Resources Allow Maximized Productivity.** The necessary policies, infrastructure and resources are in place to maximize productivity.

- **Internal Processes**

This perspective captures the core processes at which we must excel to accomplish our mission. These strategic objectives allow us to sharpen our operational focus, and thus create greater value for our customers and stakeholders.

- **Provide Expert Guidance.** Nationally-accepted MRC principles are established, promulgated and evaluated. Relevant technical assistance (TA) and capacity-building resources are developed and disseminated.
- **Enable Information Sharing.** Multiple resources and forums are provided to allow members of the MRC network to learn from each other about challenges and promising practices.
- **Standardize Routine Processes.** Consistent processes are developed and utilized in order to improve reliability and enhance credibility.
- **Leverage Strategic Relationships.** Mutually-beneficial relationships bring value to the MRC network.
- **Conduct Outreach Activities.** Potential stakeholders, supporters, volunteers and others appreciate the MRC as a community resource.
- **Demonstrate Federal Deployment Capability.** MRC members are authorized to participate in a Federal response to a public health emergency.

- **Customer**

This perspective outlines the strategic objectives that we must achieve in order to directly satisfy our customers and stakeholders.

- **Engaged and Satisfied MRC Unit Leaders.** MRC leaders are pleased with the level of attentiveness and responsiveness of OCVMRC staff members. The leaders demonstrate their engagement by conducting local activities and participating in the MRC network.
- **HHS Priorities Advanced.** The MRC serves as an important conduit by which the Surgeon General priorities are actively supported and carried out by volunteers

- throughout the Nation. OCVMRC also advances and promulgates the priorities and goals of OPHS, ASPR and other HHS divisions.
- **Credible and Valuable MRC Network.** The MRC network is robust and recognized, its value and impact are evident, and the MRC concept of local volunteer support for public health and preparedness activities is accepted.

Performance measures for each objective, and specific targets for each measure, are included in our Balanced Scorecard. The Balanced Scorecard is reviewed at least quarterly to ensure adequate implementation of this strategic plan.

FY 2011 funding will ensure that our goals and objectives are achieved through additional capacity-building support, enhanced adherence to the unit registration criteria, improved data collection and continuation of the annual technical assistance assessments. MRC expects that all MRC units will work towards having an impact on health, safety and resiliency in their communities.

Outputs and Outcomes:

The MRC is aligned with broader HHS and OPHS Priorities:

- **Prevention:** Local Medical Reserve Corps units are encouraged to conduct and support activities that address ongoing public health priorities and improve prevention efforts, such as diabetes detection, hypertension screening, and back-to-school immunizations.
- **Emergency Response:** Local Medical Reserve Corps units are encouraged to conduct and support activities that enable their community to prepare and respond to emergencies.
- **Pandemic Preparedness:** Local Medical Reserve Corps units are encouraged to be involved in pandemic preparedness activities in their local communities.

The following key outcomes are priority performance measures that we track as part of our balanced scorecard.

Key Outcomes	Most Recent Results	FY 2010 Target	FY 2011 Target	FY 2011 +/- FY 2010
Long-Term Objective 1: Demonstrate a credible and valuable MRC network				
1.1 The continued acceptance of the MRC concept by communities across the country is shown by increases in the number of MRC units. # MRC units (targets based on 5% growth rate)	856 (FY 09 - Exceeded Target)	899	943	44
1.2 Community members (including medical and public health professionals) across the country continue to join local MRC units in order to help improve public health and resiliency. # MRC volunteers (targets based on 5% growth rate)	189,245 (FY 09 - Exceeded Target)	198,707	208,642	9,935

Long-Term Objective 2: Provide expert guidance and enable information sharing				
2.1 The MRC website is an important source of information for MRC leaders, volunteers and others. # MRC website visits	779,820 (FY 08 – Met Target)	500,000	510,000	10,000
2.2 OCVMRC has provided guidance documents and training to assist with strategic planning, and has encouraged all MRC units to engage in strategic planning processes. % MRC units indicating that they engage in strategic planning	68% (FY 09 – Below Target)	75%	80%	5%
Long-Term Objective 3: Demonstrate a Federal deployment capability				
3.1 OCVMRC has encouraged all MRC units to track the willingness of their members to deploy outside of the local jurisdiction. % MRC units that track their members willingness to deploy outside of the local jurisdiction	78% (FY 09 - Exceeded Target)	80%	85%	5%
3.2 OCVMRC is developing the mechanisms, policies and procedures necessary to identify, activate and deploy MRC members who are willing, able and approved to participate in a Federal response. # MRC members who are fully processed as Federally-deployable.	0 (FY 09 Baseline Year)	150	225	75
Program Level Funding (\$ in millions)	N/A	\$12.581	\$12.694	\$0.113

Office of Security and Strategic Information

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
Budget Authority	\$3,263,000	\$4,893,000	\$6,460,000	+\$1,567,000
FTE	21	31	39	+8

Allocation Method: Direct Federal

Program Descriptions and Accomplishments:

OSSI was established by the Secretary to: 1) consolidate three overlapping, but potentially synergistic functions; 2) conduct central management oversight and apply program standards for its functional responsibilities; 3) establish a department-wide authority and focal point for matters pertaining to interactions and relationships with the intelligence and federal law enforcement communities. OSSI has responsibilities across all HHS operating and staff divisions and provides direct services to all elements of the Office of the Secretary.

OSSI is headed by a Director who reports directly to the Secretary and Deputy Secretary. On a day-to-day basis, OSSI works under the supervision and authority of the Deputy Secretary. OSSI consists of three divisions (see below), with permanent staff, detailees, and contractors. Authorities are derived from the Federal Register Statement of Functions (Federal Register Notice, April 3, 2007, Vol. 72, No. 72, 19000-19001) and direct delegations for physical security, personnel security, and original classification authority.

OSSI represents HHS on several Homeland Security Council and National Security Council committees and workgroups, and on interagency committees and councils both inside and outside the Intelligence Community. OSSI serves as a representative of and principal advisor to the Secretary and Deputy Secretary on issues concerning national security, strategic information (defined as the combination of open-source, classified, and scientific/biomedical information that will further the missions of HHS), intelligence, physical and personnel security policy, security awareness, classified information communications security, and related medical, public health, and biomedical information matters. OSSI has Department-wide responsibility for coordination, convergence, and oversight of all aspects of integrating national security information including classified and unclassified intelligence and for oversight of all details to these organizations.

OSSI does not focus on traditional intelligence analysis, but rather on the acquisition of open source and classified information and assessing its usefulness in supporting and furthering the missions of the Office of the Secretary and the HHS operating and staff divisions. Where appropriate, OSSI provides scientific assessments to the intelligence and federal law enforcement communities. OSSI's operating philosophy is one of both internal HHS and external team work and, to the extent possible, incorporates representatives from stakeholder organizations into its work.

The Division of Strategic Information (DSI) ensures that the Department has the ability to access, share, and protect strategic and classified information. DSI coordinates internal sharing and analysis of sensitive information among the OPDIVS/STAFFDIVS and external

relationships with the Intelligence Community. DSI has initiated short and long term efforts to establish a network of scientific, public health, and security professionals within the Department, and to identify points of contact in other non-title 50 agencies, in the Intelligence Community and the Information Sharing Environment Council. DSI provides policy direction to facilitate the identification of potential vulnerabilities or threats to security from unfriendly governments/countries and outside organizations; conducts analyses of potential or identified risks to security and safety; and work with agencies to develop methods to address them.

DSI provided timely, accurate, and tailored strategic information and intelligence and briefings to senior leadership and policy makers including all Operating Division and Staff Division leadership. This includes:

- Developing customer driven Priority Intelligence Requirements (PIR) that address the strategic information and intelligence needs of the Department and its diverse missions.
- Providing updated classified briefings to senior leadership and policy makers, including all agency and staff division leadership.
- Developing Department-wide priority information requirements to meet the strategic information needs of HHS's 16 Staff Division leaders. Information is the first-step in identifying critical information gaps that need to be addressed for leadership.
- Providing current and timely classified information to policy makers pertaining to food and pharmaceutical safety discussions with the People's Republic of China.
- Providing current and timely classified information to policy maker pertaining to negotiations associated with avian influenza virus sample sharing, furthering and safeguarding U.S. interests.
- Providing critical information to policy makers regarding the decision-making pertaining to the destruction of smallpox virus, to negotiate the preservation of smallpox, which is in the U.S. interest.

DSI is also responsible for security programs to protect HHS employees from exploitation and HHS assets and critical infrastructure. To accomplish this OSSI has:

- Established productive relationships with the Washington and Baltimore Field Offices of the FBI. Also established productive liaisons with HQ FBI.
- Opened multiple investigations and detained one person who was harassing an HHS employee.
- Held largest ever mass classified briefing on threats to HHS entities.
- Successfully developed and executed a plan for an on-sight Department of Defense liaison officer to further enhance our public health efforts.
- Served as the Public Health Sector lead for the Critical National Assets (CNA) initiative and sits on the CNA executive committee.

DSI is responsible for reviewing and approving all requests for visits by foreign nationals to HHS properties. This includes the implementation of foreign visitor policy Department-wide, which secured thousands of short-term visits by foreign nationals to HHS facilities and Critical Infrastructure sites. During the last five months at least 170 Chinese nationals visited HHS properties within the National Capitol Region. OSSI policies ensured that sound security practices were followed, ensuring that these visitors would have HHS hosts and escorts during their visits.

OSSI is responsible for setting HHS security policy for more than 10,000 international trips per year by HHS employees, which has included a minimum level of briefing for many of these HHS travelers.

The Division of Personnel and Classified Information Security (DPCIS) is responsible for policy and oversight for:

- Overseeing and managing personnel security and suitability background investigations and adjudications and national security clearances including for all the Department's high public trust and national security positions.
- Ensuring and enhancing communications security, including secure telecommunications equipment and classified information systems with direct management of these functions within the OS.
- Improving information security, to include protection of classified and sensitive but unclassified materials and security awareness programs and management of the document classification and declassification program.
- Managing the HHS classification management, including the classification and declassification of all HHS produced documentation that rise to the level of national security concerns.
- Operating and managing the international traveler/foreign visitor awareness program and the drug-free workplace program, including HHS employee drug testing.
- Preparing annual tracking reports for OPM and other associated Federal reporting requirements.

Recently the DPCIS has worked to refine and streamline the HHS clearance processes. Ongoing re-engineering of processing is occurring, and progress to date includes the:

- Initiation of a data base program for reduced data input time. Phase 1 and 2 are complete, and Phase 3 to follow which will automate the exchange of information between our internal Security Investigations Processing System (SIPS) and the Office of Personnel Management System (OPM) in order to populate data fields, generate reports and batch files, and expedite processing.
- Satisfying additional requirements to develop/deploy a web-based application to securely capture, store, and manage background investigation and security clearance information for all HHS employees and contractors.

DPCIS, in the next steps, will work to integrate systems that are in the process of implementation such as Agency Delivery, E-Adjudication, the Clearance Verification System (CVS), and contiguous OSSI needs in order to have a comprehensive multi-purposed database to satisfy OPM and governmental security requirements.

In the last year personnel security clearances and adjudications have increased by 50% to over 2,500 cases due to the implementation of HSPD-12.

- Funding will support the management of the ongoing and continued volume case load for PERSEC. The number of high-level background investigations is projected to increase as new employees are hired to replace anticipated retirees. Additionally, security clearance

requests are expected to increase as more employees and supervisors require access to classified strategic health information as part of the regular work. Since all new investigations require personnel security specialists to initiate the process and review and adjudicate the completed reports additional funding is needed. Some clearances require drug and alcohol testing as new positions will be added to applicant and random drug testing pooling. Alcohol testing will be added to the testing requirements for many DOT-mandated driving positions.

The COMSEC Division, responsible for HHS Secure Communications, has recently

- Updated and supported all secure communications equipment for the Office of the Secretary.
- Developed an infrastructure of sensitive and classified communications among HHS components. The infrastructure developed to include SIPRNET, JWICS, and HSDN, which are Controlled Unclassified Information systems of communication with the intelligence communities.
- Ensured that the inter-agency baseline of minimum communications requirements set forth in the National Communications System (NCS) Directive 3-10 to support execution of essential functions and allow senior leadership to collaborate in a secured environment are met for the Department (Continuity of Government and Business)
- Deployed COMSEC equipment and personnel to support HHS Continuity of Operations Plan (COOP) requirements to have secure and reliable voice and data transmission, planning and training.

The Division of Physical Security (DPS) consolidates previously divided security functions within HHS and brings key subject matter expertise together to better address policy and critical security issues, while reducing funding requirements for identified previously redundant program initiatives across the Department. Through management audits and integrated physical security assessments, the Division of Physical Security provides Department-wide leadership, coordination, policy and oversight for the following directives and core programs. The assessments provide information to identify key physical security risks, threats and vulnerabilities and determine the Department's ability to provide the appropriate response. The assessment results will also assist the Division in developing the appropriate Department strategies in coordination with the respective owners of various programs (CDC, NIH, FDA, CMS etc.), to build and refine the various programs outlined below:

- HSPD-7 - Critical Infrastructure Identification, Prioritization, and Protection
- HSPD-12 - Policy for a Common Identification Standard for Federal Employees and Contractors
- HSPD-19 - Combating Terrorist Use of Explosives in the United States
- National Select Agent Program
- Strategic National Stockpile Program
- Critical Infrastructure Protection (CIP) Program
- Continuity of Operations Plan (COOP)
- Cybersecurity Oversight Program
- Physical Security Program (guns, gates, and guards)
- Department Security Council leadership

DPS establishes and maintains the consolidated HSPD-12 Program Office, previously a part of the Assistant Secretary for Administration and Management (ASAM) organization. HSPD-12 establishes a requirement for all Federal agencies to create and use a government-wide secure and reliable form of identification for their Federal employees and contractors (a Personal Identity Verification (PIV) credential). The HSPD-12 Program Office's primary purpose is to oversee and coordinate HSPD-12 efforts across all OPDIVs to assure the Department complies with the directive and associated Federal standards. This includes addressing card issuance schedules mandated by OMB M-05-24 and recurring Certification and Accreditation processes.

Funding History:

FY 2006	--
FY 2007	\$3,263,000
FY 2008	\$3,263,000
FY 2009	\$3,263,000
FY 2010	\$4,893,000

Budget Request:

The FY 2011 request for OSSI is \$6,460,000, an increase of \$1,567,000 above the FY 2010 enacted level. This increase will enable OSSI to maintain the operational tempo requirements and responsibilities that have been assigned to OSSI. This request will cover increased personnel costs and will fulfill the anticipated January 2011 pay raise, an increase of 8 FTE, and increased costs in rent and other services. This requested increase will support critical infrastructure improvement and will result in OSSI fulfilling the numerous presidential directives, and national security organizations requirements and will result in attaining many of the scientific and Public Health and Secretarial objectives/goals. Below are additional description details for the funding request

Protection of HHS Employees and Assets

The 2011 budget request will provide resources to have dedicated staff to support, create and maintain security policies and programs to ensure HHS protects national security related public health information from nefarious exploitation and targeting Security-Accreditation Assessments and Vulnerability/Security Risk Assessments for all the HHS assets throughout the country (Security at BSL 3 and 4 Laboratories within HHS, and Cyber Security).

HHS has responsibility in the implementation of Homeland Security Presidential Directive-7 (HSPD), Critical Infrastructure Identification, Prioritization and Protection. HSPD-7 requires all Federal departments and agencies to implement plans for protecting the physical and cyber critical infrastructure that they own or operate and this position will be used to oversee and coordinate the plans developed and implemented by OPDIV and HHS headquarters activities to meet the HSPD-7 mandates. Much of this effort is applicable to classified level information and/or facilities, adding an increased level of complexity.

Foreign Visitors/Visitor Tracking System

OSSI tracks and manages all domestic and foreign visitors to HHS properties, including the NIH, CDC, FDA, and CMS campuses, and visitors to the Office of the Secretary. Currently visits are approved and tracked with a program specifically being developed for HHS. Funds will enable OSSI to better track and identify repeat visitors to HHS facilities by enhancing the established program with a domestic/foreign visitor database. This will improve the security of all Department-wide assets.

CUI – Controlled Unclassified Information

Presidential Memorandum instituting the CUI policy provides a secure and legal framework for protecting HHS sensitive information. OSSI is responsible for implementing this Department wide program. This includes the protection of Personally Identifiable Information (PII) and scientific and medical information which does not rise to the level of national security information but is sensitive. Funds requested for FY 2011 will enable OSSI to fulfill Project Manager Activities and responsibilities, and set policies for the CUI program.

OSSI's program in obtaining access to and sharing and protecting strategic and classified information will support HHS public health and science programs, protection of HHS employees, and HHS critical infrastructure. This work will entail coordination of analytical activity of HHS officials throughout the Department's organizational units and will include building relations with Federal officials in other non-title 50 agencies who conduct similar programs, as well as maintaining customer relationships with the intelligence community.

Personnel Security (PERSEC)

OSSI has previously funded contract personnel through support from the ODIVS, however, additional funding is requested in FY 2011 to hire qualified specialists to help manage the ongoing and continued volume case load. The number of high level background investigations is projected to increase by a minimum of 50% as new employees are hired to replace numerous anticipated retirees. Security clearance requests are expected to increase as more employees and supervisors require access to classified strategic health information and need to attend classified meetings as part of their mandatory program work. All new investigations require personnel security specialists to initiate the process and review and adjudicate the completed reports, and to assure that OPM and EO mandated renewals of checks occur in a timely manner. Additional drug testing will be required as numerous new positions will be added to applicant and random drug testing pooling. Alcohol testing will be added to the testing requirements for many DOT-mandated driving positions.

National Counter Terrorism Center (NCTC) Liaison

The NCTC serves as the primary organization in the United States Government for integrating and analyzing all intelligence pertaining to counterterrorism, including intelligence relating to the activities of HHS. In order to improve the relationship and communications between HHS and the NCTC, OSSI will create and fund a liaison position to the NCTC.

- The creation of a liaison position improves and accelerates the analysis/recognition/mobilization cycle for public health assets to respond to emergent terror attacks. This allows planning and coordination efforts of the US Government

Counter Terrorism community in terms of leveraging the unique subject matter expertise of the public health professionals.

- An HHS liaison position at NCTC would help ensure more rapid and accurate issue response and the persistent presence of a public health point of contact for the CT community.

Select Agents Program

OSSI has general responsibility for the oversight and management of internal programs that are directed toward securing storage and research facilities that handle select agents, in coordination with CDC, FDA, and NIH. OSSI is also responsible for representation of the Secretary and Deputy Secretary as it relates to management of intra-departmental negotiations and activities as they relate to the application and improvements of select agent regulations. The FY 2011 request will allow OSSI to more fully support this activity.

Metrics Tables: PERSEC Tracking

Measure				FY 2011 +/- FY 2010
<u>1.1:</u> Number of Clearances Processed/Adjudicated. <i>(Outcome)</i>	FY 2007: 1198 FY 2008: 2605 FY 2009: 3774	5200	6800	+1600
<u>2.1:</u> Number of E-QUIP cases initiated, which starts the clearance process and eventually is adjudicated by DPCIS/OSSI at a later date. <i>(Outcome)</i>	FY 2007: not tracked FY 2008: 1981 FY 2009: 1858	3500	4800	+1300
<u>2.2:</u> Backlog of cases, carry over from year to year <i>(Outcome)</i> <i>Note: attempting to reduce backlog while managing work load volume</i>	FY 2007: not tracked FY 2008: 670 case carried forward-2007 FY 2009: 39 case carried forward-2008	0	0	-
Program Level Funding (\$ in millions)	N/A	\$4.893	\$6.460	+\$1.567

Pandemic Influenza

	FY 2009 <u>Appropriation</u>	FY 2010 <u>Appropriation</u>	FY 2011 President's <u>Budget Request</u>	FY 2011 +/- <u>FY 2010</u>
X-Year	\$7,957,000,000	\$276,000,000	\$330,000,000	+\$54,000,000
Annual	<u>69,091,000</u>	<u>65,000,000</u>	<u>65,578,000</u>	<u>+\$578,000</u>
Program Level	\$8,026,091,000	\$341,000,000	\$395,578,000	+\$54,578,000
Less 2009 Balances	<u>--</u>	<u>--</u>	<u>-\$330,000,000</u>	<u>-\$330,000,000</u>
Budget Authority	\$8,026,091,000	\$341,000,000	\$65,578,000	-\$275,422,000
FTE	8	8	8	--

Note: Comparable adjustments for annual funding have been made to reflect the consolidation of Pandemic Influenza management funding with other BARDA funding in ASPR. In addition to the amounts above, the FY 2011 Request includes \$80,321,000 to fund ongoing annual activities at the Food and Drug Administration and the National Institutes for Health. In addition, \$156,344,000 in FY 2009 Supplemental funding will be used to fund ongoing annual pandemic influenza activities at the Centers for Disease Control and Prevention.

Allocation Methods: Direct Federal/Intramural, Contracts, Formula Grants/Cooperative Agreements, Competitive Grants/Cooperative Agreements, and Other

Program Description and Accomplishments:

In December 2005 Congress appropriated \$3.3 billion in emergency funding for HHS in a FY 2006 supplemental for the first year of the *HHS Pandemic Influenza Plan*. In June 2006 Congress appropriated \$2.3 billion for HHS in emergency funding in a second FY 2006 supplemental for the second year of the HHS Plan. In FY 2009, Congress appropriated an additional \$507 million for continuing support of pandemic influenza preparedness activities. On June 24, 2009 Congress appropriated \$7.65 billion to HHS for pandemic influenza preparedness and response in a FY 2009 supplemental to respond to the 2009 H1N1 influenza pandemic. In the FY 2010 Omnibus, Congress appropriated \$276 million for continuing support of pandemic influenza preparedness activities.

In April 2009, the novel 2009 H1N1 virus emerged as the result of a triple reassortant of avian, swine and human influenza viruses. On June 11, 2009, the World Health Organization (WHO) raised the influenza pandemic alert level for 2009 H1N1 to Phase 6, which is defined by sustained community-level outbreaks in at least two countries in one WHO region, as well as in another country outside of that region, and indicates a pandemic. As of January 3, 2010, 208 countries reported confirmed human cases of 2009 H1N1 infection. On December 10, 2009 the CDC estimated there have been about 47 million cases of 2009 H1N1 infection in the U.S., including about 213,000 hospitalizations and about 9,800 related deaths.

The 2009 H1N1 virus surfaced in the U.S. at the conclusion of the flu season typically observed in the northern hemisphere. The virus subsequently spread to the southern hemisphere where widespread outbreaks of the virus have been reported. To date the virus has remained one that causes disease of mild to moderate severity but individuals with certain underlying conditions (pregnancy, asthma, obesity, etc.) are at greater risk for developing a more severe disease. The

majority of severe illnesses resulting in death have been observed in individuals under the age of 60.

Scientific evidence indicates that the 2008-09 seasonal trivalent flu vaccine does not elicit protective immunity against 2009 H1N1 virus infections, but the virus remains sensitive to neuraminidase inhibitors, oseltamivir and zanamivir, two antivirals available in the Strategic National Stockpile. Sporadic cases of antiviral drug resistance have been reported with forty-three cases of drug resistance reported to the CDC as of the December 12, 2009 report.

HHS has worked closely across agencies and in collaboration with State and local health departments to reduce the spread and severity of the outbreak. In response to the 2009 H1N1 influenza outbreak, HHS has declared a national Public Health Emergency; deployed teams to affected States; released 25% (11 million treatment courses) of antivirals and other supplies in the Strategic National Stockpile (SNS) to the States; issued Emergency Use Authorization (EUA) for diagnostic laboratory tests, a new intravenous antiviral treatment, and N95 respirators; issued regularly updated guidance on antiviral usage, clinical symptoms and medical management, reducing the spread of infection and recommendations on travel; and increased the number of antiviral treatment courses in the SNS.

HHS has made significant progress in enhancing pandemic preparedness for our Nation and our international partners. Over the past few years, promising strides were made in both the advanced development of high throughput rapid diagnostics and the development and production of H5N1 vaccine antigen and new antigen-sparing adjuvants, and HHS continued to work with States to enhance their pandemic preparedness. Since December 2005, HHS has been funding the first stage of pandemic preparedness activities, which include: expanding and diversifying domestic vaccine production and surge capacity; enlarging H5N1 pre-pandemic vaccine and antiviral drug stockpiles; supporting advanced development of cell culture and antigen sparing influenza vaccines and new antiviral drugs; advanced development of point-of-care clinical diagnostics; stockpiling of medical supplies and ventilators; improving State and local preparedness; expanding risk communication efforts; enhancing FDA's regulatory science base; and expanding surveillance, research, and international collaboration efforts of CDC, NIH, and the HHS Office of the Assistant Secretary for Preparedness and Response and of the Office of Global Health Affairs.

Recent accomplishments include:

- ◆ As a contingency plan for mismatched vaccine or more virulent virus strains in the 2009 H1N1 pandemic, HHS procured an additional 125 million doses of a new oil-in-water emulsion adjuvant, which were developed under HHS development contracts. As conditions did not warrant the usage of these adjuvants, these products will be stockpiled and remain available for future pandemics or other outbreaks. Clinical studies in 2009 with H1N1 vaccines administered with these adjuvants demonstrated a two to four fold antigen-sparing effect.
- ◆ HHS supports the development of four cell-based seasonal and pandemic influenza vaccines; two of these cell-based influenza vaccine candidates are in very late stage development with

expectations of licensure submissions to the FDA in 2010. Two of the original contracts were terminated due to the Contractors' decisions to go in a different business direction, loss of commitment to build a manufacturing facility in the U.S., and/or less than optimal clinical results. Unused funds for these contracts were re-programmed to support advanced development of recombinant-based influenza vaccines and antiviral drugs as well as other on-going pandemic influenza activities.

- ◆ HHS awarded a contract in June 2009 for the advanced development of recombinant-based influenza vaccines towards U.S.-licensure with a commitment to build a domestic manufacturing facility having a capacity of at least 50 million pandemic vaccine doses within six months of pandemic onset and to lot release the first doses pandemic vaccine within 12 weeks of pandemic onset. Additional contract awards supporting advanced development of using recombinant and molecular technologies are expected in 2010.
- ◆ HHS awarded a contract in January 2009 on a cost-sharing basis to support the design, construction, commissioning and validation of the first U.S. cell-based influenza vaccine manufacturing facility. The building of this facility was completed with a grand opening in November 2009. This facility will undergo validation and could provide at least 25% of the U.S. pandemic vaccine supply by 2011, if needed. Additional contract awards supporting building cell- or recombinant-based influenza vaccine manufacturing in the U.S. are expected in 2010.
- ◆ To expand pandemic influenza vaccine capacity, HHS supported the development of adjuvant technologies that are in late stage development for H5N1 and H1N1 vaccines. Several of these adjuvants have demonstrated multifold antigen-sparing effects, broad immunity across virus strains, and significant long-lasting prime-boost effects. Together these products represent a major technological breakthrough for pandemic vaccine preparedness with possibilities for better seasonal influenza vaccines for select populations. Submission of licensure applications to the FDA by two manufacturers with adjuvanted flu vaccines are expected in 2010.
- ◆ HHS completed its goal of 50 million courses of influenza antiviral drugs for the Federal stockpile in December 2007. In response to the 2009 H1N1 outbreak, 11 million antiviral drug treatment courses were deployed to the States in May 2009. HHS replenished the Federal stockpile with 13 million treatment courses in June 2009. With the emergence of oseltamivir-resistant 2009 H1N1 virus strains and the disproportionate ill effects of the 2009 H1N1 pandemic on children, an additional 16.1 million treatment courses of zanamivir and pediatric formulations of oseltamivir were procured for the federal stockpile in September 2009.
- ◆ To date, States have purchased 25.8 million treatment courses of antiviral drugs towards the 31 million goal using federal subsidies. The current combined total inventory for federal and State stockpiles of antiviral drugs is over 87 million treatment courses.
- ◆ HHS also continued support of parenteral antiviral drugs for critically ill persons with influenza, including peramivir, through additional funding for advanced development of peramivir in Phase 3 clinical trials and acquisition of peramivir to establish a small Federal

stockpile under Emergency Usage Authorization during the 2009 H1N1 pandemic in order to treat critically ill persons with H1N1 infections. Over 1000 persons have been treated successfully with this drug to date.

- ◆ In 2008, HHS purchased 104 million N95 respirators and 52 million surgical masks for the SNS. In response to the outbreak of 2009 H1N1 this spring, 25% of this stockpile was deployed to the States.
- ◆ HHS purchased sufficient ancillary supplies to vaccinate the H1N1 vaccine target groups in the U.S. population, including 340M syringe/needle combinations for vaccine delivery and 8M syringe/needle combinations for mixing of vaccine and adjuvant.
- ◆ HHS awarded contracts to develop rapid diagnostics for detection of seasonal and H5N1 viruses in point-of-care (POC) settings by healthcare providers in 2007 and high throughput settings for usage by clinical laboratories in 2008. One POC device supported by HHS met product requirements during Independent Government Evaluation in 2008 and underwent clinical development in early 2009. The first 2009 H1N1 clinical case in the U.S. was detected with the POC diagnostic device developed under HHS contractual support for product development.
- ◆ In 2008 HHS completed clinical evaluation of a new 5-target PCR rapid diagnostic test for avian and seasonal influenza. This high-throughput assay test will be used in all U.S. public health laboratories and internationally at World Health Organization (WHO) reference laboratories.
- ◆ In 2007 and 2008 HHS deployed teams of experts to help investigate suspected cases of human transmission of infection with influenza A in 12 countries in Asia, Africa, and Europe. HHS also supports pandemic influenza preparedness activities in approximately 40 countries around the world.

Funding History:

FY 2006	\$5,590,000,000
FY 2007	--
FY 2008	\$66,177,000
FY 2009	\$8,026,091,000
FY 2010	\$341,000,000

Budget Request:

FY 2009 supplemental funding, including an estimated \$330 million in FY 2011, will be used to advance the Nation's pandemic preparedness through investments in:

- ◆ Expanding domestic vaccine manufacturing capacity through development of next generation recombinant and molecular vaccine technologies and supporting a new domestic cell- or recombinant-based vaccine production facility. These technologies have the potential to greatly increase the vaccine production capacity, drastically reduce

the timeframe needed to produce needed levels of vaccine, and reduce the U.S. Government's dependency on stockpiles which may or may not be suited for the current pandemic threat.

- ◆ Continuing development of antigen-sparing adjuvant technology;
- ◆ Continuing development of new and better influenza antiviral drugs which may provide short- and long-term solution sets to the emerging drug resistance among circulating human influenza viruses;
- ◆ Maintaining current vaccine stockpiles through storage, stability testing and maintenance of current antigen and adjuvants as well as maintaining contracts which will contribute to our vaccine stockpiles and ensure a warm-base of vaccine production and fill finish capabilities; and
- ◆ Expanding the rapid diagnostics program to ensure that US laboratory network(s) will have reagents and equipment for rapid response at the beginning of a pandemic and to support the advanced development of rapid and specific multiplex diagnostic platforms so that U.S. laboratory network(s) can readily distinguish influenza from non-influenza strains as well as rapidly identify subtype(s) through tests of respiratory samples. A rapid diagnostics test of this type was one of the first to isolate the current H1N1 pandemic influenza strain. The test isolated the strain during its clinical trial phase. This isolation was a part of what alerted that authorities of the presence of a novel H1N1 virus.

These continued efforts are currently being planned for with FY 2009 supplemental funding, which is immediately available and will allow ASPR to move forward at an accelerated pace to enhance the Nation's preparedness in the event of another influenza pandemic. Additionally, HHS will continue to evaluate priorities for pandemic influenza funding, including FY 2009 supplemental balances, and will notify Congress of any changes to current plans.

The FY 2011 request for Pandemic Influenza is \$65,578,000, which is requested as annual funding. The FY 2011 request supports the following activities:

\$11,098,000 is requested for international in-country advanced development and industrialization of human pandemic influenza vaccine production and to determine the effectiveness of newly developed POC diagnostic devices supported by HHS in clinical trials for influenza antiviral drugs. In FY 2011, ASPR/BARDA will continue the accelerated international development of an in-country pandemic vaccine production capability for humans to prevent influenza globally and provide in-country technical expertise for vaccine development, manufacturing and scale-up. The funding will address global and specific country needs for further pilot lot and commercial scale manufacturing of H5N1 or other pre-pandemic vaccines for clinical trials and pandemic usage; scale-up development for vaccine manufacturing; vaccine production equipment purchase; development and validation of product release assay methods; and clinical sample analysis. Additionally, ASPR/BARDA will support clinical trials in areas with endemic highly pathogenic avian H5N1 influenza viruses to test the utility of newly developed POC diagnostic devices, to evaluate the in-

country burden of influenza, and determine the effectiveness of combined influenza antiviral drugs.

\$15,133,000 is requested for the continued advanced development of simple rapid influenza diagnostic assays and devices that may be used in home and border screening settings. These devices may afford more efficient utilization of Federal and State influenza antiviral drug stockpiles.

\$4,036,000 is requested for the Office of the Assistant Secretary for Public Affairs (ASPA) to ensure effective communications for pandemic preparedness and response activities. Through APSA, HHS has undertaken a number of steps to educate the public, including the maintenance of the website www.Flu.gov; the release of television and radio public service announcements; and public outreach efforts around the 2009 H1N1 flu. HHS also conducted a Flu Summit for State and local governments to disseminate information and help ensure coordination in response to the 2009 H1N1 flu. The FY 2011 request will allow ASPA to continue educational efforts and maintain a communications operation to respond to a pandemic.

\$35,311,000 is requested for the Office of Global Health Affairs (OGHA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR) for pandemic preparedness and response planning. International pandemic preparedness and planning are key to an effective response in the US and abroad to the current H1N1 influenza pandemic and to the future pandemic influenza viruses. OGHA and ASPR will continue to work with other agencies of the Federal government and international partners to ensure that the global community has the capacity to monitor and respond to H1N1, avian influenza, and other viruses with pandemic potential. HHS will lead global, multi-lateral, bi-lateral, and inter and intra-governmental initiatives that will include global training efforts and international preparedness and response planning and exercises to ensure the United States, other countries, and international organizations use the most effective approaches to better respond to and prepare for a pandemic. OGHA and ASPR will continue working towards the facilitation of country-specific pandemic preparedness plans that are coordinated with international strategies. The targeted programs will expand medical, veterinary, and laboratory expertise and capacity abroad; enhance laboratory diagnostic capacity and technical capabilities; and improve surveillance.

Parklawn Lease Expiration

	FY 2009	FY 2010	FY 2011 President's	FY 2011 +/-
	<u>Appropriation</u>	<u>Appropriation</u>	<u>Budget Request</u>	<u>FY 2010</u>
Budget Authority	--	69,585,000	35,000,000	-\$34,585,000
FTE	--	--	--	--

Allocation Method: Other

Program Description:

This request supports build-out costs for the Parklawn Building replacement lease as it relates to relocation expenses, as well as repositioning HHS within the Parklawn Building under a short term lease extension. The General Services Administration (GSA) will lead the procurement process, but will require HHS funds to initiate the lease transaction.

Budget Request:

The current lease of the Parklawn Building expires on July 31, 2010; consequently, a long-term housing solution for the building occupants must be found. The long term lease replacement to meet updated space requirements for a modern, efficient workspace meeting current Federal standards must be done under a prospectus level procurement. GSA requires a total of \$98.585 million to support competitive lease procurement and to meet updated space requirements for a modern, efficient workplace, plus an additional \$6 million to cover costs associated with repositioning HHS within the Parklawn Building and returning roughly one-third of the building to the Lessor in a contiguous, marketable block as required by the lease extension.

Lease Replacement:

When the existing lease expires on July 31, 2010, a lease extension will be required to provide the time necessary for a competitive procurement. The expiring contract will be replaced with a prospectus-level lease, which also consolidates four other smaller leases for other HHS tenants (6010 Executive Boulevard, Rockwall I, Silver Spring Centre, and the Air Rights Building).

GSA has received Congressional authorization for this lease transaction. The Senate Environment and Public Works Committee approved the request in September of 2006 and the House Transportation and Infrastructure Committee approved the request in June of 2007.

Project Summary:

The new lease must incorporate space needs for 2,827 tenants from Parklawn as well as tenants from four other current HHS-leased properties. An estimated 801,218 useable square feet, supported by the Program of Requirements, is required to meet this housing need.

Estimate of Required Usable Square Footage	
Current Parklawn Tenants	703,912 Usable Square Feet (usf)
Other HHS Tenants included in Prospectus:	
6010 Executive Blvd	13,688 usf
Rockwall I	16,499 usf
Silver Spring Centre	50,883 usf
Air Rights Building	16,236 usf
Total Current USF Space Requirement	801,218 usf
Total Prospectus USF Space Requirement	772,553 usf

Usable square footage includes assigned tenant occupied space; it excludes common areas such as restrooms, elevator lobbies, and hallways. Rentable square footage (rsf) includes these common areas and must be included in the rent and total square footage calculation. The maximum total rsf per the Prospectus is 935,401.

Prospectus Details	
Rental Rate	\$32.00 per rentable square foot (rsf)
Total Annual Cost	\$30 million
Delineated Area	Suburban Maryland
Lease Term	15 years
Total Lease Size	935,401 rsf

Project Schedule:

The current project schedule, based on the funding level in FY 2010, estimates that all tenants will be housed in new or updated space by July 2014. The Parklawn lease extension is reflected in the adjusted project schedule.

Project Benchmark	Projected Timeline
Macro Program of Requirements (POR)	August 2005
GSA National Office Approval	October 2005
OMB Approval	January 2006
Senate Environment and Public Works Committee Approved	September 2006
Micro POR/SFO Development	December 2007
House Transportation and Infrastructure Committee Approval	July 2007
Lease Procurement Start	July 2008
HHS Funding in FY 2010	December 2009
Lease Award/Reimbursable Work Authorization for Fit-up Costs	November 2010
IT/Workstations Installation Complete	September 2013
Design & Construction Complete	February 2014
All Moves Complete	July 2014
Existing Lease Expiration	July 2010
Extended Lease Expiration	July 2014

Without the benefit of a competitive procurement, HHS may face sizeable vacancy costs, damage claim costs, and higher rent. Without the procurement support funding, HHS staff will be housed in substandard space conditions enduring multiple moves and renovation projects. The result to the taxpayer will be a less effective agency and less value at a greater cost.

Budget Authority by Object
(Dollars in Thousands)

	FY 2010 <u>Enacted</u>	FY 2011 <u>Estimate</u>	FY 2011 +/- <u>FY 2010</u>
Personnel compensation:			
Full-time permanent (11.1)	\$54,145	\$68,697	\$14,552
Other than full-time permanent (11.3)	10,738	11,564	826
Other personnel compensation (11.5)	24	44	20
Military personnel (11.7)	9,020	9,231	211
Special personnel services payments (11.8)	--	--	--
Subtotal personnel compenstion	73,927	89,536	15,609
Civilian benefits (12.1)	13,496	17,697	4,201
Military benefits (12.2)	2,781	2,854	73
Benefits to former personnel (13.0)	--	--	--
Total Pay Costs	90,204	110,087	19,883
Travel and transportation of persons (21.0)	9,567	7,169	(2,398)
Transportation of things (22.0)	3,350	1,019	(2,331)
Rental payments to GSA (23.1)	12,814	12,808	(6)
Communication, utilities, and misc. charges (23.3)	5,959	7,665	1,706
Printing and reproduction (24.0)	12	12	--
Other Contractual Services:			
Advisory and assistance services (25.1)	16,939	13,343	(3,596)
Other services (25.2)	43,377	45,257	1,880
Purchase of goods and services from government accounts (25.3)	155,417	147,301	(8,116)
Operation and maintenance of facilities (25.4)	62	3,361	3,299
Research and Development Contracts (25.5)	939,847	409,741	(530,106)
Medical care (25.6)	--	--	--
Operation and maintenance of equipment (25.7)	270	264	(6)
Subsistence and support of persons (25.8)	--	--	--
Subtotal Other Contractual Services	1,155,912	619,267	(536,645)
Supplies and materials (26.0)	1,130,724	63,282	(1,067,442)
Equipment (31.0)	2,558	5,812	3,254
Land and Structures (32.0)	200,585	160,000	(40,585)
Investments and Loans (33.0)	--	--	--
Grants, subsidies, and contributions (41.0)	414,587	414,583	(4)
Interest and dividends (43.0)	--	--	--
Refunds (44.0)	--	--	--
Total Non-Pay Costs	2,936,068	1,291,617	(1,644,451)
Total Budget Authority by Object Class	\$3,026,272	\$1,401,704	(\$560,226)

Salaries and Expenses
(Budget Authority – Dollars in Thousands)

	FY 2010 <u>Enacted</u>	FY 2011 <u>Estimate</u>	FY 2011 +/- <u>FY 2010</u>
Personnel compensation:			
Full-time permanent (11.1)	\$54,145	\$68,697	\$14,552
Other than full-time permanent (11.3)	\$10,738	\$11,564	826
Other personnel compensation (11.5)	\$24	\$44	20
Military personnel (11.7)	\$9,020	\$9,231	211
Special personnel services payments (11.8)	--	--	--
Subtotal personnel compensation	<u>73,927</u>	<u>89,536</u>	<u>15,609</u>
Civilian benefits (12.1)	13,496	17,697	4,201
Military benefits (12.2)	2,781	2,854	73
Benefits to former personnel (13.0)	<u>--</u>	<u>--</u>	<u>--</u>
Total Pay Costs	90,204	110,087	19,883
Travel and transportation of persons (21.0)	9,567	7,169	(2,398)
Transportation of things (22.0)	3,350	1,019	(2,331)
Communication, utilities, and misc. charges (23.3)	5,959	7,665	1,706
Printing and reproduction (24.0)	12	12	--
Other Contractual Services:			
Advisory and assistance services (25.1)	16,939	13,343	(3,596)
Other services (25.2)	43,377	45,257	1,880
Purchase of goods and services from government accounts (25.3)	155,417	147,301	(8,116)
Operation and maintenance of facilities (25.4)	62	3,361	3,299
Research and Development Contracts (25.5)	939,847	409,741	(530,106)
Medical care (25.6)	--	--	--
Operation and maintenance of equipment (25.7)	270	264	(6)
Subsistence and support of persons (25.8)	<u>--</u>	<u>--</u>	<u>--</u>
Subtotal Other Contractual Services	1,155,912	619,267	(536,645)
Supplies and materials (26.0)	<u>1,130,724</u>	<u>63,282</u>	<u>(1,067,442)</u>
Total Budget Authority	\$2,395,728	\$808,501	(\$1,587,227)

Detail of Full Time Equivalents (FTE)

	2009 Actual Civilian	2009 Actual Military	2009 Actual Total	2010 Est. Civilian	2010 Est. Military	2010 Est. Total	2011 Est. Civilian	2011 Est. Military	2011 Est. Total
ASPR.....									
Direct:.....	351	76	427	439	76	515	522	76	598
Reimbursable:.....	--	--	--	--	--	--	--	--	--
Total:.....	351	76	427	439	76	515	522	76	598
Pandemic Influenza.....									
Direct:.....	8	0	8	8	0	8	8	0	8
Reimbursable:.....	--	--	--	--	--	--	--	--	--
Total:.....	8	0	8	8	0	8	8	0	8
Cyber Security.....									
Direct:.....	--	--	--	17	--	17	17	--	17
Reimbursable:.....	--	--	--	--	--	--	--	--	--
Total:.....	--	--	--	17	--	17	17	--	17
Office of Security and Strategic Information									
Direct:.....	12	6	18	19	9	28	27	9	36
Reimbursable:.....	3	--	3	3	--	3	3	--	3
Total:.....	15	6	21	22	9	31	30	9	39
Medical Reserve Corps.....									
Direct:.....	--	9	9	--	9	9	--	9	9
Reimbursable:.....	--	--	--	--	--	--	--	--	--
Total:.....	--	9	9	--	9	9	--	9	9
OPDIV FTE Total.....	374	91	465	486	94	580	577	94	671

Average GS Grade

FY 2006.....	GS-13/6
FY 2007.....	GS-13/6
FY 2008.....	GS-13/7
FY 2009.....	GS-13/6
FY 2010.....	GS-13/9

Increased FTE will be used to support the new programs and increases within the PHSSEF request. Details will be found within individual sections of the request.

Detail of Positions

	2009 Actual	2010 Estimate	2011 Estimate
Executive level I	--	--	--
Executive level II.....	6	5	5
Executive level III	--	--	--
Executive level IV.....	2	2	2
Executive level V.....	--	--	--
Subtotal	8	7	7
Total - Exec. Level Salaries	1,501,013	\$1,376,789	\$1,275,607
ES-6.....	2	2	2
ES-5.....	--	--	--
ES-4.....	--	--	--
ES-3.....	--	--	--
ES-2.....	--	--	--
ES-1.....	--	--	--
Subtotal	2	2	2
Total - ES Salary	\$336,502	\$353,663	\$367,368
GS-15.....	86	89	89
GS-14.....	155	225	309
GS-13.....	64	71	76
GS-12.....	43	43	43
GS-11.....	14	16	18
GS-10.....	3	3	3
GS-9.....	20	20	20
GS-8.....	4	4	4
GS-7.....	2	2	2
GS-6.....	1	1	1
GS-5.....	--	--	--
GS-4.....	1	1	1
GS-3.....	--	--	--
GS-2.....	--	--	--
GS-1.....	--	--	--
Subtotal	393	475	566
Total - GS Salary	\$40,613,399	\$53,732,406	\$65,252,173
Commissioned Corps.....	91	94	94
Total Positions.....	494	578	669
Average ES level	5	6	6
Average ES salary.....	\$187,627	\$196,684	\$182,230
Average GS grade.....	13/6	13/9	13/10
Average GS salary.....	\$103,342	\$113,121	\$115,287
Average Special Pay (Commissioned Corps)	\$74,369	\$73,788	\$77,270

Significant Items for Inclusion in FY 2011 Congressional Justification

HOUSE REPORT NO. 111-220

Hospital Preparedness Medical Waste - ASPR should review the potential for on-site capacity at medical facilities to treat infectious medical waste during a pandemic or bioterrorism emergency including the economic impact on hospitals of implementation. ASPR should also review whether Hospital Preparedness Program (HPP) grant funding could be used to aid facilities in developing this capacity if awardees determine having this capacity on-site is a priority and would be beneficial during an emergency. Information from these reviews should be included as part of the fiscal year 2010 Congressional budget justification. (p. 193)

Action taken or to be taken

The FY 04 HPP Guidance refers to Occupational Safety and Health Administration (OSHA) standards addressing medical personnel and contaminated patents and provided website links to these standards and related legislation (see “[Hazardous Waste Operations and Emergency Response](#),” 29 CFR 1910.120 and “[Medical Personnel Exposed to Patients Contaminated with Hazardous Waste](#),”). In the FY 05 HPP Guidance, states were encouraged to conduct a Hazard and Vulnerability Analysis. This Analysis was used to identify the community’s risks and vulnerabilities, one of these being classified as hazardous waste plants.

The HPP FY 07 Guidance provided a link to the OSHA website but did not provide specific guidance for the treatment of infectious waste. Since its inception, the HPP has been concerned with the decontamination of victims of a chemical attack, in compliance with OSHA standards.

During FY 10, the HPP will utilize stakeholder input and engage in a review of the issues surrounding on-site capacity at medical facilities to treat infectious medical waste during a pandemic or bioterrorism emergency. ASPR will consider the findings in drafting the next version of our HPP Guidance.

Project BioShield Special Reserve Fund - The Committee also notes that due to the lack of medical countermeasure procurements, there are still significant carryover balances in the Project BioShield SRF. As of June 2009, approximately \$2,881,000,000, or more than 50 percent, of the \$5,593,000,000 provided in 2004 for the Project BioShield SRF remains unobligated. The Committee is closely monitoring the progress of the advanced research and development portfolio and the expenditure rates of the Project BioShield SRF through monthly reports from HHS. Once additional products have a higher probability of success to licensure, additional funding will be considered for the Project Bio-Shield SRF. (p. 194)

Action taken or to be taken

ASPR/BARDA’s mission is to provide medical countermeasures to mitigate the medical consequences of man-made chemical, biological, radiological, and nuclear threats, pandemic influenza, and other emerging infectious diseases through setting of product requirements,

product development, stockpile acquisition/building, manufacturing infrastructure building, and product innovation.

The solicitation for late stage development and acquisition of rPA vaccine was closed in FY10 due the absence of vaccine candidates that were mature enough to meet statutory timelines towards FDA licensure imposed by Project BioShield; however, HHS remains committed to anthrax vaccines and has issued Special Instructions to an existing Broad Agency Announcement soliciting proposals from potential Offerors for advanced development of anthrax vaccines including rPA vaccine candidates. These new and existing developmental contracts for anthrax vaccines will be supported by funds for advanced development of CBRN countermeasures.

In FY09 HHS/BARDA issued a solicitation for proposals for late stage development and acquisition of smallpox antiviral drugs; contract award(s) are expected in FY10 with support from the Special Reserve Fund.

As a result of FDA recommendations to Human Genome Sciences on the licensure of their anthrax monoclonal antibody, Raxibacumab[®] in FY10, ASPR/BARDA anticipates additional funds (TBD) may be obligated in FY10 to an existing Project BioShield contract to support additional nonclinical studies and validation of analytical assays that measure product potency.

To expand and maintain the stockpile of botulinum antitoxin, plasma pheresis of horses producing antibodies against the seven subtypes of botulinum toxin will continue under an existing Project BioShield contract with Cangene in FY10 using support from the Special Reserve Fund for Project BioShield projects. One similar modification to extend plasma pheresis of human donors will be made to the Project BioShield contract to Cangene for anthrax immune-globulin using support from the Special Reserve Fund.

Lastly, development of a new indication for an existing anticonvulsive drug as a chemical antidote against volatile chemical nerve agents may be far enough to become eligible for support under Project BioShield in FY11.

SENATE REPORT NO. 111-66

Emergency Care - The Committee is concerned that overcrowded emergency departments compromise patient safety and threaten access to emergency care. The Committee urges the Secretary to review the state of emergency care in the United States and to identify barriers contributing to delays in timely processing of hospital patients requiring admission as inpatients who initially sought care through the emergency department, as well as to examine available evidence of best practices to improve patient flow within hospitals. (p. 165)

Action taken or to be taken

The Emergency Care Coordination Center (ECCC) was established in January 2009 within the Office of the Assistant Secretary for Preparedness and Response (ASPR), in fulfillment of HSPD #21. The primary mission of the ECCC is to enhance USG coordination of programs and resources that improve the delivery of our nation's emergency care in order to advance a patient-focused, accountable, coordinated, regionalized emergency care system. The ECCC leads an enterprise to promote and fund research in emergency and trauma health care; promote regional partnerships and more effective emergency care systems; to enhance appropriate triage, distribution and routine care of patients; and to promote local, regional and state emergency care systems' preparedness for and response to public health threats and catastrophic events. The ECCC is specifically established to address the full spectrum of issues that have an impact on care in hospital emergency departments, including the entire continuum of patient care.

Emergency department crowding and the effective and innovative utilization of the Nation's emergency care system resources represent a high priority issue for the ECCC. In 2009, the ECCC sponsored and convened an Institute of Medicine (IOM) workshop to examine the emergency care enterprise to inform successful strategies for future programmatic development in this regard. This was followed by a second IOM workshop that examined the precepts of regionalization of emergency care as a means of addressing systematic efficiencies and dependencies. This evaluative work was followed by the development of a Regionalization of Emergency Care demonstration program that will issue a request for applications in January 2010. These activities will be funded by the American Recovery and Reinvestment Act of 2009.

In addition the ECCC has established working relationships throughout the federal departments and agencies through the coordinating roles of the Council on Emergency Care (CEMC) and the Federal Interagency Committee on EMS (FICEMS). These unique Federal collaborations will allow for an unprecedented focus and coordination of the entire federal government's efforts relating to Emergency Care. The ECCC, CEMC, and FICEMS have been established in recognition of the unique and critical role that the emergency care system plays within the overall healthcare system as well as in our nation's ability to prepare for and respond to catastrophic events.

The ECCC will continue to develop and implement programs that address vital issues in emergency care, such as overcrowding in the nation's emergency departments, as well as the entire spectrum of the emergency care enterprise.

Advanced Research and Development - The Committee has included bill language, proposed by the administration, to transfer \$305,000,000 from the Project BioShield Special Reserve Fund advance appropriations provided in the Department of Homeland Security Appropriations Act, 2004 to fund Advanced Research and Development. The fiscal year 2009 comparable amount was \$275,000,000. The Committee encourages BARDA to invest greater amounts in promising clinical diagnostic technologies so that the Nation can limit the catastrophic effects of any pandemic by immediate and accurate triage of potentially sick individuals at ports, borders, schools, hospitals, clinics, and all other points of care and entry. (p. 165-166)

Action taken or to be taken

In Feb. 2009, ASPR/BARDA issued a Broad Agency Announcement (BAA-09-36) to solicit developers of devices and tests that could be used to determine the level of radiation a person has absorbed after a nuclear or radiological event. Nine contracts were awarded in December, 2009, totaling \$35 million for the initial phases of development, and up to \$400 million over the next five years.

The contracts were awarded to Arizona State University in Tempe, Ariz.; Chromologic LLC in Pasadena, Calif.; Duke University in Durham, N.C.; Meso Scale Diagnostics LLC in Gaithersburg, Md.; Northrop Grumman Electronic Systems in Linthicum, Md.; SRI International in Menlo Park, Calif; Stanford University, Stanford, Calif; the University of Rochester, Rochester, N.Y., and Visca LLC in Troy, Mich. Each contract awardee has identified particular physical or biological characteristics, known as biomarkers, to indicate how much radiation a person has absorbed.

In 2010, BARDA anticipates issuing another announcement to solicit developers of devices and tests capable of detecting biological agents. Of importance, will be devices that cannot only detect known biological threats identified by the Department of Homeland Security (e.g., smallpox, anthrax, plague, etc.), but also those pathogens that mimic their pathology (e.g. influenza, pertussis, measles, etc.).

Transfer of Project BioShield Funding - The Committee is concerned that development of promising medical countermeasures intended to protect first responders and the general population from the dangers of exposure to radiation following a nuclear or dirty bomb radiological event is being delayed because the private investor market fears the lack of a long-term and stable Government market. The Committee recognizes that both HHS and DOD have made significant investment in the development of these medical countermeasures, but little is being done to encourage private investment in these products. The Committee urges the Secretary to work with the private investor market so that they better understand the Department's plans for Project BioShield funding. (p. 166)

Action taken or to be taken

In March 2007, BARDA published its first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation (S&I) Plan which has guided the research and

development of CBRN countermeasures. It established the strategic goals and objectives for HHS to ensure that countermeasures are available and effective against the highest priority threats. It also prioritized the programs into short-, mid- and long-term objectives. In early 2009, BARDA embarked on an update of the 2007 PHEMCE S&I Plan to more broadly focus on the mission of countermeasure development, usage, and deployment. A revised PHEMCE S&I Plan is expected in 2010.

In June, 2009, the Markets and Sustainability Working Group of the National Biodefense Science Board who reports directly to the HHS Secretary published in the Federal Register for comment its report on the “Inventory of Issues Constraining or Enabling Industrial Involvement with Medical Countermeasure Development”. The comment period closed on Oct. 30, 2009. The Working Group is presently compiling comments and recommendations accrued throughout the solicitation.

In December 2009, Secretary Sebelius announced a review of the public health medical countermeasures enterprise. The review, led by Assistant Secretary for Preparedness and Response Dr. Nicole Lurie, will look at every aspect of countermeasure development and production and ask “how can we do this better?” The report is expected in the first quarter of 2010.

Since 2007 BARDA has supported the development of several countermeasures for radiation and nuclear exposure. BARDA is supporting 12 programs totaling \$21 million managed by the Division of Allergy, Immunology, and Transplantation within the National Institutes of Allergy and Infectious Diseases. BARDA also awarded seven five-year contracts in 2008 totaling over \$90 million for the development of drugs to treat the effects of radiation. In 2009, BARDA also issued a solicitation for drugs to treat the neutropenic effects of radiation. BARDA is currently in negotiations with Offerors and expects to make award(s) in early 2010. More funding is expected to be needed in radiation/nuclear drug development to nurture programs to a state where they can become eligible for Project BioShield acquisitions.

BARDA has proactively engaged pharmaceutical and biotechnology companies by hosting yearly Stakeholders meetings and Industry Days. Moreover, BARDA has developed an effective interface with developers of all countermeasures (see Medicalcountermeasures.gov) where questions can be asked of the USG, and meetings may be requested with program staff. This site provides developers with key information on government solicitations as well as up-to-date guidance on product development.

Pandemic Influenza - The Committee continues to strongly support efforts to strengthen the Federal Government’s ability to respond to pandemic influenza. The Committee has not specified how these no-year funds are to be used, and is broadly supportive of plans for vaccine development and purchase, antiviral procurement, and research and development of diagnostics. However, the Committee encourages HHS to identify and support new technologies that might have the potential to enhance our response to a pandemic, and to be open to using the provided flexibility to make strategic investments in these potentially paradigm shifting technologies.
(p. 167)

Action taken or to be taken

- ◆ Since 2005, HHS has supported the development of six cell-based seasonal and pandemic influenza vaccines; two of these cell-based influenza vaccine candidates are in very late stage development with expectations of licensure submissions to the FDA in 2010. Two of the original contracts were terminated due to the Contractors' decisions to go in different business direction, loss of commitment to build a manufacturing facility in the U.S., and/or less than optimal clinical results. Unused funds for these contracts were re-programmed, along with funds from the 2009 Supplemental, to support advanced development of recombinant-based influenza vaccines and antiviral drugs.
- ◆ HHS awarded a contract in June 2009 for the advanced development of recombinant-based influenza vaccines towards U.S.-licensure with a commitment to build a domestic manufacturing facility having a capacity of at least 50 million pandemic vaccine doses within six months of pandemic onset and to lot release the first doses pandemic vaccine within 12 weeks of pandemic onset. Additional contract awards supporting advanced development of using recombinant and molecular technologies are expected in 2010.
- ◆ HHS awarded a contract in January 2009 for the construction of the first U.S. cell-based influenza vaccine manufacturing facility. Building of this facility was completed with a grand opening in November 2009. This facility will undergo validation and could provide at least 25% of the U.S. pandemic vaccine supply by 2011, if needed. Additional contract awards supporting building cell- or recombinant-based influenza vaccine manufacturing in the U.S. are expected in 2010.
- ◆ To expand pandemic influenza vaccine capacity, HHS has supported since 2007 the development of adjuvant technologies that are in late stage development for H5N1 and H1N1 vaccines. Several of these adjuvants have demonstrated multifold antigen-sparing effects, broad immunity across virus strains, and significant long-lasting prime-boost effects. Together these products represent a major technological breakthrough for pandemic vaccine preparedness with possibilities for better seasonal influenza vaccines for select populations. Submission of licensure applications to the FDA by two manufacturers with adjuvanted flu vaccines are expected in 2010.
- ◆ HHS has supported since 2007 development of the parenteral antiviral drug peramivir for critically ill persons with influenza. Additional funding was provided for advanced development of peramivir in Phase 3 clinical trials in September 2009 and acquisition of peramivir in November 2009 to establish a small federal stockpile during the 2009 H1N1 pandemic to treat critically ill persons with H1N1 infections under Emergency Usage Authorization. Over 1000 persons have been treated successfully to date with this drug. HHS expects to award additional contracts in FY2010 to develop additional influenza antiviral drug candidates into licensed and commercially marketed products.
- ◆ HHS awarded contracts to develop rapid diagnostics for detection of seasonal and H5N1 viruses in point-of-care (POC) settings by healthcare providers in 2007 and high throughput settings for usage by clinical laboratories in 2008. One POC device supported by HHS met

product requirements during Independent Government Evaluation in 2008 and underwent clinical development in early 2009. The first 2009 H1N1 clinical case in the U.S. was detected with the POC diagnostic device developed under HHS contractual support for product development.

- ◆ In 2008 HHS completed clinical evaluation of a new 5-target PCR rapid diagnostic test for avian and seasonal influenza. This high-throughput assay test will be used in all U.S. public health laboratories and internationally at World Health Organization (WHO) reference laboratories.

Antiviral Stockpile - The Committee notes that the Department has reached its goal of purchasing 50 million courses of antiviral drugs for the Federal portion of the antiviral stockpile. The Committee is concerned that States have only purchased 22 million courses, falling short of the goal of achieving State stockpiles of 31 million courses. The Committee also notes that some States have expressed concerns that the effectiveness of antiviral treatment may be compromised by the development of resistance by the pathogen. The Committee urges the Department to re-examine the concept of shared responsibility in light of State gaps in antiviral stockpiling and to reassess what is currently stockpiled in light of recent research on combination therapy. (p. 167)

Action taken or to be taken

- ◆ HHS completed its goal of 50 million courses of influenza antiviral drugs for the federal stockpile in December 2007. In response to the 2009 H1N1 outbreak, 11 million antiviral drug treatment courses were deployed to the States in May 2009. HHS replenished the federal stockpile with 13 million treatment courses in June 2009. With the emergence of oseltamivir-resistant 2009 H1N1 virus strains and the disproportional ill effects of the 2009 H1N1 pandemic on children, an additional 16.1 million treatment courses of zanamivir and pediatric formulations of oseltamivir were procured in September 2009 for the federal stockpile.
- ◆ To date, States have purchased 25.8 million treatment courses of antiviral drugs towards the 31 million goal using federal subsidies. With the SNS deployment of antiviral drugs in the spring and fall of 2009, State stockpiles grew to 37 million treatment courses by November 2009. States deployed very small amounts of these stockpiles. The current combined total inventory for federal and State stockpiles of antiviral drugs is over 87 million treatment courses to date.
- ◆ The composition of the influenza antiviral drug stockpile has evolved since its inception in 2003 to presently. Initially the federal stockpile was comprised of oseltamivir and zanamivir at 90:10. In 2007 this ratio changed to 80:20 (oseltamivir: zanamivir) in light of the emergence of oseltamivir drug resistance among human influenza virus strains. With the rapid emergence of drug resistance to oseltamivir by A/H1N1/Brisbane-like strains, procurements in 2009 have focused on a 50:50 composition in the federal stockpile. Additionally, the federal stockpile was enhanced with greater amounts of pediatric antiviral drug formulations. Lastly, HHS is supporting development of combination drug therapies for influenza.

**FY 2011 HHS Enterprise Information Technology Fund
Government-Wide E-Gov Initiatives**

ASPR will use \$71,418 of its FY 2011 budget to support Department-wide enterprise information technology and government-wide E-Government initiatives. Staff Divisions help to finance specific HHS enterprise information technology programs and initiatives, identified through the HHS Information Technology Capital Planning and Investment Control process, and the government-wide E-Government initiatives. The HHS enterprise initiatives meet cross-functional criteria and are approved by the HHS IT Investment Review Board based on funding availability and business case benefits. Development is collaborative in nature and achieves HHS enterprise-wide goals that produce common technology, promote common standards, and enable data and system interoperability.

Of the amount specified above, \$23,817 is allocated to developmental government-wide E-Government initiatives for FY 2011. This amount supports these government-wide E-Government initiatives as follows:

FY 2011 Developmental E-Gov Initiatives*	
Line of Business – Geospatial One-Stop	\$24
Line of Business - Financial	\$488
Line of Business - Budget Formulation and Execution	\$329
Disaster Assistance Improvement Plan	\$1,410
Federal Health Architecture	\$21,566
FY 2011 Developmental E-Gov Initiatives Total	\$23,817

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

Prospective benefits from these initiatives are:

Lines of Business-Geospatial: Promotes coordination and alignment of geospatial data collection and maintenance among all levels of government: provides one-stop web access to geospatial information through development of a portal; encourages collaborative planning for future investments in geospatial data; expands partnerships that help leverage investments and reduce duplication; and, facilitates partnerships and collaborative approaches in the sharing and stewardship of data. Up-to-date accessible information helps leverage resources and support programs: economic development, environmental quality and homeland security. HHS registers its geospatial data, making it available from the single access point.

Lines of Business –Financial Management: Supports efficient and improved business performance while ensuring integrity in accountability, financial controls and mission effectiveness by enhancing process improvements; achieving cost savings; standardizing business processes and data models; promoting seamless data exchanges between Federal agencies; and, strengthening internal controls.

Lines of Business-Budget Formulation and Execution: Allows sharing across the Federal government of common budget formulation and execution practices and processes resulting in improved practices within HHS.

Disaster Assistance Improvement Plan (DAIP): The DAIP, managed by Department of Homeland Security, assists agencies with active disaster assistance programs such as HHS to reduce the burden on other federal agencies which routinely provide logistical help and other critical management or organizational support during disasters.

Lines of Business-Federal Health Architecture: Creates a consistent Federal framework that improves coordination and collaboration on national Health Information Technology (HIT) Solutions; improves efficiency, standardization, reliability and availability to improve the exchange of comprehensive health information solutions, including health care delivery; and, to provide appropriate patient access to improved health data. HHS works closely with federal partners, state, local and tribal governments, including clients, consultants, collaborators and stakeholders who benefit directly from common vocabularies and technology standards through increased information sharing, increased efficiency, decreased technical support burdens and decreased costs.

In addition, \$2,603.53 is allocated to an ongoing government-wide E-Government initiative for FY 2011. This amount supports this government-wide E-Government initiative as follows:

FY 2011 Ongoing E-Gov Initiatives*	
Integrated Acquisition Environment	\$2,603.53
FY 2011 Ongoing E-Gov Initiatives Total	\$2,603.53

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.