DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2010

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committees

We are pleased to present the FY 2010 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 2010 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 Resources and Technology (ASRT), 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 2010 Annual Performance Plan and FY 2008 Annual Performance Report as required by the Government Performance and Results Act of 1993 (GPRA). Efforts to measure and report on results-oriented performance provide information to stakeholders on progress toward achieving established goals and objectives.

ASPR's mission is to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. In support for that mission, $891 million is requested for ASPR in FY 2010, an increase of +$103 million. The request represents a continued commitment begun in FY 2009 to support ASPR as established by the Pandemic and All-Hazards Preparedness Act. Critical investments are made across the enterprise including mid- and late-stage medical countermeasure advanced development for chemical, biological, radiological, and nuclear threats; state and local capacity to prepare, respond and recover from public health emergencies; Federal capacity as lead for Emergency Support Function-8 under the National Response Framework; and scientific, policy and management oversight. In addition, new funding is proposed to support a federal first-strike capability for direct residential dispensing of medical countermeasures; develop and promote national standards for emergency medicine and trauma health care; and to respond to National Special Security Events and public health emergencies.

The FY 2010 President's Budget also requests $354 million for Pandemic Influenza preparedness activities. Funding will continue to build vaccine production capacity, support the advanced development of influenza antiviral drugs and next generation ventilators, and support on-going activities in the Office of the Secretary.

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 program is requesting an increase in funding to 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.

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 for 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.

A central responsibility of OSSI is to serve 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 detailed here.

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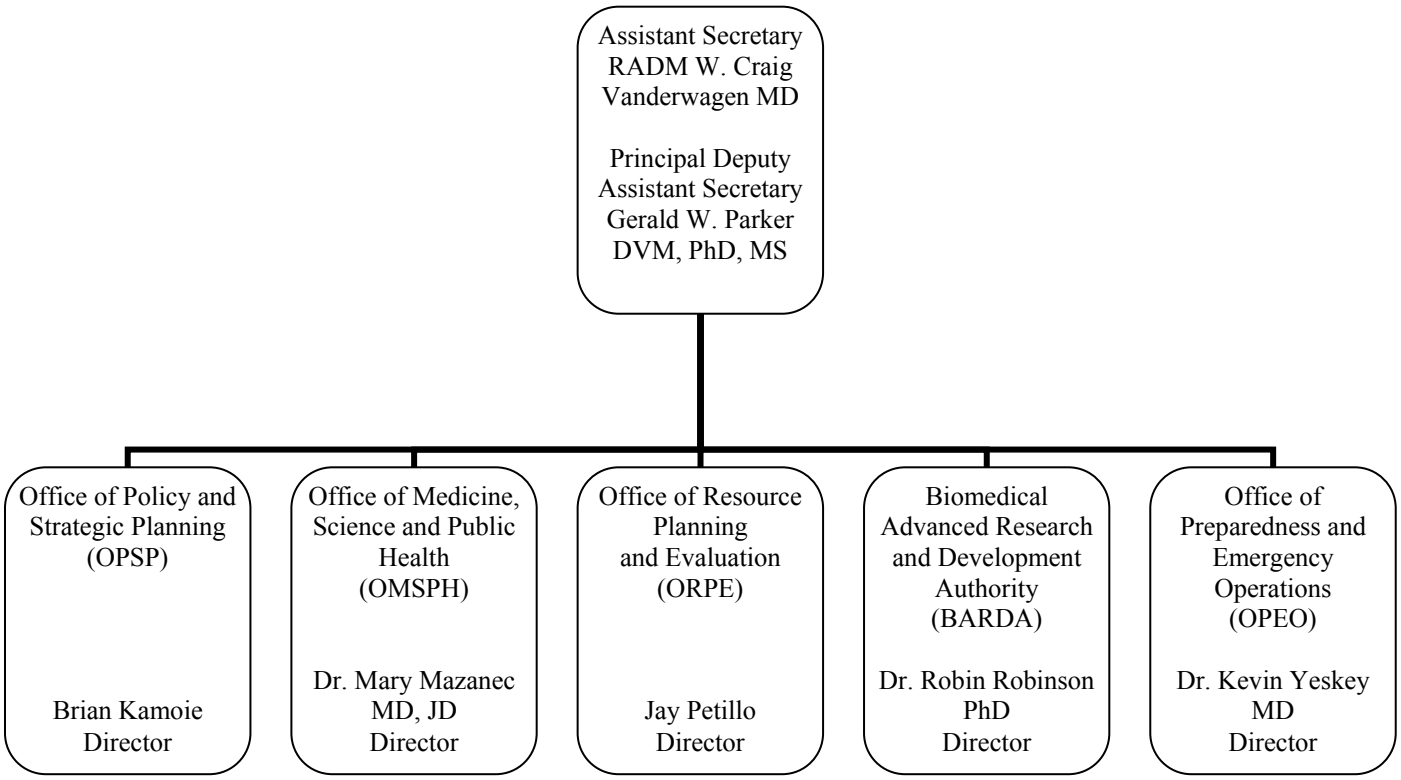
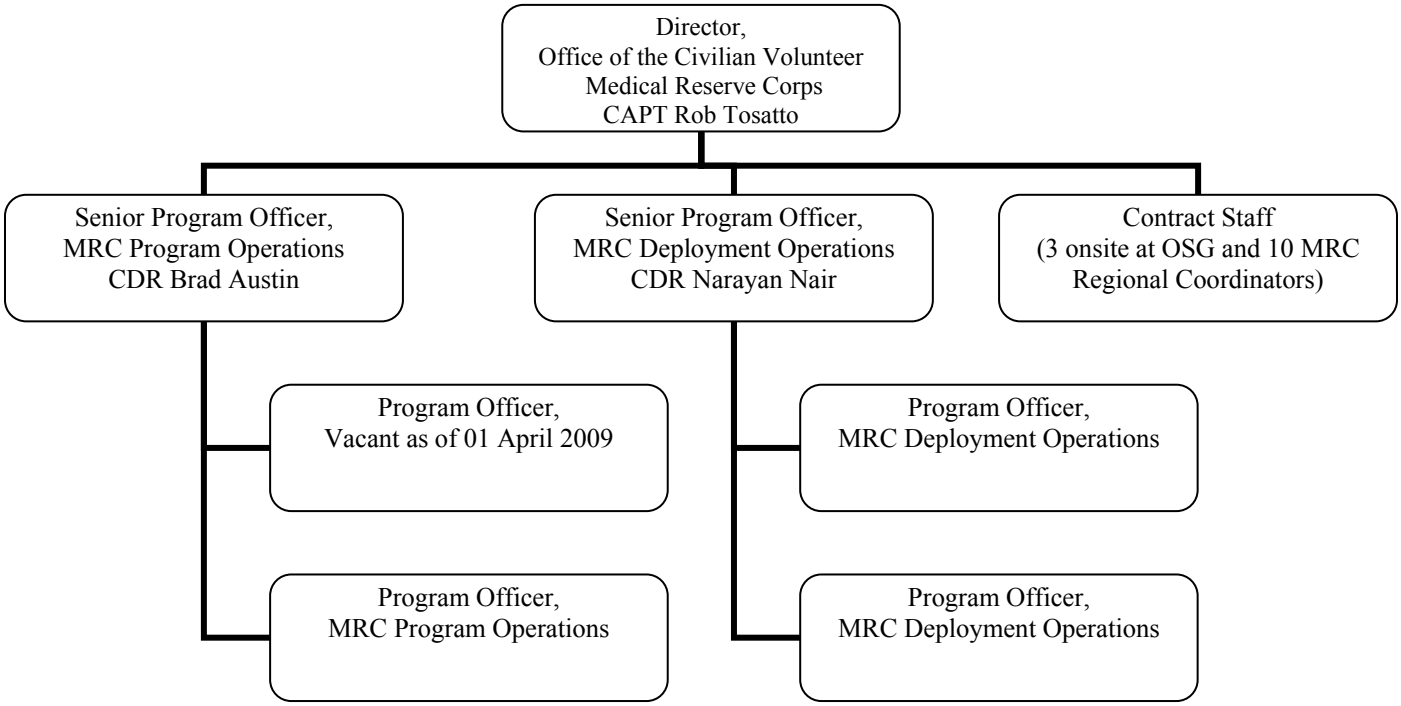
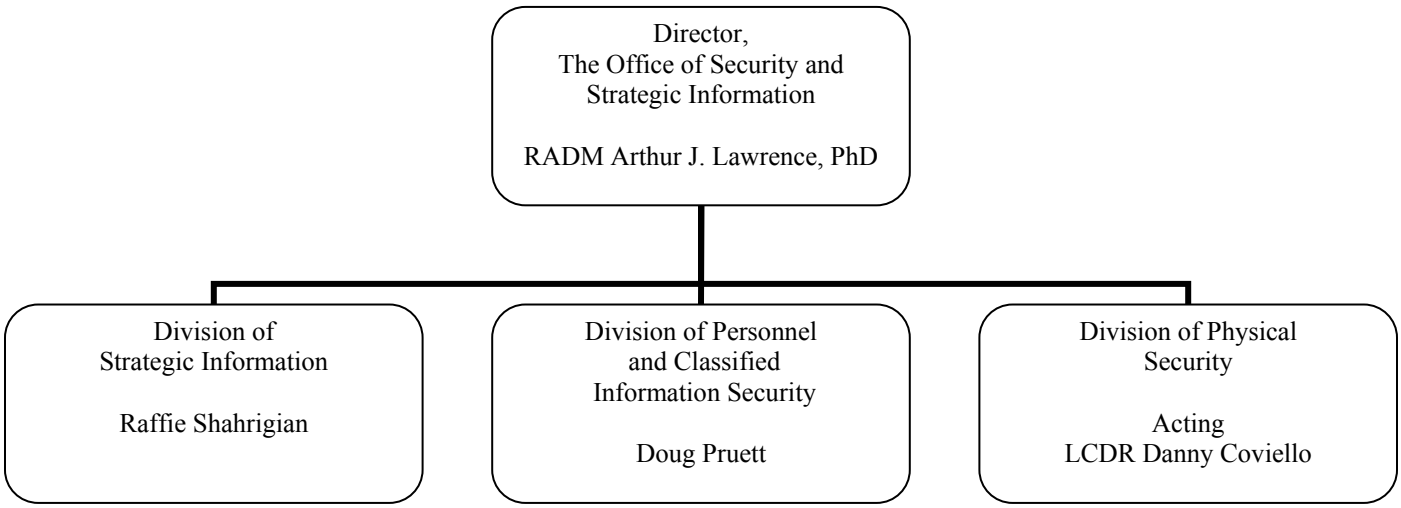
Office of the Assistant Secretary for Preparedness and Response (ASPR)



OSG/Office of the Civilian Volunteer Medical Reserve Corps



Office of Security and Strategic Information



Executive Summary

The FY 2010 request for the Public Health and Social Services Emergency Fund (PHSSEF) is $1,414,569,000, an increase of $16,744,000 and 113 FTE above the FY 2009 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 pandemic influenza activities.

The budget justification which follows represents 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 Resources and Technology (ASRT), and the Office of Public Health and Science (OPHS). This justification also requests funding for the Department's Pandemic Influenza Initiative, the Office of Security and Strategic Information (OSSI), and the Parklawn lease replacement. Additionally, the balances of the BioShield Special Reserve Fund are requested to be transferred from the Department of Homeland Security to HHS.

Programmatic Increases:

- Assistant Secretary for Preparedness and Response (+$103 million) to continue support for advanced development of medical countermeasures, plan and prepare for National Security Special Events, improve regional hospital emergency care, and develop a new medical countermeasure dispensing model with the United States Postal Service.
- Cyber Security (+$41 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.
- Parklawn Replacement (+$102 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.

Programmatic Decreases:

- Pandemic Influenza (-$231 million) to support the next phase of the *HHS Pandemic Influenza Plan* by increasing vaccine production capacity, develop new classes of antiviral drugs, and support the clinical development of next generation ventilators.

Public Health and Social Services Emergency Fund

(Dollars in thousands)

	FY 2008 Appropriations	FY 2009 Omnibus	FY 2009 Recovery Act	FY 2010 President's Budget Request
Assistant Secretary for Preparedness and Response				
Operations	$10,261	$12,847	--	$12,847
Preparedness and Emergency Operations	17,275	22,225	--	35,565
National Disaster Medical System	45,999	49,500	--	56,037
Hospital Preparedness	423,399	393,585	--	426,000
Emergency Care Systems	--	--	--	10,000
Medical Countermeasure Dispensing	--	--	--	10,000
Advanced Research and Development	101,544	275,000	--	305,000
BioShield Management	21,243	22,052	--	22,364
Medince, Science, and Public Health	8,690	8,690	--	8,748
Policy, Strategic Planning, and Communications	4,292	4,292	--	4,367
Subtotal, ASPR	632,703	788,191	--	890,928
Assistant Secretary for Resources and Technology				
CyberSecurity	8,906	8,906	50,000	50,000
Office of Public Health and Science				
Medical Reserve Corps	9,578	12,344	--	12,581
Office of the Secretary				
Office of Security and Strategic Information	3,263	3,263	--	4,893
Pandemic Influenza	74,809	585,091	--	354,167
Parklawn Repalcement	--	--	--	102,000
Total, New BA PHSSEF	**$729,259**	**$1,397,795**	**$50,000**	**$1,414,569**
*Effect of transfer of BioShield SRF Balances**	--	--	--	*1,264,000*
Total, PHSSEF including transfer	*$729,259*	*$1,397,795*	*$50,000*	*$2,678,569*

*Estimate based on current SRF balances and current FY 2009 spend plan for Project BioShield

FY 2010 Proposed Appropriations Language

For expenses necessary to support activities related to countering potential biological, nuclear, radiological[and], chemical, *and cybersecurity* threats to civilian populations, and for other public health emergencies, [$537,704,000, of which not to exceed $22,052,000 shall be]*and* to pay the costs described in section 319F-2(c)(7)(B) of the Public Health Service Act (``PHS Act''), *$653,402,000; of which $35,565,000 shall be to support preparedness and emergency operations, of which $5,000,000 shall remain available until September 30, 2011; and of which $10,000,000, to remain available until September 30, 2011, 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 the delivery of medical countermeasures.*

For expenses necessary to support advanced research and development pursuant to section 319L of the PHS Act, [$275,000,000]*$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, [2010]*2011*.

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 to prepare for and respond to an influenza pandemic, [$448,091,000, together with $137,000,000 to be derived by transfer from funds appropriated

under the heading ``Biodefense Countermeasures" in the Department of Homeland Security Appropriations Act, 2004]*$354,137,000*, of which [$507,000,000]*$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.

For expenses necessary to lease and replace or renovate a headquarters building for Public Health Service agencies and other components of the Department of Health and Human Services, including relocation and fit-out costs, $102,000,000, to remain available until expended.

Language Analysis

Language Provision	Explanation
"of which $35,565,000 shall be to support preparedness and emergency operations, of which $5,000,000 shall remain available until September 30, 2011;"	This language provides two-year availability for funding to support planning and response to National Security Special Events and unplanned public health emergencies. Two-year availability is needed due to the variable and unpredictable nature of these events.
"of which $10,000,000, to remain available until September 30, 2011, 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 the delivery of medical countermeasures."	This language provides two-year availability for a pilot project with the U.S. Postal service to examine options for the delivery of medical countermeasures in a public health emergency.
"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."	This language transfers the balance of the BioShield Special Reserve Fund from the Department of Homeland Security to HHS in order to improve the efficiency of the execution of Project BioShield.
"For expenses necessary to lease and replace or renovate a headquarters building for Public Health Service agencies and other components of the Department of Health and Human Services, including relocation and fit-out costs, $102,000,000, to remain available until expended."	This language provides no-year funding for the leasing, renovation, or replacing of the headquarters for various agencies and offices within HHS.

Amounts Available for Obligation[1]

	FY 2008 Actual	FY 2009 Enacted	FY 2010 President's Budget
Annual Appropriation	$729,259,000	$615,795,000	$721,569,000
Multi-Year Appropriation	--	275,000,000	1,579,000,000
Supplemental (P.L. 111-5)		50,000,000	
Subtotal Annual Appropriations	--	325,000,000	1,579,000,000
No-Year Appropriation	--	507,000,000	378,000,000
Total, adjusted budget authority	729,259,000	1,447,795,000	2,678,569,000
Unobligated balance, start of year	2,087,777,416	1,063,860,938	10,000,000
Unobligated balance, end of year	1,063,860,938	10,000,000	774,000,000
Unobligated balance lapsing	3,690,850	--	--
Total obligations	$1,753,175,478	2,501,655,938	$1,914,569,000

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

Summary of Changes

2009 Comparable Enacted Level	
Total estimated budget authority	$1,397,795,000
2010 Budget	
Total estimated budget authority	$1,414,569,000
Total estimated BA including SRF transfer	*$2,678,569,000*
Net change	+$16,774,000
Net change including SRF transfer	*+$1,280,774,000*

	2009 Enacted Budget Base		Change from Base	
	(FTE)	Budget Authority	(FTE)	Budget Authority
Increases:				
Assistant Secretary for Preparedness and Response		$788,191,000		+$102,737,000
Cyber-Security		$8,906,000		+$41,094,000
Office of Security and Strategic Information (OSSI)		$3,263,000		+$1,630,000
Medical Reserve Corps		$12,344,000		+$237,000
Parklawn Repalcement		--		+$102,000,000
Total Increases	467	$812,704,000	+113	+$247,698,000
Transfer of BioShield SRF		--		*+$1,264,000,000*
Total Increases including SRF transfer				*+$1,511,698,000*
Decreases:				
Pandemic Influenza		$585,091,000		($230,924,000)
Total Decreases	46	$585,091,000	--	($230,924,000)
Net Change			+113	+$16,774,000
Net Change including SRF transfer			+113	*+$1,528,472,000*

Budget Authority by Activity

(Dollars in thousands)

	FY 2008 Actual		FY 2009 Omnibus		FY 2009 Recovery Act		FY 2010 President's Budget	
	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
Bioterrorism	264	$654,450	467	$812,704	--	$50,000	580	$2,222,402
Pandemic Influenza	41	$74,809	46	$585,091	--	$0	46	$354,167
Buildings and Facilities	--	--	--	--	--	--	--	$102,000
TOTAL	305	$729,259	513	$1,397,795	--	$50,000	626	$2,678,569

Authorizing Legislation

	2009		2010	
	Amount Authorized	Enacted	Amount Authorized	President's Budget
Pandemic and All-Hazards Preparedness Act, 2006 and the Public Health Security and Bioterrorism Preparedness and Response Act, 2002		$1,447,795,000		$2,678,569,000

Appropriations History
(Non-Comparable)

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2001				
Appropriation	$264,600,000	$286,600,000	$264,600,000	$241,231,000
Rescission Supplemental				-282,000
Appropriation	–	–	–	126,150,000
FY 2002				
Appropriation	250,619,000	300,619,000	250,619,000	2,429,490,000
Defense Approp				2,644,315,500
Rescission				-1,396,000
FY 2003				
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
FY 2004				
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
FY 2005				
Appropriation	61,456,000	61,456,000	61,456,000	161,456,000
Rescissions				-1,389,984
Supplemental Appropriation				60,000,000
FY 2006				
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
FY 2007				
Appropriation	218,413,000	160,475,000	166,907,000	602,200,000
Supplemental Appropriation				99,000,000

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2008				
Appropriation	1,729,211,000	1,705,382,000	1,674,556,000	729,295,000
FY 2009				
Appropriation	2,300,831,000	1,443,827,000	1,251,758,000	1,397,795,000
Supplemental Appropriation (PL 111-5)		$900,000,000	$870,000,000	$50,000,000
FY 2010				
Estimate	$2,678,569,000			

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$632,703,000	$788,191,000	$890,928,000	+$102,737,000
FTE	305	429	529	+100

NOTE: Funding for Pandemic Influenza program management is included within the request for the Office of the Secretary in the PHSSEF. Comparable adjustments have been made for the funding of the Office of Policy and Strategic Planning, which was established in FY 2007, and for the transfer of funding for the Office of Security and Strategic Information. Full time equivalent (FTE) estimates do not include FTE supported by Pandemic Influenza program management.

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.

The FY 2010 request for ASPR is $890,928,000, an increase of $102,737,000 above FY 2009. These funds will support ASPR to direct the Department's efforts to prepare for, protect against, respond to, and recover from public health emergencies, including acts of bioterrorism that affect the civilian population. The staff to support the programmatic responsibilities of ASPR will be 545 positions, maintaining the FY 2009 level. This number does not include positions supported by funding for Pandemic Influenza program management. FTE increases are a reflection of staffing increases in FY 2009. The request includes:

- $12,847,000, maintaining the FY 2009 level, for Operations to support salaries, rent and service charges, equipment costs, travel, telecommunications, training and continued implementation of revised OMB Circular A-123.
- $35,565,000, an increase of +$13,340,000, for Preparedness and Emergency Operations to support improved regional coordination, interagency coordination for ESF #8, improve federal response capabilities, and work to address the special needs of at-risk populations. The increase includes $10,000,000 to prepare for and respond to non-Stafford Act National Special Security Events (NSSE's) and other HHS response requirements as well as unforeseen response activities; of these funds, $5,000,000 is requested with two-year availability.
- $56,037,000, an increase of +$6,537,000, for the National Disaster Medical System (NDMS) to support team capability improvements including expanded logistics support for cache maintenance including medical and pharmaceutical supplies. Also, for the reorganization and redesign of NDMS specialty teams to meet both current and future mission requirements. FY 2010 activities will include training standards, objectives and

training cycles with emphasis on regional training and exercises.

- $426,000,000, an increase of +$32,415,000, for Hospital Preparedness. The FY 2010 request is consistent with the FY 2009 Budget proposal to align federal and state funding cycles.
- $10,000,000 for the Emergency Care Systems program, a new activity in FY 2010. Funding will support the development of the Emergency Care Coordination Center and two key project objectives – national standards for emergency care performance measurement and a demonstration of regionalization of emergency care services.
- $10,000,000 for Medical Countermeasure Dispensing, a new activity in FY 2010, with funding requested with two-year availability. Funding will support the development of a federal "first strike" capability for direct residential delivery of medical countermeasures using the United States Postal Service.
- $305,000,000 for Advanced Research and Development, an increase of +$30,000,000 to support existing efforts in advanced research and development for the highest priority areas of anthrax, acute radiation syndrome, biodosimetry, and enhanced product development such as increased efficacy, new formulations to increase stability and shelf life and alternate routes of administration.
- $22,364,000, an increase of +$312,000, is requested for BioShield Management for oversight and implementation for medical countermeasure procurement under Project BioShield.
- $8,748,000 is requested, an increase of $58,000, for Medicine, Science, and Public Health to coordinate and facilitate development of international preparedness and response capabilities.
- $4,367,000, an increase of +$75,000, is requested for Policy, Strategic Planning, and Communications to maintain on-going efforts to support policy formulation, analysis, coordination, and evaluation of preparedness and response efforts across ASPR and to support the National Health Security Strategy.

Office of the Assistant Secretary for Preparedness and Response Operations

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$10,261,000	$12,847,000	$12,847,000	--
FTE	26	38	48	+10

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 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. BARDA also promotes countermeasure and product advanced research and development, facilitates contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under PAHPA, and promotes innovation to reduce the time and cost of countermeasure and product advanced research and development.

Funding History:

FY 2005	$9,404,000
FY 2006	$9,147,000
FY 2007	$7,626,000
FY 2008	$10,261,000
FY 2009	$12,847,000

Budget Request:
The FY 2010 request for Operations is $12,847,000 maintaining the FY 2009 level. Funds support ASPR's leadership for all HHS bioterrorism and emergency preparedness activities. Funding will be used for staff salaries, rent and service charges, equipment costs, travel, telecommunications, training and continued implementation of revised OMB Circular A-123. Funding requested in Operations also will support the ASPR Strategic Management Systems (SMS). This effort helps ensure that ASPR's resources are aligned with performance priorities. Primary components of the effort will improve strategic planning and internal communications, transparency and accountability of business operations, and overall organizational and employee development. The investment in SMS will give ASPR the capacity to provide feedback around critical program activities and internal business processes as well as continuously improve strategic performance and results.

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$17,275,000	$22,225,000	$35,565,000	+$13,340,000
NSSE/Public Health Emergencies(non-add)	--	--	*$10,000,000*	*+$10,000,000*
FTE	73	97	98	+1

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, to include 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 the office's regional emergency coordinators, ASPR directs and coordinates all public health and medical assets associated with 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.

Preparedness, Response Operations, and Logistics
ASPR led HHS's integrated preparedness planning, response and regional logistics support to at least 42 events that required 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 the 2008 response to Hurricanes Gustav and Ike ASPR deployed nearly 2,000 personnel to Louisiana, Texas, Florida, Mississippi, and Georgia and coordinated responses with ESF #8 support agencies such as Department of Defense (DOD), and other National Response Framework partners. The medical and public health assets included:

- 14 Federal Medical Shelters comprised of 250 beds each staffed by Federal and State personnel to provide basic care.
- Over 85 Disaster Medical Assistance Teams from NDMS to coordinate patient evacuations, provide acute care, support emergency room decompression and augment Federal Medical Stations.
- 1 Disaster Mortuary Assistance Team and 1 Disaster Portable Morgue Unit to provide mortuary services for disinterred remains.
- 7 Rapid Deployment Force teams from the United States Public Health Service

(USPHS) to provide mental health and public health staff augmentation.
- Over 10,000 patient encounters during these events
- Over 750 tons of medical materiel was moved and utilized

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, ensuring that our the IRCT A has advanced and ongoing training. These activities include the development of Presidential level exercises, exercises to ensure the successful transition of the Secretary and their cabinet, 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.

The Continuity of Operations (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 National Convention (DNC) and Republican National Convention (RNC).

National Special Security Events (NSSE's)

ASPR's Regional Emergency Coordinators are the lead in working with state/local entities and OPEO preparedness and operations offices to plan for National Special Security Events (NSSE's) 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/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 NSSE's 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 DNC, RNC and Superbowl. Historically ASPR has supported multiple events annually including some events which are unforeseen, such as a State Funeral or the space object re-entry in 2008. To date in FY 2009, ASPR has responded to two NSSE's, the Presidential Inauguration and the President's Address to Joint Session of Congress, as well as the annual Cherry Blossom Festival. Other planned events include the Lincoln Memorial re-dedication, the Police-Peace Memorial ceremony, Independence Day ceremonies in Washington DC, and the 2009 World Police and Fire Games (which will provide operational concepts testing for the 2010 Winter Olympics).

Regional Preparedness and Response Capability

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. Many Departmental and national plans have been exercised and "lessons learned" applied which allows HHS to make necessary revisions in order to expand the capabilities to respond.

Mass Casualty Care

ASPR leads planning activities required to fulfill OPEO mass casualty care responsibilities under ESF #8 of the NRF and HSPDs10 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, NSSE's, 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 that when fully operational will provide situational awareness capability using electronic inputs from various streams. Sources of streams include those maintained by ESF-8 partners (ex. 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 local/state 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. For FY 2010, the goal will be to determine 2-3 States or local governments and work to create the appropriate interconnectedness between the organizations as a pilot project for MedMap expansion. Additionally, the ability of MedMap to produce custom reports or outputs that answer the commonly requested data analysis that is needed for decision makers will be refined. For example, MedMap will produce more in-depth output on impacts for an area based on hurricane predictions.

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 senior leadership with decision making. The fusion cell is creating a "virtual rolodex" to investigate, utilize, and if necessary develop a way to contact experts to inform analysis and participate in future planning during response operations as-needed. The desired outcome of "A Nation Prepared" will be tracked through a systematic process of information management - managing the flow of information across levels and sectors of government and private industry. 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 "fusion" process will require close coordination with multiple stakeholders within and outside the agency. 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. ASPR serves as the lead Sector Specific Agency under Homeland Security Presidential Directive (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 retail drugs, biologics, and medical devices. This is all done within a complex environment of science, regulation, finance, and public policy.

Among the critical infrastructure protection challenges faced by the Sector since the beginning of this program have been the breadth and diversity of the Sector and the overlap between the Sector's Critical Infrastructure Protection (CIP) role and its emergency response role. The scope of the Sector's reach is extensive, including approximately 13 million healthcare personnel, 5,525 hospitals, 300,000 ambulatory facilities (including office practices and dental offices), 70,000 long-term care facilities, 6,928 home health agencies, 70,000 pharmacies, 3,050 state and local health agencies, 172,000 health-related laboratories, 2,500 pharmaceutical manufacturers and tens of thousands more medical manufacturing, distribution and supply entities. There is a large diversity of organizations engaged in this Sector and they are dispersed over a wide geographic area both domestically and internationally. While most services in the area of clinical care are provided by the private sector, the public sector also provides many clinical services and finances many of the services provided by the private sector. In the area of public health, most programs are financed and operated by Federal, state, local, territorial, and tribal health agencies, but functions such as disease surveillance are performed in conjunction with private sector healthcare providers. Medical products, including drugs, biologics, and medical devices, are produced almost entirely by the private sector but are regulated by government agencies.

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 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 which 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. The portal is designed to allow for the exchange between all levels of government and the private sector and includes information from various government agencies, threat reporting, private sector updates and reports and state and local public health information. The portal also allows for the extensive sharing of information related to cybersecurity issues directly with our HPH sector partners.

In addition, ASPR initiated a program to train and develop a cadre of private sector partners to serve in the HHS Secretary's Operations Center during large scale exercises or emergencies. This provides our partners with visibility on how federal agencies and specifically ESF #8 can support our sector partners and allows ASPR/OPEO to learn from the expertise of our sector partners during an incident.

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 2007, ASPR conducted a thorough assessment of the Department's emergency behavioral/mental health capabilities, including personnel, technical assistance, materials, and grants. In FY 2009, working with the Disaster Mental Health Subcommittee of the National Biodefense Science Board (NBSB), ASPR will work to develop a federal strategy to address behavioral health and look to begin implementation of the action items. In FY 2009, efforts will focus on integrating attention to at-risk/special

needs 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 2005	$12,769,000
FY 2006	$14,942,000
FY 2007	$13,564,000
FY 2008	$17,275,000
FY 2009	$22,225,000

Budget Request:
The FY 2010 request for Preparedness and Emergency Operations is $35,565,000, an increase of +$13,340,000 above FY 2009, to support improved regional and interagency coordination for ESF #8, federal response capabilities, and to address the special needs of at-risk populations. The increase includes $10,000,000 to prepare for and respond to non-Stafford Act National Special Security Events (NSSE's) and other planned and unplanned events including other mass gathering events and public health emergencies; of these funds, $5,000,000 is requested with two-year availability. In FY 2010 ASPR will support the 2010 Winter Olympics, special Federal events, and other HHS response requirements as well as unforeseen response activities. In recent years, HHS has responded to an increasing number of NSSE's and other events. Two-year availability is requested to maintain access to a limited source of funding due to the unpredictable nature of public health response requirements.

The request includes funding for deployment support and cache management to maintain regional readiness capability. The increase will enhance 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, which will identify requirements for the public health and medical needs of the National Planning Scenarios and will help quantify the assets and other capabilities needed to meet some of 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. Funding 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 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.1: Improve ESF #8 preparedness planning and response capability. *(Outcome)*	FY 2009: Regional response capabilities expanding. Regional coordinators continued integrated planning efforts to identify capability gaps for hurricane responses. The IRCT participated in multiple deployments. IRCT advanced training provided at ESF 8 Summit. First draft of the Field Operations Guide completed. 14 playbooks completed. 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 (REMM) that is now available in a PDA version and Chemical Event Medical Management (CHEMM) is under development. (In Progress)	Continue regionalization efforts for local coordination with Federal emergency care coordinators. Development of modular, mobile deployment capabilities. Regionalization of response team administrative and operations functions. Distribute and exercise region playbooks and overall response coordination. Incorporate NDMS team commanders in ESF #8 response planning activities. Interagency roles/responsibilities incorporated. Scope to include public health and medical equities. SOC SA enhanced via Fusion Cell & DTRA partnership. Finalize the implementation of regional readiness enhancements include the regionalization of OPEO/NDMS caches & warehouse consolidation. Exercise ability to deploy HHS command staff, medical stations, and initial care is supported by numerous table top and operational exercises.	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.	N/A

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$45,999,000	$49,500,000	$56,037,000	+$6,537,000
FTE	78	92	104	+12

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:
The National Disaster Medical System (NDMS) is a cooperative, asset-sharing partnership the Departments of Defense, Veterans Affairs, and Homeland Security that leverages federal and non-federal resources to care for large numbers of casualties generated in a domestic disaster or an overseas conventional war. 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, which consists of establishing and maintaining a communication, transportation, and medical regulating system to evacuate patients from a mobilization center near the disaster site to reception facilities. Once there, they may receive definitive medical care, and communicating evacuation information to federal, state, and local authorities, as needed.
- Definitive medical care, which consists of medical treatment or services beyond emergency medical care, initiated upon inpatient admission to an NDMS partner hospital and 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 and federal hospital services. 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.

In FY 2007, NDMS was transferred successfully to ASPR from the Department of Homeland Security, Federal Emergency Management Agency. The transfer included over 9,000 intermittent federal employees within NDMS. Teams have been successfully deployed to a variety of missions. The ESF-8 Integrated Training Summit (formerly NDMS Training Summit) was held in Dallas, TX in April 2009. Attendance at this year's Summit was in excess of 3,200 participants. The Summit included the Medical Reserve Corps and 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. All equipment caches have been inventoried in 2009. Additional equipment caches are being developed to meet expanded mission types and modification, upgrade, and resupply of existing caches is ongoing.

Funding History:

FY 2005	approx. $46,605,000
FY 2006	approx. $46,605,000
FY 2007	$46,605,000
FY 2008	$45,999,000
FY 2009	$49,500,000

Budget Request:
The FY 2010 request for the National Disaster Medical System is $56,037,000, an increase of +$6,537,000 above FY 2009. 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.

FY 2010 funding includes expanded 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, patient tracking system and Health Information Repository (HIR) by expanding from the current 12 acute care kits to 58 fully operational units including acute, chronic and inpatient capabilities with connectivity to the Nationwide Health Information Network (NHIN) and two dedicated training kits.

Funding will support NDMS team capability improvements to include reorganization of the National Medical Response Teams (NMRT) which are the weapons of mass destruction component of the NDMS, redesign of the Burn, Nurse, Pharmacy, and Mental Health specialty teams, and the reformulation and expansion of the International Medical/Surgical Response Teams (IMSURT) to meet both current and future mission requirements based on the ASPR vision and mission.

FY 2010 activities will include specific policies and procedures related to training standards, objectives and training cycles with emphasis on regional training and exercises for more than 100 NDMS Response Teams which 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 improve 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 operational needs of the Regional Emergency Coordinators, development, training, and deployment of six Incident Response

Coordination Teams (IRCT-A) and three Logistical Response Assistance Teams (LRAT).

FY 2010 funding 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 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$423,399,000	$393,585,000	$426,000,000	+$32,415,000
Hospital Preparedness (non-add)	*$419,439,000*	*$387,585,000*	*$420,000,000*	*+$32,415,000*
ESAR-VHP (non-add)	*$3,960,000*	*$6,000,000*	*$6,000,000*	--
FTE	32	49	56	+7

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 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 measures for FY 2008 that reflect the requirements of PAHPA, and continued to refine those measures for FY 2009 to provide a more accurate picture of the direction and focus of preparedness efforts. During 2008 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 have been standardized. 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.

The FY 2009 targets for the goal include that 70 percent of States will 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. This target was confirmed in March 2009 during a test of the HAvBED system. 74% of the states were able to

report their available beds without difficulty. Also, 70 percent of States will be able to demonstrate through reporting and/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 submitted by the states were analyzed in record time. As reported by the states 91% were able to demonstrated interoperable communications during exercises.

PAHPA also transferred responsibility for the ESAR-VHP program from HRSA to ASPR. PAHPA mandated that all states must participate in ESAR-VHP. The purpose of the program is to facilitate the use of volunteers at all tiers of response (local, regional, state, interstate, and Federal). The ESAR-VHP program has been working to establish a national network of state-based programs that manage the information needed to effectively use health professional volunteers in an emergency. These State-based systems form a national network that will ensure the efficient use of health professional volunteers in emergencies by providing up-to-date information regarding the volunteer's identity and credentials to hospitals and other health care facilities in need of the volunteer's services. 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 provides to the states standardized guidance for volunteer recruitment, registration, credential verification, classification according to verified professional credentials, legal and regulatory issues, and policies for the use of volunteers. The program also provides technical assistance to the States in all of these areas.

In FY 2008, the program finalized its national compliance requirements and worked toward finalizing the 3rd version of the *ESAR-VHP Technical and Policy Guidelines, Standards, and Definitions: System Development Tools* (*Guidelines*). The *Guideline*s provide the technical information that states need to develop systems capable of registering a wide range of health volunteers, verify their credentials and qualifications, and assign volunteers to one of four credential levels. Included are new and interim standards for 20 healthcare profession occupations. In FY 2008, states were provided access to national databases, including the American Board of Medical Specialties (ABMS), American Osteopathic Information Association (AOIA), Federation of State Medical Boards (FSMB), and Drug Enforcement Administration (DEA). These sources provide data critical to the process of performing credential verification of volunteer health professionals.

In FY 2009, ASPR will award grants to support and sustain state and territorial ESAR-VHP programs. The grants will focus on meeting the ASPR ESAR-VHP compliance requirements and support efforts to integrate state ESAR-VHP programs and local Medical Reserve Corps (MRC) units. The ESAR-VHP program will continue its partnership with the National Disaster Medical System (NDMS), Office of Force Readiness and Deployment (OFRD), and the Medical Reserve Corps (MRC) to continue state and territorial ESAR-VHP personnel participation in the Integrated Medical, Public Health, Preparedness and Response Training Summit, which provides a forum for conducting training, information sharing, and relationship reinforcement among local, state, and Federal response partner organizations to build stronger and robust response

capabilities. An evaluation of the state ESAR-VHP programs is planned to assess their progress. Funding will support progress towards performance goals, such as improved surge capacity and enhanced community and hospital preparedness for public health emergencies. The FY 2009 performance target for the goal includes that 80% of States will be able to demonstrate through reporting and/or exercises the development of fully operational and compliant ESAR-VHP programs that would ensure health care workforce surge capacity in a public health emergency. Additionally, ASPR is integrating the state ESAR-VHP programs in regional and national level exercises. In FY 2009, ASPR will release the 3rd version of the ESAR-VHP Guidelines and the updated Legal and Regulatory Issues Report. ASPR will also launch the ESAR-VHP Web site 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. Currently 49 awardees, including the District of Columbia have operational ESAR-VHP systems. The remaining awardees are in the process of implementing their ESAR-VHP systems.

Funding History:

FY 2005	$487,098,000
FY 2006	$473,882,000
FY 2007	$474,030,000
FY 2008	$423,399,000
FY 2009	$393,585,000

Budget Request:
The FY 2010 request for Hospital Preparedness is $426,000,000, an increase of +$32,415,000 above FY 2009. The FY 2010 request is consistent with the FY 2009 Budget proposal to align federal and state funding cycles. In FY 2010, consistent with directions identified in PAHPA, the program will continue the focus on aspects of medical surge planning to include 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 and health care 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 reviewing and revising current performance measures, development of state profiles of health care system preparedness, implementing a management information system to improve and simplify the process of data collection for grantees, development of exercise evaluation guidelines to standardize the methodology for reporting exercise results, 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 that are being developed 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, 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.

Also within the total, $6,000,000 will support the ESAR-VHP program to continue the development and refinement of operational and compliant state ESAR-VHP systems. Funding will be used to continue grant support to state and territorial ESAR-VHP programs, updates to the ESAR-VHP Technical and Policy Guidelines, Standards, and Definitions, and provide state access to national databases. Funding will be used to support ongoing volunteer recruitment and retention efforts, technical assistance, and support the integration of state ESAR-VHP programs in regional and national level exercises to test and improve the capability of state ESAR-VHP programs to respond to disasters and public health emergencies and improve federal and state coordination. Funding will be used to continue state and territorial ESAR-VHP personnel participation in the Integrated Medical, Public Health, Preparedness and Response Training Summit to train and interact with other ESF-8 response partners, including the National Disaster Medical System (NDMS), Office of Force Readiness and Deployment (OFRD), and the Medical Reserve Corps (MRC).

Outcomes and Outputs:

Long Term Objective: Enhance State and Local Preparedness

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
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)	80%	90%	+10
B: % of States demonstrating use of Interoperable Communications Systems *(Outcome)*	FY 2007: 91% (Target Exceeded)	95%	98%	+3
C: % of States demonstrating development of Fatality Management Plans *(Outcome)*	FY 2007: 62% (Target Exceeded)	70%	85%	+15
D: % of States demonstrating development of Hospital Evacuation Plans *(Outcome)*	FY 2007: 80% (Target Exceeded)	85%	90%	+5
E: % of States demonstrating development of fully operational and compliant ESAR-VHP programs *(Outcome)*	FY 2008: 88% (Target Exceeded)	85%	95%	+10
2.4.3: Increase the ratio of preparedness exercises and drills per total program (Coop. Agreement) dollar by 50% each year. *(Outcome)*	FY 2006: 14.4 per million dollars (Target Not In Place)	22.69 per million dollars	34.03 per million dollars	+11.34

Hospital Preparedness Grants	
STATE/TERRITORY	**FY 2008 Actual**
Alabama	$6,073,401
Alaska	1,312,013
Arizona	7,972,742
Arkansas	3,906,396
California	45,181,611
Colorado	6,260,449
Connecticut	4,747,354
Delaware	1,534,297
District of Columbia	1,707,585
Florida	22,422,494
Georgia	11,847,828
Hawaii	2,057,849
Idaho	2,277,157
Illinois	16,550,610
Indiana	8,151,131
Iowa	4,113,883
Kansas	3,849,684
Kentucky	5,597,192
Louisiana	5,696,194
Maine	2,101,569
Maryland	7,305,500
Massachusetts	8,301,006
Michigan	12,734,552
Minnesota	6,761,826
Mississippi	4,027,180
Missouri	7,580,577
Montana	1,644,766
Nebraska	2,642,978
Nevada	3,524,243
New Hampshire	2,093,475
New Jersey	11,072,985
New Mexico	2,868,709
New York	24,396,479
North Carolina	11,232,884
North Dakota	1,270,585

STATE/TERRITORY	FY 2008 Actual
Ohio	14,409,789
Oklahoma	4,837,520
Oregon	4,984,817
Pennsylvania	15,576,347
Rhode Island	1,793,799
South Carolina	5,736,768
South Dakota	1,447,580
Tennessee	7,818,211
Texas	28,988,249
Utah	3,590,331
Vermont	1,256,092
Virginia	9,762,140
Washington	8,250,841
West Virginia	2,703,739
Wisconsin	7,233,733
Wyoming	1,124,115
Subtotal	**390,333,255**
Indian Tribes Migrant Program	
American Samoa	320,099
Guam	448,253
Marshall Islands	318,384
Micronesia	381,055
Northern Mariana Islands	342,258
Palau	273,896
Puerto Rico	5,259,932
Virgin Islands	381,868
Subtotal	**7,725,745**
Total States/Territories	**398,059,000**

Office of the Assistant Secretary for Preparedness and Response
Emergency Care Systems

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	--	--	$10,000,000	+$10,000,000
FTE	--	--	12	+12

Allocation Method: direct federal/intramural; contracts

Program Description and Accomplishments:
Emergency care is unique and essential part of the healthcare delivery system. Hospital emergency department visits account for approximately 10% of all ambulatory medical care visits in the United States increasing to over 120 million patient encounters per year and growing. Yet the number of hospital emergency departments (EDs) in the United States continues to decrease. Demand and capacity issues have contributed to increased patient wait-time and decreased physician productivity, and this places patients at risk for poor outcomes. A comprehensive and collaborative quality initiative that seeks to establish a standardized metrics of performance for emergency care will improve the care of patients and reduce excessive healthcare costs.

The issue of regionalization is one of great interest across academic and clinical communities. Unfortunately, many aspects of this system wide approach have yet to be fully examined. The current State trauma care systems are the most established regional care delivery platforms and are an obvious test bed for examining its generalized application. An effective approach to regionalized emergency care will require real time situational awareness on asset location availability. A seamless link between pre-hospital and in-hospital assets is vital. Most states currently utilize some system to collect this kind of information however they vary in sophistication and purpose. Some are proprietary, some locally developed, and all collect and report different data with different data languages. An effective regionalized care delivery system will require that these systems at the very least be able to communicate. While in total the US trauma care system represents a robust model of regionalized care, there is great variability among state trauma systems. For example, there are several state systems that are well developed and offer a variety of benefits, such as systems like those in North Carolina and Maryland are highly integrated and well supported. Other less resourced regions that must deal with the challenge of providing access to care with in increasing number of ED and trauma center closures.

The Emergency Care Coordination Center (ECCC) was established in January 2009 within ASPR, in fulfillment of HSPD #21 The primary mission of the ECCC is to enhance USG coordination of in-hospital emergency care activities and to promote programs and resources that improve the delivery of our nation's emergency care in order to advance a patient-focused, accountable, coordinated, regionalized organization of the nation's emergency medical care systems. The ECCC leads an enterprise to promote and fund research in emergency medicine and trauma health care; promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution and care of routine community

patients; and promote local, regional and State emergency medical systems' preparedness for and response to public health 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 from pre-hospital to disposition from emergency or trauma care. The ECCC will coordinate with existing executive departments and agencies that perform functions relating to emergency medical systems in order to ensure unified strategy, policy and implementation.

Funding History:

FY 2005	--
FY 2006	--
FY 2007	--
FY 2008	--
FY 2009	--

Budget Request:
The FY 2010 request for the Emergency Care Systems program is $10,000,000. This is a new program proposal in FY 2010. Funding will support ECCC program initiation and development and two key project objectives – national standards for emergency care performance measurement and a demonstration of regionalization of emergency care services. As part of the national standards for emergency care performance measurement, funding will support the development and implementation of a consensus program for ED performance measures. It is also critical to the development and implementation of a collaborative assessment of proposed ED performance measures; the identification of gaps in emergency care; the development and implementation of a promotion/dissemination of emergency care metrics program; and the publication of summary reports of ongoing program findings.

As part of the demonstration of regionalization of emergency care services, some funds will support the examination of currently developed systems to identify best practices. The best practices will become the foundation for identification and promotion of a common data language. A common understanding of significant elements will encourage the integration of various state information systems and the development of a model system for Emergency Care information management. A demonstration project will be conducted in coordination with a comprehensive evaluation of regionalized trauma services. Regionalized input is necessary to identify the best practices among well integrated systems and comprehensively examine goals and effects of regionalized care delivery. It will also identify the unintended consequences of regionalized care and the potential obstacles to its application.

Outcomes and Outputs:
Performance measures for this new activity are under development.

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
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 (HHS) established the Cities Readiness Initiative (CRI) to prepare major US cities and metropolitan areas to effectively respond to a large scale bioterrorist event by dispensing antibiotics to their entire identified population within 48 hours of the decision to do so. Recognizing the challenges of distributing and dispensing antibiotics to a population in this timeframe, the development of an initial Federal "first strike" capability utilizing assets from the U.S. Postal Service (USPS) was directed.

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 USPS personnel and assets. 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. In the intervening years, HHS and USPS – in collaboration with several major cities and assisted by CDC and regional USPS staff – systematically have developed the "first strike" concept. 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. This activity, which is a component of CRI, has become known as the "Postal Module".

Funding History:

FY 2005	--
FY 2006	--
FY 2007	--
FY 2008	--
FY 2009	--

Budget Request: The FY 2010 request for the Medical Countermeasure Dispensing program is $10,000,000, with funding requested with two-year availability. Of this total, up to $8,000,000 may be transferred to the USPS. This is a new program in FY 2010. Funds requested will seek to expand the initial conceptual program to develop a federal "first strike" 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. Funding is required for personnel costs of those participating in

training and exercises, CRI route design planning, medical and safety screening of the USPS volunteers and their families, antimicrobial and kit materiel, disposable carrier uniforms. IT support, and program management. In addition, funds will be used to provide initial fit-testing and respiratory protection to the volunteer carriers.

The overall objective achieved by the USPS component of the CRI would be to begin the development of a "first strike" capability that can dispense and deliver antibiotics in designated zip codes in up to 4 CRI cities. Dispensing and delivery would 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.

Outcomes and Outputs:
Performance measures for this new activity are under development.

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$101,544,000	$275,000,000	$305,000,000	+$30,000,000
FTE	12	29	49	+20

Allocation Method: Direct federal/intramural; contracts; grants

Program Description and Accomplishments:
The Office of Biomedical Advanced Research and Development Authority (BARDA), a division within ASPR, was established in April 2007. BARDA is charged with all applicable responsibilities for 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 development and acquisition of medical countermeasures, including those activities related to pandemic influenza preparedness, emerging infectious diseases and the implementation of Project BioShield for chemical, biological, radiological, and nuclear (CBRN) threats. Under new authorities provided in PAHPA, BARDA now extends its focused advanced development product portfolio approach initiated successfully for pandemic influenza preparedness in FY 2006 to promising medical countermeasure candidates for CBRN threats and into emerging infectious diseases in FY 2011. BARDA balances investments across the medical countermeasure development pipeline to mitigate risks for stockpiling acquisition, building product manufacturing infrastructure, and innovating product efficacy, manufacturing and testing.

BARDA facilitates collaboration among the United States Government (USG), industry, and academia; supports the advanced research and development of medical countermeasures; and promotes innovation to reduce development and production time and cost of medical countermeasures. 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*, BARDA assists in the management of the *PHEMC Enterprise*, under the direction of the Enterprise Governance Board, composed of the HHS leadership of ASPR, CDC, FDA and NIH with members from the Department of Homeland Security, Department of Defense, Department of Veterans Affairs, and Department of Agriculture. BARDA is responsible for coordinating medical countermeasure research and development and acquisition programs across HHS and with interagency partners.

In March 2007, the *PHEMC Enterprise* released the *Public Health Emergency Medical Countermeasures Enterprise Strategy for CBRN Threats* (*PHEMCE Strategy*). It defined the goals for HHS development and acquisition programs and provided a framework for priority-setting to establish top priority medical countermeasures. In April 2007, the *PHEMC Enterprise* (led by ASPR) identified top priorities for the advanced development and acquisition of medical countermeasures for CBRN threats. Determinations were based on principles established in HSPD-18 and the goals and framework for priority-setting detailed in the *PHEMCE Strategy*. HHS published the *Public Health Emergency Medical Countermeasures Enterprise*

Implementation Plan (*PHEMCE Implementation Plan*) which describes the top priority medical countermeasure development and acquisition programs for CBRN threats. The investments in both advanced research and development and in Project BioShield acquisitions were aligned with these priorities.

Medical countermeasure requirements for CBRN threats are established under the PHEMC Enterprise Governance Board, chaired by ASPR. The highest priority requirements are reflected in the *PHEMCE Implementation Plan* and are based on population threat assessments developed by the Department of Homeland Security and medical and public health consequences of the threat as determined through HHS-coordinated modeling efforts led by BARDA.

Broad agency announcements 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 in September of 2008. Additionally, BARDA supported several existing NIAID contracts that were consistent with the *PHEMCE Implementation Plan*.

To ameliorate the many illnesses associated with the threat of radiation, FY 2008 funding supported the awarding of seven contracts for Acute Radiation Syndrome (ARS), one contract to support good laboratory practices (GLP) radionuclide facility support services, and eight grants for both radiation-induced cutaneous and lung injuries. Additionally, funding on three contracts for oral DTPA (diethylene triamine pentaacetic acid) was continued in FY 2008. Requests for proposals (RFPs) for development of biodosimetry devices and neutropenia associated with ARS were issued in FY 2009.

Funding was continued on several broad spectrum antimicrobial agent projects in FY 2008. Further, BARDA continued to fund inhalational gentamicin studies, the US Army Medical Research Institute of Infectious Diseases (USAMRIID) 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 (PEP) indication.

Funding History:

FY 2005	$4,923,000
FY 2006	$54,421,000
FY 2007	$103,921,000
FY 2008	$101,544,000
FY 2009	$275,000,000

Budget Request:
The FY 2010 request for CBRN Advanced Research and Development is $305,000,000, an increase of +$30,000,000 above FY 2009. The request is financed by a transfer of funding from the Project BioShield Special Reserve Fund. (In FY 2009, $275 million was provided for advanced research and development, including $25 million for development of next generation

of ventilators for all-hazards preparedness especially for pandemic influenza. In FY 2010, continuing support for advanced development of ventilators is requested in Pandemic Influenza.) Funding in FY 2010 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. These funds continue to be requested with two years of fiscal availability to maximize flexibility to direct resources to multiple development efforts over time, improve the U. S. Government's negotiating position, and allow for an increased timeframe required for the procurement process using broad-agency announcements Funds will support the advanced development of only the highest priority medical countermeasures among the twelve biological threat agents, a class of chemical threats (volatile nerve 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/efficacy studies to become eligible for consideration in an emergency and towards FDA approval. The $305 million funds requested for FY 2010 will support existing efforts in advanced research and development for the highest priority areas of anthrax, acute radiation syndrome, biodosimetry, and enhanced product development such as increased efficacy, new formulations to increase stability and shelf life and alternate routes of administration. ASPR/BARDA will be able to continue contracts in these areas that were awarded in FY 2007, FY 2008 and FY 2009. Investing in the research and development of these specific medical countermeasures supports future successful acquisitions of medical countermeasures under Project BioShield.

Specifically, funding is requested for continued advanced development of third-generation anthrax vaccines and anthrax polyclonal and monoclonal antitoxins on existing ASPR/BARDA contracts. This support for a high priority MCM will augment anthrax vaccines under development and/or stockpiled currently and enable further development of only several anthrax medical countermeasure product candidates that may mature in several years towards FDA approval and for stockpile acquisition consideration.

Additionally funding is requested for development of next generation broad spectrum antimicrobial drugs for treatment of 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, and/or ASPR/BARDA contracts.

For a third high priority need, funding will support the advanced development of therapeutics under existing ASPR/BARDA contracts to address illnesses associated with acute radiation syndrome. These funds will afford additional development of some but not all the of therapeutic candidate products in the ASPR/BARDA widely-diverse product pipeline for the six illnesses resulting from radiological and/or nuclear event injury.

Further, funding will support the second year of the ASPR/BARDA-sponsored innovation program to enhance late stage or existing CBRN MCMs and diagnostics; improve the manufacturing processes of these products; or the testing of the products during manufacturing or clinical study analysis. Funds are also requested for supportive projects on CBRN product assays, animal modeling, and bioproduction facility design. The request also includes support for management and administrative support of these and previously awarded advanced research and development projects.

Outcomes and Outputs:
Long Term Objective: Define requirements for and deliver safe and effective medical countermeasures to identified threats (biological, chemical, radiation and nuclear) to the SNS through coordination of interagency activities, interfacing with industry and acquisition management.

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.4: Obtain sufficient evidence for the safety, efficacy and product characteristics of candidate medical countermeasures for priority chemical, biological, radiological and nuclear agents to accelerate their potential for procurement under Project BioShield *(Outcome)*	FY 2009: BARDA issued BAAs in FY09; Offerors submitted white papers for BARDA consideration; results of technical evaluation are pending; contract awards expected in 2009. (In Progress)	Continue to issue special instructions under the CBRN BAA for high priority threats and for those threat areas where programs are matured enough to be considered for ARD funding. Continue to issue RFPs for ARD of specific products that have the potential to quickly transition into procurement contracts.	Targets, which may be addressed by contract awards in FY10 from CBRN BAA MCM ARD, include anthrax, acute radiation syndrome, and biothreats including enhanced agents such as antibiotic-resistant forms of anthrax, plaque, and tularemia.	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.4A: Anthrax (vaccines, therapeutics, and medkits) *(Outcome)*	FY 2009: BARDA issued BAAs in FY09; Offerors submitted white papers for BARDA consideration; results of technical evaluation are pending; contract awards expected in 2009. IAA executed to manufacture anthrax antibiotic MedKits and conduct labeling comprehension studies. (In Progress)	Issue BAA for evaluation of antibody-based therapeutic antitoxins currently available and small-molecule antitoxin innovations (contracts planned for award in FY10). Issue BAA for CBRN MCM ARD including anthrax vaccines, antitoxins, and antibiotics. Fund development of one anthrax vaccine enhancement program. Fund manufacturing of doxycycline MedKits for anthrax and labeling comprehensions studies.	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.	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.4B: Radiation *(Outcome)*	FY 2009: BARDA issued BAAs in FY09; Offerors submitted white papers for BARDA consideration; results of technical evaluation are pending; contract awards expected in 2009. Additional funding will be added to existing contracts awarded in FY08 for advanced development of ARS MCMs. Contracts will be awarded on BAA issued in FY09 for development of biodosimetry diagnostic devices and assays for rad/nuc exposure. (In Progress)	Continue support of ARS MCM ARD contracts awarded in FY08. Issue RFP for development of MCMs to address ARS-associated neutropenia. Issue BAA for development of biodosimetry diagnostic devices and assays for rad/nuc exposure. Work with the CDC to determine the most cost effective path forward to maintain stockpiles of Prussian Blue. Issue special instruction under CBRN BAA for ARD to support development of a pediatric indication for Prussian Blue.	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.	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.4C: Broad Spectrum Antimicrobials (BSA) *(Outcome)*	FY 2009: BARDA issued BAA for CBRN MCM ARD that included BSA. Pre-clinical studies of inhalational gentamicin are on-going. (In Progress)	Issue CBRN MCM for ARD including BSA, Continue pre-clinical studies of inhalational gentamicin.	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. .	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.4D: Innovation *(Outcome)*	FY 2009: BAA is under final review for issuance in FY09. (In Progress)	Issue BAA to solicit proposals for (i) technologies to accelerate evaluation of vaccines and therapeutics, (ii) formulation chemistry, protein stabilization, and vaccine delivery technologies as applied to products in advanced stages of development or to licensed products. (iii) methods in bioprocess development and manufacturing. and (iv) methods to enhance rapid diagnostic tests for CBRN threats.	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 *in vitro* testing methods to determine a product's efficacy, support assay development. In addition this effort will support development of late stage diagnostics.	N/A
2.4.4E: Smallpox	FY 2008: BARDA awarded 1 new contract for the enhancement of a smallpox antiviral product (new formulation and new indication). In addition BARDA continued to fund 1 existing contract.	Continue funding of ARD of enhanced formulation and new indication. Products have matured enough to the point where BARDA has issued a Project BioShield RFP for procurement of product for the strategic national stockpile (SNS)		
2.4.4F: Viral Hemorrhagic Fevers *(Outcome)*	FY 2009: BAA issued in FY09, and white paper proposals are under technical review. (In Progress)	Issue CBRN BAA to call for products to treat viral hemorrhagic fevers.	No new activity.	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.4G: Botulism *(Outcome)*	FY 2009: BAA issued in FY09, and white paper proposals are under technical review. (In Progress)	Issue CBRN BAA for ARD including products to treat botulism. Review white papers.	No new activity.	N/A
2.4.4H: Chemical *(Outcome)*	FY 2009: BAA issued in FY09, and white paper proposals are under technical review. (In Progress)	Issue CBRN BAA for ARD including products to treat illnesses resulting from chemical attacks or accidents. Review white papers.	No new activity	N/A

Office of the Assistant Secretary for Preparedness and Response
BioShield Management

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$21,243,000	$22,052,000	$22,364,000	+$312,000
FTE	54	83	116	+33

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:
The Project BioShield (PBS) Act of 2004 is part of a broad strategy to defend America against the threat of weapons of mass destruction. The purpose of PBS is to accelerate the research, development, purchase, and availability of effective medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) agents.

Contracts for two licensed products, anthrax vaccine (AVA) and pediatric potassium iodide (KI), were awarded in 2005, and the products have been delivered to the SNS (5 million AVA doses and 1.7 million bottles of pediatric KI). In FY 2006, a contract was awarded for calcium and zinc DTPA (diethylene triamine pentaacetic acid), chelating agents that remove radioactive particulates from the body, and all 474,000 doses have been delivered to the Strategic National Stockpile (SNS). In FY 2006, an additional 5 million doses of AVA and 3.1 million bottles of the pediatric formulation of KI were purchased; delivery of these products has been completed. The following contracts were also awarded under Project BioShield in FY 2006:

- Anthrax therapeutic – 10,000 treatment courses of Anthrax Immune Globulin
- Anthrax therapeutic – 20,000 treatment courses of a monoclonal antibody, Raxibacumab
- Botulism antitoxin – 200,000 treatment courses of an equine plasma-derived heptavalent botulism antitoxin.

These three acquisition contracts all involve late-stage development. They have all met FDA requirements for pre-licensure use under an emergency and are being delivered to the SNS.

In June 2007, a Project BioShield contract was awarded for 20 million doses of a novel smallpox Modified Vaccinia Ankara (MVA) vaccine to protect 10 million immunocompromised persons. This contract uses the original Project BioShield 10% advance payment provision as well as the milestone payment authorities provided by PAHPA. In September 2007, a second contract was awarded for 18.75 million doses of AVA anthrax vaccine. This contract calls for not only the delivery of product but also an extension of the licensed indication (pre-exposure prophylaxis) to post-exposure prophylaxis.

In 2008, BARDA issued a Request for Proposals (RFP) for next generation recombinant protective antigen (rPA) anthrax vaccines with expectations of contract awards in FY 2009. In addition, BARDA issued an RFP for medical countermeasures to treat the neutropenia associated with Acute Radiation Syndrome (ARS); this RFP was cancelled in FY 2009 due to the immaturity and excessive risk associated with awarding contracts to the Offerors that submitted

proposals. Subsequently, an RFP for advanced development of these ARS MCM products was issued to address this threat. A RFI for an Anthrax Antibiotic MedKit was issued in 2008, which was followed by an interagency agreement for development of a MedKit. Lastly an RFP was issued in FY 2009 for a smallpox antiviral drug; contract award(s) are expected in 2009.

Funding History:

FY 2005	$8,167,000
FY 2006	$12,313,000
FY 2007	$15,820,000
FY 2008	$21,243,000
FY 2009	$22,052,000

Budget Request:
The FY 2010 request for BioShield Management is $22,364,000, an increase of +$312,000 above FY 2009. These funds are requested for oversight and implementation infrastructure for medical countermeasure procurement under Project BioShield. The goal of the program is to deliver licensed, licensable and approvable medical countermeasures for priority chemicals, biological, radiation and nuclear agents.

ASPR/BARDA expects up to four new PBS awards to be made in 2009. Funding will support program management, regulatory affairs, 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. Staff will be responsible for monitoring previous acquisitions as well as well as for new efforts planned in FY 2009 and FY 2010 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 (PEP), 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 resulting in proper oversight by the USG and ensuring contractors are submitting high quality documents to the FDA that will expedite the review process. This in turn will result 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 also will result in proper programmatic oversight of all contracts by the USG and allow for the USG 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 MCM requirements and assessing response capacities as well as maintaining the web-based stakeholder portal for information management and sharing, professional staff training in medical countermeasure research, development and acquisition, document management, and program management. In FY 2010, ASPR will continue to support policy and strategic planning to set requirements and

acquisition strategies for needed public health emergency medical countermeasures including a stakeholder outreach to solicit input from industry, academia, and other interested parties of the planning process. In FY 2010, BARDA will hold the annual Industry Day and PHEMCE Stakeholder's Workshop to facilitate collaboration with all stakeholders.

Outcomes and Outputs:

Long Term Objective: Define requirements for and deliver safe and effective medical countermeasures to identified threats (biological, chemical, radiation and nuclear) to the SNS through coordination of interagency activities, interfacing with industry and acquisition management.

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.5: Deliver licensed, licensable and approvable top priority medical countermeasures for chemical, biological, radiological and nuclear threats. *(Outcome)*	FY 2009: RFP issued in FY09 for development/acquisition of a smallpox antiviral drug; contract awards expected in 2009. Contract negotiations are on-going for rPA vaccine RFP. Deliveries of Raxibacumab and AVA on schedule for completion in FY09. Data package and EUA are under review by FDA for smallpox vaccine MVA. Deliveries of h-BAT and AIG are on schedule in FY09. Contract modifications are pending to establish in FY09 plasma pools for h-BAT and AIG and warm base manufacturing operations for Raxibacumab. (In Progress)	Issue RFP for smallpox antiviral drug. Award contract(s) for rPA vaccine from RFP in FY08. Complete deliveries of Human Genome Science's (HGS) Raxibacumab and file BLA. Complete delivery of anthrax vaccine AVA to SNS in FY09. Initiate deliveries of smallpox vaccine MVA to SNS. Continue deliveries of h-BAT and AIG to SNS. Establish in FY09 plasma pools for h-BAT and AIG and warm base manufacturing operations for Raxibacumab.	Award contract(s) for smallpox antiviral drugs. Award contract(s) for rPA vaccine, if not completed in FY09. Complete BLA submission to FDA for Raxibacumab. Complete animal studies to inform AVA PEP. Continue deliveries of MVA, h-BAT, and AIG to SNS	N/A

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$8,690,000	$8,690,000	$8,748,000	+$58,000
FTE	15	20	20	--

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' immediate responsibility is to advance and support policies and programs that will help safeguard and protect Americans from international 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 influenza outbreaks with pandemic potential and other infectious disease threats overseas. ASPR, in coordination with the Office of Global Health Affairs (OGHA), 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 continues to coordinate and facilitate the development of international preparedness and response capabilities through agreements with the WHO, with Ministries of Health and other international organizations, and by leveraging global partnerships to increase preparedness and response capabilities around the world. Recently, ASPR has 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 continued implementing a collaborative program among U.S. and Mexican states and Canadian provinces, immediately along the U.S. international borders, to enhance disease detection capacities.

Additionally, ASPR has continued its engagement in international preparedness and response partnerships, including the Global Health Security Initiative (GHSI), the Security and Prosperity Partnership of North America (SPP), and with the WHO.

Members of the GHSI continue to plan and share their experiences and lessons learned in preparing for chemical, biological, radiological and nuclear (CBRN) events and pandemic influenza threats to public health. 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 2008 ASPR organized a special workshop on this topic for GHSI members and will be organizing a two-day expanded

workshop on this issue in 2009. ASPR will be organizing and hosting some of the additional workshops that the GHSI Working Groups have identified as priority needs, including a workshop on how best to deal with the surge in demand for health care that medical institutions will experience during an influenza pandemic. In 2008, ASPR supported substantive engagement or hosted 18 GHSI meetings or workshops that advanced the identification and dissemination of public health emergency preparedness needs, promising strategies, and best practices among its member countries and organizations.

As part of the SPP, 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. Canada will provide a liaison to ASPR by mid-FY 2009. With Mexico, ASPR has sent a short-term liaison to help determine the ideal location for a long-term assignment.

ASPR has increased its international outreach efforts, in collaboration with the WHO, to implement the revised International Health Regulations (IHR) globally. ASPR led the US government implementation of the revised IHR and established the IHR Program to monitor IHR compliance for the USG. The IHR Program has supported IHR implementation globally by sharing USG IHR implementation best practices and providing technical assistance to 43 countries across all six WHO regions.

In addition to these partnership activities, ASPR began the development and exercising of 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. 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 USG international response. In FY 2009 ASPR developed 10 supporting annexes to the Framework and assisted Department of State, US Agency for International Development, and Department of Defense (DOD) 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. Both these planning efforts will soon be taken to the WHO and other USG Departments with which HHS would collaborate in such efforts.

ASPR led HHS engagement in the whole-of-government effort to establish a civilian capacity to prevent or prepare for post-conflict situations, and to 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. Beginning in FY 2009, ASPR detailed a US Public Health Service officer to the US Army War College Peacekeeping and Stability Operations Institute to serve as their health and humanitarian assistance advisor, with focus on developing doctrine and training on the health and medical aspects of DOD stability, security, and transition and reconstruction operations.

Biodefense and biosecurity are national priorities. To address this priority, ASPR has markedly expanded, intensified, and accelerated its support for critical national security biodefense and biosecurity activities. ASPR's Office of Medicine, Science and Public Health (OMSPH) serves as the focal point within ASPR for activities related to the newly established Tran-Federal Task Force on Optimizing Biosafety Oversight. The Task Force has undertaken an intensive analysis of the current framework of biosafety and biocontainment oversight of high and maximum containment research on hazardous biological agents and toxins, with the goal of exploring strategies to address concerns voiced by Congress and the general public. The purpose of the Task Force is to propose options and recommendations to improve biosafety and biocontainment oversight of research activities at high and maximum containment research laboratories in the United States through a comprehensive review of mechanisms by which individual research (local) institutions and the Federal Government can ensure safe working conditions. Other areas of expansion include 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; and support for continuing and new USG efforts to strengthen pathogen security.

Established by the Pandemic and All Hazards Preparedness Act of 2006, The National Biodefense Science Board (NBSB) is charged with providing expert advice and guidance to the Secretary of Health and Human Services on scientific, technical, and other matters of interest regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance on other matters related to public health emergency preparedness and response. The 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. The working groups will examine the current state of pandemic influenza research efforts; conduct an overview of the U.S. government's research portfolio of medical countermeasure and biosurveillance efforts; consider efforts to address and strengthen the medical countermeasure marketplace; and explore the development of an integrated disaster medicine framework. At the June 2008 public meeting the Board voted to establish a Personal Preparedness Working Group and welcomed the members of the Disaster Mental Health Subcommittee established in response to Homeland Security Presidential Directive -21. From FY 2008 through the first half of FY 2009, the Board convened four public meetings in-person and three 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. Recommendations from the Disaster Mental Health Subcommittee were reviewed, discussed and received final approval by the Board, and provided to the Secretary. The recommendations promote integration of mental and behavioral health into public health and medical preparedness and response activities. In addition to these activities the Board considered

issues of individual preparedness including diverse viewpoints on the home stockpiling of antibiotics for use in the event of a release of anthrax.

Funding History:

FY05	$9,354,000
FY06	$8,988,000
FY07	$8,808,000
FY08	$8,690,000
FY09	$8,690,000

Budget Request:
The FY10 request for Medicine, Science, and Public Health is $8,748,000, an increase of +$58,000 above FY 2009. The funds will be used to continue development of public health infrastructure in the Western Pacific, Southeast Asia, the Americas, and other regions to further enhance epidemiological surveillance and laboratory capacities, and associated information technology to foster accurate and prompt reporting of and response to naturally occurring and intentional infectious disease outbreaks. In the Western Pacific and Southeast Asia, funds will be used for programs with a specific emphasis on increasing capacity for influenza detection, surveillance and response. 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 support ASPR efforts to increase preparedness and response capabilities around the world through continued participation in international partnerships and initiatives, including the GHSI, SPP, and implementation of the IHR 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 ASPR's abilities to assist and to receive assistance from partner countries during public heath emergencies. ASPR will also fund the further development and exercise of international all-hazards response plans with the U.S. 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 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 implementation of recommendations and expansion of biosafety and biosecurity efforts within HHS.

(This activity was formerly known as International Early Warning Surveillance. One of the major projects supported with these funds is the International Early Warning Infectious Disease Surveillance project, which enhances the capacity of public health systems along the U.S. border to rapidly detect infectious disease outbreaks. The name has been changed to reflect the wider array of programs and initiatives, and policy and technical work that ASPR/OMSPH conducts.

Outcomes and Outputs:

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

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.6: Coordinate and facilitate development of international preparedness and response capabilities. *(Outcome)*	FY 2009: Dev. 10 supporting annexes to all-hazards HHS International Emergency Response Framework, assisted DOS, USAID, DOD to harmonize interagency plans related to intrnat'l response. Further dev/exercised HHS internat'l pandemic flu containment plans in coord. w/ internal, USG, WHO partners. Led HHS engagement in the whole-of-gov't effort to est. a civilian capacity to prevent or prepare for post-conflict situations and help stabilize and reconstruct societies in transition from conflict. Detailed USPHS officer to the US Army War College Peacekeeping and Stability Operations Instit. to serve as their health and humanitarian assistance advisor with focus on dev. doctrine and training on the health and medical aspects of DOD stability, security, transition and reconstruct ops. (In Progress)	Continue to collaborate with U.S. border states, neighboring countries, other cross-border and international partners, and with multilateral initiatives to advance domestic and international preparedness and response to all public health emergencies. Continue to support and manage international response exercises and to collaborate with international partners to support universal implementation of the IHR. Continue to build international preparedness and response capabilities, specifically in the areas of MCM development, stockpiling & deployment, and testing/exercising of emergency preparedness plans.	Continue to collaborate with HHS Agencies, USG 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.	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.7: Provide medical, scientific, and public health subject matter expertise *(Outcome)*	FY 2009: National Biodefense Science Board held one public teleconference in October 2008 and a public face-to-face meeting in November 2008 and April 2009. Recommendations were submitted to the Secretary following approval by the Board, in November 2008. (In Progress)	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 additional in-person public meeting in September 2009	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.	N/A

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$4,292,000	$4,292,000	$4,367,000	+$75,000
FTE	15	21	23	+2

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:
The enactment of PAHPA has elevated the profile of the Department's emergency preparedness and response activities, now coordinated by ASPR. As a result of the new authorities and program requirements, there is a need for the office to enhance its strategic communications to internal USG stakeholders as well as external audiences including domestic and international media and the public at large. 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 work internally within HHS to enhance public health risk communications. HHS will continue to 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 utilizing existing mechanisms and new media strategies.

Planning and development of emergency crisis risk communications as necessary as part of the response to a pandemic influenza outbreak is well underway. Ongoing collaboration on crisis and emergency risk communications related to public health emergencies, including a pandemic influenza outbreak or terrorism, has expanded to include not only federal partners via the interagency working groups including the Department of Homeland Security (DHS) Border Communications Working Group and National Public Health Information Coalition of state and local public health communicators. The ASPR Communications Team continues to work collaboratively with our North American partners Canada and Mexico, and the entire international health community via Global Health Security Action Group. The development and publication of the National Health Security Strategy is required by PAHPA and will be published in 2009.

Funding History:

FY 2005	$4,726,000
FY 2006	$2,756,000
FY 2007	$3,116,000
FY 2008	$4,292,000
FY 2009	$4,292,000

Budget Request:
The FY 2010 request for Policy, Strategic Planning and Communications is $4,367,000, an increase of +$75,000 above FY 2009. The funds are requested to maintain on-going efforts to support policy formulation, analysis, coordination, and evaluation of preparedness and response efforts across ASPR. This includes coordination, analysis and implementation of relevant laws (e.g., PAHPA, Public Readiness and Emergency Preparedness Act), proposed policies, Presidential directives (e.g., Homeland Security Presidential Directives and Presidential Study/ Action Directives) and regulations. Activities also include the development of short and long-term policy and strategic objectives and 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 National Health Security Strategy, which is required by PAHPA to be published beginning in 2009 and every four years thereafter. 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:
Long Term Objective: Improve HHS response assets to support municipalities and States.

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.8: Improve strategic communications effectiveness. *(Outcome)*	FY 2009: Research for the development of a communication strategy around the use of "social media" as an additional mechanism to communicate during public health emergencies. Working with GHSAG to develop messages around border protection issues for Pandemic Influenza. (In Progress)	Improve communication and support for external stakeholder around public health emergencies. Improve communication with international entities including increasing involvement in SPP and GHSAG communication activities.	Implement the ASPR strategic communications plan to the extent possible. Maintain ASPR's central infrastructure for public web communications with ESF 8 partners.	N/A

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.4.9: Establish and improve awareness of the ASPR strategy for preparedness and response *(Outcome)*	FY 2009: Provide outreach support to expanded stakeholder groups to socialize the NHSS in the strategic development phase and in the broader rollout of Strategy and implementation plan. (In Progress)	Complete the draft of the National Health Security Strategy. Work with partners and stakeholders on draft outreach materials.	Maintain current outreach and awareness strategy via web, video, and presentations at major meetings of stakeholders.	N/A

Office of the Assistant Secretary for Resources and Technology
Cyber Security

	FY 2008 Actual	FY 2009 Omnibus	FY 2009 Recovery Act	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$8,906,000	$8,906,000	$50,000,000	$50,000,000	$41,094,000
FTE	--	8	--	11	+3

FY 2010 Authorization: Indefinite

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 Resources and Technology (ASRT), assures that all automated information systems and data throughout HHS are designed, operated, and maintained with the appropriate information technology security and privacy protections. Most programs, projects, and activities administered by HHS depend upon the trust of citizens, corporations, and service delivery partners in HHS' ability to retain the confidentiality of personally identifiable and commercially proprietary information. At the same time, large amounts of public information needs to be readily accessible to support research, innovation, and efficient service delivery. Maintaining public trust is a primary objective of the HHS IT Security Program. As a result, every general-purpose computing environment and every specific program application system must be subjected to risk-based security control testing prior to implementation and must be persistently monitored to guard against an increasing number of 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 in the ASRT General Departmental Management budget and within the Cyber-Security appropriation in FY 2009 and FY 2010.

The HHS IT Security Program has established the HHS Computer Security Incident Response Center (CSIRC), providing an enterprise-wide capability to monitor the Department's computers and networks for security incidents and attacks. HHS plans to expand CSIRC capabilities in FY

2009 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. In addition, the Department also initiated 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.

2008 Accomplishments

The IT Security Program successfully achieved all critical FISMA milestones and performance measures, to include the timely submission of quarterly and annual FISMA reports to the OMB. The Program implemented the Department of Defense's (DoD) Information Systems Security (ISS) Lines of Business (LoB) Shared Service Center for security awareness training, and also implemented Federal Desktop Core Configuration (FDCC) settings for all desktop computer systems throughout the Department. 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. 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.

Funding History

FY 2005	$9,846,000
FY 2006	$9,586,000
FY 2007	$9,482,000
FY 2008	$8,906,000
FY 2009	$58,906,000

Budget Request

The FY 2010 request for IT Security is $50,000,000, an increase of +$41,094,000 over the FY 2009 level. This increase supports the implementation of a number of urgent security enhancements at each of the HHS Operating Divisions.

The request continues and builds 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. HHS will also enhance the IT security at the Operating Divisions by pursuing a number of short-term, high impact investments that will address and correct existing security gaps. This includes the implementation of Network Access Control (NAC) security technology, providing commercially available access control solutions required to securely access HHS computers and network resources. This will also include funding for a number of secure remote access projects that will implement multi-factor authentication solutions in order to fully comply with OMB guidance. This will include authentication solutions that comply with Homeland Security Presidential Directive-12 that makes use of the Personal Identity Verification (PIV) cards that have been issued throughout HHS. 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. Enhancements to OPDIV disaster recovery capabilities will also be accomplished for high risk mission essential systems supporting HHS and Operating Division Continuity of Operations (COOP).

In addition, the IT Security Program will expand security engineering and implementation of secure social networking technologies (Web 2.0), including additional solutions for computer endpoint protection and data loss prevention. 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 procure a Department-wide license for one of the designated ISS LOB solutions and tools supporting

FISMA reporting processes, security weakness tracking, and automated certification and accreditation. The Department will 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

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 including refinements to the *Breach Response Team Policy*, the *Breach Response Team Charter*, and *Breach Response Team Standard Operating Procedures.* This will enable the Department to evaluate OPDIV breach response assessments to determine the appropriate response to any reported breaches of PII.

While the Department has begun addressing these areas via the FY 2009 appropriation and Recovery Act funding, the requested increase in FY 2010 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 2008	FY 2009 Target	FY 2010 Target
1.1 Percentage of desktop computers operating in compliance with Federal Desktop Core Configuration (FDCC) security guidance (windows computers)	0% (FY 2007)	98%	100%	100%
1.2 Percentage of HHS laptops and desktops secured with encryption	35% (FY 2007)	40%	55%	95%
1.3 Percentage of HHS enterprise network infrastructure monitored with automated intrusion detection systems	50% (FY 2007)	55%	60%	95%
1.4 Percentage of HHS IT systems protected with advanced Internet content filtering and anti-malware solutions	50% (FY 2007)	60%	85%	95%
Program Level Funding ($millions)	9.42	8.906	8.906	50.000
ARRA Level Funding ($millions)	N/A	N/A	50.0	N/A

Office of Public Health and Science
Medical Reserve Corps

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$9,578,000	$12,344,000	$12,581,000	+$237,000
FTE	6	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 2006 Pandemic and All-Hazards Preparedness Act.

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 without receiving the Demonstration Project funding support. As of April 2009, there are over 800 MRC units in 49 states, Washington, DC, Guam, Palau, Puerto Rico and the US Virgin Islands, with more than 170,000 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 staff and the MRC Regional Coordinators.

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 Council, the Surgeon General, the Assistant Secretary for Health (ASH), the Assistant Secretary for Preparedness and Response, 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, including:

- Cooperative agreement with the National Association of County and City Health Officials (NACCHO). This three-year cooperative agreement was initiated in FY 2006 (FY06 - $8 million; FY07 - $6 million; FY08 - $5.3 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 ($5-10,000 per eligible/selected MRC unit) are used by MRC units to offset a variety of administrative costs, including personnel, training, travel, supplies and equipment.
- 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 Regional Coordinators situated in the ten HHS regional 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 MRC outreach.
- Interagency Agreement with Centers for Disease Control and Prevention which provides funding supplements to CDC Cooperative Agreements with the Public Health Foundation (PHF). The funding to PHF supports MRC-Train, a learning management resource offered 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 (to date)	32	803	174,927

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. 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, HHS expects to have approximately 45 new units and 15 de-registrations each year.

Funding History:

FY 2005	$9,846,000
FY 2006	$9,748,000
FY 2007	$9,748,000
FY 2008	$9,578,000
FY 2009	$12,344,000

Budget Request:

The FY 2010 request is $12,581,000, an increase of $237,000 above the FY 2009 Omnibus Appropriations level. The increase provides funds for staff pay increases and enables the program to continue to support salaries, travel, cooperative agreements, contracts, grants and contract management, technical assistance, outreach, deployment operations and other programmatic activities.

While OCVMRC seeks continued growth in the number of registered MRC units, the programmatic focus has shifted to ensuring that all MRC units are strong and active in their communities. FY 2010 funding will ensure that this focus is achieved through enhancement and 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:

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
- Strengthen our internal capacity to support MRC units

Key Outcomes	Most Recent Results	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
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**	787 (FY 08 - Exceeded Target)	817	847	30
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**	168,996 (FY 08 - Exceeded Target)	177,450	186,322	8,872
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)	600,000	600,000	---
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**	58% (FY 08 Baseline Year)	70%	80%	10%

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**	68% (FY 08 Baseline Year)	75%	80%	5%
3.2OCVMRC 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)	75	150	75

Office of Security and Strategic Information

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$3,263,000	$3,263,000	$4,893,000	+$1,630,000
FTE	17	21	31	+10

Allocation Method: Direct Federal

Program Description and Accomplishments:
OSSI was established in May 2007 to consolidate functions related to physical security, personnel/classified information security, and strategic information, working across all HHS operating and staff divisions. OSSI represents HHS on several Homeland Security Council and National Security 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, 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 has been assigned a broad portfolio of responsibilities in support of the varied missions of HHS. These responsibilities are overseen by the Director and a leadership team that is organized into the three functional divisions described below. The 2010 budget request will also promote the responsibilities and programs in obtaining access to and sharing and protecting strategic and classified information that will support HHS public health and science programs, protection of HHS employees, and HHS critical infrastructure security. This work will entail coordination of analytical activity of HHS officials throughout the Department 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 and with DHS.

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 (IC). 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 IC 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 agencies, Operating Division, and Staff Division leadership.

- Developed customer driven Priority Intelligence Requirements (PIR) that address the strategic information and intelligence needs of the Department and its diverse missions.
- OSSI is responsible for providing updated classified briefings to senior leadership and policy makers, including all agency and staff division leadership.
- DSI has developed 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.
- OSSI has been able to provide current and timely classified information to policy makers pertaining to food and pharmaceutical safety discussions with the People's Republic of China.
- OSSI has been able to provide current and timely classified information to policy maker pertaining to negotiations associated with avian influenza virus sample sharing, furthering and safeguarding U.S. interests.
- OSSI has been able to provide critical information regarding the decision-making pertaining to the destruction of smallpox virus. Policy makers have used this information to negotiate the preservation of smallpox, which is in the U.S. interest.

OSSI is responsible for security programs to protect HHS employees from exploitation and HHS assets and critical infrastructure.

- Established productive relationships with the Washington and Baltimore Field Offices of the FBI. Also established productive liaisons with HQ FBI.
- Resulted in multiple open investigations and the detention of 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.
- Public Health Sector lead for the Critical National Assets (CNA) initiative. (Also sit on the CNA executive committee)

OSSI is responsible for reviewing and approving all requests for visits by foreign nationals to HHS properties.

- Implemented foreign visitor policy Department-wide, which brought discipline and security to thousands of short-term visits by foreign nationals to HHS facilities and Critical Infrastructure sites.
- During recent five month period, at least 170 Chinese nationals visited HHS properties within the National Capitol Region. OSSI policies ensured that sound security practices would be followed; e.g., these visitors would have HHS hosts and escorts during their visits.

OSSI is responsible for HHS policy for more than 10,000 trips per year overseas by HHS employees

- OSSI leadership has resulted in a minimum level of briefing for some of these 10,000 HHS travelers.

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.

- 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.

DPCIS provides Departmental guidance and oversight for these security functions and provides centralized adjudication of background investigations for all the Department's high public trust and national security positions. DPCIS prepares annual tracking reports for OPM and other associated Federal reporting requirements.

Clearance process refined and streamlined. Ongoing re-engineering of processing is occurring.

- Data base program initiated for reduced data input time. Phase 1 and 2 are complete, Phase 3 to follow: IT Requirement in Personnel Security: HHS had an immediate need to 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.
- The completion of the first two phases of the project satisfied 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.
- There is a need to integrate systems that we are in the process of implementing 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.

Personnel security clearances and adjudications have increased to over 2,500 cases, increase of 50% over the last year due to HSPD-12 initiative by the President.

- Funding in FY 2010 will support the management the ongoing and continued volume case load for PERSEC. The number of high level background investigations is projected to increase by a minimum of 50% 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.

- See table 1.0, attached

Secure Communications: COMSEC Division

- Updated and support of all secure communications equipment for the Office of the Secretary. Developed of an infrastructure of sensitive and classified communications among HHS components. The infrastructure developed to include SIPRNET, JWICS, and HSDN. Controlled Unclassified Information systems of communication.
- 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 date transmission, planning and training.

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 Departmental 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*
- Bioterrorism
- 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.

Short Term Goals begun to support the following:

1. Reviewing and approving all requests for visits by foreign nationals to HHS properties.
    - Development of a foreign visitor data base for HHS and other NT-50 agencies. OSSI lacks resources to institute, track and manage all 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 without an ability to track and identify repeat visitors.

2 Foreign Travel monitoring and policy
- Develop HHS policy for more than 10,000 trips per year overseas by HHS employees
- Develop and disseminate foreign travel briefs for personnel.
- Develop pre- and post-travel contact procedures to facilitate information exchanges between official HHS travelers and communities of interest.
- Develop a Post Travel instruction and expectation sheet.
- Continue to pioneer scheduling of 90 min slots for post travel interviews to facilitate the maximum amount of information about the activities of interest without requiring a second round of interviews.
- Develop formalized scheduling and contact procedures
- Continue to provide information sharing that has been very valuable to the USG at large.

3. CUI – Controlled Unclassified Information program
- Presidential Memorandum instituting the CUI policy provides a secure and legal framework for protecting government sensitive information. This will provide minimum standard practices to allow improved secure information sharing between federal, state, and local governments; tribal authorities; and private industry.
- OSSI is responsible for implementing this Department wide program. This includes protecting Personally Identifiable Information (PII) and scientific and medical information which does not rise to the level of classified national security information but is sensitive and requires protection.

4. NSPD: National Security Professional Development (NSPD) pursuant to Presidential Executive Order 13434: states that, "In order to enhance the national security of the United States, including preventing, protecting against, responding to, and recovering from natural and manmade disasters, such as acts of terrorism, it is the policy of the United States to promote the

education, training, and experience of current and future professionals in national security positions (security professionals) in executive departments and agencies." The mandate of Executive Order 13434, National Security Professional Development, set forth a framework that will provide to designated national security professionals in HHS, and other departments and agencies, required access to education, training and professional experience opportunities

The National Security Professional Development (NSPD) program is currently being designed to ensure that national security professionals:

- Integrated courses required by NSPD Executive Committee into HHS University database so we can track those completing the various courses
- Determined those who should be in the NSPD program
- In the process of establishing HHS Implementation Plan for NSPD
- In the process of establishing SES promotion regulation requiring NSPD training before one can be promoted
- Personnel are needed who can focus a significant amount of time developing and tracking this program in accordance with the requirements set by Presidential Executive Order 13434

The Director of OSSI represents the Department on the steering committee that is responsible for implementation of the national strategy, and HHS will be taking the lead role in the development of plans and approaches for science-based departments and agencies. The scope of the National Security Professional Community is estimated to be approximately 20,000 Federal Government employees. National security professionals are those personnel in positions responsible for developing strategies, creating plans to implement, and executing common missions in direct support of U.S. national security objectives. This estimate is based on the number of GS-13 through GS-15 and Senior Executive Service (SES) or equivalent positions whose responsibilities involve direct support to our national security objectives. The total SES or equivalent positions are estimated at 1,500.

5. Training/Orientation program development for all personnel and the Special Operations Group (SOG) supporting the Secretary and Deputy Secretary

- Individual Development Plan
- System Accesses and national security clearances
- Sourced the training curriculum and materials for the US Air Force basic intelligence officer training to use as a baseline in building a HHS-specific master training plan.

6. Support to Emergency Operations- Support to Emergency Operations

- Developed and fine tuning of a draft OSSI Emergency Response plan. This document will provide the concept of operations that outlines the Office of Security and Strategic Information / Division of Strategic Information (OSSI/DSI) procedures and responsibilities for providing intelligence support to the Assistant Secretary for Preparedness and Response Office of Preparedness and Emergency Operations.

7. Provide DSI intelligence support for the National Implementation Plan (NIP)

- Coordinating with FBI analyst from the WMDIAS/Strategic Assessment and Threat Forecasting Unit on the development of joint intelligence assessments.

8. Collaboration with Intelligence and Federal Law Enforcement (LE) Communities

- Established and maintained working relationships with members of the intelligence and LE communities to enhance information exchange and collaboration in accordance with the guidance provided by Senior HHS Leadership.
- Established productive relationships with the Headquarters and Regional Field Offices of the FBI.
    - WFO – Established contacts with multiple squads that facilitated follow on operations regarding foreign persons.
    - BFO – Established contacts with multiple squads that resulted in one arrest of a person that was trying to elicit information from an HHS employee.
    - HQ – Established productive relationships with the DOMAIN section leads. Forwarded a proposal for an FBI liaison to HHS through the office. This office is also the FBI executive agent for running the Critical National Assets program and serves as the co-chair of the CNA Executive Committee (CNAEC)

9. Actively participate in interagency meetings with the intelligence and LE communities to foster improved information exchange and ensure HHS's mission is appropriately represented.

- National Counterintelligence (CI) Working Group (NCIWG) – Actively participate in 2 meetings of the NCIWG as the lead HHS CI agency. The NCIWG brings all USG and many private and academic institutions together for bi-annual meetings to discuss issue of interest to the community. Attending these meetings helps establish and maintain HHS as a player in the national USG CI efforts.
- Actively participate in meetings with Other Government Agencies to articulate the positions of the department and enhance the ability of the agencies to support HHS operations. In addition, the coordination and information exchanges resulting from these meetings ensured that the department is fully supporting the efforts of those agencies in line with EO 12333, Presidential directives, and HHS Secretary mandates.
- Serve as the HHS lead for the development of a CI protection plan for the Integrated Research Facility and the surrounding laboratory complex. Ensured that the HHS personnel and facilities would be protected from exploitation while maintaining a collaborative atmosphere to facilitate scientific research and development.

10. RE-Establishment of the HHS Security Council to facilitate change and policy oversight for physical security structure and recommendations

- Vulnerability assessments and accreditation (HSPD12) assessments

<u>Long Term Goals have begun to support the following:</u>

11. Sponsor mass briefings to enhance the overall operational security and threat awareness of HHS leadership/personnel.

- Continue to execute the largest classified mass briefing on relevant threat issues (Foreign Collection Activities) to date for HHS staff. The audience included reps from all Operating and Staff Divisions representatives and the DEPSEC. There were also legislative liaisons present to help them understand the complexity of the threat facing HHS activities today.
- Coordinate an additional speaker from a national agency to address the threats to life sciences and brief out leadership on a regular basis.

12. Cybersecurity Initiatives
    OSSI has been given the overall responsibility to ensure the department can strengthen and enhance Department-wide cyber incident prevention, warning, detection, forensics, response, and remediation in coordination with ASRT/OCIO.

Funding History:

FY 2005	--
FY 2006	--
FY 2007	$3,263,000
FY 2008	$3,263,000
FY 2009	$3,263,000

Budget Request:

The FY 2010 request for OSSI is $4,893,000, an increase of $1,630,000 above FY 2009. 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 2010 pay raise, an increase of 10 FTE, and increased costs in other services. This requested increase will support critical infrastructure improvement and will result in OSSI fulfilling the numerous presidential directives, and national security organizations and will result in attaining many of the scientific and Public Health and Secretarial objectives/goals for this 2 year old organization. Below are additional description details for the funding request

Protection of HHS Employees and Assets

The 2010 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, 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. Additional major duties that were initiated in

FY 2008 pertaining to the physical security of key emergency response facilities, the Strategic National Stockpile, deployed personnel, and other potentially vulnerable assets, and will be in implementation phases through FY 2009, thus requiring added resources, attention, and oversight in FY 2010.

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 without an ability to track and identify repeat visitors. HHS needs to develop a domestic/foreign visitor data base for the protection of all HHS 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 protecting Personally Identifiable Information (PII) and scientific and medical information which does not rise to the level of national security information but is sensitive. OSSI CUI currently does not have enough staff members to fulfill Project Manager Activities and responsibilities for this important policy and 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.

Select Agents program

OSSI has been assigned 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 the resources to support the assignment of select agent oversight activities to OSSI have not been provided. OSSI has also been assigned the responsibility for consolidate 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. This responsibility was assigned in the absence of corresponding resources. OSSI maintains interactions with elements of the Department of Homeland Security.

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
1.1: Number of Clearances Processed/ Adjudicated. *(Outcome)*	FY 2007: 1198 FY 2008: 2605	4800	6800	+2000
2.1: Number of E-QUIP cases initiated, which starts the clearance process and eventually is adjudicated by DPCIS/OSSI at a later date. *(Outcome)*	FY 2007: not tracked FY 2008: 1981	2800	4800	+2000

Measure	Most Recent Result	FY 2009 Target	FY 2010 Target	FY 2010 +/- FY 2009
2.2**:** Backlog of cases, carry over from year to year *(Outcome)* *Note: attempting to reduce backlog while managing work load volume*	FY 2007: not tracked FY 2008: 670 case carried forward from 2007	560	430	-130
Program Level Funding ($ in millions)	**N/A**	**$3.263**	**$4.893**	**+$1.63**

Pandemic Influenza

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	$74,809,000	$585,091,000	$354,167,000	-$230,924,000
FTE	41	46	46	--

Authorizing Legislation: Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006.

Allocation Methods: Federal/Intramural/International, Competitive Grants, Cooperative Agreements, Contracts; and Other

Program Description and Accomplishments:
Reassortment of avian, swine and human influenza viruses has led to the emergence of a new strain of H1N1 influenza A virus, (2009-H1N1 Flu) that is transmissible among humans, and is confirmed to have caused infections in humans in Mexico, the United States, Canada, Spain, and the United Kingdom. On April 28, 2009 the President announced a supplemental request of $1.5 billion for the Federal response to this outbreak. These funds, in addition to the FY 2010 request and the remaining balances, will allow HHS to develop, produce, and distribute antivirals and vaccines, and personal protective equipment as well as conduct public health surveillance to track the outbreak. At the time of the President's announcement, HHS had released 11 million courses of influenza antivirals to the States, deployed staff to regions with outbreaks in the U.S. and Mexico, provided community mitigation guidance, and expanded laboratory testing capacity across the U.S.

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.

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:

- HHS has established a national pre-pandemic influenza vaccine stockpile of H5N1 vaccine representing four virus strains during the last four years. As of April 2009, HHS has approximately 11.5 million courses of pre-pandemic vaccine. Recognizing the continuous

evolution of the H5N1 virus, the stockpile includes both clade 1 and clade 2 vaccines. To expand the pandemic vaccine supply and improve vaccine efficacy, HHS procured 5.6 million doses of a new oil-in-water emulsion adjuvant.

- HHS supported the continued development of six cell-based seasonal and pandemic influenza vaccines that are currently in clinical development trials ranging from Phases 1 to 3. A milestone was achieved in February 2009 when one of the manufacturers submitted the first licensing application to the FDA for a cell-based seasonal influenza vaccine, the development of which was supported by HHS. Lastly, HHS awarded a contract in January 2009 for the construction of the first North American cell-based influenza vaccine manufacturing facility.

- To expand pandemic influenza vaccine capacity, HHS supported the development of three adjuvant technologies which are in Phase 2 and 3 clinical development with H5N1 vaccines. Several of these adjuvants have demonstrated 12-24 fold antigen-sparing effects, broad immunity across H5N1 virus clades, and 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. Licensure applications to the FDA by two manufacturers, supported by HHS for these adjuvants formulated with H5N1 vaccine antigens, are expected to be submitted in 2009.

- HHS completed the purchase of 50 million courses of influenza antiviral drugs for the Federal portion of its antiviral drug stockpile goal in December 2007. HHS continues to subsidize the State purchase of influenza vaccine. To date, States have purchased 23 million treatment courses towards the 31 million goal. HHS also continues to support the advanced development of new classes of influenza antiviral drugs.

- In 2008, HHS purchased 104 million N95 respirators and 52 million surgical masks for the SNS.

- 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 will undergo clinical development in 2009.

- 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.

- HHS awarded a total of $576 million for State and local preparedness, including medical surge capacity.

- 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 2005	$500,198,000
FY 2006	$5,590,000,000
FY 2007	--
FY 2008	$74,809,000
FY 2009	$585,091,000

Budget Request:

$354,167,000 is requested in FY 2010 for Pandemic Influenza preparedness activities in the Public Health and Social Services Emergency Fund. Of the total, $276,000,000 is requested as no-year funding and $78,167,000 is requested as annual funding. The FY 2010 request supports the following activities:

$158,000,000 is requested to continue to build vaccine production capacity. The FY 2010 budget request for enhanced pandemic vaccine production capacity includes $50 million for development next generation recombinant influenza vaccines that may be available sooner during influenza pandemics, $40 million to expand the domestic fill-finish pandemic vaccine manufacturing network to shorten the production timeline for pandemic vaccines, and $63 million to start building of another cell-based influenza vaccine manufacturing facility in the U.S. that will enable the manufacturing surge capacity to reach the pandemic vaccine goal of 600 million doses within six months of pandemic onset. Lastly, $5 million will support a new project to establish a library of influenza vaccine potency assay reagents for seasonal, pre-pandemic, and pandemic vaccine manufacturing purposes which may facilitate vaccine potency testing and make vaccines available sooner.

$53,000,000 is requested for the advanced development of new classes of influenza antiviral drugs and for studies to determine whether combined drug therapies comprised of currently licensed influenza antiviral drugs may be safe, effective, and less susceptible to drug-resistance development. Together these efforts may provide short- and long-term solution sets to the emerging drug resistance among circulating human influenza viruses.

$65,000,000 is requested to support further clinical development of next generation ventilators supported by HHS contracts that funded concept design and prototype development in 2009. In FY 2009, an initial $25 million was provided for development of next generation ventilators as part of ASPR's Advanced Research and Development activities.

$78,167,000 is requested in FY 2010 for ongoing OS Pandemic Influenza preparedness activities through the Public Health and Social Services Emergency Fund. The FY 2010 request supports the following activities:

$4,000,000 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.PandemicFlu.gov, development and distribution of the *Individuals and Families Pandemic Planning Guide*;-the release of television and radio public service announcements; and the launch of a stakeholder campaign. HHS also held pandemic planning summits with public health and emergency management and response leaders in 56 States and localities which receive pandemic preparedness funding. The FY 2010 request will allow ASPA to continue educational efforts and maintain a communications operation to respond to a pandemic.

$35,000,000 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. Preparedness and response is key to effective containment of an outbreak of influenza with pandemic potential in the US or abroad. To prepare for a global epidemic, 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 and the commitment to contain an outbreak at its site of origin, and to limit its spread. HHS will lead global, multi-lateral, bi-lateral, and inter- and intra-governmental initiatives that will include global training efforts and international preparedness exercises to ensure the United States, other countries, and international organizations use the most effective approaches to better prepare for an influenza pandemic. 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.

$11,000,000 is requested for international in-country advanced development and industrialization of human pre-pandemic influenza vaccine and to determine the effectiveness of newly developed POC diagnostic devices supported by HHS in clinical trials for influenza antiviral drugs. In FY 2010, ASPR will continue the accelerated international development of an in-country H5N1 vaccine for humans to prevent avian H5N1 influenza globally and provide in-country technical expertise for vaccine development and manufacturing scale-up. The funding will address global and specific country needs for further pilot lot and commercial scale manufacturing of H5N1 vaccines for clinical trials and pandemic usage, scale-up development for vaccine manufacturing, vaccine production equipment and development and validation of product release assay methods and clinical sample analysis. Additionally, ASPR 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 determine the effectiveness of combined influenza antiviral drugs.

$15,000,000 is requested for the 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.

$13,167,000 is requested for management and administration of pandemic influenza preparedness activities. Funds will be used for salaries of scientists, project managers, contracting officers and other program staff; travel, including site visits to facilities and for convening technical evaluation panels; rent and utilities; intermittent subject matter experts, and contractor support.

Parklawn Lease Expiration

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	--	--	$102,000,000	+$102,000,000
FTE	--	--	--	--

Allocation Method: Other

Program Description:
This request supports 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. 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 $96 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 three other smaller leases for other HHS tenants (6010 Executive Boulevard, Rockwall I, and Silver Spring Centre).

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 three other current HHS-leased properties. The Housing Plan attached to the Prospectus projected a total of 779,502 usable square feet. However, the estimated usable square feet in the Program of Requirements is 772,553 due to space planning efficiencies in the more detailed Program of Requirements.

Estimate of Required Usable Square Footage	
Current Parklawn Tenants	697,126 Usable Square Feet (usf)
Other HHS Tenants included in Prospectus:	
6010 Executive Blvd	12,845 usf
Rockwall I	16,187 usf
Silver Spring Centre	68,305 usf
Total Current USF Space Requirement	794,463 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, which assumes funding in FY 2010, estimates that all tenants will be housed in new or updated space by August 2013. 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
HHS Funding in FY 2010	October 2009
Lease Procurement Start	July 2008
Lease Award/Reimbursable Work Authorization for Fit-up Costs	October 2009
IT/Workstations Installation Complete	January 2013
Design & Construction Complete	April 2013
All Moves Complete	August 2013
Existing Lease Expiration	July 2010
Extended Lease Expiration	July 2013

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.

Transfer of Project BioShield Funding

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
Budget Authority	--	--	$1,264,000,000	+$1,264,000,000
FTE	--	--	--	--

Program Description:
The Project BioShield Act (P.L. 108-276) was enacted in 2004 as part of a broader strategy to defend America against the threat of weapons of mass destruction. The purpose of Project BioShield is to accelerate the research, development, purchase, and availability of effective medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) agents. The Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90) appropriated $5,593,000,000 to the Department of Homeland Security (DHS) for the Project BioShield Special Reserve Fund (SRF). The Project BioShield Act delineates the procedures for using the SRF to procure and stockpile emergency medical countermeasures. The funds are available for obligation through 2013.

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) created the Office of the Assistant Secretary for Preparedness and Response (ASPR) in HHS. 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). PAHPA also created the Biomedical Advanced Research and Development Authority (BARDA) to facilitate collaboration among the United States Government (USG), industry, and academia to support the advanced research and development of medical countermeasures and promote innovation to reduce time and cost of medical countermeasures.

Budget Request:
The FY 2010 President's Budget proposes to transfer all remaining balances from the Project BioShield SRF from DHS to HHS. Since the passage of the BioShield Act and the establishment of the SRF, HHS has and will continue to work with DHS to ensure a coordinated approach for the development and acquisition of medical countermeasures. The proposed transfer more accurately aligns the financial responsibilities for the SRF to the program managers in ASPR. Established processes for inter-Agency coordination with DHS related to MCM and threat determinations will be maintained.

Budget Authority by Object
(Dollars in Thousands)

	FY 2009 Enacted	FY 2010 Estimate	FY 2010 +/- FY 2009
Full-time equivalent employment	506	581	+75
Average SES salary	$171,329	$180,300	$8,971
Average GS grade	GS-13/7	GS-13/10	
Average GS salary	$103,306	$115,884	$12,578

	FY 2009 Enacted	FY 2010 Estimate	FY 2010 +/- FY 2009
Personnel compensation:			
Full-time permanent (11.1)	$45,167	$62,582	$17,415
Other than full-time permanent (11.3)	5,411	5,144	(267)
Other personnel compensation (11.5)	--	-	-
Military personnel (11.7)	7,510	7,864	354
Special personnel services payments (11.8)	--	--	--
Subtotal personnel compenstion	58,088	75,589	17,501
Civilian benefits (12.1)	10,624	14,997	4,372
Military benefits (12.2)	3,864	3,958	94
Benefits to former personnel (13.0)	--	--	--
Total Pay Costs	72,577	94,545	21,968
Travel and transportation of persons (21.0)	5,552	4,906	(647)
Transportation of things (22.0)	1,430	129	(1,300)
Rental payments to GSA (23.1)	11,530	10,286	(1,244)
Communication, utilities, and misc. charges (23.3)	1,709	1,966	257
Printing and reproduction (24.0)	12	13	1
Other Contractual Services:			
Advisory and assistance services (25.1)	4,632	5,858	1,226
Other services (25.2)	84,800	73,311	(11,489)
Purchase of goods and services from government accounts (25.3)	95,517	98,184	2,667
Operation and maintenance of facilities (25.4)	60	70	10
Research and Development Contracts (25.5)	904,145	473,000	(431,145)
Medical care (25.6)	--	--	--
Operation and maintenance of equipment (25.7)	259	301	42
Subsistence and support of persons (25.8)	--	--	--
Subtotal Other Contractual Services	1,089,413	650,724	(438,690)
Supplies and materials (26.0)	433,675	553,289	119,614
Equipment (31.0)	12,963	2,796	(10,168)
Land and Structures (32.0)	486,579	165,000	(321,579)
Investments and Loans (33.0)	--	--	--
Grants, subsidies, and contributions (41.0)	396,216	430,916	34,700
Interest and dividends (43.0)	--	--	--
Refunds (44.0)	--	--	--
Total Non-Pay Costs	2,439,079	1,820,024	(619,055)
Total Budget Authority by Object Class	$2,511,656	$1,914,569	($560,226)

Salaries and Expenses
(Budget Authority – Dollars in Thousands)

	FY 2009 Enacted	FY 2010 Estimate	FY 2010 +/- FY 2009
Personnel compensation:			
Full-time permanent (11.1)	$45,167	$62,582	$17,415
Other than full-time permanent (11.3)	5,411	5,144	(267)
Other personnel compensation (11.5)	--	-	-
Military personnel (11.7)	7,510	7,864	354
Special personnel services payments (11.8)	--	--	--
Subtotal personnel compenstion	58,088	75,589	17,501
Civilian benefits (12.1)	10,624	14,997	4,372
Military benefits (12.2)	3,864	3,958	94
Benefits to former personnel (13.0)	--	--	--
Total Pay Costs	72,577	94,545	21,968
Travel and transportation of persons (21.0)	5,552	4,906	(647)
Transportation of things (22.0)	1,430	129	(1,300)
Communication, utilities, and misc. charges (23.3)	1,709	1,966	257
Printing and reproduction (24.0)	12	13	1
Other Contractual Services:			
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Other services (25.2)	84,800	73,311	(11,489)
Purchase of goods and services from government accounts (25.3)	95,517	98,184	2,667
Operation and maintenance of facilities (25.4)	60	70	10
Research and Development Contracts (25.5)	904,145	473,000	(431,145)
Medical care (25.6)	--	--	--
Operation and maintenance of equipment (25.7)	259	301	42
Subsistence and support of persons (25.8)	--	--	--
Subtotal Other Contractual Services	1,089,413	650,724	(438,690)
Supplies and materials (26.0)	433,675	553,289	119,614
Total Budget Authority	$1,604,368	$1,305,572	($298,796)

Detail of Full Time Equivalents (FTE)

	2008 Actual Civilian	2008 Actual Military	2008 Actual Total	2009 Est. Civilian	2009 Est. Military	2009 Est. Total	2010 Est. Civilian	2010 Est. Military	2010 Est. Total
ASPR									
Direct:	221	83	304	350	79	429	451	78	529
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	221	83	304	350	79	429	451	78	529
Pandemic Influenza									
Direct:	38	3	41	45	1	46	45	1	46
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	38	3	41	45	1	46	45	1	46
Cyber Security									
Direct:	--	--	--	8	--	8	11	--	11
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	--	--	--	8	--	8	11	0	11
Office of Security and Strategic Information									
Direct:	10	4	14	12	6	18	19	9	28
Reimbursable:	3	--	3	3	--	3	3	--	3
Total:	13	4	17	15	6	21	22	9	31
Medical Reserve Corps									
Direct:	--	6	6	--	9	9	0	9	9
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	--	6	6	--	9	9	0	9	9
OPDIV FTE Total	272	96	368	418	95	513	529	97	626

Average GS Grade

FY 2005	GS-13/6
FY 2006	GS-13/6
FY 2007	GS-13/6
FY 2008	GS-13/6
FY 2009	GS-13/7

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

	2008 Actual	2009 Estimate	2010 Estimate
Executive level I	0	0	0
Executive level II	6	6	5
Executive level III	0	0	0
Executive level IV	2	2	2
Executive level V	0	0	0
Subtotal	8	8	7
Total - Exec. Level Salaries	1,501,013	$1,376,789	$1,275,607
ES-6	0	2	2
ES-5	2	0	0
ES-4	0	0	0
ES-3	0	0	0
ES-2	0	0	0
ES-1	0	0	0
Subtotal	2	2	2
Total - ES Salary	$307,132	$336,502	$347,101
GS-15	58	89	89
GS-14	105	160	271
GS-13	44	68	71
GS-12	29	45	45
GS-11	10	16	17
GS-10	2	3	3
GS-9	13	21	18
GS-8	3	4	4
GS-7	1	2	2
GS-6	1	1	1
GS-5	0	0	0
GS-4	1	1	1
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	267	410	522
Total - GS Salary	$26,764,617	$42,355,322	$60,470,692
Commissioned Corps	97	94	93
Total Positions	374	514	624
Average ES level	5	6	6
Average ES salary	$153,566	$168,251	$173,551
Average GS grade	13/7	13/7	13/10
Average GS salary	$100,242	$103,306	$115,844
Average Special Pay (Commissioned Corps)	$69,768	$73,788	$78,101

Significant Items for Inclusion in FY 2010 Congressional Justification

SENATE REPORT 110-410:

Item 1: Hospital Preparedness. - The Committee's recommendation includes $361,660,000 for hospital preparedness grants, the same as the administration's request. The Committee understands that ASPR intends to reduce the grant cycle for these monies to 9 months, 3 weeks (August 9 to June 1 rather than August 9 to August 8) and that support for hospital preparedness activities will not be reduced on a monthly basis. The Committee encourages the Secretary, in consultation with the Departments of Homeland Security and Defense, along with State and local healthcare providers to develop and publish guidance identifying minimum performance, safety, and interoperability requirements for deployable medical facilities that may be purchased using Federal funds.

Action taken or to be taken

In FY 2009 and FY 2010, the ASPR Hospital Preparedness Program (HPP) is planning continued cooperative agreement funding to awardees for the development of four "Overarching Requirements" and six "Level One" Sub-Capability priority areas. The purchase of Mobile Medical Assets (MMA) is a "Level Two" Sub-Capability and not routinely funded through HPP awards, as the majority of awardee-specific funding is spent on the primary requirements/priorities. The FY 2009 and FY 2010 HPP funding priorities are as follows:

HPP Overarching Requirements

- National Incident Management System (NIMS)
- Needs of At-Risk Populations
- Education and Preparedness Training
- Exercises, Evaluation and Corrective Actions

HPP Level-One Sub-Capability Priority Areas

- Interoperable Communication Systems
- Tracking of Bed Availability (HAvBED)
- ESAR-VHP
- Fatality Management
- Medical Evacuation/Shelter in Place
- Partnership/Coalition Development

HPP Level-Two Sub-Capabilities

- Alternate Care Sites (ACS)
- Mobile Medical Assets
- Pharmaceutical Caches
- Personal Protective Equipment
- Decontamination
- Medical Reserve Corps (MRC)
- Critical Infrastructure Protection (CIP)

In FY2009 and FY 2010 HPP will engage all awardees to collect promising practices and models around deployable MMA for review. In addition, HPP will use communication strategies to disseminate MMA information widely to all stakeholders. Further, HPP will work to ensure these models are highlighted during future HPP awardee conferences and other meetings, and the need for creating workgroups on MMA issues will be evaluated.

Item 2: Other Activities. - The Committee recommendation includes the following amounts for the following activities within the Office of the Assistant Secretary for Preparedness and Response: —Operations/Preparedness and Emergency Operations— $27,536,000; —National Disaster Medical System—$45,999,000; —BioShield Management— $21,743,000; —International Early Warning Surveillance—$8,690,000; —Policy, Strategic Planning & Communications— $4,292,000. Four years after Project BioShield's creation, the development and acquisition of most high priority vaccines and therapeutics remains much too slow. The Committee recognizes that progress is being made and that general acquisition goals have been identified. However, the Committee remains concerned by the slow pace of advanced research funding and procurement of medical products. The Committee therefore urges the Secretary to accelerate the issuance of procurement RFPs and awards under Project BioShield.

Action taken or to be taken

ASPR/BARDA received the authority to support advanced research and development (ARD) of medical countermeasures (MCMs) under the Pandemic All-Hazards Preparedness Act (PAHPA) passed in December of 2006. The first installment of ARD funding was made available to ASPR in May 2007, eight months into the fiscal year. Even with the extremely tight timeline ASPR/BARDA was able to obligate the funds toward ARD contracts to support development of MCMs in the areas of anthrax vaccines, anthrax therapeutics, smallpox antivirals, broad spectrum antibiotics, decorporation agents for Rad/Nuc, radionuclide facilities for Rad/Nuc and chemical threats. The total amount award for these projects was $98.8 M. In FY 2008 ASPR/BARDA received $101 M to support ARD of MCMs and was able to obligate the funds toward ARD contracts. ASPR/BARDA has been very successful in awarding ARD contracts for the continued development of MCMs across the "valley of death". The table below shows the success of the program as highlighted by the number of contracts awarded in the particular threat areas.

ASPR/BARDA Advanced Research and Development Activities

Countermeasure	# of Contracts	Product
Anthrax Therapeutics	4	Anthrax antitoxins monoclonal and polyclonal
Anthrax Vaccines	4	2nd generation vaccines and vaccine enhancement programs
Anthrax Medkits	1	Medkits and comprehension study
Broad Spectrum Antibiotics	1	Inhalational Gentamicin
Smallpox Antivirals	2	Antiviral and new formulations of drug
Rad/Nuc ARS	7	Drugs to combat acute radiation syndrome

Rad/Nuc Decorporation Agents	3	New drugs and formulations
Rad/Nuc Nuclide Facility	1	GLP facility for animal studies
Rad/Nuc Skin and Lung Injury	8 (grants)	Development of new MCMs
Chemical	1 contract 19 grants	Development of MCMs for Chemical agents
Total	**51 contracts or grants**	

As seen by the table above, ASPR/BARDA has been successful in awarding contracts and grants for the ARD of MCMs. As evidenced by the table below ASPR/BARDA also has been successful in awarding contracts under the Special Reserve Fund (SRF) and delivering product to the Strategic National Stockpile (SNS). Since 2004 ASPR/BARDA has awarded 9 contracts under the SRF. Seven contracts have completed or are delivering product to the SNS, one contract is anticipated to initiate delivery in the Summer of CY09, and one contract was terminated due to default by the contractor.

ASPR/BARDA Procurement Activity

Company	Contract Value	Product	Doses	Doses Delivered
Emergent	$243 M	AVA anthrax vaccine	10 M	10 M (Feb 07)
Emergent	$448 M	AVA anthrax vaccine	18.75 M	16,446,490
HGS	$176 M	Raxibacumab	20,001	20,001 (Apr 09)
Cangene	$142 M	Anthrax Immune Globulin	10,000	2,075
Cangene	$413 M	Heptavalent Bot Antitoxin	200,000	53,459
Bavarian Nordic	$505 M	MVA smallpox vaccine	20 M	Expected July 09
Fleming	$18 M	Potassium Iodide (Thyroshield)	4.8 M	4.8 M (Dec 07)
Akorn	$22 M	IV Ca – DTPA IV Zn – DTPA	394,350 79,460	394,350 (Mar 06) 79,460 (Mar 06)
Total	**$1,967 M**			

Integral to the success of the program are the people. Since 2004 the staff under Project BioShield (now called the Chem/Bio/Rad/Nuc [CBRN] Division) has grown from a handful of talented individuals to more than 32 fulltime Federal employees and subject matter experts (SMEs) in the CBRN Division alone. The program group is supported by contracts, acquisitions management, regulatory, and policy divisions all working toward the same goal of delivering licensed or approved MCMs to the SNS.

Actions to be taken are:

- Continue to award ARD contracts to support development of MCMs toward procurement
- Continue to award procurement contracts under the SRF and deliver products to the SNS
- Continue to streamline the acquisition process and learn from past experiences
    - The CBRN division has a number of teams in place tasked with streamlining the acquisition process, putting together lessons learned, and developing SOPs to assist in the acquisition process
- Continue to hire key personnel to support the mission.

Item 3: 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.

Action taken or to be taken

Within HHS it is the mission of ASPR/BARDA to identify and foster the advanced development of technologies that will prepare the country for man-made and naturally occurring outbreaks of infectious diseases. Preparedness for pandemic influenza is a significant part of this mission. ASPR/BARDA has made strategic investments in existing and new technology development to improve national preparedness for pandemic influenza. This portfolio of investments includes: advanced development, stockpiling and infrastructure building for vaccines; advanced development and stockpiling of antiviral drugs; advanced development for diagnostics; and advanced development of respiratory disease countermeasures such as masks, respirators and ventilators.

Investments in existing technology have included programs to secure a year round egg supply (started in 2004), H5N1 vaccine stockpiling programs (started in 2004), and projects to support and increase the domestic capacity for egg-based vaccines (started in 2007). The only pre-pandemic influenza vaccine which is currently licensed in the US (in 2007) was supported by this program. This investment in existing technology continues to be an important part of our preparedness efforts but investments in new and developing technologies are needed to meet the HHS pandemic influenza preparedness goals.

In order to fully meet the HHS goals for influenza preparedness HHS has made a number of investments in new and improved technologies. Since 2005 ASPR/BARDA has made several investments in cell-based influenza vaccine technology with a total of six contracts for the advanced development of cell-based influenza vaccines ($1.3B). In January 2009 a contract was awarded for the construction of the first cell-based influenza vaccine facility in the US ($487M) to expand domestic vaccine production capacity. In February 2009, a BLA was filed with the FDA to license the first of these cell-based vaccines in the Nation.

ASPR/BARDA has made significant investments in antigen sparing technologies (adjuvants) with three programs started in 2007. Adjuvant technology reduces the amount to antigen required for a successful vaccination. It also appears to generate a broader, stronger immune response that will protect immunized individuals against a wider range of viruses with pandemic potential. This program has been expanded since its start to include investments in other adjuvants and a Mix-n-Match program. The Mix-n-Match program relies on the ASPR/BARDA anti-trust authorities to combine the antigens of one manufacturer with adjuvants from other manufacturers to increase the flexibility that HHS has with management and utilization of the national pre-pandemic H5N1 vaccine stockpile. Indeed these investments have led to technological breakthroughs with the new oil-in-water emulsion adjuvants used with pre-pandemic influenza vaccines like H5N1 vaccines. Not only do these adjuvants provide more antigen-sparing (12-24 fold) than anticipated, but broad cross-immunity against virus strains and prime-boost effects are afforded that may render a single pandemic vaccine dose sufficient for protection. Submissions this year to the FDA for licensure of these influenza vaccines with adjuvants represent a major milestone of vaccine adjuvants in the US.

Investments have been made in new diagnostic technologies to improve the national capability to rapidly detect and identify influenza patients. These include a Point of Care diagnostic program started in 2006 for rapid diagnosis in a primary care setting and a Laboratory Influenza Test program started in 2008 for handling larger volumes of tests that would need to be performed during and influenza pandemic.

HHS continues to look for new and improved technologies that further its goals for national pandemic preparedness. Requests for Proposals (RFP) released in 2005 and 2007 targeted recombinant vaccine technologies that could be supported by advanced development funding in order to complete the development of these vaccines and make them available for pandemic preparedness. None of the offers met the program requirements for these RFP in 2005 and 2007. Several companies have now successfully completed Phase 1 testing of recombinant influenza vaccines and a new recombinant vaccine RFP is planned for 2009.

A Broad Agency Announcement (BAA) is planned for the near future that targets innovative technologies to improve the vaccine production and diagnostic capability of the nation. This will be renewed on an annual basis to allow ASPR/BARDA to identify and support new and emerging technologies as they develop. Finally, ASPR/BARDA uses a TechWatch program and sponsors an annual BARDA Industry Day to allow organizations making technical improvements that advance preparedness to identify themselves. This allows the US Government to monitor these advances and strategically invest in those that are most promising.

Item 4: Pandemic Influenza. - The Committee is concerned by reports that many small and large companies have difficulty communicating with the Department regarding vision, timing, strategy, and procurement plans. The Committee urges the Department to make the creation and continuity of open lines of communication with these entities a priority. Their participation is critical to successful implementation of any disease outbreak response.

Action taken or to be taken

ASPR/BARDA is committed to maintaining transparent and open lines of communication with companies regarding its vision, timing, strategy and procurement plans for countermeasures related to pandemic influenza and emerging diseases as well as chemical, biological, radiological and nuclear threats. Information on ASPR/BARDA's vision, timing, strategy and procurement plans is available on its website, http://www.hhs.gov/aspr/barda. The Draft ASPR/BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement is available at this web site. Since 2005, ASPR/BARDA has awarded over 35 contracts to its corporate partners. Through its "Tech Watch" program, which monitors technology advances applicable to medical countermeasures, ASPR/BARDA has met regularly since 2003 with over 300 large and small companies, including over 100 companies during the past year. Companies are also invited to interact with the Department through the annual BARDA Industry Day in Washington. Industry Day participants have the opportunity to meet and present to ASPR/BARDA, as well as to government, corporate, and non-profit partners. The website www.medicalcountermeasures.gov was established last year and serves as a portal to facilitate dialogue with companies. It allows companies to register their products, upload product information, and request meetings with the Department. ASPR/BARDA has fulfilled almost all meeting requests received, and requests that the committee inform them which companies have expressed difficulty in communicating with the Agency. The only meeting requests declined by ASPR/BARDA have been with those companies currently in negotiations with the Department, as such a meeting would have violated the Federal Acquisition Regulations (FAR), and when a meeting request was not for a relevant countermeasure, in which case the company was referred to the appropriate US Government entity.

ASPR/BARDA published a Broad Agency Announcement (BAA) for the advanced development of CBRN medical countermeasures on the Federal Business Opportunities' website on March 3, 2009. Companies with products meeting the criteria in the announcement are invited to submit white papers for review. ASPR/BARDA anticipates issuing a second BAA for innovative production, testing and diagnostic technologies relating to CBRN, influenza and emerging diseases countermeasures later this year.

Lastly, the BARDA Director has an open line for communication with all private sector stakeholders in the ASPR/BARDA mission and encourages industry representatives to call or visit periodically. Site visits, presentations at national and international meetings, and hosting topic-specific workshops are other means that ASPR/BARDA utilizes to communicate to stakeholders.

Item 5: Annual Flu Vaccine. - The Committee again encourages HHS and CDC to continue to support public and professional education, media awareness and outreach programs related to the annual flu vaccine. The Committee strongly encourages CDC and HHS to aggressively implement initiatives for increasing influenza vaccine demand to match the increased domestic vaccine production and supply resulting from pandemic preparedness funding. Developing a sustainable business model for vaccine production will go a long way toward making vaccine available when needed.

Action taken or to be taken

HHS collaborates with health care providers, industry partners, and State, local, and tribal public health authorities to develop public information campaigns and other mechanisms to stimulate increased seasonal influenza vaccination. The performance measure for these efforts is domestic vaccine use increased relative to historical norms.

HHS implements regular integrated communications campaigns to increase vaccination rates for seasonal influenza. The annual six-month campaigns include traditional and new media outreach, public service announcements, paid advertising, and market research. The centerpiece is National Influenza Vaccine Week, which takes place the week after Thanksgiving. The 2006-07 campaign resulted in over 835 million audience impressions (the potential number of persons exposed to all campaign products based on overall audience size of each outlet), and the 2007-08 campaign resulted in over 950 million impressions. During the 2008-09 flu season, communications efforts were focused on select target audiences that would benefit from immunization. As of March 2009, the campaign has generated over 880 million impressions with efforts continuing due to a late arriving influenza season. To date there have been 6,150 broadcast and print sites providing influenza vaccination stories, 31 million radio targeted listeners, 6.6 million Web M.D. viewers, and 26, 500 You Tube and 4220 CDC web site viewers for the video "Why Flu Vaccination Matters".

The National Vaccine Program Office leads the HHS influenza vaccination promotion for health care personnel, begun in 2008. This initiative is described in detail at http://www.hhs.gov/ophs/initiatives/vacctoolkit/index.html. HHS has reached out in particular to health care personnel unions, long term care facilities' organizations, and health care professional schools to promote influenza vaccination of their personnel and students. As a result of the initiative, the NIH Clinical Center, the Federal Occupational Health staff, the Indian Health Service, the Health Resources Services Administration, and the Centers for Disease Control and Prevention have all documented significant increases in influenza vaccination of their personnel and HRSA-funded federally qualified health centers, with vaccination rates above 70% for NIH, FOH, in a sample of HRSA health centers' employees, and IHS. The initiative will continue into 2010 in an effort to reach the Healthy People 2010 objective of 60% vaccination coverage for all health care personnel.

In the 2008-09 influenza season, all children aged 6 months through 18 years were recommended for annual vaccination for the first time. Since 2000, influenza vaccine recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP) have expanded rapidly to include most of the US population. Currently, an estimated 84% of the United States population is recommended to receive vaccination annually. Young adults who do not currently have a risk or contact-based recommendation can still get vaccinated if they choose to, and are encouraged to seek vaccination if they want to avoid illness and reduce risk of transmitting influenza to others. Vaccinating such a large proportion of the population annually in the relatively narrow time window available presents an enormous implementation challenge. Many innovative, community level approaches, such as school- or work-placed vaccination programs, are currently

being evaluated with the goal of developing of sustainable, effective immunization programs that should lead to increased vaccine coverage across the age spectrum.

With respect to the number of doses distributed, HHS has seen a significant increase. More than 102 million doses were distributed during the 2006-07 flu season and 113 million doses were distributed during the 2007-08 season. This represents nearly 20 million doses more than the prior record of 83.1 million doses distributed in 2003-04. Due to the longer than normal flu season this year, the number of doses distributed during 2008-09 flu season are not currently available.

In addition to these efforts, there are other efforts underway which will use the expanding supply of antigen available to the US market to make improved vaccines. These include the proposed development of a quadravalent that adds a second B strain to the vaccine to increase its effectiveness and other efforts that will increase the amount of antigen in the vaccine for certain populations.

Item 6: Flu Vaccines - The Committee is concerned about the ineffectiveness of the flu vaccine used last winter. Preliminary data about vaccine effectiveness for the 2007–2008 influenza season indicates that those who received trivalent inactivated influenza vaccine were only 44 percent less likely to have medically attended influenza illnesses than those who were not vaccinated. The failure of the flu vaccine raises concerns regarding our Nation's effort to combat the potential for pandemic influenza. Data has shown that incorporation of new technologies, in conjunction with traditional methods of vaccine evaluation, would have predicted that last winter's flu vaccine would fail to perform adequately in the field. The animal model method has not proven an ideal model system to predict human immunity and thus, there is an unmet need for new in vitro approaches that could provide reliable and predictive efficacy, safety, and adverse reaction data. The Committee encourages CDC and ASPR to support development of technologies that will accurately predict the effectiveness of influenza, biodefense, and pre-pandemic vaccines in the future.

Action taken or to be taken

The strain selection process for the seasonal influenza vaccine relies heavily on domestic and international surveillance programs that collect data on about 10,000 influenza isolates each year. This information is analyzed and presented to the VRBPAC committee in February for a decision on the make up of the seasonal vaccine for the coming fall. For the 2007-2008 season the match was not as good as usual and vaccine performance was affected. The most recent data from this season suggests that the vaccine for the 2007-2008 season was only about 60-70% effective. Several efforts are underway or planned that will improve the seasonal vaccines and the process by which the seasonal vaccine is selected.

Two lineages of influenza B viruses circulate in humans and each year one lineage is included in the vaccine based on the surveillance data. The increased capacity of antigen now available to the US market has led several companies to propose adding a second B strain to the current trivalent seasonal vaccine to improve its effectiveness against B viruses. Other efforts are

investigating the use of antigen sparing adjuvants to improve the vaccine effectiveness in populations with the greatest need for improved influenza vaccines. Adjuvants have the added benefit of broadening the immune response so vaccines can still be effective when the vaccine strain does not match the circulating strain.

The US Government is working with the WHO to improve the international surveillance process so the best information can be gathered for improved strain selection of the seasonal vaccine. A joint meeting is planned for September 2009 to discuss how to move this process forward. The CDC and WHO are working on systems to select strains for cell-based vaccines. This has two potential advantages. First, potentially promising vaccine candidates may be eliminated each year because only a percentage of viruses grow in the eggs used for selection. Second, viruses need to be adapted to eggs and the changes required for adaptation may reduce its effectiveness as a vaccine candidate.

Future efforts are planned to support the advanced development of recombinant vaccines which have more rapid cycle times. This would allow for strain selection in mid-year for the fall vaccine. Two previous RFP by ASPR/BRADA in 2005 and 2007 failed to identify successful offers for the advanced development of recombinant vaccines. A new RFP is planned for 2009 and with several companies recently completing phase 1 trials for recombinant vaccines there is a very good chance of identifying a good candidate out of this solicitation.

A BAA will be released shortly by ASPR/BARDA for technologies that improve the vaccine production and evaluation process. This will be renewed on an annual basis to allow BARDA to identify and support new and emerging technologies as they develop. In addition, BARDA uses a TechWatch program and sponsors an annual BARDA Industry Day to allow organizations making technical improvements that advance preparedness to identify themselves. This allows the US Government to monitor these advances and strategically invest in those that are most promising.

Finally, recent reports have shown that broadly neutralizing sites exist on the HA of influenza virus. This observation may eventually be developed into a universal influenza vaccine that would eliminate the need to pick strains for the annual seasonal vaccine and pandemic vaccines.

Draft House Report for the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2009

Item 1: Trauma Centers. - The Committee continues to be concerned about the need for the Hospital Preparedness Cooperative Agreement Grants Program to emphasize improvements in the efficiency, effectiveness, and expandability of trauma care services. The Committee encourages ASPR to include specific program benchmarks aimed at bolstering trauma center capacity.

Action taken or to be taken

The ASPR Hospital Preparedness Program (HPP) mission is to improve the capacity and capability of hospitals (including Trauma Centers) and emergency departments nationally to respond to all-hazards events. Since FY 2002, Trauma Centers have been included as fundable healthcare entities through cooperative agreement awardees directed to State/Territory Departments of Public Health. Activities aimed at increasing hospital/Trauma Center surge capacity and capability have centered on, but are not limited to, acquiring communication and decontamination equipment, developing situational awareness capabilities, developing fatality management and evacuation plans, upgrading isolation capabilities, training hospital/Trauma Center personnel, and developing plans and mutual aid agreements for the sharing of staff and resources in defined geographic areas. Trauma Centers will remain fundable healthcare entities nationally for HPP in FY2009/2010.

In addition, *Partnership/Coalition Development* requiring the participation of a Trauma Center is a HPP Level-One Sub-Capability Priority Area in addition to five (5) other priority areas including:

- Interoperable Communication Systems
- Tracking of Bed Availability (HAvBED)
- ESAR-VHP
- Fatality Management
- Medical Evacuation/Shelter in Place
- *Partnership/Coalition Development*

During FY2009/2010, the HPP will continue to ensure that operational Partnerships/Coalitions that include a Trauma Center exist in all states. These Partnerships/Coalitions will continue to plan and develop memoranda of understanding (MOU) to share assets, personnel and information, unify ESF-8 management of healthcare during a public health emergency, integrate communication with jurisdictional command in the area, and test response ability through exercises.

Per PAHPA Partnerships/Coalitions will consist of:

- one or more hospitals, at least one of which shall be a designated Trauma Center;
- one or more other local healthcare facilities, including clinics, health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; and
- one or more political subdivisions;
- one or more awardees; or
- one or more awardees and one or more political subdivisions.

FY 2010 HHS Enterprise Information Technology Fund: e-Gov Initiatives

The PHSSEF account will contribute $204,121 of its FY 2010 budget to support Department enterprise information technology initiatives as well as E-Government initiatives. Operating Division contributions are combined to create an Enterprise Information Technology (EIT) Fund that finances both the specific HHS information technology initiatives identified through the HHS Information Technology Capital Planning and Investment Control process and E-Government initiatives. These 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, $32,483 is allocated to support the E-Government initiatives for FY 2010. This amount supports the E-Government initiatives as follows:

FY 2010 HHS Contributions to E-Gov Initiatives*	OS
Line of Business - Federal Health Architecture (FHA)	$4,208
Line of Business - Human Resources	$267
Line of Business - Financial	$182
Line of Business - Budget Formulation and Execution	$121
Line of Business - IT Infrastructure	$204
Disaster Assistance Improvement Plan	$27,500
E-Gov Initiatives Total	**$32,483**

*The total for all HHS FY 2010 inter-agency E-Government and Line of Business contributions for the initiatives identified above, and any new development items, is not currently projected by the Federal CIO Council to increase above the FY 2009 aggregate level. 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-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.

Lines of Business-Human Resources Management: Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of Human Capital. HHS has been selected as a Center of Excellence and will be leveraging its HR investments to provide services to other Federal agencies.

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.

Lines of Business-IT Infrastructure: This initiative provides the potential to leverage spending on commodity IT infrastructure to gain savings; to promote and use common, interoperable architectures that enable data sharing and data standardization; secure data interchanges; and, to grow a Federal workforce with interchangeable skills and tool sets.

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.