DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2012

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committees

We are pleased to present the FY 2012 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 2012 budget justifications for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Pandemic Influenza, Cyber-Security in the Office of the Assistant Secretary for Administration (ASA), the Medical Reserve Corps in the Office of the Assistant Secretary for Health (ASH), and the Office of Security and Strategic Information (OSSI).

Today, our Nation faces a growing number of threats to our way of life. One of the primary responsibilities of the ASPR is to ensure we have safe and effective medical countermeasures (MCM) available for response efforts. The MCM enterprise encompasses the development, manufacturing, production, stockpiling, and distribution of products deemed critical to protecting or treating our population against a variety of naturally occurring or intentionally delivered chemical, biological, radiological, and nuclear (CBRN) threats. The MCM enterprise has demonstrated unprecedented successes including development of the first human vaccine for avian flu. Countermeasures for anthrax (vaccines and therapeutics) and other bacterial threats (therapeutics), chemical threats, radiation exposure, and botulism have been delivered to the Strategic National Stockpile (SNS), and research and development efforts are underway for a smallpox vaccine and additional countermeasures to diversify the SNS.

While the MCM enterprise has been successful in moving the Nation forward in preparedness efforts, there is still much work to be done. In August 2010, ASPR released the *Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to meet Long-Range National Needs* (MCM Review). Secretary Sebelius had requested a review of HHS's MCM enterprise with the goal of ensuring the nation has a forward-looking, 21st-century MCM enterprise system upon which it can rely during an emergency or other major public health event. The MCM Review examined the steps involved in the research, development, and FDA approval of medications, vaccines, and medical equipment and supplies for a health emergency.

The MCM enterprise is one component of a broader response strategy to mitigate the effects of a CBRN and pandemic disease events. To be resilient in the face of these disasters, we need a fully integrated and coordinated strategy to address how services will work together, from various sectors of our healthcare system, to respond and save lives. We need a health care system that is nimble and versatile and can address patients' needs when and where necessary. After we work to procure valuable medical countermeasures to treat CBRN effects, we need adaptable distribution plans in place to deliver countermeasures to every American quickly. A larger framing of all public health infrastructure needs for national health security is described in the National Health Security Strategy (NHSS). The purpose of the NHSS is to guide the Nation's efforts to minimize the risks associated with a wide range of potential large-scale incidents that put the health and well-being of the U.S. population at risk, whether at home, in the workplace, or in any other setting. National health security is achieved when the Nation and its people are prepared for, protected from, and are able to respond effectively to and recover from public health emergencies. While major investments in the preparedness and response

components are bearing fruit, we also recognize that recovery is an integral part of the full-spectrum capability.

The FY 2012 Budget request includes $1.3 billion for ASPR, an increase of +$411 million over FY 2010. The request continues investments in advanced development of MCMs against CBRN threats, as called for in the MCM Review. Funding is also requested for investments in Federal, State, and local preparedness; strategic planning; and operational coordination.

The HHS IT Security Program ensures that the appropriate levels of security are in place to protect the sensitive information systems and data that support the mission and functions of HHS. The FY 2012 request of $40 million will implement security upgrades and reconfiguration of the Department's network infrastructure. This will provide additional layers of security protections needed to prevent IT system compromises and the loss of sensitive data. The program will also continue to enhance enterprise-wide capabilities to continuously monitor the Department's computers and networks for security incidents and attacks.

A total of $11 million is included in the FY 2012 President's Budget for the Medical Reserve Corps. The Medical Reserve Corps is comprised of organized medical and public health professionals who serve as volunteers to respond to natural disasters and emergencies. These volunteers assist communities nationwide during emergencies and with ongoing efforts in public health. Medical Reserve Corps units represent those at the local level, as they are responsible for implementing volunteer capabilities for emergency medical response and public health initiatives to match specific community needs.

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

Nicole Lurie, M.D., M.S.P.H
RADM, USPHS
Assistant Secretary for Preparedness and Response

E.J. Holland, Jr.
Assistant Secretary for Administration

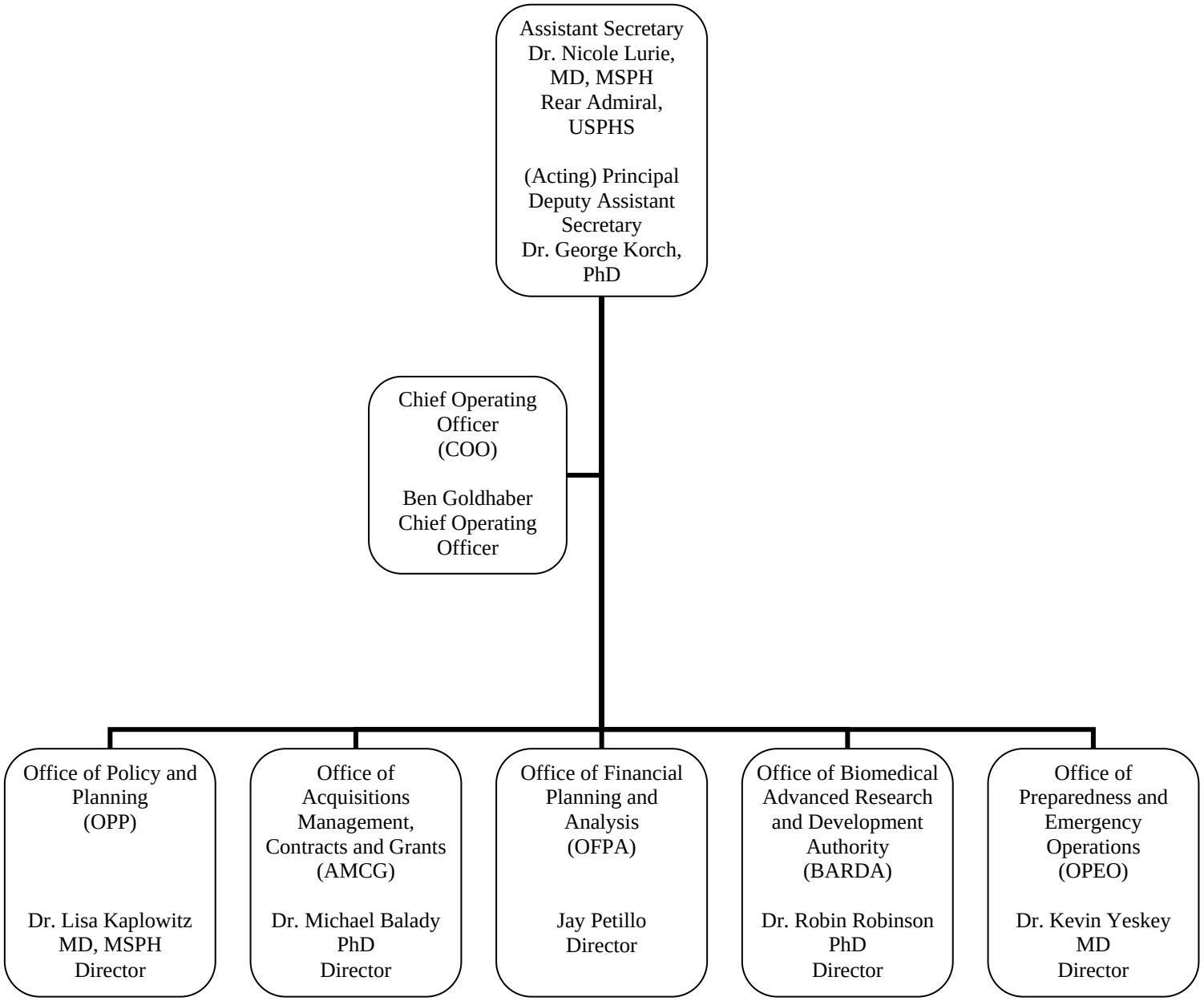
Howard K. Koh, M.D., M.P.H.
Assistant Secretary for Health

Raffie Shahrigian
Acting Director, Office of Security and Strategic Information

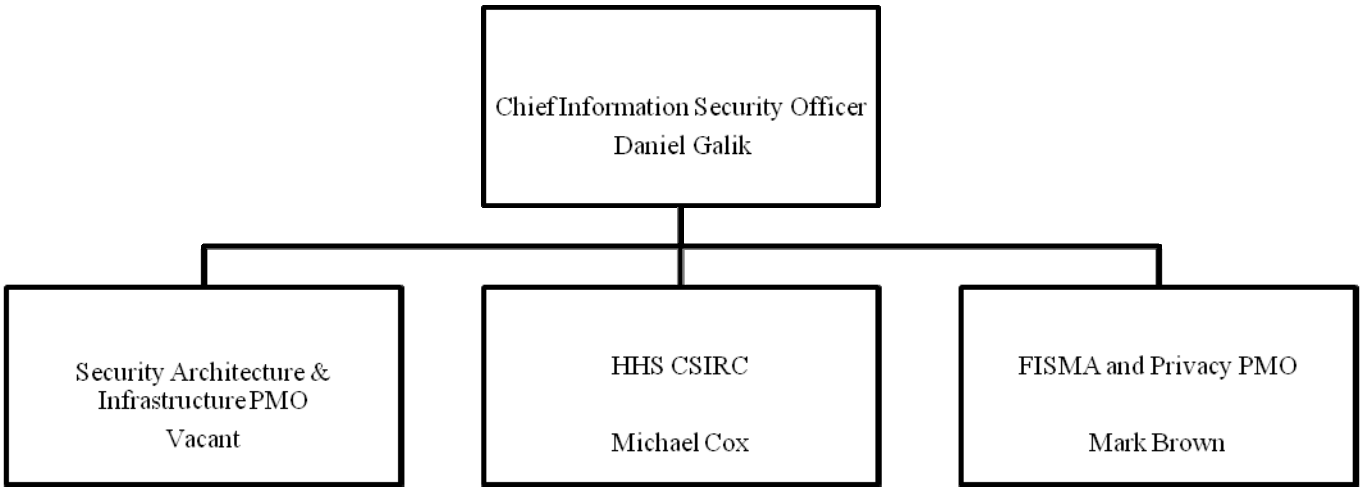
TABLE OF CONTENTS

Organizational Charts

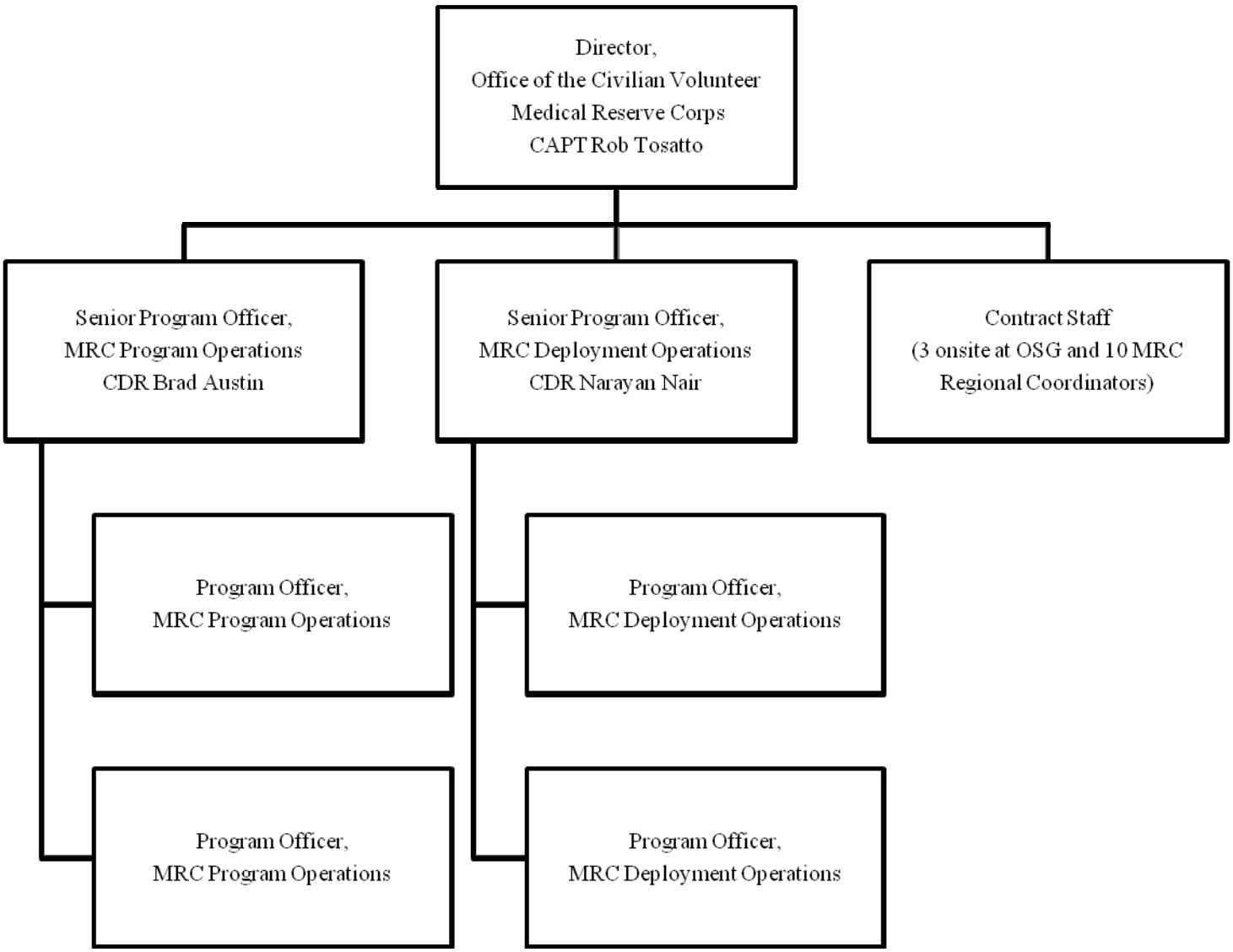
Office of the Assistant Secretary for Preparedness and Response



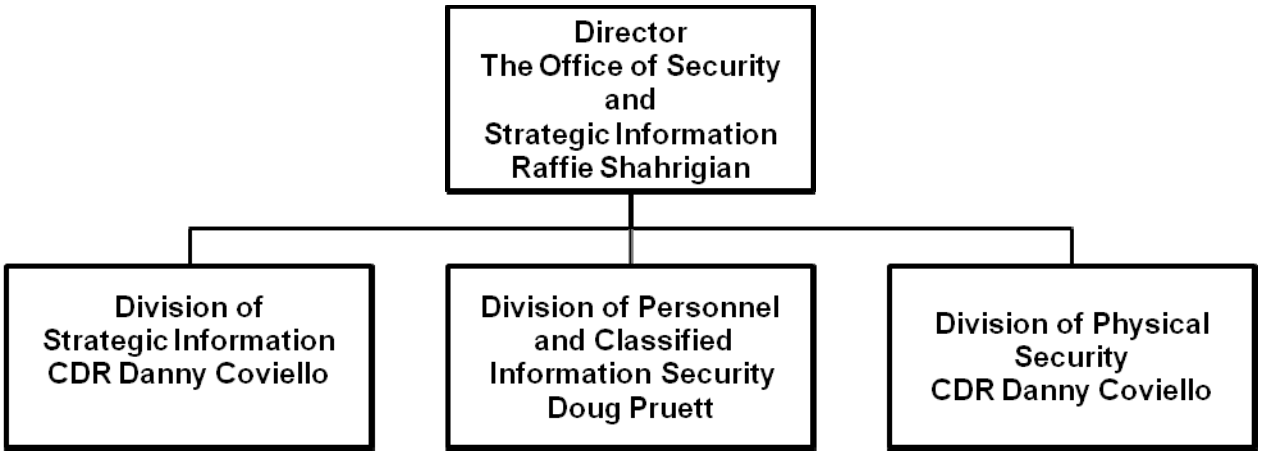
Office of IT Security



OSG/Office of the Civilian Volunteer Medical Reserve Corps



Office of Security and Strategic Information



Executive Summary

The FY 2012 request for the Public Health and Social Services Emergency Fund (PHSSEF) is $1,360,023,000 and 668 FTE, an increase of -$206,113,000 below and 156 FTE above the FY 2010 enacted level. These funds will provide the necessary resources to:

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

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 Administration (ASA), and the Office of the Assistant Secretary for Health (AHS). This justification also requests funding for the Office of Security and Strategic Information (OSSI) and describes the Department's Pandemic Influenza plan.

Programmatic Increases:

- Assistant Secretary for Preparedness and Response (+$411 million, $1.3 billion total) to support the recommended investments outlined in the *HHS Medical Countermeasures Review*, including expansion of advanced development of medical countermeasures.
- Cyber Security (+$3 million, $40 million total) to build on work started in FY 2009 with the $50 million for HHS IT Security 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, $6.5 million total) to secure, enhance and strengthen HHS critical assets.

Programmatic Decreases:

- Pandemic Influenza (-$341 million, $0 total), as HHS will be able to support the pandemic preparedness activities through existing balances from the 2009 H1N1 supplemental.
- Medical Reserve Corps (-$1.4 million, $11 million total) to support the national network of local groups of volunteers committed to improving the health, safety and resiliency of their communities.
- Parklawn Replacement (-$70 million, $0 total), will reach completion in FY 2011, and will not require funding in FY 2012.

Overview of Performance

The activities that support ASPR's core mission – ensuring that all aspects of society/communities are prepared for, can respond to, and can recover from events with large scale health consequences – are vital to national security.

ASPR's FY 2012 Online Performance Appendix contains updated FY 2010 and prior year performance details and FY 2011 and FY 2012 performance planning information for each of ASPR's performance measures. The selected measures support the organization's overall goals of:

- Ensuring that the public health and responder community is fully capable
- Developing and procuring medical countermeasures
- Building community resilience
- Ensuring that the health care infrastructure is able to meet anticipated and unanticipated needs

In FY 2012, ASPR has ten new indicators and seven discontinued indicators that reflect a focus on new priorities and a commitment to facilitating the most effective use of performance data.

The HHS Cyber Security program will ensure that the Computer Security Incident Response Center (CSIRC) will achieve full operational capability (FOC) in late FY 2011 and early FY 2012, which will be critical to achieving security performance measures associated with the monitoring of intrusion detection systems to detect any attacks against our systems. The Department will also implement the Trusted Internet Connections (TIC) in FY 2012. The Department's security performance measures associated with the implementation of Internet security content filtering and anti-malware solutions will better enable the Department to prevent infections caused by sophisticated malicious software that infects HHS systems when users visit Internet web sites that may be infected. The network security infrastructure project efforts and the performance measures associated with the fielding of robust encryption and endpoint protection technologies will enable the Department to protect sensitive information from being compromised or stolen. Each of the security performance measures supports the President's and the Department's goals of providing the proper levels of security and privacy protections for sensitive information and personal health information. Security and privacy are essential in order to protect Americans' health and safety during emergencies, and foster resilience in response to public health emergencies.

Summary of Targets and Results

ASPR

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2007	8	7	88%	7	88%
2008	10	10	100%	10	100%
2009	9	8	89%	7	78%
2010	9	7	78%	4	44%
2011	9	0	0%	0	0%
2012	9	0	0%	0	0%

Cyber Security

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2007	4	4	100%	4	100%
2008	4	4	100%	4	100%
2009	4	4	100%	4	100%
2010	3	3	100%	3	100%
2011	4	0	0%	0	0%
2012	4	0	0%	0	0%

All Purpose Table
(dollars in thousands)

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

	FY 2010 Appropriation	FY 2011 CR*	FY 2012 President's Budget Request
Assistant Secretary for Preparedness and Response			
Preparedness and Emergency Operations	$29,647	$29,653	$34,647
National Disaster Medical System	52,493	52,502	52,850
Hospital Preparedness	417,400	417,471	375,466
ESAR-VHP	5,841	5,842	5,000
Medical Countermeasure Dispensing	9,998	10,000	5,000
Biomedical Advanced Research and Development	320,111	320,167	665,000
Strategic Investor	-	-	100,000
Policy and Planning	19,008	19,010	15,708
Operations	36,948	36,950	38,624
Co-Located Office Facility	--	--	10,000
Subtotal, ASPR Program Level	891,446	891,595	1,302,295
Assistant Secretary for Administration			
CyberSecurity	27,040	27,040	$40,000
Office of Public Health and Science			
Medical Reserve Corps	12,581	12,581	$11,268
Office of the Secretary			
Haiti Supplemental	220,000	--	--
Office of Security and Strategic Information	4,893	4,893	6,460
Pandemic Influenza	340,591	341,000	--
Parklawn Replacement	69,585	69,585	--
Total, PHSSEF Program Level	**$1,566,136**	**$1,346,694**	**$1,360,023**
Less funds from other Sources			
Shift of BioShield balances to other purposes	(609,000)	(305,000)	(765,000)
Total, PHSSEF Budget Authority	**$957,136**	**$1,041,694**	**$595,023**
Transfer of Bioshield Balances to HHS	$2,423,617	--	--

*Note- All FY 2011 funding levels provided in this justification are based on a full year calculation of the current CR based on FY 2010 PPAs, and does not reflect programmitic decision on how funds would be executing under a full year CR.

FY 2012 Proposed Appropriations Language

For expenses necessary to support activities related to countering potential biological, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies, $585,023,000; of which $15,000,000 shall remain available until expended to support emergency operations; and of which $5,000,000, to remain available through September 30, 2013, 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 $4,000,000 may be made available to the U.S. Postal Service to support delivery of medical countermeasures.

From funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to $665,000,000 shall be available for expenses necessary to support advanced research and development pursuant to section 319L of the Public Health Service Act ("PHS Act"), and other administrative expenses of the Biomedical Advanced Research and Development Authority to support additional advanced research and development.

For expenses necessary for fit-out and other costs related to the consolidation of office space for the Office of the Assistant Secretary for Preparedness and Response, $10,000,000, to remain available until expended.

Of the remaining balances of funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to $100,000,000 shall be available for the purpose of funding a strategic investment corporation established to further the purposes of section 319L of the PHS Act (42 U.S.C. 247d-7e) to foster innovation in the development of medical countermeasures.

Language Analysis

Language Provision	Explanation
"For expenses necessary to support activities related to countering potential biological, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies, $585,023,000; of which $15,000,000 shall remain available until expended to support emergency operations; and of which $5,000,000, to remain available through September 30, 2013, 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 $4,000,000 may be made available to the U.S. Postal Service to support delivery of medical countermeasures."	This language provides general authority for the department to prepare for and respond to public health emergencies. Provides most of the funding for ASPR, MRC, Cyber Security, and OSSI.
"From funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to $665,000,000 shall be available for expenses necessary to support advanced research and development pursuant to section 319L of the Public Health Service Act ("PHS Act"), and other administrative expenses of the Biomedical Advanced Research and Development Authority to support additional advanced research and development."	This language provides for the Biomedical Advanced Research and Development Authority within ASPR, by make funds currently in the BioShield Special Reserve Fund available for advanced development activities as well.
"For expenses necessary for fit-out and other costs related to the consolidation of office space for the Office of the Assistant Secretary for Preparedness and Response, $10,000,000, to remain available until expended."	This language provided to support the relocation of ASPR staff into two office facilities, and allows the funds to have no-year availability.
"Of the remaining balances of funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to $100,000,000 shall be available for the purpose of funding a strategic investment corporation established to further the purposes of section 319L of the PHS Act (42 U.S.C. 247d-7e) to foster innovation in the development of medical countermeasures."	This makes BioShield and funding available and provides the authorization for the creation of a strategic investment firm to support small and new business developing new medical countermeasures.

Amounts Available for Obligation[1]

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget
Annual Appropriation	$680,962,000	$681,109,000	$565,023,000
Multi-Year Appropriation	2,743,615,000	15,000,000	5,000,000
Subtotal Multi-Year Appropriations	2,743,615,000	15,000,000	5,000,000
No-Year Appropriation	345,176,000	345,585,000	25,000,000
Supplemental (P.L. 111-32)	220,000,000		
Recission (P.L. 111-226)	-6,630,393		
Subtotal No-Year Appropriations	558,545,607	345,585,000	25,000,000
Total, adjusted budget authority	3,983,122,607	1,041,694,000	595,023,000
Unobligated balance, start of year	4,654,152,000	6,676,396,000	5,154,750,000
Unobligated balance, end of year	6,676,396,000	5,154,750,000	2,812,577,000
Unobligated balance lapsing	--	--	--
Total obligations	**$1,960,878,607**	**$2,563,340,000**	**$2,342,173,000**

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

Summary of Changes

2010 Comparable Enacted Level	
Total estimated budget authority	$957,136,000
2012 President's Budget	
Total estimated budget authority	$595,023,000
Net change	($362,113,000)

	2010 Enacted Budget Base		Change from Base	
	(FTE)	Budget Authority	(FTE)	Budget Authority
Increases:				
Cyber-Security		$27,040,000		+$12,960,000
Office of Security and Strategic Information (OSSI)		$4,893,000		+$1,567,000
Total Increases	512	$31,933,000	+156	+$14,527,000
Decreases:				
Assistant Secretary for Preparedness and Response		$586,446,000		($49,151,000)
Pandemic Influenza		$340,591,000		($340,591,000)
Medical Reserve Corps		$12,581,000		($1,313,000)
Parklawn Replacement		$69,585,000		($69,585,000)
Total Decreases		$1,009,203,000		($460,640,000)
Net Change			+156	($446,113,000)
FY 2010 Transfer to NIH				+$304,000,000
Total Net Change				**($142,113,000)**

Budget Authority by Activity
(Dollars in thousands)

	FY 2010 Enacted		FY 2011 CR		FY 2012 President's Budget	
	FTE	Amount	FTE	Amount	FTE	Amount
Bioterrorism	504	$326,960	581	$631,109	668	$585,023
Pandemic Influenza	8	340,591	8	341,000	--	--
Buildings and Facilities	--	69,585	--	69,585	--	10,000
TOTAL	512	$737,136	589	$1,041,694	668	$595,023

Authorizing Legislation

	FY 2010		FY 2012	
	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		$1,566,136,000		$1,360,023,000

Appropriations History
(Non-Comparable)

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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
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	3,160,795,000
Supplemental				
Appropriation (PL 111-5)		900,000,000	870,000,000	50,000,000
Appropriation (P.L. 111-32)				7,650,000,000
Transfer to CDC				-200,000,000

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2010				
Appropriation	2,678,569,000	$2,100,659,000	2,621,154,000	3,770,694,000
Supplemental				
Appropriation (PL 111-212)				220,000,000
Recission (111-226)				-$6,630,393
FY 2011				
Estimate	1,041,694,000		$1,050,795,000	
FY 2012				
Estimate	$595,023,000			

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Program Level	$891,446,000	$891,595,000	$1,302,295,000	+$410,849,000
Budget Authority (non-add)	*$586,446,000*	*$586,595,000*	*$537,295,000*	*-$49,151,000*
*Other Sources (non-add)**	*$305,000,000*	*$305,000,000*	*$765,000,000*	*+$460,000,000*
FTE	447	522	598	+151

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices. Comparable adjustments have also been made for the consolidation of BARDA funding sources, including Pandemic Influenza management, originally proposed in FY 2011. The President's Budget proposes to make funds from the Project BioShield Special Reserve Fund available for BARDA advanced development and other activities.

The mission of the Office of the Assistant Secretary for Preparedness and Response (ASPR) – to lead the Nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters – and its vision – a Nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters – reflect the essential role of ASPR in the Nation's public health preparedness and emergency response arena. ASPR focuses its efforts on promoting community preparedness and prevention; building public health partnerships with Federal departments and agencies, academic institutions and private sector partners; and coordinating Federal public health and medical response capability.
In FY 2012 the total request is $1,302,295,000, which includes $765,000,000 made available from the Project BioShield Special Reserve Fund, an increase of +$410,849,000 above FY 2010. The request consolidates funding sources supporting ASPR's Biomedical Advanced Research and Development Authority (BARDA) operations, including Pandemic Influenza management funding, which has previously been provided as part of the Office of the Secretary Pandemic Influenza funding. The request also re-aligns funding consistent with the re-organization of ASPR offices which was completed in FY 2010.

The request includes:

- $765 million, an increase of +$444.9 million to the Biomedical Advanced Research and Development Authority to fund advanced development projects including anthrax vaccines and antitoxins, countermeasures for acute radiation syndrome, and broadspectrum antibiotics. The request is financed by making funds from the Project BioShield Special Reserve Fund available for BARDA advanced development and other activities. These funds support oversight and management of all BARDA programs, including Project BioShield (over $2 billion awarded to date) and Pandemic Influenza (over $5 billion awarded to date). This includes $100 million for the establishment of a Medical Countermeasure Strategic Investor. This new entity would function as an independent government-sponsored program to provide both financial support and business expertise to newly emerging businesses in the biodefense sector similar to other venture capitalist endeavors undertaken by the Federal government. The Strategic

Investor concept will seek companies that have technologies which will be both successful commercially but also serve to develop specific government-required products.

- $473.0 million, a decrease of -$42.4 million over FY 2010, for Federal, State and local capacity and capabilities in emergencies. A total of $15 million, an increase of +$5 million, will support responses to National Special Security Events (NSSEs) and other planned events and unplanned emergencies.

- $64.3 million, an increase of +$8.4 million over FY 2010, to support ASPR strategic oversight and operational coordination for preparedness and response activities. The budget proposes the elimination of funding for the Early Warning Infectious Disease Surveillance System program, which provides grant funding to U.S. border states, a reduction of -$3.3 million. Also, $10 million is requested to improve operational efficiency by co-locating approximately 90% of ASPR staff in a single facility.

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	$29,647,000	$29,653,000	$34,647,000	+$5,000,000
NSSE/Public Health Emergencies (non-add)	*$10,000,000*	*$10,000,000*	*$15,000,000*	*+$5,000,000*
FTE	80	92	96	+16

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices.

Allocation Method: Direct federal/intramural; contracts

Program Description and Accomplishments:

Under the National Response Framework (NRF) HHS serves as the primary agency for Emergency Support Function (ESF) #8 – preparedness and response to the public health and medical consequences of disasters, including terrorist incidents involving weapons of mass destruction – during National Security Special Events, and during other potential public health emergencies. Additionally, in support of the Department of State (DOS), United States Agency for International Development (USAID) or the Department of Defense (DoD), or under its own authorities, HHS can provide public health and medical resources to support international events or incidents. ASPR is the lead for all activations of ESF #8 and for its independent authorities, such as activations under Sections 311 and 319 of the Public Health Service Act, Federal-State cooperation, and temporary assistance to states. As such, the Office of Preparedness and Emergency Operations (OPEO) is required to build and maintain an effective planning, coordination, and response capability, including significant logistics capabilities, for public health and medical emergencies. Through the Secretary's Operations Center (SOC), the Incident Response Coordination Team (IRCT), the National Disaster Medical System (NDMS), the Regional Emergency Coordinators (REC), and the Hospital Preparedness Program (HPP), ASPR directs and coordinates all public health and medical assets associated with an ESF #8 response. 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.

OPEO supports overall planning and response coordination including with State, local and Federal partners. This includes having the right information and systems to deliver the right assets – human and materiel – at the right time and to the right place during a disaster or public health emergency. It also includes support for the RECs who work with states and other HHS and non-HHS partners to understand the specific needs of cities, regions, states, territories, and Tribes, and to plan together with other HHS partners for responses to emergencies.

Preparedness, Planning, Operations, and Logistics

OPEO leads HHS's integrated international and domestic preparedness planning, including response and regional logistics support that require public health, medical, human services and

recovery support under ESF #8, and supports both ESF #6 (Mass Care, Emergency Assistance, Housing, and Human Services) and ESF #14 (Long-Term Community Recovery). During FY 2010, OPEO deployed over one million pounds of medical supplies and equipment in response to several events and incidents including, but not limited to; the G-20 Nuclear Security Summit, the Haiti Earthquake, Deepwater Horizon oil spill in the Gulf, the State of the Union address, the 2010 Olympics in Vancouver, Red River Flooding, Flooding in Rhode Island, Montana and Kentucky, the Tsunami in American Samoa, the Caribbean Games in Puerto Rico, and multiple vaccination team missions to assist states and territories with the 2009 H1N1 influenza response.

OPEO is continuing to enhance its regional response capability by consolidating and restructuring HHS's medical cache warehouses, modularizing medical supply and equipment caches for rapid deployment, and engaging OPEO's 34 Regional Emergency Coordinators in conducting integrated planning with State/local and other Federal entities (e.g., FEMA) to include detailed analyses of potential gaps in state/local capabilities that may require federal support during disaster response. The regional exercises for the New Madrid and Southern California earthquake zones are examples of this integrated planning. Exercises based on departmental and national plans have allowed HHS to make necessary revisions to expand response capabilities based on "lessons learned" and to work with state and local partners to fill gaps identified and become more resilient. For example, exercises with North Dakota regarding responses to flooding have enabled the State to modify its plans and make it less dependent on federal support. In FY 2012, OPEO will continue these critical efforts. Using ongoing gap analysis studies with the states, OPEO will work to identify needs that will most likely be unmet during a public health emergency and response. Potential solutions to those gaps will then be identified by working with local, State, and Federal partners, and the private sector.

OPEO is enhancing its international response capabilities by creating an international response programs branch to coordinate efforts with DoS/USAID/DoD and other entities. Significant effort has gone into developing an International Response Framework (annex for health services response). A major section of this branch focuses on *Reconstruction and Stabilization* (R&S), and is supported by DoS resources. This branch coordinates HHS civilian capacity to prevent or prepare for post-conflict situations, and to help stabilize and reconstruct societies transitioning from conflict or civil strife, so they can reach a sustainable path toward peace, democracy and a market economy. OPEO leads the Department's efforts to provide and train technical expertise which can be deployed directly to an R&S environment. This branch collaborates with partners to develop criteria for at-risk countries with failing healthcare infrastructure indicators. They create international reach-back through the operations center, as well as planning and logistics support.

Training, Exercises and Lessons Learned (TELL)

OPEO leads training and exercise activities within the Department under ESF #8. This includes ensuring that preparedness and response personnel are National Incident Management System (NIMS) compliant and have completed both Incident Command System (ICS) 300 and 400, and that the IRCTs have advanced and ongoing training such as the Incident Management Team (IMT) All Hazards Section Chief training from the Emergency Management Institute (EMI). Training and exercise activities include the development of Presidential level, National level and departmental quarterly exercises, as well as those meant to enhance the abilities of our

Emergency Management Group (EMG) to lead response operations during an event. In addition, the Training, Exercise and Lessons Learned team in OPEO leads the lessons learned and corrective action process for all events/incidents as well as training events. TELL also supports the other offices in ASPR by leading exercises and through a rigorous 'after action' process to identify lessons learned. For example, as ASPR has played a more active role in coordinating ESF #8 wide policy response for the Secretary, the lessons learned process has extended to reviewing ASPR's policy response as well. Examples include working with the ASPR Office of Planning and Policy on areas such as pandemic influenza strategies and policies and with BARDA to review lessons from contracting and procurements as well as to inform the development of appropriate logistics / transportation networks required to move countermeasures developed through private industry. Additionally, the process of developing the training requirements, through the OPEO Response Training Guidelines and Course catalog, has begun so as to ensure OPEO has sufficient, culturally competent and proficient public health, health care and emergency management workforce to meet the needs.

National Special Security Events (NSSEs)

OPEO's Regional Emergency Coordinators lead coordination with state and local entities and OPEO preparedness and operations offices to plan for National Special Security Events (NSSEs) and other planned and unplanned events. The OPEO Operations section leads the OPEO Special Event Working Group that focuses on tactics and resources to meet the goals and objectives for each of these events. Activities include building a capabilities-based assessment, developing preparedness plans in collaboration with all stakeholders, development of interagency concepts of operations, resource typing of these capabilities, event planning, deployment of teams, and required logistical, travel, and equipment support. These planning and response activities focus on five overarching goals: to save and sustain lives, protect the public's health, assure the integrity of medical infrastructure, maintain situational awareness, and assure the safety of deployed personnel. The majority of NSSEs and other mass gathering special events that OPEO supports occur in the National Capitol Region, although support is provided as requested to other events such as the Democratic National Convention, Republican National Convention, and Super Bowl. Historically OPEO has supported multiple events annually, including some events which were unforeseen, such as a State Funeral or the re-entry of a U.S. satellite into the Earth's atmosphere in February 2008. In FY 2010, OPEO responded to two NSSEs, the G-20 Nuclear Security Summit and the State of the Union. The State of the Union is a different type of response than other OPEO response events in that it combines COOP and response, where a redundancy of government functions is created that is not necessary in other events. Other events OPEO provided support for include the Peace Officers Memorial ceremony and the annual Cherry Blossom Festival. Responses to many of these events serve a dual purpose, as they also allow NDMS teams to work and train together in preparation for future public health emergency events.

Mass Casualty Care

OPEO leads planning activities required to fulfill OPEO mass casualty care responsibilities under ESF #8 of the NRF and Homeland Security Presidential Directives (HSPDs) -10 and -21. This includes regional planning for pre-staging Federal Medical Stations (FMS) especially in high risk areas of the country. The FMS project supports ASPR/OPEO, working with CDC, in fulfilling the responsibility under mandates noted above to develop a federal asset to provide

over 30,000 patient beds. OPEO is also enhancing 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, such as the Radiation Emergency Medical Management (REMM) web-based tool that provides guidance on diagnosis and treatment on radiological and nuclear exposure for health care providers;
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.

The 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 those events for which the civilian sector and our state and local partners have not begun to plan, requires OPEO 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. For example, we will conduct conferences on improvised explosive devices (IED) preparedness in two cities in FY 2011; these will involve local emergency responders, EMS, hospitals, public health, law enforcement, and other partners.

Funding History:

FY 2007	$10,152,000
FY 2008	$13,863,000
FY 2009	$18,813,000
FY 2010	$29,647,000
FY 2011 CR	$29,653,000

Budget Request:

The FY 2012 request for Preparedness and Emergency Operations is $34,647,000, a +$5,000,000 increase over FY 2010. The request includes $15,000,000 requested as no-year funding for emergency operations, including preparing for and responding to non-Stafford Act National Special Security Events (NSSEs) and other planned and unplanned events, including other mass gathering events and public health emergencies. The entire amount of the increase is for this NSSE funding. Funding for this activity was first requested in FY 2010, and it supported the activation of response teams for the State of the Union, the 2010 Olympics, and unplanned events where quick response is critical for saving and sustaining lives such as the Haiti

Earthquake.

OPEO will continue to improve the quality and availability of data used to prepare for and respond to public health emergencies. OPEO programs will work to analyze and advise state and local public health and medical preparedness and response programs to encourage the integration of preparedness plans across all the tiers of response (local/State/Tribal/Federal/territorial). The enhanced regional presence, composed of HPP field officers, will assist in testing of the integrated plans with state/local/Tribal/territorial partners to create strategic partnerships for preparedness. Past experience in real events, along with exercises and studies, will form the foundation of corrective action planning that includes advanced data systems to track preparedness and response and will allow for reviewing response metrics from each of our events/incidents to include those from exercises. OPEO will continue its campaign to enhance situational awareness and information sharing among all levels of government and the private sector, in both the classified and unclassified domains. Continued emphasis will be placed on Continuity of Operations (COOP) program in FY 2012.

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

Funding also will support training and exercises, including Tier 1 and II National Level Exercises, regional exercises (focuses on validating potential requests for ASPR's response capabilities), 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 the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) and HSPD-21.

Outcomes and Outputs:

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.1: Improve ESF #8 preparedness planning and response capability. (Outcome)	FY 2010: ASPR has responded to the G-20 Nuclear Security Summit, the Haiti Earthquake, Deepwater Horizon oil spill in the Gulf, the State of the Union address, the 2010 Olympics in Vancouver, Red River flooding, flooding in Rhode Island, the Tsunami in American Samoa, and multiple vaccination teams to assist states with 2009 H1N1 influenza vaccinations. (Target Met)	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.	Development of regional/state/local playbooks through gap analyses and regional exercises. Field exercises for Incident Response Coordination Team in collaboration with other ESF #8 response assets. Corrective action plans developed based on exercises and real world events. Fully developed MedMap that serves as platform that provides a common operating picture across state and federal response operations. Readiness workforce training standards for personnel involved in preparedness and response operations. Readiness standards fully developed for all teams deployed for ESF #8 response efforts. Refinement of an information management process that uses automated business intelligence and other technological solutions to aid decision makers and to feed the Fusion process. Fully developed situational awareness tools and systems in support of MedMap and other technologies utilized by the Emergency Management Group. Full fielding of the Disaster Medical Information Suite electronic medical record, patient tracking system and Health Information Repository.	N/A

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	$52,493,000	$52,502,000	$52,850,000	+$357,000
FTE	65	82	87	+22

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices.

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

The National Disaster Medical System (NDMS) is the nation's flagship program for providing health and medical response when States are overwhelmed by the magnitude of the emergency. It is a cooperative, asset-sharing partnership with the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Department of Homeland Security (DHS) that leverages Federal and non-federal resources to care for large numbers of casualties resulting from a disaster. NDMS consists of three key functions:

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

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

NDMS teams have been successfully deployed to a variety of missions, including: the G-20

Nuclear Security Summit, the Presidential State of the Union, and the earthquake in Haiti. In addition, NDMS team members regularly assist the DoD and Coast Guard with medical evacuation of ill and injured citizens, specifically in the remote Pacific region.

The ESF #8 Integrated Training Summit (formerly NDMS Training Summit) is an annual event and attendance exceeds 3,000 participants. The summit brings together state, local, public and private medical and public health responders to review protocols, best practices and state-of-the-art science related to national preparedness and response. The Summit includes the Medical Reserve Corps and the Emergency System for the Advance Registration of Volunteer Health Professionals (ESAR-VHP) programs and incorporated specialized trainings for Incident Response Coordination Team (IRCT) personnel, OPEO logistics and the DoD for aero-medical evacuation.

OPEO NDMS Program Development Branch (PDB) and the NDMS Chief Medical Office (CMO) lead the effort within HHS to develop an integrated, scalable and deployable health care delivery system by a thorough review of after action reports, accessing subject matter experts, evidence-based research, and review of literature. Based on the previous tools, PDB and CMO can effectively reduce variables such as: "time to deploy" to site; deployment in stages rather than large entities; and create financially more feasible response teams.

Through the execution of the multiple NDMS field training events, NDMS was able to pilot the Medical Operative Detachment (MOD) units which are functional units within Disaster Medical Assistance Teams (DMATs) that allow DMATs to be scalable and able to respond as smaller strike teams with appropriate caches. Refinement of mission sets, staffing, and logistical needs are being currently reviewed and documented for feasibility to support all the various ESF # 8 mission sets.

Additional response elements during FY 2010 included the Joint Patient and Tracking Teams (JPATs) which have proved a benefit to support the DoD and VA Federal Coordinating Centers (FCC). This was evident during the 2010 Haiti Response when teams were deployed.

Mobile Acute Care (MAC) team development has commenced during FY 2010 to fill a gap in patient movement requirements. Along with the DoD, OPEO/NDMS has started to and develop teams that would support the care of critical and urgent care patients on flight lines during mass patient evacuations.

Through the active recruitment of medical professionals throughout the country, NDMS has been capable to enrich teams with skilled individuals in various medical specialties. For example, the addition of the Medical Specialty Enhancement Team (MSET), will allow a venue for medical professionals who are forefront of their medical communities/organizations, to deploy and provide subject matter expertise to OPEO/NDMS. ASPR has 15 NDMS teams in development. The growth of NDMS not only strengthens the system but also creates a support network for local and state communities. Trained NDMS employees provide input within their communities based on their training and expertise from responding.

Funding History:

FY 2007	$43,070,000
FY 2008	$42,464,000
FY 2009	$45,965,000
FY 2010	$52,493,000
FY 2011 CR	$52,502,000

Budget Request:

The FY 2012 request for the National Disaster Medical System is $52,850,000, an increase of +$357,000 above FY 2010. Funding will support central headquarters operations, regional emergency coordination, as well as medical response assets, including teams, supplies, and equipment including continued standardization and regionalization of equipment caches. NDMS is a unique capability, supported by the partnership of four Federal agencies (HHS, DHS, DoD, and VA). The NDMS mission has grown substantially since 2005. NDMS remains the only system able to mesh Federal response with civilian infrastructure and human capital assets. Due to improved standardization of our medical materiel and regionalization of warehouses, NDMS is able to respond more quickly to public health emergencies. The standardization and regionalization made response assets less vulnerable to geographic hazards (i.e., earthquakes, floods, etc.) which would hamper the ability to move supplies to meet the deployment goal of having response assets on site within 12 hours of a public health emergency. Through these efforts, NDMS will be a more nimble and flexible response asset to the nation during public health emergencies.

FY 2012 funding includes logistics support for cache maintenance including medical and pharmaceutical supplies, IT and communications capabilities to ensure all equipment caches will sustain deployed medical personnel throughout the full range of emergent care in the field. Funding will support the Disaster Medical Information Suite (DMIS), which is the NDMS electronic medical record and patient tracking system. This system was used to inform and adapt the response to the Haiti Earthquake; data from the electronic medical record showed that children were more significantly represented in the patient population than in a typical deployment, and ASPR responded by sending additional pediatricians. ASPR has also made components of DMIS available to states, some of which are adopting it for their own needs and uses.

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

FY 2012 activities will include further development of policies and procedures related to training

standards, objectives and cycles, with emphasis on regional training and exercises for more than 100 NDMS Response Teams. Teams include: DMATs, 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 advance improvements in planning and preparedness activities associated with the development of an integrated ESF #8 National Strategy for Fatality Management, as outlined in the ESF #8 concept of operations. Funding will support the operational needs of the Regional Emergency Coordinators, in addition to the continued development, training, and deployment of six IRCT-A teams and three Logistical Response Assistance Teams (LRAT).

Historically, NDMS has emphasized the 'response' portion of NDMS – the team building, training, cache development, etc. NDMS has two other major parts; Patient Transportation and Definitive Care. Over the past year, these components have been major concerns of our State partners. Funding requests in FY 2012 include building development and training (with exercises) those two critical portions of NDMS.

Outcomes and Outputs:

See Preparedness and Emergency Operations.

Office of the Assistant Secretary for Preparedness and Response
Hospital Preparedness

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	$417,400,000	$417,471,000	$375,466,000	-$41,934,000
FTE	32	35	35	+3

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices.

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

Program Description and Accomplishments:

The Hospital Preparedness Program (HPP) enhances the ability of the health care system to prepare for and respond to public health emergencies. Since its move to ASPR in 2007 from HRSA, the program has continued to build medical surge capacity and capability, as well as enhance overall hospital, other healthcare organization (HCO), and healthcare system preparedness and response to medical and public health emergencies. The program has become an integral part of the OPEO response mission through grant-funded program activities and the strategic use of the staff who administer them. HPP has strengthened Federal, State, local, territorial, Tribal and regional partnerships to improve overall medical surge preparedness nationally. While the program continues to focus on strengthening the capability of hospitals, other HCOs and healthcare systems are an increasing part of the program. The entire system must be able to plan for, respond to, and recover from all-hazards 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, healthcare 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 HPP is an integral part of the OPEO response mission through grant-funded activities, developed using HPP relationships with awardees and sub-recipients at the State, local, and healthcare system level, which are integrated into day-to-day hospital mission space and enable medical surge capacity and capability during a response. In addition, the technical assistance and real-time situational awareness available to OPEO, from the HPP headquarters and field staff, enhance overall hospital, HCO, and healthcare system preparedness and subsequent response to medical and public health emergencies, through its ability to leverage and connect to all ASPR programs and assets, including the National Disaster Medical System (NDMS), Critical Infrastructure Preparedness (CIP), Emergency Care Coordination Center (ECCC), the Regional Emergency Coordinator (REC) program, and the Regional Health Administrators (RHA), which maximizes ASPR's lead ESF #8 response and coordination responsibilities.

The program also supports the activities of the HPP Program Evaluation Section (PES) and the Emergency Care Coordination Center (ECCC). The Healthcare and Public Health Sector CIP Program is a public and private sector partnership dedicated to protecting the essential goods, services, and functions of healthcare and public health that, if destroyed or compromised, would negatively affect the Nation. The National Infrastructure Protection Plan (NIPP) provides the framework for the healthcare and public health sector protection, as well as 17 other designated critical infrastructure sectors mandated by the Homeland Security Presidential Directive #7. In FY 2012, the CIP program will continue to focus on key initiatives essential to meeting the requirements of NIPP and building partnerships with local, state, and regional stakeholders under the NIPP framework.

A program evaluation section was established in 2006 in order to evaluate the HPP program and overall healthcare systems preparedness. PES contributes to the development of program measures, improvements in the quality of data available for analysis, and study designs necessary to critically evaluate national programs and their implementation at state and local levels and in communities. As the nation has recognized that prepared hospitals cannot exist in a vacuum but are an integral part of a prepared community, PES is working with State, local, and private sector partners to measure whether healthcare systems in communities are prepared.

In addition to internal analyses, PES has also funded independent reports to assess the progress of the HPP program, the utility of healthcare coalitions, and the expansion of healthcare systems preparedness. PES also extends the team's experience in assessment, program development, and policy within a number of projects that include: supporting the Secretary's Operation Center (SOC) with disaster management analysis, aiding the Fusion cell in the event of pandemic flu to assess hospital readiness, and providing support and evaluation of comprehensive national exercise activities.

ECCC fulfills Homeland Security Presidential Directive #21 and was launched as a direct response to the 2006 Institute of Medicine Series of Reports: *Emergency Care for Children, Hospital-Based Emergency Care and Emergency Medical Services: At the Crossroads.* The program was established in January 2009 within ASPR to support coordination of Federal activities, programs, and initiatives relating to the routine delivery of emergency care and to promote programs, resources, and research that improve the delivery of emergency care. This is accomplished through the promotion of basic science, clinical and systems-based research emergency medical care, dissemination of lessons learned, the development of partnerships throughout the Federal government as well as active stakeholder outreach efforts in order to encourage maximal coordination of Federal programs relating to emergency care.

In coordination with the Council for Emergency Medical Care and the Federal Interagency Committee for Emergency Medical Services, ECCC contributes to the Emergency Care Enterprise (ECE) that spans the entire spectrum of the Emergency Care System (ECS). Optimization of the ECS for routine patient care operations is fundamental to a prepared and resilient community. For example, if emergency departments are overcrowded, they will struggle more to manage a mass casualty emergency, such as simultaneous improvised explosive devices, an earthquake, or a dirty bomb. Situated within ASPR, the ECCC is ideally positioned to serve this critical role within the medical community. A highly effective ECS is a critical

building block of hospital preparedness.

OPEO continues to focus on greater outcomes and efficiencies in the HPP program. In addition to coordinating all of ASPR preparedness and response programs, OPEO has led a number of efforts to improve coordination of HPP, CDC Public Health Emergency Preparedness (PHEP), and Federal Emergency Management Agency (FEMA) grants with the ultimate goal of developing a seamless interface with State and local partners. Senior ASPR HPP staff coordinate with CDC PHEP staff to develop shared strategic planning for future grant opportunities. Specifically, priority capabilities for funding are being created and vetted, along with multiple levels of supplemental materials, in order to guide awardees in state/local planning for future use of HPP grants, including seamless connections to the public health priorities funded through the CDC PHEP grant opportunity. This direct connection has led to a crosscutting document released in the FY 2010 HPP Grant Guidance to help states develop more comprehensive strategic planning as well as streamlining their grants application processes.

In addition, a grant steering committee spearheaded by ASPR is working to align and coordinate Federal preparedness grant programs. These efforts will, for example, enable awardees to better execute statewide and regional exercises meeting the requirements of both programs, while following overarching criteria developed by the Department of Homeland Security, Homeland Security Exercise and Evaluation Program (HSEEP). Also, ASPR is leading an effort to coordinate the performance measures of the grant programs, and the National Health Security Strategy Biennial Implementation Plan metrics.

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

One of the FY 2009 performance targets was that 80 percent of states be able to demonstrate the ability to report hospital bed data using the Hospital Available Beds in Emergencies and Disasters (HAvBED) System in at least one drill, exercise, or real life event. Progress on this target was validated in March 2009 during a test of the HAvBED system when 74 percent of states were able to report their available beds without difficulty. Additional validation came in response to 2009 H1N1 influenza where 49 of 50 states consistently reported bed status to the HHS Secretary's Operation Center. Another FY 2009 performance target was that 95 percent of states be able to demonstrate through reporting or exercises the use of interoperable communications systems with multiple communications technologies that would ensure connectivity and operability in a public health emergency; 100% of states achieved this goal.

In addition, HPP funding has played a critical role in building State and local capacity to respond to events and incidents without the need for federal response assets. For example:

- Fort Hood Incident
  In central Texas, HPP-funded preparedness efforts enhanced the regional hospitals' response during the November 2009 Fort Hood shooting incident. Specifically, HPP partnership and coalition funds used for ongoing hospital planning meetings helped to ensure continued coordination between and among hospitals and Emergency Medical Systems (EMS). As a part of the planning associated with participation in HPP hospital officials developed a regional Hospital Disaster Plan that was signed off on by all Chief Executive Officers involved. Soon after word of the shootings arrived, Darnell Hospital on Fort Hood called the Regional Advisory Council (RAC) and HPP regional contractor and requested that this plan be activated. Three HPP-funded tools – EMResource, EMTrack, and WebEOC-facilitated hospital communication and patient tracking. In an attempt to continuously learn from live events, the Texas Department of State Health Services (DSHS) has authorized the use of HPP funds to support a planned after-action review meeting.

- Minnesota Bridge Collapse
  Using the Minnesota System for Tracking Resources, Alerts, and Communication (MNTrac), Minnesota can rapidly send critical information to hospitals and first responders during a disaster. As part of the response to the bridge collapse in Minneapolis-St. Paul, MNTrac alerts were sent via multiple methods, including text messages to mobile devices.

- Tennessee Flooding
  The Middle Tennessee Flood response of May 2010 relied upon resources, services, plans, and systems developed and sustained with HPP grants. The Tennessee State Emergency Operations Center opened during the event to aid in response efforts. These efforts included activation of the ESF #8, to support the medical needs of the public. Several hospitals were forced to implement their medical evacuation plans. Several nursing homes evacuated their patients, many of whom went to local hospitals. The HAvBED system made these evacuation and relocation efforts possible by providing available bed counts on request. Communication, sharing and partnership also played a key role in successful response efforts. The Regional Medical Communication Centers funded by ASPR grants were actively involved in the flood response and enhanced interoperable communications systems allowed hospitals to use their Base Station Radios, and one hospital used its grant-funded HAM radio as its sole source of communication.

In FY 2008, the HPP programmatically institutionalized the DHS HSEEP methodology used across government, and implemented an execution strategy for HPP awardees and sub-recipient healthcare systems and other HCOs to maximize participation in coordinated multi-disciplinary exercises in accordance with the DHS initiative. HSEEP is a capabilities and performance-based exercise program that provides a standardized methodology and terminology for exercise design,

development, conduct, evaluation, and improvement planning. The HSEEP constitutes a national standard for all exercises. Through exercises, the National Exercise Program (NEP) supports organizations to achieve objective assessments of their capabilities, so that strengths and areas for improvement are identified, corrected, and shared prior to a real incident. The HPP goal is to ensure state and territory departments of public health awardees and sub-recipient healthcare systems engage appropriately in planning and conducting exercises. HSEEP implementation has resulted in a program shift, starting in FY 2008, from increasing and measuring the number of hospital-based drills and exercises, to ensuring fewer, but more comprehensive, multidisciplinary regional and statewide exercises with hospital, HCO and healthcare coalition participation, and exercising of the over-arching and Level 1-capabilities outlined in the HPP guidance.

Funding History:

FY 2007	$467,541,000
FY 2008	$416,979,000
FY 2009	$385,056,000
FY 2010	$417,400,000
FY 2011 CR	$417,471,000

Budget Request:

The FY 2012 Budget for Hospital Preparedness is $375,466,000, a decrease of -$41,934,000 below FY 2010. In light of previous support for these activities and a constrained budget, the HPP grant program and related Federal administration activities (which will absorb the increased proportion of funding supporting PHS Evaluation activities) will be reduced commensurate with overall budget reductions. Funding will be provided to the existing cooperative agreement awards to further enhance surge capacity and capability. In addition funding will support program management and administrative costs, and evaluation and technical support. Specifically, awards will improve preparedness plans for all-hazards, increase the ability of hospitals and other HCOs to provide needed beds, engage with other responders through interoperable communication systems, and track bed and resource availability using electronic systems.

Also, funding will support ESAR-VHP systems, protection of healthcare workers with proper equipment, decontamination of patients, enable healthcare coalitions, educate and train healthcare workers, enhance fatality management and hospital evacuation/shelter in place plans, and enable healthcare system coordination within regional exercises.

In FY 2012, consistent with directions identified in PAHPA, the program will continue to focus on community-level medical surge planning as well as 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 agreed upon target capabilities that are identified as part of the National Preparedness Goal. There will be ongoing requirements for the states,

health-care systems, and HCOs to report available assets in support of seamless preparedness and response across the tiers of health care asset management. Funding also supports evaluation activities, such as review and revision of current performance measures, development of profiles of state health care system preparedness, implementation of a management information system to improve and simplify the process of data collection for grantees, continued development of exercise evaluation guidelines to standardize the methodology for reporting exercise results, continued development of guidelines for states on allocation of scarce resources during catastrophic events and modeling of the resiliency of the health care system's ability to respond when the infrastructure surrounding the health care system has been damaged. The data information systems under development will allow for more rigorous data analysis and program evaluation.

The request will also support the activities of the Program Evaluation Section (PES), the Emergency Care Coordination Center (ECCC), and the Critical Infrastructure Protection (CIP) program for the Healthcare and Public Health Sector. PES evaluates the HPP program and overall healthcare systems preparedness. ECCC supports coordination of Federal activities and programs relating to the routine delivery of emergency care and the improvement of the delivery of emergency care. The CIP program includes collaboration with federal, state, local, territorial, tribal, and private sector stakeholders on a range of activities from information sharing to threat risk assessments, to participation in exercises to enhance the resiliency of the sector.

Outcomes and Outputs:

Long Term Objective: Enhance State and Local Preparedness

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.2.B: Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of States demonstrating use of Interoperable Communications Systems: % of States demonstrating use of Interoperable Communications Systems. (Outcome)	FY 2009: 100% (Target Exceeded)	98%	100%	+2
2.4.2. F: Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of States with the ability to electronically report healthcare organization (HCO) bed data: % of States with the ability to electronically report HCO bed data. (Outcome)	N/A	N/A	40%	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.2 G: Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states with heightened healthcare organization (HCO) engagement in statewide/regional exercises: % of States with heightened HCO engagement in statewide/regional exercises. (Outcome)	N/A	N/A	20%	N/A
2.4.2.H: Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states with established operational healthcare coalitions: % of States with established operational healthcare coalitions. (Outcome)	N/A	N/A	30%	N/A
2.4.2.I: Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states with established operational ESAR-VHP programs: % increase in the total number of registered volunteers. (Outcome)	N/A	N/A	5% increase over baseline	N/A
2.4.3: Increase the ratio of preparedness exercises and drills per total program (Coop. Agreement) dollar by 50% each year. (Approved by OMB) (Outcome)	FY 2009: 46.9 per million dollars (Target Exceeded)	34 per 1 million dollars	N/A	N/A

Grant Awards Table:

Hospital Preparedness: (whole dollars)	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget
Number of Awards	62	62	62
Average Award	$6,360,411	$6,360,411	$5,684,056
Range of Awards	$273,656 - $32,302,412	$273,656 - $32,302,412	$270,943 - $28,649,663

FY 11/12 Discretionary State/Formula Grants

Hospital Preparedness Program

STATE/TERRITORY	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	Difference +/- 2010
Alabama	$6,017,284	$6,017,284	$5,383,581	($633,703)
Alaska	$1,303,838	$1,303,838	$1,211,511	($92,327)
Arizona	$7,897,500	$7,897,500	$7,047,841	($849,659)
Arkansas	$3,872,098	$3,872,098	$3,484,786	($387,312)
California	$32,302,412	$32,302,412	$28,649,663	($3,652,749)
City of Chicago	$3,910,062	$3,910,062	$3,518,390	($391,672)
Colorado	$6,202,448	$6,202,448	$5,547,478	($654,970)
Connecticut	$4,704,587	$4,704,587	$4,221,659	($482,928)
Delaware	$1,523,883	$1,523,883	$1,406,282	($117,601)
District of Columbia	$1,695,426	$1,695,426	$1,558,122	($137,304)
Florida	$22,201,759	$22,201,759	$19,709,146	($2,492,613)
Georgia	$11,733,568	$11,733,568	$10,443,307	($1,290,261)
Hawaii	$2,042,163	$2,042,163	$1,865,034	($177,129)
Idaho	$2,259,263	$2,259,263	$2,057,198	($202,065)
Illinois	$12,483,970	$12,483,970	$11,107,520	($1,376,450)
Indiana	$8,074,093	$8,074,093	$7,204,150	($869,943)
Iowa	$4,077,495	$4,077,495	$3,666,593	($410,902)
Kansas	$3,815,957	$3,815,957	$3,435,094	($380,863)
Kentucky	$5,545,868	$5,545,868	$4,966,312	($579,556)
LA County	$12,434,339	$12,434,339	$11,063,589	($1,370,750)
Louisiana	$5,643,874	$5,643,874	$5,053,061	($590,813)
Maine	$2,085,442	$2,085,442	$1,903,342	($182,100)
Maryland	$7,236,977	$7,236,977	$6,463,183	($773,794)
Massachusetts	$8,222,459	$8,222,459	$7,335,475	($886,984)
Michigan	$12,611,363	$12,611,363	$11,220,281	($1,391,082)
Minnesota	$6,698,777	$6,698,777	$5,986,800	($711,977)
Mississippi	$3,991,665	$3,991,665	$3,590,621	($401,044)

STATE/TERRITORY	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	Difference +/- 2010
Missouri	$7,509,283	$7,509,283	$6,704,214	($805,069)
Montana	$1,633,239	$1,633,239	$1,503,078	($130,161)
Nebraska	$2,621,400	$2,621,400	$2,377,741	($243,659)
Nevada	$3,493,792	$3,493,792	$3,149,932	($343,860)
New Hampshire	$2,077,430	$2,077,430	$1,896,250	($181,180)
New Jersey	$10,966,526	$10,966,526	$9,764,366	($1,202,160)
New Mexico	$2,844,859	$2,844,859	$2,575,534	($269,325)
New York	$13,806,364	$13,806,364	$12,278,027	($1,528,337)
New York City	$10,354,538	$10,354,538	$9,222,669	($1,131,869)
North Carolina	$11,124,816	$11,124,816	$9,904,475	($1,220,341)
North Dakota	$1,262,826	$1,262,826	$1,175,209	($87,617)
Ohio	$14,269,733	$14,269,733	$12,688,174	($1,581,559)
Oklahoma	$4,793,846	$4,793,846	$4,300,665	($493,181)
Oregon	$4,939,660	$4,939,660	$4,429,731	($509,929)
Pennsylvania	$15,424,545	$15,424,545	$13,710,348	($1,714,197)
Rhode Island	$1,780,771	$1,780,771	$1,633,665	($147,106)
South Carolina	$5,684,040	$5,684,040	$5,088,613	($595,427)
South Dakota	$1,438,039	$1,438,039	$1,330,298	($107,741)
Tennessee	$7,744,525	$7,744,525	$6,912,436	($832,089)
Texas	$28,701,403	$28,701,403	$25,462,257	($3,239,146)
Utah	$3,559,214	$3,559,214	$3,207,841	($351,373)
Vermont	$1,248,479	$1,248,479	$1,162,510	($85,969)
Virginia	$9,668,881	$9,668,881	$8,615,765	($1,053,116)
Washington	$8,172,799	$8,172,799	$7,291,519	($881,280)
West Virginia	$2,681,550	$2,681,550	$2,430,982	($250,568)
Wisconsin	$7,165,931	$7,165,931	$6,400,298	($765,633)
Wyoming	$1,117,831	$1,117,831	$1,046,868	($70,963)
Subtotal	**$386,674,890**	**$386,674,890**	**$345,363,484**	**($41,311,406)**
Indian Tribes	$0	$0	$0	$0
Migrant Program	$0	$0	$0	$0
American Samoa	$319,393	$319,393	$311,423	($7,970)
Guam	$446,256	$446,256	$423,715	($22,541)
Marshall Islands	$317,696	$317,696	$309,920	($7,776)

STATE/TERRITORY	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	Difference +/- 2010
Micronesia	$379,735	$379,735	$364,834	($14,901)
Northern Mariana Islands	$341,329	$341,329	$330,839	($10,490)
Palau	$273,656	$273,656	$270,943	($2,713)
Puerto Rico	$5,212,005	$5,212,005	$4,670,795	($541,210)
Virgin Islands	$380,540	$380,540	$365,547	($14,993)
Subtotal	**$7,670,610**	**$7,670,610**	**$7,048,016**	**($622,594)**
Total States/Territories	**$394,345,500**	**$394,345,500**	**$352,411,500**	**($41,934,000)**
Technical Assistance	$0	$0	$0	$0
State Penalties	$0	$0	$0	$0
Contingency Fund	$0	$0	$0	$0
Other Adjustments (specify)	$0	$0	$0	$0
Subtotal Adjustments	**$0**	**$0**	**$0**	**$0**
Total Resources	**$394,345,500**	**$394,345,500**	**$352,411,500**	**($41,934,000)**

Office of the Assistant Secretary for Preparedness and Response
Emergency System for Advance Registration of Volunteer Health Professionals

	FY 2010 Actual	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	$5,841,000	$5,842,000	$5,000,000	-$841,000
FTE	3	4	5	+2

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices.

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

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

The Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) transferred responsibility for the ESAR-VHP program from HRSA to ASPR. PAHPA mandates that States are not eligible to receive the Hospital Preparedness Program and CDC Public Health Emergency Preparedness Program funding unless they participate in ESAR-VHP. Forty-nine states have fully operational ESAR-VHP systems, and the remaining state is working to become fully operational. There are over 147,600 registered ESAR-VHP volunteers.

In FY 2010, ASPR awarded 25 three-year awards to support and sustain State and territorial ESAR-VHP programs. The focus of the grants was to meet compliance requirements, adopt and implement guidelines, support activities related to the integration of local Medical Reserve Corps (MRC) volunteer resources and state ESAR-VHP programs, and support training and exercises. The ESAR-VHP program continued to provide state access to national data sources, such as the American Board of Medical Specialties (ABMS), Federation of State Medical Boards (FSMB), American Osteopathic Information Association (AOIA), the Drug Enforcement Administration (DEA), the American Society for Clinical Pathology (ASCP), and National Council of State Boards of Nursing (NCSBN). The ESAR-VHP program partnered with the National Disaster Medical System (NDMS), the Office of Public Health and Science (OPHS), the Office of Force Readiness and Deployment (OFRD), and the MRC to conduct the Integrated Medical, Public

Health, Preparedness, and Response Training Summit. In addition to an ESAR-VHP program coordinators meeting, the Summit provided a forum for training, discussion, information sharing, and networking with public health and response partner organizations. The program collaborated with other HHS and ASPR programs to prepare and plan for the use of volunteers in response to the Haiti earthquake. In Florida, volunteers supported Operation Haiti Relief by participating in the triage and transfer of 22 Haitian survivors. Eight pediatric patients were on this flight, four with critical injuries. Additionally, volunteers participated in the Haitian medical evacuations and provided medical assistance to 72 patients received via airlift and assisted in the triaging of patients at a Haiti repatriation center. Further, the program collaborated with MRC to develop joint messaging and conduct joint conference calls with local MRC and state ESAR-VHP program coordinators to provide updates during the response effort.

In FY 2010, the ESAR-VHP program launched a recruitment initiative to elevate the awareness of the ESAR-VHP program and encourage health professionals to register for ESAR-VHP in their states. The program launched a national website to create a central location for potential volunteers to learn about ESAR-VHP. Also, the purpose of the site is to drive potential volunteers to the state websites for registration, provide a central location for social media (i.e., Twitter, Facebook, YouTube) to facilitate interest in the program, and to create a central location for potential partners and employers. The program provided technical assistance to the state ESAR-VHP programs by developing marketing and outreach resources, such as logos, program and individual volunteer testimonial videos, a customizable brochure, and newsletter and public service announcement templates.

During FY 2011, the ESAR-VHP program is working with State representatives, stakeholders, and subject matter experts to develop a series of documents that will define and clarify policies and procedures required of state and territorial ESAR-VHP programs, including activation and deployment protocols, training, collaboration with other volunteer and ESF #8 entities and sustainability. The program is continuing efforts to implement an approach to meet Section 303 of PAHPA to link existing state systems to maintain a single national interoperable network of systems. The program is continuing efforts to support the integration of local MRC programs and state ESAR-VHP programs to develop a unified and systematic approach for resources, to improve the health, safety, and resiliency of local communities, states, and the Nation in public health and medical emergency responses.

In FY 2011, the program will fund the existing state and territorial ESAR-VHP grants. Priorities for these grants are:

- Meeting the compliance requirements;
- Implementing the ESAR-VHP Guidelines;
- Integration of local MRC resources and state ESAR-VHP programs; and
- Training and exercises.

ESAR-VHP will continue its partnership with NDMS, OFRD, and MRC to facilitate the 2011 Integrated Training Summit and will support the attendance of up to 62 state and territorial ESAR-VHP participants. These groups work together to provide Federal, state, and local resources and assistance, and this training summit provides the unique opportunity for ESAR-

VHP coordinators to meet, share information, network with their counterparts, discuss program issues, and share promising practices and lessons learned. Federal and state ESAR-VHP programs will participate in national and regional level exercises. The program is continuing outreach activities to raise public awareness of the national ESAR-VHP program and state registries and recruit and direct potential health professional volunteers to the state ESAR-VHP web sites to register to become volunteers.

Funding History:

FY 2007	$3,802,000
FY 2008	$3,733,000
FY 2009	$5,842,000
FY 2010	$5,841,000
FY 2011 CR	$5,842,000

Budget Request:

The FY 2012 request includes $5,000,000 for ESAR-VHP, a -$841,000 decrease below the FY 2010 enacted level. Funding will be used to support the existing state and territorial ESAR-VHP grants, state access to national data sources for credentials verification, and the participation of state and territorial ESAR-VHP personnel in the Integrated Training Summit. Participation in ASPR-coordinated exercises will provide an opportunity to exercise the federal protocol for mobilizing civilian volunteers, test and improve the capability of state ESAR-VHP programs to respond to disasters and public health emergencies, and improve federal and state coordination. In FY 2012, funding for ESAR-VHP will also be used to support contracts which provide technical assistance to the state and territorial ESAR-VHP programs.
.

Outcomes and Outputs:

See Hospital Preparedness section – measure 2.4.2.I in HPP Section.

Grant Awards Table:

ESAR-VIP:

(whole dollars)	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget
Number of Awards	25	24	23
Average Award	$151,799	$150,947	$146,358
Range of Awards	$53,414 - $200,000	$58,478 - $200,000	$58,478 - $200,000

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 + / - FY 2010
Budget Authority	$9,998,000	$10,000,000	$5,000,000	-$4,998,000
FTE	0	1	3	+3

Allocation Method: Competitive grant/cooperative agreement; direct federal/intramural; contracts

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

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

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

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

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

capacity. Section 2 of the EO tasks HHS and USPS to develop a concept of operations and national postal model for other cities interested in utilizing a residential delivery system through the USPS to deliver medical countermeasures for a biological attack.

ASPR has entered into a Memorandum of Understanding that established a Joint Program Enterprise (JPE) to coordinate the collaboration with local municipalities who have made the decision to integrate the Postal capability into their Strategic Security Plans (SSP). The JPE has worked closely with Minneapolis-St. Paul to further develop and test the operational capability in this municipality. There are currently 378 US postal workers who could be called upon to deliver antibiotics to 20 zip codes in Minneapolis-St. Paul should that city experience an anthrax attack. To assure the readiness of the postal workers to respond, they have been screened and "fit tested" for personal protect equipment, they and their family members have been given "Medkits" of antibiotics to keep at work and in their homes to assure their safety should they be asked to deliver antibiotics to the residents of Minneapolis-St. Paul. These home Medkits must be replaced every year and the postal workers and their families must be screened again by medical providers if there have been changes to their status. This "refresh" of the home Medkits is underway and will be completed by the end of January 2011. A table top exercise was conducted January 2011 and a full scale exercise is planned for Spring 2011. Conducting robust exercises ensures the postal workers will be able to perform this operational capability if needed.

The lessons learned from the implementation of the postal option in Minneapolis-St. Paul served as the basis for a national model that clearly identifies the requirements necessary for new cities who wish to implement the postal option. Planning meetings have begun with Louisville, KY who is interested in serving as a second pilot site. Additionally, through stakeholder engagement activities, a number of additional cities have expressed interest in the program including New York City, Washington DC, Chicago, Philadelphia, and Boston. Funds have been set aside to support funding a cooperative agreement for five new municipalities and one full scale exercise.

Work is being done to create a program infrastructure that will support new cities who wish to implement the postal option. These infrastructures include:

- Creating databases to roster the postal workers and track their health records;
- Establishing procedures to do screening and fit testing for personal protective equipment;
- Streamlining procedures for health screening for the workers and their families to determine whether they can take the antibiotics that are included in the home Medkits;
- Streamlining processes for prescribing, packaging and delivering the home Medkits;
- Developing a cooperative agreement for municipalities to request funds to support development and testing of their capability; and
- Creating standardized exercise templates to test the effectiveness of the program across municipalities.

Additional cities will be enrolled once the infrastructures have been fully established. Continuing and sustainment costs will dictate the number of cities that can be enrolled each year. Sustainment includes annually refreshing the home Medkits, recruiting new postal workers to replace those who drop out of the program, annual exercises to maintain operational readiness and updating operational plans based on the lessons observed during the exercises.

Funding History:

FY 2007	--
FY 2008	--
FY 2009	--
FY 2010	$9,998,000
FY 2011 CR	$10,000,000

Budget Request:

The FY 2012 request for the Medical Countermeasure Dispensing program is $5,000,000, a -$4,998,000 decrease below FY 2010. Funding continues to be requested with two-year availability. Funds requested will seek to continue to expand the initial conceptual program to develop a federal "first strike" capability for direct residential delivery of medical countermeasures using the USPS in other interested state and local municipalities. This postal capability is envisioned to support the initial mass dispensing of antibiotics throughout a large metropolitan area during a catastrophic incident, specifically the outdoor release of a biological agent such as the anthrax germ. The overall objective achieved by the USPS component would be to begin the development of a "first strike" capability that can dispense and deliver antibiotics in designated zip codes in up to four metropolitan statistical areas per year. The presence of a carrier volunteer strike capability would allow dispensing and delivery to be initiated within hours of a notification of an aerosolized anthrax attack and in advance of the points of dispensing (PODs) providing inventory from the Strategic National Stockpile (SNS) to broader exposed populations.

Continued funding will support building of information technology infrastructure for tracking postal worker volunteers and for tracking health safety data such as medical screening for antibiotics and fit testing for N95 masks. Exercises will test concepts and best practices for the Postal Model for each interested city. Following the exercise, courses of corrective action will be developed to ensure deficiencies identified in the exercise are corrected.

In FY 2012, OPEO will adjust the target to two cities participating in the program. As cities join the program, there will be sustainment costs to maintain their readiness (e.g., doing annual exercises, replacing medkits, keeping rosters up to date, etc). Given the sustainment and continuing costs, there will be limits to bringing new cities into the program because an increasing percentage of the annual amount will be required to sustain the existing cities' operational readiness. OPEO realizes there is a significant investment required of cities to join the program, and has established a cooperative agreement funding opportunity so interested cities can apply to participate in the program. Successful applicants will receive up to $50,000 for achieving specific milestones for program development. With successful completion of the phase one program development deliverables the cities will be eligible to apply for funding to complete a full scale exercise. Also, as required in the Executive Order, ASPR is working with other federal partners to see which of them may also have medical countermeasure dispensing capabilities for rapid deployment.

Outcomes and Outputs:

Long Term Objective: *Enhance State and Local Preparedness*

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.10: Expansion of the Cities Readiness Initiative USPS Strike Teams in up to 15 cities (Outcome)	One city is operational (Minneapolis-St. Paul, MN) while one city is still planning (Louisville, KY). Activity is continuing.	4 cities	2 cities	-2

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 + / - FY 2010
Program Level	$320,111,000	$320,167,000	$765,000,000	+$444,889,000
Advanced Research and Development (non-add)	*$274,356,000*	*$274,356,000*	*$600,000,000*	*+$325,644,000*
Strategic Investor (non-add)	--	--	*$100,000,000*	*+$100,000,000*
BARDA Operations (non-add)	*$45,755,000*	*$45,811,000*	*$65,000,000*	*+$19,245,000*
FTE	79	103	157	+78

NOTE: The FY 2012 Budget for the Biomedical Advanced Research and Development Authority proposes to consolidate funding previously requested separately for Advanced Research and Development including management activities, Project BioShield Management, and Pandemic Influenza management. This was also proposed in the FY 2011 President's Budget. Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices. In FY 201, funding for BARDA is offset by the BioShield Special Reserve Fund and includes $3.7 million for advanced development related acquisition and administrative support now managed centrally as a result of the March 2010 ASPR reorganization. FY 10 and FY 11 funding is adjusted comparably.

Allocation Method: Direct Federal/intramural; contracts; grants

Program Description and Accomplishments:

History and Mission

The mission of the Biomedical Advanced Research and Development Authority (BARDA) is to provide medical countermeasures that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases. As an office within ASPR, BARDA also aligns with the ASPR mission to "Lead the Nation in preventing, preparing for and responding to the adverse health effects of public health emergencies and disasters."

BARDA was established by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA; PL 109-417). Title IV of PAHPA established BARDA as an office within the Department with the goal of accelerating the development of medical countermeasures (MCMs). BARDA fulfills its mission by supporting advanced research and development, working in collaboration with manufacturers, developing regulatory strategies with the Food and Drug Administration (FDA), and by supporting innovation in technologies and strategic initiatives.

BARDA was created to fill an existing gap in the Federal government MCM enterprise—advanced development and innovation of countermeasures. BARDA facilitates the transition of promising MCM candidates from early development through advanced development. BARDA funding supports activities such as industrialization, clinical testing, scaling-up of manufacturing for commercial production, FDA regulatory review and procurement and stockpiling. BARDA

bridges the proverbial "valley of death" that separates product discovery and early development from advanced development and potential FDA licensure by providing funding and technical support necessary to advance candidate products through the developmental pipeline.

In August 2010, HHS released the Department's *Public Health Emergency Medical Countermeasures Enterprise Review*, a document designed to evaluate the policies and processes required to develop a product through research and development to acquisition and stockpiling. Recognizing the integral role BARDA plays in transitioning prospective MCMs from the lab bench to the marketplace, the MCM review recommended two new initiatives that BARDA will lead: (1) fostering flexible manufacturing and advanced development core service partnerships that focus on new platforms for novel product development and manufacturing by establishing Centers of Innovation for Advanced Development and Manufacturing; and (2) expanding the product pipeline by exploiting new concepts emerging from the science base and addressing multi-purpose potential for these products for preparedness and everyday healthcare.

Medical Countermeasure Strategic Investor
Plans for a third initiative, referred to as the Medical Countermeasure Strategic Investor, are under development to assist government by serving in the role as an independent but government-sponsored program to provide both financial support and business expertise to newly emerging businesses in the biodefense sector similar to other venture capitalist endeavors undertaken by the USG. The Strategic Investor concept will seek companies that have technologies which will be both successful commercially but also serve to develop specific government-required products.

Coordination across the Medical Countermeasure Enterprise
As mandated by PAHPA, BARDA facilitates collaboration with stakeholders in Federal, State, and local governments, industry, and academia, in order to promote innovation to reduce time and cost of medical countermeasures development, production, distribution, and stockpiling. To foster MCM development among its partners, BARDA provides core services including regulatory and quality systems guidance and technical expertise in advanced development and manufacturing of products for product innovators. ASPR is responsible for coordinating the activities of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). The PHEMCE is composed of HHS operating and staff divisions and intergovernmental partners including the Departments of Defense, Homeland Security, Veterans Affairs, and Agriculture. PHEMCE engages in activities relative to MCMs that include: threat detection, research and development, acquisition and stockpiling, distribution, and utilization.

In March 2007, the PHEMCE released the *Public Health Emergency Medical Countermeasures Enterprise Strategy for CBRN Threats*. In April 2007, the PHEMCE identified top priorities for the advanced development and acquisition of medical countermeasures for CBRN threats based on principles established in Homeland Security Presidential Directive - 18, the *National Strategy for Medical Countermeasures against Weapons of Mass Destruction*, and the goals and framework for priority-setting detailed in the *PHEMCE Strategy*. Goals set forth in the 2005 *National Strategy for Pandemic Influenza* and the 2009 *Executive Order on Medical Countermeasures Following a Biological Attack* also guide BARDA interactions and partnerships.

The August 2010 release of the HHS *Public Health Emergency Medical Countermeasures Enterprise Review* and the President's Council of Advisors on Science and Technology (PCAST) *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* are the most recent documents that articulate the short- and long-term priorities of the PHEMCE and BARDA's roles and responsibilities within it.

Chemical, Biological, Radiological, and Nuclear Threats
In FY 2009, BARDA issued its first Broad Agency Announcement (BAA) for CBRN medical countermeasures to support the advanced research and development of products against priority threats. In this BAA, special instructions were issued for anthrax vaccines, anthrax antitoxins and countermeasures for skin and lung injury associated with acute radiation syndrome (ARS). Also, a request for proposals was posted for neutropenia associated with ARS, and a BAA was posted for the development of bioassays to detect exposure levels after a nuclear or radiological event. In FY 2010, BARDA renewed the BAA for CBRN medical countermeasures and issued special instructions that established a broad spectrum antimicrobial program within BARDA. This program will address critical issues in effective countermeasures against current and future bioterrorist threats and emerging infectious diseases. In subsequent fiscal years this BAA will continue to assist BARDA in identifying candidate projects for advanced development commensurate with the MCM Review.

BARDA continues to support the development of medical countermeasures against CBRN threats. In the anthrax portfolio, BARDA supports the expansion of the domestic manufacturing capacity for the only currently licensed vaccine, anthrax vaccine absorbed, and continued support of the advanced development of three next-generation anthrax rPA vaccine candidates in FY 2010. Under the CBRN BAA, ten contracts were awarded in FY 2010 to develop biodosimetry devices. These awards are managed under new oversight and decision practices including HHS' interagency in-process review (IPR) that evaluate progress and determine whether funding should continue. The IPRs provide the best value to the government by rewarding high-level performance and product potential, and quickly discarding products that do meet performance and product specification criteria, while allowing development of many candidates. To support advanced research and development of medical countermeasures for neutropenia associated with acute radiation syndrome, BARDA awarded new contracts in FY 2010. Additionally, BARDA awarded two contracts in FY 2011 for product candidates that may used to treat lung and skin injury associated with acute radiation syndrome. Lastly, BARDA exercised an option on the advanced development contract with Bavarian Nordic to support vaccine formulation studies that may lead to longer shelf life, lower cold chain storage and delivery costs, and simplify vaccine deployment for safer smallpox vaccines.

BARDA continues to work within the HHS and USG Interagency process via Interagency Agreements (IAAs) to support research studies that enable MCM development and strengthen the overall product pipeline. These efforts help to diversify the breadth of work supporting medical countermeasure development while managing the portfolios centrally.

Multi-purpose Products
Addressing the lack of effective medical countermeasures against emerging infectious diseases is another priority of the Federal government. As demonstrated by consolidation of the pharmaceutical industry and by a general decline in the number of new drug products, commercial market incentives are no longer driving a robust antimicrobial development pipeline, further requiring government initiative to ensure that the system operates in the public interest. BARDA's role is to ensure progress through the critical development and manufacturing phases of the enterprise. In collaboration with NIH, CDC, and FDA, BARDA pursues this role in a two-phase coordinated strategy on countering antimicrobial resistance, comprised of: (1) funding the acceleration of new antimicrobial product pipelines, and (2) supporting advanced development of other products for high-priority microbial pathogens. In August 2010, BARDA awarded the first contract under its broad spectrum antimicrobial program for the advanced development of a new cephalosporin against plague and tularemia. The product will also be evaluated as a potential treatment against hospital-acquired pneumonia and urinary tract infections. In addition, this marks the first CBRN MCM supported by BARDA that has direct multi-purpose potential for biothreat preparedness and routine healthcare.

Product Innovation
In FY 2009, BARDA formally addressed the PAHPA mandate to foster product innovation by establishing an Innovations Program. The program was designed to identify and support novel technologies that can improve the nation's ability to manufacture, test, and utilize medical countermeasures, as part of a public health emergency response. The focus of the BARDA Innovations Program was to facilitate the development of technologies that accelerate the development pipeline and make the manufacturing process more flexible by emphasizing platform and broad-spectrum approaches. The program awarded eight contracts in FY 2010 through a Broad Agency Announcement. Among others these projects included: the development of new lot release product sterility assays for vaccines, the optimization of high-production vaccine virus seed strains for influenza, and *in vitro* immunity testing. These are initiatives that were called for in both the MCM review and the PCAST report on Pandemic Influenza Vaccine Production. Efforts will be prioritized to focus on innovation of existing products that can modulate host immunity to provide broad spectrum therapeutic or prophylactic value in the face of known or unknown biothreats.

Animal Studies
In FY 2011, BARDA awarded the first contracts to establish a network of contractors that can perform Current Good Laboratory Practices (cGLP) studies to refine current animal models and create new models to understand better the pathogenesis and product efficacy. Animal challenge models will be developed and utilized in support of CBRN MCMs to fulfill the FDA's Animal Rule requirements. These studies will be coordinated with programs at NIH and DoD and in consultation with FDA and CDC. FY 2012 will see expansion of this network and testing of prioritized MCMs and threat agents.

Efficient Use of Advanced Research and Development Funding
BARDA obligated $500 million of Advanced Research and Development funding in FY 2010, including carry-over funding from FY 2009, and $3 million remained from its FY 2010

appropriations as carryover at the beginning of FY 2011. This demonstrated the availability of promising candidate products to support and the increased performance of BARDA to solicit, review, and award contracts for these products in a timely manner.

Project BioShield and the Special Reserve Fund
BARDA continued its management of Project BioShield. The purpose of Project BioShield was to accelerate the research, development, purchase and availability of effective medical countermeasures against CBRN agents. In FY 2004, Congress appropriated a total of $5.6 billion to establish Project BioShieldto support late-stage development and acquisitions of CBRN medical countermeasures. To date, contracts have been awarded for medical countermeasures for anthrax, botulism, smallpox, and radiological/nuclear exposure. The availability of smallpox vaccines for immunocompromised individuals in the U.S. was realized in FY 2010, as Bavarian Nordic delivered the first doses of MVA smallpox vaccine developed and manufactured under a Project BioShield contract with BARDA to the Strategic National Stockpile. These deliveries highlighted the successful partnership between the U.S. Government and industry. This was the first Project BioShield contract to be awarded using milestone payments authorized under PAHPA. BARDA has an open solicitation under Project BioShield for late-stage development and acquisition of 1.7 million treatment courses of smallpox antiviral drugs. A Sources Sought Notification was issued in FY 2011 for the market analysis of products to treat neutropenia associated with acute radiation syndrome. This activity signaled BARDA's intent to issue a solicitation to support late-stage development and acquisition of anti-neutropenic drugs in FY 2011.

Pandemic Influenza
BARDA is also responsible for management of Pandemic Influenza MCM development, manufacturing infrastructure-building, and acquisition activities, including H5N1 and H1N1 related activities. Funding for Pandemic Influenza acquisitions and other programmatic activities is requested and appropriated separately.

In September 2010, BARDA issued its much-anticipated new contract for $6.4 million to develop a next-generation ventilator for all-hazards preparedness, including pandemic influenza. The new ventilators are expected to be less expensive, easier to operate by nonprofessionals, more portable, and universally-compatible with equipment parts. This award was made using BARDA (ARD) funding. These ventilators will also satisfy a similar requirement for treating botulism intoxication from a bioterrorist-related event.

Funding History:

FY 2007	$113,905,000
FY 2008	$110,875,000
FY 2009	$285,688,000
FY 2010	$320,111,000
FY 2011 CR	$320,167,000

Budget Request:

The FY 2012 request for the Biomedical Advanced Research and Development Authority (BARDA) is $665,000,000; an increase of +$344,889,000 over the FY 2010 level. In addition, the request includes up to $100,000,000 to finance the new Strategic Investor entity. Both of these requests are financed by making funds from the Project BioShield Special Reserve Fund available for BioShield procurements advanced development contracts, and the MCM Strategic Investor.

Advanced Research and Development Activities
Funding in FY 2012 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 and utilization prior to, during, and after CBRN threat events. Funds will support the advanced development of the highest priority medical countermeasures among the twelve biological threat agents and radiological or nuclear threats identified in the *PHEMCE Strategy and Implementation Plans* and the Secretary's MCM review conducted by the ASPR. BARDA will manage the advanced research and development of promising MCM products from proof-of-concept Phase 1 clinical studies and scale-up process manufacturing development and validation through Phase 2 and 3 human safety clinical studies and animal challenge and efficacy studies, to become eligible for consideration for use during a declared emergency and towards FDA approval.

Specifically, funding requested at this level will support continued advanced development of anthrax vaccine candidates and anthrax polyclonal and monoclonal antitoxins on new and existing BARDA contracts. The funding will allow candidate anthrax vaccines and therapeutics under development to progress toward licensure, thus increasing preparedness for a high-priority threat. In addition, funding is being requested to increase manufacturing capacity for the currently licensed vaccine, bringing the Federal government closer to the goal of acquiring enough anthrax vaccine to protect 25 million people.

Funding will support the advanced development of therapeutics under existing BARDA contracts to address illnesses associated with acute radiation syndrome. This funding level will support additional development of some, but not all, therapeutic candidate products in BARDA's widely-diverse product pipeline for the six illnesses resulting from injuries from radiological and/or nuclear events. Funds will also allow for further development of physical biodosimetry devices to measure radiation exposure during an event. Finally the funds would be used to collect additional clinical data to support an expanded FDA indication for Prussian Blue, a treatment for radiological exposure.

Consistent with the MCM Review, funding is also requested for development of broad spectrum antimicrobial drugs to treat infections resulting from biothreats such as anthrax, plague, and tularemia, especially enhanced antibiotic-resistant forms of these bacterial threat agents. Funding will support further product development of antibiotic candidates primarily under existing NIH, National Institute of Allergies and Infectious Diseases, Department of Defense, or BARDA contracts. Funds will also support the development of broad spectrum antiviral agents. An increase in funding will allow for development of additional candidates as well as continued

funding for those identified in FY 2010 and FY 2011, which will have increased costs associated with advanced development in the out-years.

Funding will continue support of BARDA's Innovation Program to promote innovation of medical countermeasures and diagnostics having all-hazards or multi-purpose potential. Funding in FY 2012 will support existing and new projects that improve existing products, manufacturing processes, or testing. Support is sought for funding in the same major areas—acceleration of candidate vaccine and therapeutic evaluation; formulation chemistry, protein stabilization, and vaccine delivery technologies; and innovative methods in bioprocess development and manufacturing. In FY 2012 the Innovation Program will continue to make existing products better including those used against known and unknown biothreats.

BARDA requests funding to complete the establishment of a network of contractors able to perform cGLP studies in animals to assess the safety and efficacy of MCMs to treat or prevent the medical consequences of CBRN agents in fulfillment of FDA's Animal Rule requirements. The FY 2012 goal will be the completion of contract awarding and initiation of animal challenge studies.

The requested funding increase will support the initial operational costs incurred at the new Centers of Innovation for Advanced Development and Manufacturing (ADM) that have become operational. This new MCM initiative establishes public-private partnerships that build, maintain, and operate U.S.-based facilities for development and manufacturing of vaccines and biologics to counter CBRN threats and known and unknown emerging infectious diseases, including 2009 H1N1 influenza pandemic. The ADM program addresses national domestic vaccine production surge capacity needs in an emergency for pandemic influenza and known and unknown infectious diseases, and provides much needed advanced development and manufacturing core services to government-supported CBRN vaccine and biological product candidates on a routine day-to-day basis. The funding request will cover the operational expenses incurred for core services towards advanced development and manufacturing CBRN MCMs in one or more of these facilities as they come on line in FY 2012.

Advanced research and development programs have an increased cost as they progress through the development pipeline. The increased funding level requested for FY 2012 will provide BARDA with the ability to maintain programs initiated in previous years. BARDA's strategic goals are to establish and maintain a robust and replete pipeline of candidates for threats that include anthrax, radiological and nuclear, chemical, broad spectrum antimicrobials, diagnostics and innovation and a domestic development and manufacturing MCM capability to respond nimbly and effectively in an event. In addition to fully funding those contracts awarded in prior years, this increased funding will allow BARDA to initiate new projects within existing programs, and to replace those that have been down-selected in a particular threat area to maintain a robust pipeline. Industry standards recommend at least five products in phase I clinical studies to have a 90% probability of success for achieving one licensed product. BARDA will need to maintain this level of effort to develop licensed products for high priority threat areas. It should be emphasized that progression of the programs to the next technology readiness level (TRL) may not be appropriate metrics for all programs. Those programs funded under ARD may require multiple years within a particular TRL as clinical studies and advances

in manufacturing will require multiple years of development to achieve the advances necessary to potentially transition the programs to Project BioShield funding and acquisition.

Strategic Investor

Often, the companies who control promising technologies struggle, or fail, due to an inability to attract capital or they lack the appropriate business skills and knowledge to complete product development. The MCM Review stressed that a new approach was needed to support not only the technical aspects of MCM product development, but also the business needs of nascent companies seeking to develop products for the commercial market. Following from the MCM review, HHS is also requesting the authority to establish a Medical Countermeasures Strategic Investor. The Strategic Investor (SI) would operate in a similar, but not necessarily identical fashion to how a venture capital organization operates in the investment community, by looking for promising businesses that can return greater value to the investor through the initial capital and knowledge provided to the business through the investment. The SI would be provided public funds, but would operate independently of the government, as a non-profit organization, such as within the 501(c)3 framework. HHS would inform the SI of its specific program or product needs, but it is the role of the SI then to address all aspects of meeting those programmatic needs in an independent fashion.

The SI initiative will provide both financial and business support to companies who either are pursuing the development of products that directly address the U.S. government needs for medical products against biological, chemical, radiological, nuclear and pandemic disease threats, or who are creating a novel technology that could be adapted for these public health threats. The SI will be designed to invest in companies that have a viable commercial future. It will serve as a professional scouting or "informed consumer" capability for the Federal government, looking for best value, and interacting with these companies in ways that the Federal government could not function. In addition to financial support, the SI will provide these companies with the necessary business acumen to develop their promising technology into a marketable product. The connectivity between the SI and the federal sponsor generally would occur through a coordinating manager or unit within the government, who would transmit government's requirements and would receive information in return regarding the status of the effort toward the government's objectives.

Outcomes and Outputs:

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.4: Support development and innovation of candidate medical countermeasures for CBRN threats to facilitate their eligibility for procurement under Project BioShield. (Outcome)	FY 2010: See below. (Target Met)	Targets, which may be addressed by contract awards in FY10 from BAA for CBRN MCM AD, include anthrax, acute radiation syndrome, and biothreats including enhanced agents such as antibiotic-resistant forms of anthrax, plaque, and tularemia.	See specific targets by countermeasure area below.	N/A
2.4.4.A: Anthrax (vaccines, therapeutics, and Medkits) (Outcome)	FY 2010: BARDA awarded multiple contracts in FY10 supporting development of third generation anthrax vaccines to prevent anthrax and therapeutic monoclonal antibody to treat anthrax. BARDA awarded 3 contracts in FY10 for advanced development of new and existing anthrax rPA vaccine candidates and 1 contract for promising broad spectrum antibiotics for treatment of anthrax, plague and tularemia. Additionally, a contract in FY10 was awarded to support expanding domestic manufacturing capacity for existing licensed anthrax vaccine production and product testing. (Target Met)	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.	Progress anthrax therapeutic programs, continue to support program to expand domestic manufacturing capacity of AVA, initiate phase I clinical study for anthrax vaccine enhancement and dose-sparing studies programs, and continue to fund rPA anthrax vaccine programs.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.4.B: Radiation (Outcome)	FY 2010: BARDA awarded multiple contracts in FY10 supporting development of biomarker and biodosimetry devices to measure radiation exposure (10 contracts). BARDA awarded a single contract in FY10 for advanced development of therapeutics to treat neutropenia and continued funding on numerous awards made in previous years. Awards for cutaneous skin afflictions and pulmonary illnesses associated with acute radiation exposure were delayed to FY 2011 due to lack of funding. (Target Met)	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.	Continue to fund biodosimetry programs deemed appropriate after USG internal review. Award 1-2 new contracts for biodosimetry programs to expand pipeline of products, continue to fund programs for neutropenia, skin and lung injury associated with ARS. Award 2-3 new contracts for development of products for neutropenia, skin and lung injury associated with ARS to expand product pipeline.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.4.C: Broad Spectrum Antimicrobial (BSA) (Outcome)	FY 2010: BARDA awarded a new contract and supported an existing contract (gentamicin) in FY10 for advanced development of promising broad spectrum antibiotics for treatment of anthrax, plague and tularemia. (Target Met)	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.	Continue funding development of BSA programs awarded in previous years. Award 1-2 new contracts for BSA to expand the development pipeline.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.4.D: Innovation (Outcome)	FY 2010: BARDA awarded seven new contracts for the innovation of products to facilitate measurement of host immune competency for vaccines, to evaluate the effects of several novel adjuvants on the immunogenicity of anthrax vaccines, to evaluate new platform expression systems for commercial scale antigen production, and new rapid diagnostic methods for broad spectrum antimicrobial detection and assessment of drug resistance. (Target Met)	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.	Continue support of original contracts started in FY10-11 with down selection of poor performers, continued funding towards promising products, and continued focus on new projects on immune modulators.	N/A
2.4.4.E: Smallpox (Outcome)	FY 2010: BARDA awarded one contract to enhance smallpox vaccine for at-risk individuals. (Target Met)	Continue funding ARD program and ensure no overlap with scope of work for potential SRF award(s).	Continue funding development of programs awarded in previous years. Initiate phase I clinical study of smallpox vaccine enhancement program.	N/A
2.4.4.F: Viral Hemorrhagic Fevers (Outcome)	FY 2010: BAA issued in FY09, and white paper proposals were under technical review. (Target Met)	No new activity.	No new starts, programs are too immature for ARD	N/A
2.4.4.G: Botulism (Outcome)	FY 2009: BAA issued in FY09, and white paper proposals were under technical review. (Target Met)	No new activity.	Continue to support development of programs initiated in FY 2011. No new starts.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.4.H: Chemical (Outcome)	FY 2010: BARDA continued to support an anticonvulsive drug as a chemical antidote. (Target Met)	No new activity.	Award 1-2 new contracts for development of MCMs to ameliorate the effects of exposure to chemical agents.	N/A
2.4.4.J: Bioproduction Facility (Outcome)	FY 2010: BARDA issued a draft solicitation in FY10 for the establishment of Centers of Innovation for Advanced Development and Manufacturing. (Target Not Met)	Release RFP for concept design for multipurpose use manufacturing facility.	(1) Award contracts to establish Centers of Innovation for Advanced Development and Manufacturing; (2) Monitor construction and/or renovation of facilities. (3) Select and match CBRN MCM candidates for assistance in the Centers of Innovation for Advanced Development and Manufacturing pending operational status of the facilities; (4) Determine timelines for facility operation and manufacturing capacities of pandemic influenza vaccines.	N/A

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.4.I: Animal Studies (Outcome)	N/A	N/A	Award more contracts for development of animal challenge models for CBRN MCMs and implement testing of MCMs to Contractors for safety and efficacy against prioritized CBRN agents.	N/A
2.4.13: Increase the number of new CBRN and emerging infectious disease medical countermeasures under EUA or licensed (Outcome)	FY 2010: N/A (Target Met)	N/A	Annual targets under development. FY 2015 targets are: CBRN Licensed=4; EUA=2; Pan Flu/EID Licensed=5; EUA=3	N/A

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 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.5: Deliver licensed, licensable and approvable top priority medical countermeasures for chemical, biological, radiological and nuclear threats. (Outcome)	FY 2010: Continued deliveries of MVA, Raxibacumab, h-BAT and AIG products to the SNS. BARDA was unable to award a contract for the development and acquisition of smallpox antivirals due to a protest that delayed the potential award. Additional funding will be directed to anthrax and botulinum antitoxins. (Target Not Met)	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. Initiate delivery of additional doses of Raxibacumab if contract is awarded. Issues procurement RFP for ARS associated neutropenia. Programs will have been in ARD for approximately two years and have the potential to transition to procurement contracts. Release RFP for procurement of anthrax antitoxins.	Continue deliveries of MVA, Raxibacumab, h-BAT and AIG to the SNS. Award contract for development and procurement of candidate products for neutropenia associated with ARS.	N/A

Office of the Assistant Secretary for Preparedness and Response
Office of Policy and Planning

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	$19,008,000	$19,010,000	$15,708,000	-$3,300,000
FTE	47	50	51	+4

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices.

Allocation Methods: Formula grant/cooperative agreement; direct federal/intramural; contracts

Program Description and Accomplishments:

In 2010, the ASPR consolidated its policy functions (e.g., Office of Policy, Strategic Planning and Communications; Office of Medicine, Science and Public Health; Office of At-Risk Individuals, Behavioral Health, and Human Services Coordination; and Office of Medical Countermeasure Policy, Planning and Requirements) in the newly established Office of Policy and Planning (OPP). OPP advises the ASPR on policy options and strategic planning to support domestic and international public health emergency preparedness and response activities. OPP provides both in-house subject matter expertise and coordination of HHS-wide and U.S. Government stakeholders to bolster health security-related policy and planning efforts and support implementation of the *National Health Security Strategy* (NHSS) objectives. This includes the coordination, analysis and implementation of relevant laws (e.g., Pandemic and All-Hazards Preparedness Act (PAHPA); Public Readiness and Emergency Preparedness Act; Project BioShield Act), proposed policies, Presidential Directives, Executive Orders, regulations, and the development of requirements for medical countermeasure research, development and acquisitions.

In December 2009, the Department issued its first quadrennial NHSS as called for in PAHPA. The NHSS represents the Department's first comprehensive strategy focusing specifically on the Nation's goal of protecting the health of the public in the case of an emergency. The purpose of the NHSS is to guide the Nation's efforts to minimize the risks associated with a wide range of potential large-scale incidents that put the health and well-being of the U.S. population at risk, whether at home, in the workplace, or in any other setting. In this context, national health security is achieved when the Nation and its people are prepared for, protected from, and are able to respond effectively to and recover from public health emergencies. OPP uses the NHSS as its primary strategic guide for public health emergency preparedness and response policy development, and uses a science-based and risk-informed process to shape policies when recommending priorities for national health security. The two overarching goals of the NHSS are to build community resilience, and strengthen and sustain health and emergency response systems.

OPP helps oversee and coordinate the implementation of NHSS, which takes a "systems approach" to health in recognizing that many interrelated systems are needed to support the

health of individuals and communities and to protect them from and support their recovery after an incident. These include, but are not limited to, traditional health care and public health systems. They also include systems that address elements essential to maintaining public health, such as water, food, housing, the environment, and access to health care. In addition to its policy and planning responsibilities, OPP manages a variety of other functions. OPP leads international programs and initiatives to enhance U.S. cross-border and global public health emergency preparedness and response activities. In support of NHSS objectives, OPP incorporates post-incident health recovery into planning and response, working with cross-border and global partners to enhance national, continental, and global health security, in support of the Administration's Global Health Security Initiative. OPP supports implementation of the White House National Security Staff's *National Strategy for Countering Biological Threats* and coordinates HHS-wide implementation of this Strategy's objectives and reporting. OPP coordinates the transparency, participation, and collaboration of HHS under the Biological and Toxin Weapons Convention (BWC), on the foundation built by the *National Strategy for Countering Biological Threats* and the President's Open Government Directive. On behalf of the Secretary and the ASPR, OPP provides coordination, management, and operational services for the National Biodefense Science Board (NBSB). Furthermore, OPP provides its partners, stakeholders, and response assets with education and guidance to assist with the implementation of policies and practices addressing the functional needs of at-risk individuals (including children), the behavioral health needs of disaster survivors and responders, and community resilience. In addition, OPP provides policy and strategic direction for the NHSS objective to promote an effective medical countermeasure enterprise.

OPP's recent accomplishments include:

- Leading the interagency development of *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* (released October 2010), which aims to minimize the risk that unauthorized individuals will gain access to biological agents of concern through the use of nucleic acid synthesis technology;
- Coordinating HHS participation in the annual Confidence Building Measures reporting under the Biological and Toxin Weapons Convention (BWC), posted publicly online for the first time in 2010;
- Providing technical assistance and coordination to implement a behavioral health workforce protection and stress management framework for HHS responders deployed to the Haiti 2010 earthquake event. The framework included medical and behavioral health in-briefings, in-theater support, out-briefings for deployed staff, and stress management materials disseminated in partnership with SAMHSA and CDC;
- Producing several videos/Webcasts to provide education and guidance to assist with the implementation of policies and practices addressing at-risk individuals, behavioral health, and community resilience, including Functional Needs of At-Risk Individuals and Communication, Medical Care, Independence, Supervision and Transportation (6/2010), and Behavioral Health and Community Resilience (6/2010);
- Developing of medical countermeasure requirements to address chemical, biological, radiological and nuclear threats;

- Coordinating the Deepwater Horizon oil spill HHS policy process, the HHS' Chapter for the White House Deepwater Horizon recovery plan, and an Institute of Medicine workshop on the health effects of the oil spill;
- Establishing of the Federal Experts Security Advisory Panel, together with USDA, as directed by *Executive Order 13546:* "*Optimizing the Security of Select Agents and Toxins in the United States,*" and developing recommendations for the designation of Tier 1 biological select agents and toxins (BSAT), the establishment of practices to ensure reliability of personnel with access to Tier 1 BSAT, and the establishment of practices for physical and cyber security for facilities with Tier 1 BSAT;
- Developing the *HHS Implementation Plan* to support the objectives of the *National Strategy for Countering Biological Threats,* which is targeted to reduce biological threats by instituting a suite of coordinated activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences;
- Establishing the Interagency Biosafety and Biosecurity Outreach Working Group, within the National Science and Technology Council;
- Developing U.S. regional and national guidance and decision support tools on recovery and restoration after a large-area biological attack;
- Supporting the WHO Advisory Committee on Variola Virus Research, representing the U.S. Government on the Advisory Committee and facilitating communication and coordination with CDC and WHO to assure oversight of funded activities;
- Coordinating HHS support to U.S. Government policy development on BWC compliance and implementing United Nations Security Council Resolution 1540;
- Organizing, with the U.S. Department of Defense, two international workshops with tabletop exercises in Southern Caucasus and Eastern Europe, to improve regional and global partnerships in building international preparedness and response capacity;
- Coordinating the NBSB in delivering reports and recommendations related to disaster mental health, and the Department's efforts to develop and procure medical countermeasures;
- Obtaining key stakeholder input for medical countermeasure research, development, stockpiling and utilization through workshops, summits, and roundtable events;
- Coordinating ASPR and OGHA efforts to develop a Biosecurity Level 3 laboratory in Mexico City which will be part of the CDC's Laboratory Response Network;
- Convening the Roundtable on the National Health Security Strategy and At-Risk Individuals, Behavioral Health, and Community Resilience with a spectrum of federal, national, state, and local experts, public health stakeholders, and emergency planners;
- Co-chairing (with ACF) the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group with completion of the group's final report to the Secretary with recommendations for HHS to better address the disaster-related needs of children; and
- Convening and coordinating the HHS Disaster Behavioral Health Concept of Operations (DBH CONOPS) Working Group to develop a DBH CONOPS document for the Federal-level behavioral health response to disasters.

Funding History:

FY 2007	$11,761,000
FY 2008	$19,057,000
FY 2009	$18,877,000

FY 2010	$19,008,000
FY 2011 CR	$19,010,000

Budget Request:

The FY 2012 request for the Office of Policy and Planning is $15,708,000, a decrease of -$3,300,000 below FY 2010. The request will support the ASPR-wide infrastructure for domestic and international policy formulation, analysis, and coordination, though on a more limited basis due to a constrained budget environment.

The FY 2012 President's Budget proposes to eliminate funding for Early Warning Infectious Disease Surveillance System (EWIDS), which provides grant funding to U.S. border states. This program supported public health surveillance activities in U.S. border states including strengthening of epidemiological and public health infrastructure for early recognition of and prompt response to biological events; enhancement of laboratory-supported surveillance, diagnostics, and sharing of laboratory information systems for rapid outbreak management and disease control; and capacity-building, training, and education for the public health workforce including the identification of lessons-learned and best practices.

The request supports coordination and implementation of the NHSS. ASPR will coordinate the implementation of activities in the NHSS Biennial Implementation Plan (BIP) as well as activities identified in the HHS Implementation Plan to support the *National Strategy for Countering Biological Threats*. OPP will coordinate the HHS participation, collaboration, and transparency under the BWC, in accordance with the *National Strategy for Countering Biological Threats* and the Open Government Directive.

OPP will share with domestic and international partners ASPR's plans to support the promotion of and engagement in strategic bilateral and multilateral collaborations with and among international partners. ASPR will also manage international programs and collaborate with other U.S. Government Departments and Agencies to strengthen the capabilities and capacities of international partners and U.S. border states.

The request will allow ASPR to work closely with global partners to coordinate responses to international public health emergencies and to share information on suspected or confirmed public health threats. There is a need to establish and strengthen links with other countries and international organizations to enhance both our nation's health security and global health security by sharing and developing aligned preparedness plans and strengthening direct communications links that could be critical in coordinating responses to international public health emergencies. On the multilateral level, OPP will continue to support the U.S. Government's efforts to advance the universal values of the BWC in order to promote effective mechanisms to forge international cooperation for mitigating challenges that recognize no borders such as infectious diseases regardless of cause and for improving national public health systems and capabilities for disease surveillance, detection and diagnosis. OPP will ensure that a dialog on global health security is added to HHS's engagements at the World Health Assembly. The office will also coordinate U.S. participation in the Global Health Security Initiative (GHSI) and work with GHSI partners, specifically in the areas of global infrastructure for medical countermeasures; development of

protocols for responding to emergencies during mass-gathering events and exercises; international threat and risk assessment of biological agents (bioterrorism or natural disasters); international communication protocols during the uncertainty period of a public health emergency; and international assistance for International Health Regulations (IHR) implementation. At the bilateral level, OPP will continue to build key preparedness partnerships, in particular with countries where ASPR has helped to build capacity, including IHR core capacities, influenza surveillance, and vaccine manufacturing.

The request supports the NBSB, its five working groups, and its Subcommittee on Disaster Mental Health. Funding will ensure the NBSB has sufficient resources to hold the two public meetings required by PAHPA, as well as any additional public meetings that may be necessary, and support the inclusion of the public in the NBSB's deliberations prior to sending recommendations to the Secretary.

The request provides education and guidance to assist with the coordination and implementation of policies and practices addressing the functional needs of at-risk individuals (including children), behavioral health needs of disaster survivors and responders, and community resilience. ASPR will increase competencies and knowledge of its partners, stakeholders, and response assets regarding at-risk individuals, behavioral health, and community resilience by providing subject matter expertise to public health and medical planners and responders and sponsoring stakeholder outreach, education, listening sessions, and roundtables.

OPP supports the development of biosafety and biosecurity plans and mechanisms within HHS to implement recommendations from several U.S. government task forces and working groups. Funding will assist implementation of recommendations in the *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*, and the *Report of the Working Group on Strengthening the Biosecurity of the United States.* These funds will also help ASPR meet the objectives of the *National Strategy for Countering Biological Threats*, the July 2009 *Executive Order: Optimizing the Security of Select Agents and Toxins in the United States,* the *Screening Framework Guidance for Providers of Double-Stranded DNA,* and the December 2009 *Executive Order: Medical Countermeasures Following a Biological Attack*, and help address emerging infectious disease threats.

OPP provides policy direction for the MCM enterprise, and develops medical countermeasure strategies and requirements, a function that was moved to OPP from BARDA as part of the ASPR re-organization in 2010. OPP performs this mission with a combination of in-house science policy expertise and input from a broad range of subject matter experts to ensure that policies and requirements for medical countermeasure research, advanced development, and procurement will be based on sound scientific, medical, and epidemiological principles and will lead to the development and acquisition of medical countermeasures that can be effectively utilized following a public health emergency. The budget request supports an in-house staff with science policy expertise, and provides for outreach to key stakeholders through events such as the annual Enterprise Stakeholders Workshop and additional smaller roundtables and workshops.

Outcomes and Outputs:

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.9: Establish and improve awareness of the ASPR strategy for preparedness and response. (Outcome)	FY 2010: Participated in numerous national conferences and meetings to highlight the goals and objectives of the NHSS; produced several videos/Webcasts to provide education and guidance to assist with the implementation of policies and practices addressing at-risk individuals, behavioral health, and community resilience. Conducted several conference calls with key State and local public health stakeholders regarding key components of the NHHS. Conducted several conference calls with key State and local public health stakeholders regarding the implementation of Executive Order 13527. Discussions directly related to key components of the NHHS including the "effective countermeasure enterprise" objective. Obtained key stakeholder input for medical countermeasures through a townhall session, a summit and roundtable meetings. Provided technical assistance and coordination to implement a behavioral health force protection and stress management framework for deployed HHS responders to the Haiti 2010 earthquake event. Provided just-in-time information and technical assistance for public health communication messages and materials during HHS H1N1 response activities. Surveyed HHS agencies and federal departments regarding disaster behavioral health capabilities and gaps and developed Advancing Disaster Mental and Behavioral Health Preparedness and Response report. Convened Pediatric Preparedness and Response in Public Health Emergencies and Disasters	Continue to build on current outreach and awareness strategy via web, video, and presentations at major meetings of stakeholders.	Complete an approach for conducting the first NHSS Quadrennial Review. Approach will achieve the intended purpose of informing the development of the second NHSS. The same approach also will help inform progress toward the ASPR strategy.	N/A

	Workshop and produced report focusing on improving pediatric medical countermeasures and enhancing pediatric readiness of Federal medical staff and other responder systems. Convened a Regional Disaster Behavioral Health Coordination Workshop focused on coordination and identification of capabilities and gaps pertaining to the disaster behavioral health response within ESF #8. (Target Met)			

Agency Long-Term Objective: Enhance State and Local Preparedness

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.11.A: Informed and empowered individuals, communities: Percent of NHSS Implementation plan activities implemented. (Outcome)	N/A	N/A	100%	N/A
2.4.11.B: Integrated, scalable healthcare delivery systems: Percent of NHSS implementation plan activities implemented. (Outcome)	N/A	N/A	80%	N/A
2.4.11.C: Effective Countermeasure Enterprise: Percent of NHSS implementation plan activities implemented. (Outcome)	N/A	N/A	75%	N/A
2.4.11.D: Prevention/mitigation of environmental/other health threats: Percent of NHSS implementation plan activities implemented. (Outcome)	N/A	N/A	100%	N/A
2.4.11.E: Cross-border and global partnerships: Percent of NHSS implementation plan activities implemented. (Outcome)	N/A	N/A	80%	N/A
2.4.12: Percent of NHSS capabilities that have been defined and for which validated and accepted measures, baselines, and targets exist. (Outcome)	N/A	N/A	20%	N/A

Office of the Assistant Secretary for Preparedness and Response Operations

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 + / - FY 2010
Budget Authority	$36,948,000	$36,950,000	$38,624,000	+$1,676,000
FTE	141	155	164	+23

NOTE: Comparable adjustments have been made for the re-alignment of funding, proposed in FY 2012, consistent with the re-organization of ASPR offices.

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). The responsibilities of ASPR, as defined in PAHPA, include "to serve as the principal advisor to the Secretary of the U.S. Department of Health and Human Services (HHS) on all matters related to federal public health and medical preparedness and response to public health emergencies." ASPR has the authority to deploy federal public health and medical personnel, including the National Disaster Medical System, to respond to public health emergencies. ASPR oversees the advanced research, development, and procurement of qualified countermeasures. ASPR is also responsible for coordinating with relevant federal, state, local, and tribal public health officials to ensure integration of federal public health and medical assets during an emergency.

As noted previously, the FY 2012 budget request includes comparable adjustments made for the re-alignment of funding consistent with the re-organization of ASPR offices. In the spring of 2010, several functions within ASPR were re-aligned, and new offices were created including the Office of Policy and Planning, the Office of the Chief Operating Officer (COO), the Office of Acquisitions Management, Contracts, and Grants (AMCG), and the Office of Financial Planning and Analysis (FPA). The requests for COO, AMCG, FPA and the Immediate Office are aligned to Operations. Operations funding also supports ASPR-wide efforts to ensure the maximum alignment of resources to strategy. Recent efforts in this area include the continued development of an in-house budget execution and monitoring function, and an expanded assessment of ASPR's risk management of business functions consistent with OMB Circular A-123.

COO supports all of ASPR through Human Resource Management, Facility Operations, Records and Information Management, Logistics and Emergency Travel (both operational and for the ten regions), and Executive-Secretary level correspondence support. In addition, COO provides the facility, logistics, and infrastructure support services necessary to maintain the day-to-day operations of ASPR. COO also prepares outreach guidance and support for all external communications, including legislative and executive branch inquiries. Lastly, COO serves as the principal advisor to the ASPR on all legislative strategies to satisfy PAHPA requirements.

AMCG provides ASPR with acquisition and grants management support to ASPR's offices. AMCG focuses on providing acquisition and contractual support to BARDA in two specific

program divisions: Chemical, Biological, Radiological, and Nuclear Division (CBRN) and Influenza and Emerging Diseases (IED) Division. The Division of Acquisition Program Support (APS) provides a wide range of program management support to the ASPR as well as direct program support to BARDA. Functional support activities of the office include requirements analysis for Statement of Work (SOW)/Statement of Objectives (SOO), operations development and support, acquisition strategy development and tracking assistance to include contractual milestone development with measurable success criteria. The office also serves as ASPR's focal point for management, leadership and administration of grants and cooperative agreements.

FPA ensures that ASPR's financial resources are aligned to its strategic priorities. FPA carries out its responsibilities by formulating, monitoring, and evaluating ASPR budgets and financial plans that support program activities and ensures the effective and efficient execution of ASPR financial resources. FPA has administrative oversight of the Administration and Finance section of the Emergency Management Group that is activated under ESF #8 of the National Response Framework during a public health emergency. On behalf of the ASPR, FPA serves as the primary point of contact with the Office of the Assistant Secretary for Financial Resources, the Office of Management and Budget (OMB) and Congressional Appropriation Committees. In compliance with OMB Circular A-123, FPA ensures accountability and effectiveness of ASPR's financial programs and operations by establishing, assessing, correcting, and reporting on internal controls.

Funding History:

FY 2007	$23,439,000
FY 2008	$34,364,000
FY 2009	$36,950,000
FY 2010	$36,948,000
FY 2011 CR	$36,950,000

Budget Request:

The FY 2012 request is $38,624,000, an increase of +$1,676,000 over FY 2010. Funding will continue to support staff salaries for the Immediate Office of the Assistant Secretary, COO, AMCG, and FPA, rent and service changes, equipment costs, travel, telecommunications, training and continued implementation of revised OMB Circular A-123. Funds will also support the continued development of ASPR performance measurement and strategic human capital management. Funding will continue to support the development of short and long-term policy and strategic objectives and of strategic communication including programming support for the HHS-TV studio, which provides 24-hour emergency health preparedness information to the public.

Outcomes and Outputs:

Agency Long-Term Objective: Improve HHS response assets to support municipalities and States.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
2.4.8: Improve strategic communications effectiveness. (Outcome)	FY 2011: Continued to incorporate ASPR's strategic communications plan into all preparedness and response activities, such as the federal Deepwater Horizon response, the National Health Security Strategy announcement, and the medical countermeasure review rollout and used public health forums to educate stakeholders on ASPR mission and activities. Maintained and improved the interagency collaboration tool, the ASPR Knowledgebase, to better communicate with federal partners in the exchange of information and drafting of policy documents. The ASPR Knowledgebase is now operating as the "one-stop-shop" for ESF #8 partners to share information and collaborate. Once finalized, information posted on the ASPR Knowledgebase is posted on ASPR's PHE.gov website for public review. (Target Met)	Implement the ASPR strategic communications plan, including initiating a branding and marketing effort of ASPR. Implement ASPR's central infrastructure for public web communications with ESF #8 partners and the public.	Renew and implement an ASPR strategic communications plan. Continue to maintain and improve ASPR's central infrastructure for public web communications and interagency collaboration.	N/A

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	--	--	$10,000,000	+$10,000,000
FTE	--	--	--	--

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

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

ASPR is seeking funding for costs associated with a project that would co-locate approximately 90% of ASPR staff in a single facility in the Washington DC area. A co-located facility would include the following: office space for up to 700 staff (in addition to approximately 80 staff that would remain in HHS Humphrey headquarters building along with the existing Secretary Operation Center (SOC)), joint-use meeting rooms that will double as surge space during emergency responses, and a Secure Compartmentalized Information Facility (SCIF) to support communications and knowledge sharing with the intelligence community which is critical for situational awareness and responding to emerging threats.

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

The ASPR co-location project is essential to improving ASPR's readiness function and mission accomplishment and will work toward improving management efficiencies and optimizing scarce resources. Maintaining ASPR's present space in the HHS HQ building (including the existing Secretary Operation Center (SOC)), will ensure that the ASPR can fulfill the responsibility to serve as the HHS Secretary's principal advisor for public health and medical preparedness and response.

In May 2010, ASPR signed an occupancy agreement with GSA committing it to the new 154,000 sq. ft. of space in Federal Office Building #8 (FOB8), located immediately across C Street S.W. from the Hubert H. Humphrey Building. In June 2010, ASPR began design, renovation, security and IT/telecom meetings with project team members, and meetings are scheduled to occur throughout the project's life-cycle. Initial renovation is underway. ASPR is scheduled to make its first payment before the end of FY 2011. In 2011, the Department of Education (DOE) will be reclaiming its space currently occupied by approximately 230 ASPR staff and contractors from one of the five buildings within the Southwest Complex. ASPR is required to vacate DOE's space and it is anticipated that temporary space in Patriot's Plaza will be needed until final move-in to the new office facility. ASPR is expecting to move into FOB8 in FY 2013.

Funding History:

FY 2007	--
FY 2008	--
FY 2009	--
FY 2010	--
FY 2011 CR	--

Budget Request:

The FY 2012 President's Budget requests $10,000,000 to be used for the second year of the project including: physical moves, IT infrastructure installation, telecom system equipment, design, construction or renovation, project and construction management services, and furniture for a new 154,000 sq. ft. consolidated ASPR office facility. These funds are requested with no-year availability. ASPR's new office facility would co-locate approximately 90% of ASPR staff in a single facility in the Washington DC area. The ASPR co-location project is essential to improving ASPR's readiness function and mission accomplishment and will work toward improving management efficiencies and optimizing resources.

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

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	27,039,000	27,040,000	40,000,000	+12,962,000
FTE	7	19	22	+15

Allocation method: Contracts and Direct Federal/Intramural

Program Description and Accomplishments:

The HHS IT Security Program within the Office of the Chief Information Officer (OCIO), under the Assistant Secretary for Administration (ASA), assures that all automated information systems throughout HHS are designed, operated, and maintained with the appropriate information technology security and privacy data 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 need 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 federal laws and compliance with OMB and NIST guidance related to IT security and privacy. In FY 2011 and FY 2012, the Department will shift emphasis to efforts that will enhance the automation of the continuous security monitoring of our operational systems.

The HHS IT Security Program has established the HHS Computer Security Incident Response Center (CSIRC), which includes the security technologies that will provide an enterprise-wide capability to monitor the Department's computers and networks for security incidents and attacks. HHS plans to continue to expand CSIRC capabilities in FY 2011 and early FY 2012 to enable the Department to better determine the overall enterprise security risk posture of our operational IT systems, by deploying secure Internet gateways, additional intrusion detection

systems, network security forensics and analysis, expanded security information and event management (SIEM), and other enterprise security technologies throughout the Department.

The HHS IT Security Program efforts will include the design, engineering, and implementation work necessary for the Department to implement the Department of Homeland Security (DHS) Trusted Internet Connections (TIC) and Einstein monitoring initiatives in order to enable the Department to meet our obligations specified in the DHS TIC and Einstein service level agreements (SLA). TIC requirements to be met include the ability to support session traceability and auditability for compromised systems, proxy and management of secure web sessions, stateful packet inspection, Einstein operations, TIC level IDS monitoring, backup TIC data capability, and secure classified communications with DHS.

In addition, the Department will sustain efforts to implement network security infrastructure enhancement projects at the major Operating Divisions, (to specifically include the NIH, CMS, the Indian Health Service, and the Office of the Secretary), in order to further strengthen the Department and OPDIV network infrastructures, and prevent IT system compromises and the loss of sensitive data. In addition, these OPDIVs will continue efforts to improve enterprise security risk management and enhance security continuous monitoring of operational networks and information technology systems.

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 continuous security monitoring, vulnerability scanning, asset inventory, 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 HHS IT Security Program continued efforts to re-validate and update its inventory of information systems. The Department's annual Federal Information Security Management Act (FISMA) report was submitted on time in November 2009, using OMB's new Cyberscope system. With the issuance of updated guidance from NIST that specified an expanded set of security controls for Federal systems and major revisions to system security authorization processes, the Department is updating its Department-wide IT security policies and processes to conform to the latest Federal guidance. Processes are also being updated to begin implementation of the new guidance requiring the automated reporting of systems security continuous monitoring. The Department also issued policy guidance related to the secure use of social media technologies. Department-wide licenses were also procured or renewed 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 by providing a central resource for coordination, communication, and management of security information, threats, and

incidents. Primary contracts were awarded to sustain core HHS CSIRC capabilities and 24/7 staffing. Network access control technologies and security infrastructure enhancement projects were initiated at CDC, CMS, and the NIH. CDC has begun implementation of network security upgrade plans and zone based architectures in order to protect the most critical data and systems. In partnership with the HHS CSIRC, the NIH is implementing plans to enhance security continuous monitoring by expanding their capabilities to detect and respond to attacks against the infrastructures of the NIH Institutes. CMS has significantly strengthened its security program in FY 2010. The CMS has begun implementation of an enterprise-wide vulnerability and configuration management solution that will be implemented at multiple data centers across the CMS enterprise environment. The CMS is also leveraging the HHS CSIRC efforts by further expanding CMS security continuous monitoring capabilities over the many CMS contractor operated data centers.

Funding History:

FY 2007	$9,482,000
FY 2008	$8,906,000
FY 2009	$58,906,000
FY 2010	$27,040,000
FY 2011 CR	$27,040,000

Overview of Budget Request:

The FY 2012 request for IT Security is $40,000,000, an increase of $12,960,000 over the FY 2010 actual level. The FY 2012 request will enable the HHS IT Security Program to continue to provide management and oversight of the Department's IT Program, to ensure compliance with the requirements of FISMA, and also to sustain the security investments made in FY 2009 and FY 2010 with Recovery Act funding.

This includes the continued staffing and sustained operation of the HHS Computer Security Incident Response Center (CSIRC), which serves to provide continuous monitoring and security incident response coordination for the Department's computer systems and networks. The request, also includes funds to support design, planning and security engineering for the DHS Trusted Internet Connection (TIC) and Einstein initiatives, funds for a suite of Endpoint Protection Security Tools, which will be required to comply with recent guidance requiring the automated reporting of the security continuous monitoring of all HHS and OPDIV IT systems and networks and also includes continued funding for OPDIV major network security infrastructure enhancement projects. OPDIV projects will also enhance security situational awareness and vulnerability management efforts, and also result in the mitigation of security weaknesses that are currently impacting the security risk posture of the OPDIVs.

FISMA Program Management ($12 million): The request will allow the HHS IT Security program to continue to perform the functions and processes required to comply with federal IT security and privacy laws. This will include efforts to fully implement the automated reporting of security performance measures to the Department of Homeland Security. Funds will also enable the more effective implementation of security weakness remediation in response to

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

Security Incident Response & Situational Awareness; CSIRC ($15 million): Full operational capability (FOC) for all CSIRC components will be achieved in late FY 2011. CSIRC will continue enhancements while operating at FOC in FY 2012. The systems engineering and integration efforts associated with monitoring and securing these technologies will be demanding, and will also need to be closely aligned with the TIC initiative and other Department of Homeland Security efforts to improve the Federal government's ability to counter attacks. Initial procurement of technologies to support TIC and Einstein implementations will begin in FY 2012. TIC, Einstein and the CSIRC technologies will have a major impact on the Department being able to achieve the continuous security monitoring of our systems and software applications. The CSIRC will be operating at FOC in FY 2012 and will enable the Department to sustain a very robust capability to defend against computer attacks, and also better detect and respond to any attacks. Significant security technologies will continue to be funded in FY 2012 to include enterprise network intrusion detection and prevention solutions, network traffic analysis tools, security event and information management solutions (SIEM), data mining and log analysis, and tools to support the forensic analysis of malicious software (malware). As threats evolve and become more sophisticated and technology changes, the Department must also evolve and make security use of technologies that allow the protection mechanisms used by our systems and data to keep pace with the changes. Smartphones, mobile and cloud computing will significantly change the way we store, access, and secure our data while meeting the information access and protection demanded by the public's interest in public health.

Computing Infrastructure Security Re-design Projects ($8.5 million): The OIG specifically identified the computing and network infrastructure domains of the OPDIVs as being flawed and recommended that the Department take action to eliminate the currently flawed designs. This project provides for the reconfiguration of the computing infrastructures at the OPDIVs to enable the computing infrastructure to be re-configured into secure segments and zones, resulting in a significantly improved defense in depth approach to security. This will provide for multiple layers of security controls to protect our most critical HHS information, while also enabling HHS to securely conduct scientific research with our partners. This work continues and builds on work started in FY 2009 with the $50 million for IT Security in HHS provided by the Recovery Act, and efforts initiated in FY 2010 with annual funding. FY 2012 funds will enable HHS to continue to implement security architecture upgrade plans, network security infrastructure enhancement projects, and strategies that will ensure that the most critical data and systems are appropriately protected utilizing a cost effective, risk based approach to security. The IT

Security Program will support the continuing efforts of major OPDIV network infrastructures security upgrade projects to establish separate, secure network and data segments for development, testing, and production environments. This will also include the establishment of dedicated hosting environments 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. OPDIVs will implement security solutions to upgrade their abilities to perform the security continuous monitoring of their applications and IT systems.

Upgrades to and the re-architecture of network infrastructures at the NIH, CMS, the Office of the Secretary, and the Indian Health Service environments will continue in order to provide enhanced protection for OPDIV database and application servers by establishing multiple security zones within these HHS and OPDIV networks. This will include the establishment of an additional level of protection within the HHS and OPDIV network's protected demilitarized zone (DMZ), in order to isolate critical servers while maintaining internal and external accessibility. These re-architecture efforts will directly support the Department's implementation of the DHS Trusted Internet Connections (TIC) and Einstein initiatives. The Department will also continue to pursue efforts to significantly enhance the enterprise security program at CMS and the Indian Health Service, to include strengthening enterprise risk management capabilities, intrusion detection, security information and event management, and incident response.

Endpoint Protection Security Tools ($4.5 million): HHS will enhance the IT security at the Operating Divisions by pursuing a number of high impact investments that will address and correct existing security gaps. This includes the implementation of Network Access Control (NAC) security technology and endpoint protection technologies which will provide commercially available access control solutions required to better secure access HHS computers and network resources. This will provide for additional solutions to counter malicious software (malware) and other sophisticated computer viruses and worms that continue to plague government computer systems. The Department will also renew the Department-wide licenses for a number of security technologies including solutions for encryption, enterprise malware and content filtering, data loss prevention, vulnerability scanning software, and automated tools for FISMA reporting, and security weakness tracking.

The requested funding in FY 2012 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.

Outcomes and Outputs:

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
1.1 Percentage of HHS computing devices that are in compliance with Federal security configuration guidance (i.e., USGCB).	FY 2010: N/A (New Measure)	N/A	95%	N/A
1.2 Percentage of HHS laptops and desktops with capabilities to encrypt sensitive information on removable media.	FY 2010: 73% (Target Met)	55%	99%	+44%
1.3 Percentage of HHS network infrastructure monitored with automated intrusion detection systems.	FY 2010: 88% (Target Met)	60%	95%	+35%
1.4 Percentage of HHS IT systems protected with advanced Internet content filtering and anti-malware solutions.	FY 2010: 99% (Target Met)	85%	100%	+15%
Program Level Funding ($ in millions)	FY 2010: 27.04	27.04	40	+12.96
ARRA Level Funding ($ in millions)	FY 2009/2010: 50	N/A	N/A	N/A

OS Cybersecurity - Summary of Recovery Act Available Resources, Outlays and Performance

(dollars in millions)

ARRA Implementation Plan	Total Resources Available	FY 2009/ FY 2010 Outlays	FY 2011 Outlays	FY 2012 Outlays
Cybersecurity (IT Security)	50.00	38.24	11.62	0

Selected Performance Measures for Implementation Plan

Performance Measure	FY 2009 Result	FY 2010 Result	FY 2011 Target/Date	FY 2012 Target/Date
Percentage of HHS laptops and desktops with sensitive information secured with encryption capabilities.	40%	73%	95% (9-30 - 2011)	99% (9-30-2012)

Implementation Data Source: OPDIV Annual FISMA Report
Narrative: Recovery Act funds have greatly assisted the OPDIVs in meeting and exceeding the targets. Several procurements were made that purchased new encryption solutions. Efforts are ongoing to continue to meet the targets.

Office of Public Health and Science
Medical Reserve Corps

	FY 2010 Actual	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2010
Budget Authority	12,581,000	12,581,000	11,268,000	-1,131,000
FTE	7	9	9	+2

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 established by the Office of the Surgeon General (OSG), within the HHS Office of the Assistant Secretary for Health (OASH), 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 that provided start-up grants to 166 communities across the U.S. Many other communities have since established MRC units outside of the demonstration project. As of August 2010, there are over 900 MRC units in all 50 states, Washington, DC, Guam, Palau, Puerto Rico and the US Virgin Islands, with more than 207,000 volunteers.

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

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

emergency management and other entities vital to their success and sustainability.

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

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

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

- Cooperative agreement with the National Association of County and City Health Officials (NACCHO). The original cooperative agreement was initiated in FY 2006 (FY06 - $8 million; FY07 - $6 million; FY08 - $5.3 million; FY09 - $7.2 million) and a new cooperative agreement was awarded in FY 2010 ($6.775 million). Activities include providing "Capacity-building Awards" directly to MRC units (FY06 - 491 awards; FY07 - 507 awards; FY08 – 537 awards; FY09 – 552 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 are used by MRC units to support 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, Deployment Coordinator and 10 Regional Coordinators situated in the HHS Regional Health Administrator offices. The Regional Coordinators provide day-to-day connection with the MRC units and conduct annual technical assistance assessments. Z-tech hosts and maintains the MRC website (www.medicalreservecorps.gov), a developing Geographic Information System, and the database of MRC unit profiles. Other activities supported by this contract include the technical assistance materials and resources, MRC promotional materials (i.e. brochures, exhibit booth, information packets), and support for MRC outreach. A new technical support contract will be awarded in FY 2011.
- Interagency Agreement with the Centers for Disease Control and Prevention (CDC) which provides a funding supplement to an existing CDC Cooperative Agreement with the Public Health Foundation (PHF). The funding to PHF supports MRC-Train, a learning management resource offered (free-of-charge) to all MRC units.
- Interagency Agreement with the OPHS Regional Health Administrators. OCVMRC provides funding to the RHAs to help support operations in the ten HHS Regions since the regional

offices provide support for various MRC projects and operations. This funding helps to defray regional overhead and other costs.

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

	New MRC Units	Total Number of MRC Units	Total Number of Volunteers
FY02	42	42	(Inception)
FY03	124	166	10,116
FY04	66	232	34,164
FY05	118	350	62,982
FY06	247	597	112,089
FY07	116	713	146,414
FY08	103	787	168,996
FY09	90	856	189,245
FY10	84	940	210,114

The continually increasing number of MRC units indicates the success 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, OCVMRC expects to see a 5-10% annual growth rate.

Funding History:

FY 2007	$9,748,000
FY 2008	$9,578,000
FY 2009	$12,344,000
FY 2010	$12,581,000
FY 2011 CR	$12,581,000

Budget Request:

The FY 2012 Request of $11,268,000 is $1,313,000 below the FY 2010 Appropriation. OCVMRC will accommodate this decrease by reducing funding for the cooperative agreement and support contracts, while maintaining support and service for MRC units at the local level.

Outputs and Outcomes:

The MRC is aligned with broader HHS and OASH Priorities:

- **Creating Better Systems of Prevention**: Local Medical Reserve Corps units are encouraged to conduct and support activities that address ongoing public health priorities and improve prevention efforts, such as diabetes detection, hypertension screening, and back-to-school immunizations.
- **Eliminating Health Disparities and Achieving Health Equality**: Local Medical Reserve Corps units are encouraged to conduct and support activities that address health disparities that occur by race and ethnicity, gender, education, income, geographic location, disability status, or sexual orientation.
- **Emergency Response**: Local Medical Reserve Corps units are encouraged to conduct and support activities that enable their community to prepare and respond to emergencies.
- **Pandemic Preparedness**: Local Medical Reserve Corps units are encouraged to be involved in pandemic preparedness activities in their local communities.

Key Outcomes	Most Recent Results	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
Long-Term Objective 1: Demonstrate a credible and valuable MRC network				
1.1 The continued acceptance of the MRC concept by communities across the country is shown by increases in the number of MRC units. **# MRC units (targets based on 5% growth rate)**	856 (FY 09 - Exceeded Target)	899	990	+91
1.2 Community members (including medical and public health professionals) across the country continue to join local MRC units in order to help improve public health and resiliency. **# MRC volunteers (targets based on 5% growth rate)**	189,245 (FY 09 - Exceeded Target)	198,707	219,074	+20,376
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**	58,439 (FY10 Q1 - Data reporting refined in this quarter)	500,000	238,431	-261,569

2.2 OCVMRC has provided guidance documents and training to assist with strategic planning, and has encouraged all MRC units to engage in strategic planning processes. **% MRC units indicating that they engage in strategic planning**	68% (FY 09 – Below Target of 70%)	75%	75%	---
Long-Term Objective 3: Demonstrate a Federal deployment capability				
3.1 OCVMRC has encouraged all MRC units to track the willingness of their members to deploy outside of the local jurisdiction. **% MRC units that track their members willingness to deploy outside of the local jurisdiction**	78% (FY 09 - Exceeded Target)	80%	80%	---
3.2 OCVMRC is developing the mechanisms, policies and procedures necessary to identify, activate and deploy MRC members who are willing, able and approved to participate in a Federal response. **# MRC members who are fully processed as Federally-deployable.**	0 (FY 09 Baseline Year)	150	225	+75
Program Level Funding ($ in millions)	**N/A**	**$12.581**	**$11.268**	**-$1.313**

Office of Security and Strategic Information

	FY 2010 Enacted	FY 2011 CR	FY 2012 President's Budget	FY 2012 +/- FY 2011
Budget Authority	4,893,000	4,893,000	6,460,000	1,567,000
FTE	31	31	39	+8

Allocation Method: Direct Federal

Program Descriptions and Accomplishments:

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

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

OSSI represents HHS on several and National Security Staff 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 for oversight of all details to these organizations. OSSI also houses Original Classification Authority for the Department, which is the authority to classify information and material produced by any HHS component.

OSSI does not focus on traditional intelligence analysis, but rather on the acquisition of open source and classified information and assessing its usefulness in supporting and furthering the mission of HHS. Where appropriate, OSSI provides scientific assessments to the intelligence and federal law enforcement communities. OSSI, to the extent possible, incorporates representatives from stakeholder organizations into its work.

The Division of Strategic Information (DSI) ensures that the Department has the ability to access, share, and protect strategic and classified information. DSI coordinates internal sharing

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

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

- Developing customer driven Priority Intelligence Requirements (PIR) that address the strategic information and intelligence needs of the Department and its diverse missions.
- Providing updated classified briefings to senior leadership and policy makers, including all agency and staff division leadership.
- Developing Department-wide priority information requirements to meet the strategic information needs of HHS's 18 Staff Division leaders. Information is the first-step in identifying critical information gaps that need to be addressed for leadership.
- Providing current and timely classified information to policy makers pertaining to food and pharmaceutical safety discussions with the People's Republic of China.
- Providing current and timely classified information to policy maker pertaining to negotiations associated with avian influenza virus sample sharing, furthering and safeguarding U.S. interests.
- Providing critical information to policy makers regarding the decision-making pertaining to the destruction of smallpox virus, to negotiate the preservation of smallpox, which is in the U.S. interest.

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

- Established and maintained working relationships with members of the Intelligence and Federal Law Enforcement Communities to enhance information exchange and collaboration in accordance with the guidance provided by senior HHS leadership.
- Established productive relationships with the Washington and Baltimore Field Offices of the FBI, and established productive liaisons with FBI headquarters.
- Actively participated 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 was fully supporting the efforts of those agencies in line with EO 12333, Presidential directives, and HHS Secretary mandates.
- Served as the Public Health Sector lead for the FBI's Critical National Assets (CNA) initiative and sat on the CNA executive committee.
- 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.

DSI is responsible for reviewing and approving all requests for visits by foreign nationals to HHS properties. This includes the implementation of foreign visitor policy Department-wide, which secured thousands of short-term visits by foreign nationals to HHS facilities and critical infrastructure sites. OSSI policies ensured that sound security practices were followed, ensuring that these visitors would have HHS hosts and escorts during their visits. The new database program (implemented in April of 2010) is set up to track all visits to HHS facilities nationwide.

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

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

- Overseeing and managing personnel security and suitability background investigations and adjudications and national security clearances including for all the Department's high public trust and national security positions.
- Ensuring and enhancing communications security, including secure telecommunications equipment and classified information systems with direct management of these functions within the OS.
- Improving information security, to include protection of classified and sensitive but unclassified materials and security awareness programs and management of the document classification and declassification program.

Managing the HHS classification management, including the classification and declassification of all HHS produced documentation that rise to the level of national security concerns. Recently the DPCIS has worked to refine and streamline the HHS clearance processes. Ongoing re-engineering of processing is occurring, and progress to date includes the:

- Initiation of a new data link and database program which has reduced data input time dramatically and the required staff needed to facilitate the processing of clearances has been reduced as well. All phases have been complete and now operations and maintenance of the programs are in place moving forward. This program/link system automates the exchange of information between our internal Security Investigations Processing System (SIPS) and the Office of Personnel Management (OPM) System in order to populate data fields, generate reports and batch files, and expedite processing. This program serves the entire department of HHS and funding for operations and maintenance of this program will be required for 2012.
- Satisfying additional requirements to develop/deploy a web-based application to securely capture, store, and manage background investigation and security clearance information for all HHS employees and contractors.
- Enabling the integration of systems that are in the clearance process such as Agency Delivery, E-Adjudication, the Clearance Verification System (CVS), and contiguous OSSI needs in order to have a comprehensive multi-purposed database to satisfy OPM and governmental security requirements.

In the last year, personnel security clearances and adjudications have increased by 20% to over 4,000 cases adjudicated per year due to the implementation of HSPD-12.

The COMSEC Division within DPCIS, which is responsible for HHS Secure Communications, has recently:

- Developed a plan which will support the management the ongoing and continued development of an infrastructure of sensitive and classified communications among HHS components. The infrastructure developed to include SIPRNET, JWICS, and HSDN, which are Controlled Unclassified Information systems of communication with the intelligence communities.
- Ensured that the inter-agency baseline of minimum communications requirements set forth in the National Communications System (NCS) Directive 3-10 to support execution of essential functions and allow senior leadership to collaborate in a secured environment are met for the Department (Continuity of Government and Business).
- Deployed COMSEC equipment and personnel to support HHS Continuity of Operations Plan (COOP) requirements to have secure and reliable voice and date transmission, planning and training.
- In development is an HHS wide Standard Operating Procedures (SOP) for ensuring implementation of procedures prescribed for safeguarding and controlling of COMSEC material and classified information systems. Serve as the central point of contact for COMSEC equipment and systems for authorization and approval throughout the Department.

Future goals and objectives for the COMSEC program:

- Provide staff supervision and guidance to all HHS COMSEC Custodians and Alternate Custodians as well as Classified Information System Security Managers and Officers. This involves participating in training to stay abreast of current trends and technologies and relaying and/or exchanging information with Agency COMSEC personnel
- Research, determine and procure the most appropriate COMSEC devices/equipment/systems available to fulfill HHS' mission requirements
- Coordinate/Perform staff assistance and inspection visits of HHS COMSEC Accounts Holders and Classified System users throughout the Department to ensure compliance with appropriate standards/guidelines.
- Develop and implement a training plan for users of secure communication devices that includes hands-on instructions and quick-reference operating guides as well as COMSEC briefings on handling and safeguarding equipment/material/systems.
- Develop and implement Incident Reporting Procedures for any COMSEC material that may have been compromised.
- Develop a program to track and account for all material and a notification/alert system to inform users of re-keying, upgrade, modification, or change requirements.

The Division of Physical Security (DPS) brings key subject matter expertise together to better address policy and critical security issues, while reducing funding requirements for identified previously redundant program initiatives across the Department. Through management audits and integrated physical security assessments, the Division of Physical Security provides Department-wide leadership, coordination, policy and oversight for the following directives and

core programs. The assessments provide information to identify key physical security risks, threats and vulnerabilities and determine the Department's ability to provide the appropriate response. The assessment results will also assist the Division in developing the appropriate Department strategies in coordination with the respective owners of various programs (CDC, NIH, FDA, CMS etc.), to build and refine the various programs outlined below:

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

HHS has responsibility in the implementation of Homeland Security Presidential Directive (HSPD)-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.

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

Funding History**:**

FY 2007	$3,263,000
FY 2008	$3,263,000
FY 2009	$3,263,000
FY 2010	$4,893,000
FY 2011	$4,893,000

Budget Request:

The FY 2012 request for OSSI is $6,460,000, an increase of $1,567,000 above the FY 2010 enacted level. This increase will enable OSSI to maintain the operational tempo requirements and responsibilities that have been assigned to OSSI. Additionally, this request will cover personnel costs and will fulfill the anticipated January 2012 uniformed services pay raise, and

increased costs in rent and other services. This requested increase will support program improvements, which will result in OSSI fulfilling the numerous presidential directives, and national security requirements. This budget will result in attaining many of the scientific, public health and Secretarial objectives/goals.

Background on additional activities supported by OSSI

Security breaches from HHS could cause major issues for the Secretary and create questions about HHS's ability to safeguard its personnel and information and National Security interests. Our vulnerabilities create vulnerabilities in other Departments/ Agencies. The programs enable a nation-wide Departmental response capability that also provides senior leadership with science-based, intelligence-informed, threat reporting.

Investigations are conducted to resolve allegations or suspicions of actions by, or on behalf of, foreign entities, preserve the potential for follow-on FBI or the Office of the Inspector General (OIG) actions and when appropriate cooperate with Intelligence and Law Enforcement partners. These investigations seek to identify insider (lone wolf) threats to HHS. Investigations are about discovering the facts and conveying them to decision makers while maintaining a full range of Departmental response options including support of the OIG during investigations.

Results of OSSI investigations also contribute to the identification and elimination of HHS security vulnerabilities; identification of current foreign intelligence tradecraft, agent handlers/operatives, and their support networks; the assessment of potential damage to HHS and National Security; national counter proliferation efforts; and improvement of the overall HHS security posture, as well as assisting decision makers in making fact based, intelligence-informed, operational risk management decisions.

Foreign Visitors/Visitor Tracking System

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

CUI – Controlled Unclassified Information

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

OSSI's program in obtaining access to and sharing and protecting strategic and classified information will support HHS public health and science programs, protection of HHS employees, and HHS critical infrastructure. This work will entail coordination of analytical activity of HHS officials throughout the Department's organizational units and will include

building relations with Federal officials in other non-title 50 agencies who conduct similar programs, as well as maintaining customer relationships with the intelligence community.

To implement this program OSSI will:

- Conduct OPDIV/StaffDIV-specific training for CUI, which will be an annual requirement for personnel who process CUI.
- Execute all activities required to begin designating, marking, safeguarding, and disseminating CUI.
- Design Departmental records systems for appropriate sharing and safeguarding of CUI, and facilitate its decontrol when it no longer meets the standards for continued control.
- Integrate CUI requirements into information systems as they are developed or, if already developed, when upgraded.
- Develop CUI oversight programs as well as enforcement mechanisms and penalties for improper handling of CUI. These programs will necessitate the development of a variety of metrics for internal HHS management use as well as for use by appropriate non-HHS government management entities.
- Assemble and maintain the list of CUI categories available to HHS and to be submitted by the Secretary and approved by EA/NARA for use by HHS.
- Develop and/or update Classification Security Officer (CSO) guides for:
    - NSI: Classification and De-classification
    - CUI: Control and De-control
- Design, develop, and implement a CUI web site and portal to facilitate communication and awareness throughout HHS.
- Foster the development of and provide access to CUI training for the HHS CSOs.
- Develop a standard Challenge procedure (for those that think a document is labeled CUI in error) for use throughout HHS.
- Develop a HHS CUI self-inspection process and set of procedures as required by the CUI Executive Order.

Personnel Security (PERSEC)

OSSI has previously funded contract personnel through support from the ODIVS, however, additional funding is requested in FY 2012 to hire qualified specialists to help manage the ongoing and continued volume case load. The number of high level background investigations is projected to increase by a minimum of 20% as new employees are hired to replace numerous anticipated retirees. Security clearance requests are expected to increase as more employees and supervisors require access to classified strategic health information and need to attend classified meetings as part of their mandatory program work. All new investigations require personnel security specialists to initiate the process and review and adjudicate the completed reports, and to assure that OPM and EO mandated renewals of checks occur in a timely manner. Additional drug testing will be required as numerous new positions will be added to applicant and random drug testing pooling. Alcohol testing will be added to the testing requirements for many DOT-mandated driving positions.

Outcomes and Outputs: PERSEC Tracking

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2011
1.1**:** Number of Clearances Processed/ Adjudicated. *(Outcome)*	FY 2007: 1198 FY 2008: 2605 FY 2009: 3774 FY 2010: 3096	3096	5200	+2,104
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 FY 2009: 1858 FY 2010: 2593	2593	3200	+607
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-2007 FY 2009: 39 case carried forward-2008 FY 2010 -0	0	0	0
Program Level Funding ($ in millions)	**N/A**	**$4.893**	**$6.460**	**+$1.567**

Pandemic Influenza

	FY 2010 Encated	FY 2011 CR	FY 2012 President's Budget	FY 2012 + / - FY 2010
No-Year	$275,591,000	$276,000,000	--	-$275,591,000
Annual	$65,000,000	$65,000,000	--	-$65,000,000
Total Budget Authority	$340,591,000	$341,000,000	--	-$340,591,000

NOTE: Comparable adjustments have been made for the re-alignment of pandemic influenza management funding to ASPR, proposed in FY 2012, consistent with the re-organization of ASPR offices.

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

Program Description and Accomplishments:
Since the release of the HHS Pandemic Influenza Plan in November 2005, HHS has made significant progress in enhancing pandemic preparedness for our Nation and our international partners. HHS plans to continue vital pandemic preparedness activities, including activities identified in response to lessons learned from the 2009 H1N1 pandemic, using funding remaining from previous pandemic influenza appropriations. In FY 2006, Congress appropriated a total of $5.6 billion for HHS in two emergency supplemental appropriations to implement the first two years of the HHS Pandemic Influenza Plan. In FY 2009, Congress appropriated an additional $507 million for continuing support of pandemic influenza preparedness activities as well as $7.65 billion for pandemic influenza preparedness and response in a FY 2009 supplemental to respond to the 2009 H1N1 influenza pandemic. In the FY 2010 Omnibus, Congress appropriated $276 million for continuing support of pandemic preparedness activities.

Since December 2005, HHS has been funding the first stage of pandemic preparedness activities. Promising strides have been made with these investments that enhance the Nation's ability to respond to influenza pandemics, including advanced development of high-throughput rapid diagnostics and the development and production of H5N1 vaccine antigen and new antigen-sparing adjuvants. Funding has supported the following pandemic preparedness activities: 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 at CDC, NIH, ASPR and OGHA.

The novel 2009 H1N1 influenza, a triple reassortant virus comprised of avian, swine and human influenza viruses, emerged in April 2009. On June 11, 2009, the World Health Organization raised the influenza pandemic alert level for 2009 H1N1 influenza to Phase 6 and declared a global pandemic. CDC estimates that in the U.S. between 43 million and 88 million cases, between about 192,000 and 398,000 hospitalizations, and between about 8,720 and 18,050 2009 H1N1 influenza-related deaths occurred between April 2009 and March 2010. The H1N1 pandemic virus is included in the influenza vaccine for the 2010-2011 influenza season, as the virus continues to circulate along with other influenza strains.

In response to the H1N1 pandemic, HHS worked closely across agencies and in collaboration with State and local health departments. Building on the earlier pandemic investments described above, HHS purchased and distributed licensed H1N1 vaccine, released 25% (11 million treatment courses) of antivirals and other supplies in the Strategic National Stockpile (SNS) to the States; issued Emergency Use Authorization (EUA) for diagnostic laboratory tests, antiviral drugs including a new intravenous antiviral treatment, and N95 respirators from the SNS; issued regularly updated guidance on antiviral usage, clinical symptoms and medical management, reducing the spread of infection, and recommendations on travel; and replenished and diversified the antiviral treatment courses in the SNS.

Recent accomplishments include:

- On September 15, 2010, HHS posted a draft solicitation for a new initiative to establish Centers of Innovation for Advanced Development and Manufacturing (ADM) in the U.S. These Centers are expected to provide advanced development and manufacturing capabilities for CBRN medical countermeasures on a routine basis to address national security needs and to manufacture pandemic influenza vaccine in an emergency. Construction of new or renovated facilities in the U.S. will be supported with $478 million in existing pandemic influenza funding. The issuance of the final Request for Proposals is expected in early 2011 with contract awards in late 2011.

- On September 29, 2010, HHS awarded a three-year contract totaling $57 million to sanofi pasteur. Of the $57 million, $49.5 million came from the FY 2009 supplemental appropriation. This contract continues the successful program established in 2004 to provide a secure year-round supply of eggs and other supplies essential for influenza vaccine production in response to seasonal vaccine shortages or an influenza pandemic. During the 2009 H1N1 influenza pandemic response, eggs supplied under this contract were used to support the production of approximately 40 million 2009 H1N1 influenza vaccine doses.

- In August 2010, in response to the recommendations of the PCAST report and the Medical Countermeasure Review, HHS began a new initiative to shorten the time frame for production of pandemic influenza vaccines. This HHS interagency effort is comprised of ASPR/BARDA, NIH, CDC, and FDA with vaccine manufacturers and consists of three projects – vaccine virus strain optimization, potency and sterility assay development, and implementation.

- HHS contracted with five U.S.-licensed influenza vaccine manufacturers to produce 186 million filled finished doses of 2009 H1N1 vaccine for use in the U.S. and for international donation. HHS also purchased sufficient ancillary supplies to vaccinate target groups in the U.S. population with the H1N1 vaccine, including 348 million syringe/needle combinations for vaccine delivery and mixing of vaccine and adjuvant.

- HHS awarded a contract in June 2009 for the advanced development of recombinant-based influenza vaccines towards U.S.-licensure with a commitment to build a domestic manufacturing facility having a capacity of at least 50 million pandemic vaccine doses within six months of pandemic onset and the ability to ship the first doses of vaccine within 12 weeks of pandemic onset. Additional contract awards supporting advanced development of using recombinant and molecular technologies are expected in 2011.

- HHS awarded a contract in January 2009 on a cost-sharing basis to support the design, construction, commissioning and validation of the first U.S. cell-based influenza vaccine manufacturing facility. The building of this facility was completed with a grand opening in November 2009. This facility will undergo validation and could provide at least 25 percent of the U.S. pandemic vaccine supply by 2011. Additional contract awards supporting cell- or recombinant-based influenza vaccine manufacturing in the U.S. are expected in 2011.

- To expand pandemic influenza vaccine capacity, HHS supported the development of adjuvant technologies that are in late stage development for H5N1 and H1N1 vaccines. Several of these adjuvants have demonstrated multifold antigen-sparing effects, broad immunity across virus strains, and significant long-lasting prime-boost effects. Together these products represent a major technological breakthrough for pandemic vaccine preparedness with possibilities for better seasonal influenza vaccines for select populations.

- HHS procured an additional 125 million doses of a new oil-in-water emulsion adjuvant, which were developed under HHS development contracts, as a contingency plan for mismatched vaccine or more virulent virus strains in the 2009 H1N1 pandemic. While not required during the H1N1 pandemic, these stockpiled adjuvants remain available for future pandemics or other outbreaks. Clinical studies with H1N1 vaccines administered with these adjuvants demonstrated a 2-4 fold antigen-sparing effect.

- HHS supported the development of four cell-based seasonal and pandemic influenza vaccines. Two of these cell-based influenza vaccine candidates are in very late stage development with expectations of licensure submissions to the FDA in 2011.

- HHS completed its goal of 50 million courses of influenza antiviral drugs for the federal stockpile in December 2007. In response to the 2009 H1N1 influenza outbreak, 11 million antiviral drug treatment courses were deployed to the States in May 2009. HHS replenished the federal stockpile with 13 million treatment courses in June 2009 and purchased an additional 16.1 million treatment courses for the federal stockpile in September 2009 to address concerns about the emergence of oseltamivir-resistant 2009 H1N1 influenza virus strains and the disproportionate ill effects of H1N1 on children.

- HHS also continued support of parenteral antiviral drugs for critically-ill persons with influenza, including peramivir, through additional funding for advanced development of peramivir in Phase 3 clinical trials and acquisition of peramivir to establish a small federal stockpile under Emergency Usage Authorization (EUA) during the 2009 H1N1

influenza pandemic in order to treat critically ill persons with H1N1 infections. To date, over 1000 persons have been treated with this drug through the EUA program.

- HHS awarded contracts to develop rapid diagnostics for detection of seasonal and H5N1 viruses in point-of-care (POC) settings by healthcare providers in 2007 and high throughput settings for usage by clinical laboratories in 2008. One POC device supported by HHS met product requirements during Independent Government Evaluation in 2008 and underwent clinical development in early 2009. The first 2009 H1N1 influenza clinical case in the U.S. was detected with the POC diagnostic device developed under HHS contractual support for product development.

- In September 2008, FDA cleared the Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel for *in vitro* diagnostic detection of influenza types A, B, and three subtypes: seasonal A/H1 and A/H3, and A/H5 (i.e., H5 Eurasian highly pathogenic avian influenza). In response to the H1N1 outbreak, FDA granted an Emergency Use Authorization to allow CDC to manufacture and distribute the pH1N1 PCR assay for use by public health and other qualified laboratories. Within two weeks of the first recognition of pH1N1, CDC developed and validated the new PCR assay, began manufacturing the reagents, obtained FDA authorization for use, and distributed PCR kits domestically and internationally. In the subsequent weeks, the CDC pH1N1 PCR assay was made available at 146 public health laboratories in the U.S. In June 2010, the test system was 510(k) cleared to include the additional pandemic H1N1 assays.

- In 2006, HHS purchased 104 million N95 respirators and 52 million surgical masks for the SNS. In response to the outbreak of 2009 H1N1 influenza, 80 percent of the stockpiled N95 respirators and 25 percent of surgical masks in the stockpile were deployed to the States.

Funding History:

FY 2007	--
FY 2008	$66,177,000
FY 2009	$8,026,091,000
FY 2010	$340,591,000
FY 2011 CR	$341,000,000

Budget Request:

The Department will continue supporting Pandemic Influenza activities in FY 2012 with existing pandemic preparedness and response funding, including balances from the FY 2009 supplemental. Following the release of the Department's *Public Health Emergency Medical Countermeasures Enterprise Review* in August 2010, the Department has moved swiftly and efficiently to execute the pandemic influenza preparedness priorities enumerated in the review. This includes the Centers of Innovation for Advanced Development and Manufacturing mentioned above, which are expected to provide advanced development and manufacturing capabilities for CBRN medical countermeasures on a routine basis to address national security

needs and to manufacture pandemic influenza vaccine in an emergency. Initially, this program will be supported with $478 million in existing pandemic influenza funding for the construction of new or renovated facilities in the U.S.

The Department is also making a significant investment in the advanced development of recombinant and molecular vaccines, antiviral drugs, and advanced antigen sparing technology (adjuvants). Awards are expected in all three areas early in 2011. To support the advanced development of additional influenza vaccine candidates using recombinant- or molecular-based technologies, HHS issued an RFP in September 2009. Contract awards for this activity are anticipated in February 2011. In August 2010, HHS issued a new RFP for the advanced development of antiviral drugs and biologics against the influenza virus. The RFP's focus is the advanced development of new influenza antiviral agents designed to target novel mechanisms of action or to enhance the effects of currently existing influenza antiviral agents. The next phase of the antigen sparing technology program will focus on assessing the performance of these adjuvants with vaccine antigens from other influenza virus subtypes of pandemic potential. These studies will include both homologous studies where the vaccine and adjuvant are produced by a single manufacturer and "mix-n-match" studies where adjuvants are combined with vaccine antigens from another manufacturer. Assessment of these combinations will develop pandemic vaccine response plans that are flexible and that make the most effect use of the available technologies.

The Department continues to invest in shortening the time it takes to develop, manufacture, and deploy influenza vaccines. In August 2010, in response to the recommendations of the President's Council of Advisors on Science and Technology's (PCAST) report and the Medical Countermeasure Review, HHS began a new initiative designated "Improved Influenza Vaccine Manufacturing" to shorten the time frame for production of pandemic influenza vaccines. This HHS interagency effort is comprised of BARDA, NIH, CDC, and FDA, with vaccine manufacturers, and consists of three projects—vaccine virus strain optimization and potency and sterility assay development, and implementation.

The Department will also invest in establishing a national fill and finish manufacturing network. This network of fill and finish manufacturers will provide surge and emergency capacity to fill influenza (and other vaccines) during an influenza pandemic. This will assure that pandemic influenza vaccines can be produced and delivered as rapidly as possible. Additional filling capacity is needed to ensure that filling vaccines does not become a rate-limiting step in the response to an influenza pandemic.

The Department also supports the advanced development of influenza diagnostics. Existing pandemic influenza funding will continue the rapid diagnostics program in collaboration with the CDC to ensure that the U.S. laboratory network will have reagents and equipment for rapid response at the beginning of a pandemic. Funding will also support the advanced development of rapid and specific multiplex diagnostic platforms so that U.S. laboratory network can readily distinguish influenza from non-influenza strains as well as rapidly identify subtypes through tests of respiratory samples.

Budget Authority by Object
(dollars in thousands)

	FY 211 CR	FY 2012 Estimate	FY 2012 +/- FY 2011
Direct Obligations			
Personnel compensation:			
Full-time permanent (11.1)……	$62,931	$72,789	$9,857
Other than full-time permanent (11.3)……	13,987	14,254	267
Other personnel compensation (11.5)……	47	57	10
Military personnel (11.7)……	7,413	7,817	404
Special personnel services payments (11.8)	--	--	--
Subtotal personnel……	84,379	94,916	10,538
Civilian benefits (12.1)……	14,825	17,597	2,772
Military benefits (12.2)……	3,809	3,913	104
Benefits to former personnel (13.0)	--	--	--
Subtotal Pay Costs, ….……	103,012	116,426	13,414
Travel and transportation of persons (21.0)……	11,782	12,175	392
Transportation of things (22.0)……	789	778	(11)
Rental payments to GSA (23.1)……	9,367	10,355	989
Communication, utilities, and misc. charges (23.3	6,877	3,382	(3,495)
Printing and reproduction (24.0)……	37	40	3
Other Contractual Services:			
Advisory and assistance services (25.1)……	181,224	296,795	115,571
Other services (25.2)……	67,121	124,700	57,579
Purchase of goods and services from government accounts (25.3)……	174,628	286,532	111,904
Operation and maintenance of facilities (25.4)..	4,816	4,868	52
Research and Development Contracts (25.5)…	824,526	355,320	(469,206)
Medical care (25.6)……	11,200	-	(11,200)
Operation and maintenance of equipment (25.7	29,718	42,754	13,036
Subsistence and support of persons (25.8)……	--	--	--
Subtotal Other Contractual Services	1,293,234	1,110,970	(182,264)
Supplies and materials (26.0)……	608,363	243,523	(364,840)
Equipment (31.0)……	5,182	5,301	119
Land and Structures (32.0)	109,585	478,000	368,415
Investments and Loans (33.0)……	-	-	-
Grants, subsidies, and contributions (41.0)……	415,112	361,223	(53,889)
Interest and dividends (43.0)……	--	--	--
Refunds (44.0)	--	--	--
Subtotal Non-Pay Costs……..……	2,460,328	2,225,747	(234,581)
Total Direct Obligations……...……	$2,563,340	$2,342,173	($221,167)
Average Cost per FTE			
Civilian FTEs	498	572	74
Civilian Average Salary	$126	$127	$1
Military FTEs	87	87	--
Military Average Salary	$85	$90	$5
Total OPDIV FTEs	585	659	74
Total OPDIV Average Salary	$120	$122	$2

Salaries and Expenses
(dollars in thousands)

	FY 211 CR	FY 2012 Estimate	FY 2012 +/- FY 2011
Personnel compensation:			
Full-time permanent (11.1)	$62,931	$72,789	$9,857
Other than full-time permanent (11.3)	13,987	14,254	267
Other personnel compensation (11.5)	47	57	10
Military personnel (11.7)	7,413	7,817	404
Special personnel services payments (11.8)	--	--	--
Subtotal personnel compenstion	84,379	94,916	10,538
Civilian benefits (12.1)	14,825	17,597	2,772
Military benefits (12.2)	3,809	3,913	104
Benefits to former personnel (13.0)	--	--	--
Total Pay Costs	103,012	116,426	$13,414
Travel and transportation of persons (21.0)	11,782	12,175	392
Transportation of things (22.0)	789	778	(11)
Communication, utilities, and misc. charges (23.3)	9,367	10,355	989
Printing and reproduction (24.0)	6,877	3,382	(3495)
Other Contractual Services:			
Advisory and assistance services (25.1)	181,224	296,795	115,571
Other services (25.2)	67,121	124,700	57,579
Purchase of goods and services from government accounts (25.3)	174,628	286,532	111,904
Operation and maintenance of facilities (25.4)	4,816	4,868	52
Research and Development Contracts (25.5)	824,526	355,320	(469,206)
Medical care (25.6)	11,200	--	(11,200)
Operation and maintenance of equipment (25.7)	29,718	42,754	13,036
Subsistence and support of persons (25.8)	--	--	--
Subtotal Other Contractual Services	1,293,234	1,110,970	(182,264)
Supplies and materials (26.0)	608,363	243,523	(364,840)
Total Budget Authority	$2,033,424	$1,497,609	($535,815)

Detail of Full Time Equivalents (FTE)

	2010 Actual Civilian	2010 Actual Military	2010 Actual Total	2011 Est. Civilian	2011 Est. Military	2011 Est. Total	2012 Est. Civilian	2012 Est. Military	2012 Est. Total
ASPR									
Direct:	387	59	446	451	70	521	528	70	598
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	387	59	446	451	70	521	528	70	598
Pandemic Influenza									
Direct:	8	--	8	8	--	8	--	--	--
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	8	--	8	8	--	8	--	--	--
Cyber Security									
Direct:	19	--	19	19	--	19	22	--	22
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	19	--	19	19	--	19	22	--	22
Office of Security and Strategic Information									
Direct:	20	8	28	20	8	28	28	8	36
Reimbursable:	3	--	3	3	--	3	3	--	3
Total:	23	8	31	23	8	31	31	8	39
Medical Reserve Corps									
Direct:	--	7	7	--	9	9	--	9	9
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	--	7	7	--	9	9	--	9	9
PHSSEF FTE Total	437	74	511	501	87	588	581	87	668

Average GS Grade

FY 2007	GS-13/6
FY 2008	GS-13/7
FY 2009	GS-13/6
FY 2010	GS-13/3
FY 2011	GS-13/5
FY 2012	GS-13/7

Detail of Positions

	2010 Actual	2011 CR	2012 Estimate
Executive level I	--	--	--
Executive level II			
Executive level III	--	--	--
Executive level IV	--	--	--
Executive level V	--	--	--
Subtotal	--	--	--
Total - Exec. Level Salaries			
ES-6	2	2	2
ES-5	--	--	--
ES-4	1	1	1
ES-3	1	1	1
ES-2	7	7	7
ES-1	--	--	--
Subtotal	11	11	11
Total - ES Salary	$1,920,675	$1,922,776	$1,928,534
GS-15	102	115	115
GS-14	146	250	327
GS-13	66	77	76
GS-12	43	47	46
GS-11	31	28	29
GS-10	1	1	1
GS-9	13	13	13
GS-8	2	2	2
GS-7	2	9	9
GS-6			
GS-5	1	4	4
GS-4		1	
GS-3			
GS-2			
GS-1			
Subtotal	407	547	622
Total - GS Salary	$39,434,679	$55,178,615	$67,500,248
Commissioned Corps	74	87	87
Total Positions	492	645	720
Average ES level	3	3	3
Average ES salary	$174,607	$174,798	$175,321
Average GS grade	13/3	13/5	13/7
Average GS salary	$96,891	$100,875	$108,521
Average Special Pay (Commissioned Corps)	$83,944	$85,204	$89,845

SIGNIFICANT ITEMS FOR INCLUSION IN
THE FY 2012 CONGRESSIONAL JUSTIFICATION
SENATE REPORT NO. 111-243 (August 2, 2010)

Advanced Research and Development—The Committee has included bill language, proposed by the administration, to transfer $476,194,000 from the Project BioShield Special Reserve Fund advance appropriation to fund in FY12 advanced research and development of medical countermeasures against intentional man-made and naturally occurring infectious disease threats. This is the same as the administration request. The fiscal year 2010 comparable amount is $340,066,000. The Committee has not included additional bill language requested by the administration allowing the Secretary, with 15 days notice to the Committee, to transfer additional amounts from Project BioShield to advanced research and development activities. The Committee notes that, in addition to the funds provided in this bill, the most recent obligation reports from the Department indicate that approximately $358,000,000 in prior year unobligated balances remain available for advanced research and development activities. Due to the large amount of funds available to promote promising countermeasures, the Committee has not given the Secretary the authority to independently transfer Project BioShield balances. The Committee believes that additional transfers from Project BioShield should be made with the full consideration and prior approval of Congress, following sufficient justification from the administration.

Action taken or to be taken

ASPR/BARDA awarded numerous advanced research and development contracts or exercised options on existing contracts in FY 2010. Funding was expended on programs for the advanced development of MCMs, such as: anthrax vaccines, anthrax therapeutics, biodosimetry assays and devices, new broad spectrum antimicrobials, smallpox vaccine for immunocompromised individuals, anticonvulsants, therapeutics for acute radiation exposure, and BARDA's Product Innovation program.

BARDA obligated $500 million of Advanced Research and Development funding in FY 2010, including carry-over funding from FY 2009, and had only $3 million from its FY 2010 appropriations remaining as carryover at the beginning of FY 2011. This demonstrated the availability of promising candidate products to support and the increased performance of BARDA to solicit, review, and award contracts for these products in a timely manner.

BARDA had numerous contract awards and contract options under negotiation at the end of FY 2010 awaiting availability of funds, since all potential awards would be larger than the remaining balance. As BARDA moved into FY 2011 under the continuing resolution it is prioritizing funding on countermeasure programs and continues building a robust development pipeline of products for the multiple threats.

Adjuvants—Advanced adjuvants have the potential to be dose-sparing and to increase the immunogenicity of influenza vaccine antigen in future pandemics. The Committee recognizes the need to develop these adjuvants with pandemic strains and demonstrate that potential now, before the next pandemic. The Committee encourages ASPR, along with NIH and the FDA, to facilitate the development of advanced adjuvants for influenza vaccine.

Action taken or to be taken

ASPR/BARDA has used FY 2006 supplemental appropriations to support the advanced development of antigen sparing adjuvant technologies for influenza vaccines. The use of adjuvant would enable the production of more doses of vaccine from a limited supply of vaccine antigen and to bring licensure of these vaccines in the U.S. Since 2007, the BARDA program has awarded four contracts for the advanced development of pandemic influenza vaccines using adjuvants including:

- Two of the funded programs are moving towards submission of a Biologics License Application (BLA) to FDA in 2011. Two additional programs are in earlier stages of development.
- A "mix-n-match" program that combines adjuvants of one company with antigens produced by another company has been started.
    - In 2009 NIH completed clinical studies with 2009 H1N1 influenza vaccine from sanofi pasteur in combination with adjuvant from GSK
        - This NIH study showed this combination of technologies was safe and immunogenic reducing the dose needed for successful immunization from 15 µg to 3.75 µg.
    - On December 16, 2010, NIH filed an Investigational New Drug application in order to conduct a second mix-n-match study using H5N1 influenza vaccine from sanofi pasteur in combination with adjuvant from either GSK or Novartis.
        - Clinical testing of this combination will start in early 2011.

The next phase of the antigen sparing program will focus on testing the performance of these adjuvants with vaccine antigens from other influenza virus subtypes of pandemic potential. These studies will include both homologous studies where the vaccine and adjuvant are produced by a single manufacturer and mix-n-match format studies where adjuvants are combined with vaccine antigens from manufacturers that do not have an advanced adjuvant program ready for clinical development in order to develop pandemic vaccine response plans that are flexible and make the most effect use of the available technologies. Another component of this phase will be to pre-clinically and clinically evaluate the performance of H5N1 vaccine antigens in the national stockpile that have been stored for several years in combination with adjuvants in a homologous or mix-n-match format.

Antibacterial Resistance.-The Committee notes that antibacterial resistance and the diminishing antibacterial pipeline are complex problems. Multi-pronged solutions are required to sufficiently limit the impact of antibacterial resistance on patients and the public and to spur the development of products to address antibacterial resistant infections. The Committee encourages ASPR and the National Institute for Allergy and Infectious Diseases to create a seamless approach to the research and development of new antibacterial drugs, particularly those designed to combat gram-negative infections, which will help the transition across the spectrum of enterprise from basic research to product development and procurement.

Action taken or to be taken

ASPR/BARDA is funding advanced research and development for broad spectrum antimicrobials using Congressional appropriated funding. The advanced research and development funds are distinct from the Project Bioshield Special Reserve Fund. The advanced research and development funds support products through the "valley of death" with the intent to build a sustainable medical countermeasure pipeline for future Project Bioshield acquisitions.

The Broad Spectrum Antimicrobial (BSA) program is responsible for incentivizing the antimicrobial product pipeline with the goal to increase ongoing research and development of broad spectrum products that are effective against biodefense pathogens as well as antimicrobial resistant, clinically prevalent, infectious diseases. In an effort to engage all industry partners, the BSA strategy includes supporting commercial development in tandem with biodefense development. Through the support of pre-clinical and clinical studies, manufacturing activities, the BSA program can expedite antibiotic development for clinically prevalent infectious diseases. This strategy has the potential to increase the robustness of the antimicrobial developmental pipeline to address both the threat of antimicrobial resistance and attack with a biological threat agent.

Related, ASPR/BARDA was added to the HHS Interagency Task Force on Antimicrobial Resistance in 2010. This taskforce was created in 1999 to coordinate the activities of federal agencies in addressing antimicrobial resistance in recognition of its increasing importance as a public health threat. In 2001, the Task Force developed an initial Action Plan; this Action Plan is currently in the process of being updated. The draft Action Plan outlines specific issues, goals, and actions important for addressing the problem of antimicrobial resistance and includes four main focus areas: surveillance, prevention and control, research, and product development. Through these Task Force-identified activities as well as other interactions, ASPR/BARDA and NIH/ National Institute of Allergy and Infectious Diseases (NIAID), coordinate research and development towards new antibacterial drugs and other antimicrobial agents.

Manufacturing Surge Capacity—The Committee is concerned that the response to the 2009 H1N1 influenza pandemic strained the manufacturing surge capacity for products that are required for surveillance, detection, and administration of vaccine. The Committee urges ASPR to review the existing manufacturing surge capacity for these products as well as the adequacy of the Strategic National Stockpile's current inventory of these products. The Committee believes ASPR should continue to develop advance procedures and guidance with respect to relationships with private parties in emergency situations, including establishing advance contracting logistics and developing distribution channels for non-emergency products that would be used in emergency situations.

Action taken or to be taken

In addition to ongoing activities to increase manufacturing surge capacity for influenza and anthrax vaccines (see below), ASPR/BARDA has initiated additional programs to further increase domestic preparedness for pandemics and other public health emergencies by the establishment of Centers of Innovation for Advanced Development and Manufacturing in the U.S. as recommended in *The Public Health Emergency Medical Countermeasure Enterprise Review*.

BARDA used FY 2004 appropriations and FY06 supplemental appropriations to build domestic manufacturing surge capacity for pandemic influenza vaccines. These ongoing programs have met with success and also benefited the Nation during the response to the 2009 H1N1 influenza pandemic. Successes so far have been:

- Establishment of a year-round supply of embryonated eggs for manufacturing of inactivated influenza vaccine.
    - This contract was initially awarded in 2004 and a new three-year contract was awarded in September 2010
        - Eggs and other supplies from this contract provided approximately 20% of the vaccine doses supplied in response to the 2009 H1N1 pandemic
- Two retrofitting contracts were awarded in June 2007 to expand and update domestic facilities for the production of influenza vaccine.
    - The contract with MedImmune has been completed.
        - In December, 2010 FDA licensed a U.S. facility for bulk vaccine production of their live, attenuated influenza vaccine
        - Additional fill-finish manufacturing lines were approved by FDA in October 2009
            - The expanded filling capacity more than doubled the vaccine manufacturing surge capacity of MedImmune in 2009 and supplied approximately 8% of the vaccine doses supplied in response to the 2009 H1N1 influenza pandemic
    - The contract with sanofi pasteur is ongoing
        - This contract permitted the older facility to remain in operation and produce 2009 H1N1 vaccine alongside the new bulk vaccine production facility and thus more than double the influenza vaccine manufacturing surge capacity in 2009. This production facility was used to respond to the 2009 H1N1 pandemic and accounted for 20% of the vaccine produced in

response to the 2009 H1N1 influenza pandemic, as noted previously regarding the egg supply contract.
        - When this project is completed in 2012 the domestic production capacity for inactivated influenza vaccine will be tripled in comparison to 2004.
- In January 2009 a cost-sharing contract was awarded to Novartis for the construction of a cell-based vaccine manufacturing facility in the US.
    - Construction of this facility is largely completed and the adjuvant production suite has been qualified, making it available to produce adjuvant.
        - Engineering runs are in progress to start the qualification for production of a cell-based influenza vaccine.
        - The facility is expected to be available for emergency use in late 2011 and licensed for vaccine production by early 2013
        - The vaccine manufacturing capacity for this facility is 150M doses within a six month timeframe.

As a major outcome of the recent Public Health Emergency Medical Countermeasure Review, BARDA will establish Centers of Innovation for Advanced Development and Manufacturing (CIADM), which will be public-private partnerships that share facility construction costs, facilitate medical countermeasure (MCM) product development, and ensure domestic vaccine manufacturing surge capacity. These Centers will provide advanced development and manufacturing capabilities for MCMs to address national security and to augment public health needs on a cost-effective, reliable, and sustainable basis. These Centers will provide on a routine day-to-day basis advanced development and manufacturing core services to less experienced commercial partners under contract to the U.S. Government for development of vaccines and other biologics against chemical, biological, radiological, and nuclear (CBRN) threats. Additionally, the CIADM is required to provide new or renovated manufacturing facilities in the U.S. that utilize flexible manufacturing and modern platform technologies to produce vaccines in an emergency for an influenza pandemic, CBRN attack, or outbreaks of known or unknown emerging infectious pathogen. The issuance of the solicitation for this program is expected to be posted in early 2011 with contract awards by late 2011.

A biologic product fill and finish network will be established to support the U.S. Government's needs generated by the ADM and to provide additional filling capacity that can support the surge in vaccine production needed for the response to an influenza pandemic. The RFP for this program is expected to be posted in mid-2011 and award by the end of 2011.

Next Generation Ventilators—The Committee is aware of a request for proposals solicitation made by the Biomedical Advanced Research and Development Authority (BARDA) in ASPR to support advanced development of domestically manufactured next generation portable ventilators. The Committee supports this effort and requests that the ASPR provide to the Committee an update on this solicitation and its other activities in this area in its fiscal year 2012 budget justification.

Action taken or to be taken

ASPR/BARDA awarded in September 2010 a three-year contract for the development of a next generation portable ventilator using FY 2010 BARDA Advanced Research and Development (ARD) appropriations. These ventilators are intended to provide respiratory support for large numbers of severely-ill patients when mass casualties and shortages of experienced care providers may be expected, e.g. a severe influenza pandemic or other public health emergency. The contract supports development of ventilators that utilize advanced technology enabling easier use by healthcare providers without special training for a wider patient population. Additionally, the ventilators developed under this contract will be manufactured domestically and have a lower cost versus conventional portable ventilators (less than $3000 each compared with $6,000-30,000 each).

A second RFP will be issued in early 2011 to support development of additional ventilator candidates. Contract awards supported with ARD funding are expected in early FY 2012 to support development of existing and new next-generation ventilators.

Universal Flu Vaccine—The Committee is encouraged that a universal influenza vaccine, which could potentially provide protection from all flu strains for decades, may become a reality because of research performed by the National Institute of Allergy and Infectious Diseases (NIAID). Due to the strain-specific nature of current flu vaccine, the Committee recognizes that Federal funds could be saved every year and the public's health could be better protected if a universal influenza vaccine were available. The Committee encourages ASPR to work with NIAID to ensure that sufficient research is being done to develop and test a safe and effective influenza vaccine that protects against all strains of the virus.

Action taken or to be taken

ASPR/BARDA continues to monitor technology advances both at NIH/NIAID and in the biotechnology community that could enable the development of a universal influenza vaccine. Monitoring is performed by such mechanisms as the TechWatch program. This program allows developers to meet with BARDA subject matter experts to present their new technology. Also, BARDA currently supports one recombinant technology vaccine platform that could be utilized to support a universal vaccine and will be making additional recombinant vaccine awards in early 2011 to support advanced development of vaccines using molecular technologies that may serve as platforms for the development and production of universal influenza vaccines. Current trends in the development of several promising universal influenza vaccine candidates in early development supported by NIAID currently suggest that BARDA funding for universal influenza vaccine advanced development may be needed in FY 2013 or FY 2014. The key criteria for BARDA support are the completion of Phase 1 clinical studies and the demonstration of cross-reactive neutralizing antibodies against virus strains within a subtype (e.g., H1N1) and across subtypes (e.g., H1, H3, and H5). In FY 2012, BARDA does not request funding for advanced development of universal influenza vaccines.

FY 2012 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives

PHSSEF Allocation Statement:

The office funded through the **PHSSEF** will use **$596,459** of their **FY 2012** budgets to support Department-wide enterprise information technology and government-wide E-Government initiatives. Staff Divisions help to finance specific HHS enterprise information technology programs and initiatives, identified through the HHS Information Technology Capital Planning and Investment Control process, and the government-wide E-Government initiatives. The HHS enterprise initiatives meet cross-functional criteria and are approved by the HHS IT Investment Review Board based on funding availability and business case benefits. Development is collaborative in nature and achieves HHS enterprise-wide goals that produce common technology, promote common standards, and enable data and system interoperability.

Of the amount specified above, **$22,670** is allocated to developmental government-wide E-Government initiatives for **FY 2012**. This amount supports these government-wide E-Government initiatives as follows:

FY 2012 Developmental E-Gov Initiatives*	
Line of Business - Human Resources	$0.00
Line of Business - Grants Management	$223.00
Line of Business - Financial	$489.00
Line of Business - Budget Formulation and Execution	$364.00
Disaster Assistance Improvement Plan	$0.00
Federal Health Architecture (FHA)	$21,570.00
Line of Business - Geospatial	$24.00
FY 2012 Developmental E-Gov Initiatives Total	**$22,670.00**

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

In addition, **$414,719** is allocated to ongoing government-wide E-Government initiatives for **FY 2012**. This amount supports these government-wide E-Government initiatives as follows:

FY 2012 Ongoing E-Gov Initiatives*	
E-Rule Making	$0.00
Integrated Acquisition Environment	$409,310.00
IAE – Loans and Grants	$326.00
GovBenefits	$0.00
Grants.Gov	$5,083.00
FY 2012 Ongoing E-Gov Initiatives Total	**$414,719.00**

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