



**DEPARTMENT  
of HEALTH  
and HUMAN  
SERVICES**

**Fiscal Year  
2013**

Public Health and Social  
Services Emergency Fund

*Justification of  
Estimates for  
Appropriations Committees*





We are pleased to present the FY 2013 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 submission includes the FY 2013 budget justifications for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Pandemic Influenza, Cybersecurity and Security and Strategic Information in the Office of the Assistant Secretary for Administration (ASA), and the Medical Reserve Corps in the Office of the Assistant Secretary for Health (OASH).

As a nation, we must be prepared to respond on a global stage to catastrophic events - whether man-made or natural. One of the primary responsibilities of the ASPR is to ensure safe and effective medical countermeasures (MCM) are available to protect our population in public health emergencies. The MCM enterprise encompasses a host of complex and interdependent processes including the development, manufacturing, production, stockpiling, and distribution of medical products for potential threats, distributing and administering countermeasures to people in need, and evaluating these products to make sure they're effective. The MCM enterprise continues to invest in the development of promising countermeasures, technologies and diagnostics across a broad array of chemical, biological, radiological and nuclear (CBRN) and pandemic threats. Countermeasures for anthrax (vaccines and therapeutics) and other bacterial threats (therapeutics), smallpox (vaccines), chemical threats, radiation exposure, and botulism have been delivered to the Strategic National Stockpile (SNS). Research and development efforts are also underway for a variety of diagnostic platforms, smallpox therapeutics and additional countermeasures. Additionally, efforts to protect at-risk populations as well as extend the utility of existing countermeasures will be addressed in the upcoming year.

In August 2010, ASPR released the *Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to meet Long-Range National Needs* (MCM Review). 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, identified areas of systemic risk, and made recommendations to mitigate those risks. Several recommendations emerged from the Review. These included improvements to FDA regulatory science, establishment of an advanced development and manufacturing capability as well as an MCM strategic investor. Implementation of the recommendations made in the review began in earnest and their implementation will continue over the next year.

The MCM enterprise is one component of a broader response strategy aimed at mitigating the effects of CBRN and pandemic disease events. To be resilient in the face of these disasters, we need a health care system that is nimble and able to deliver coordinated and effective care during public health emergencies and mass casualty events. And we need an integrated strategy for the healthcare, public health, and emergency management systems to work in concert to save lives. A larger framing of all public health infrastructure needs for national health security is described in the National Health Security Strategy (NHSS), which guides 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. National health security is only possible when our approaches are founded on a good base of scientific knowledge, proactive strategic planning, and systematic practices for applying lessons learned and continuously improving. And while major investments in the preparedness and response components are bearing fruit, there is still much work to be done there and in planning for recovery and building resilience.

The FY 2013 Budget request includes \$982 million for ASPR, an increase of +\$56 million over FY 2012. The request continues investments in advanced development of MCMs and diagnostics against CBRN threats, as well as implementation of the recommendations from the MCM Review. Funding is also requested for investments in federal, state, and local preparedness; strategic planning; and operational coordination.

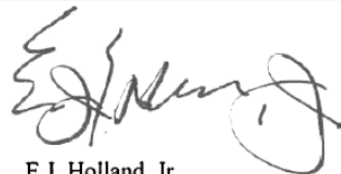
The HHS IT Security Program ensures that the appropriate levels of security are in place to protect the sensitive information systems and data that support the mission and functions of HHS. The FY 2013 request of \$40 million will provide for the continued staffing and sustained operation of the HHS 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 security engineering, ongoing maintenance and operations for the DHS Trusted Internet Connection (TIC) and Einstein initiatives, and funds 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 2013 President's Budget for the Medical Reserve Corps. The Medical Reserve Corps (MRC) is a national network of local groups of volunteers committed to improving the health, safety, and resiliency of their communities. Over the past ten years, the program has grown to more than 200,000 volunteers in almost 1,000 units across the United States—ready to respond to emergencies, reduce vulnerabilities and build resiliency in local communities through prevention, preparedness and public health activities. The network of MRC volunteers includes medical and public health professionals who provide health care and education to community members, as well as non-medical volunteers who provide leadership, logistic and other support. MRC units are community-based and are developed to meet the local needs.

The Budget includes \$7.4 million for 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 classified operations which cannot be fully described here.



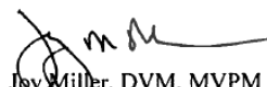
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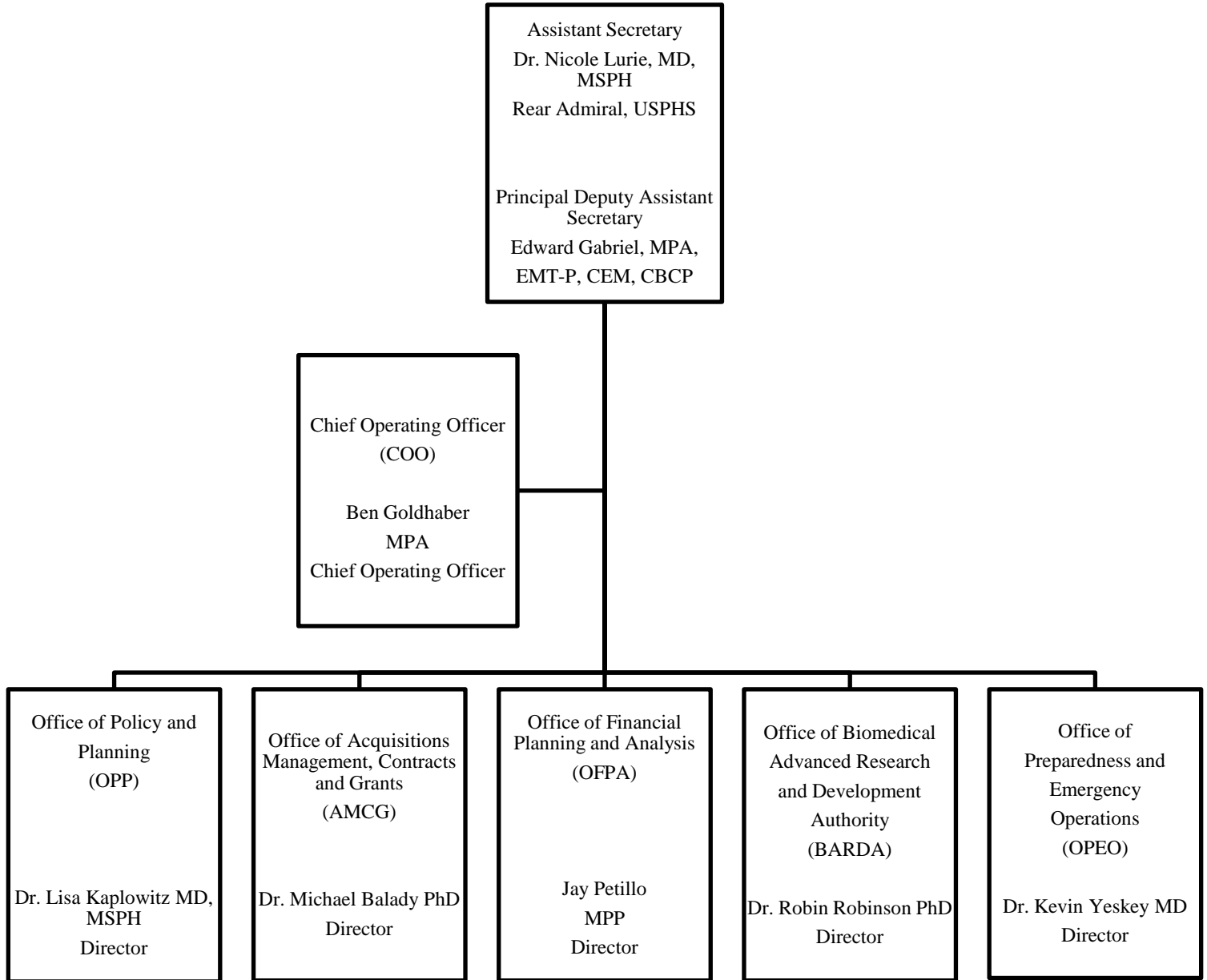
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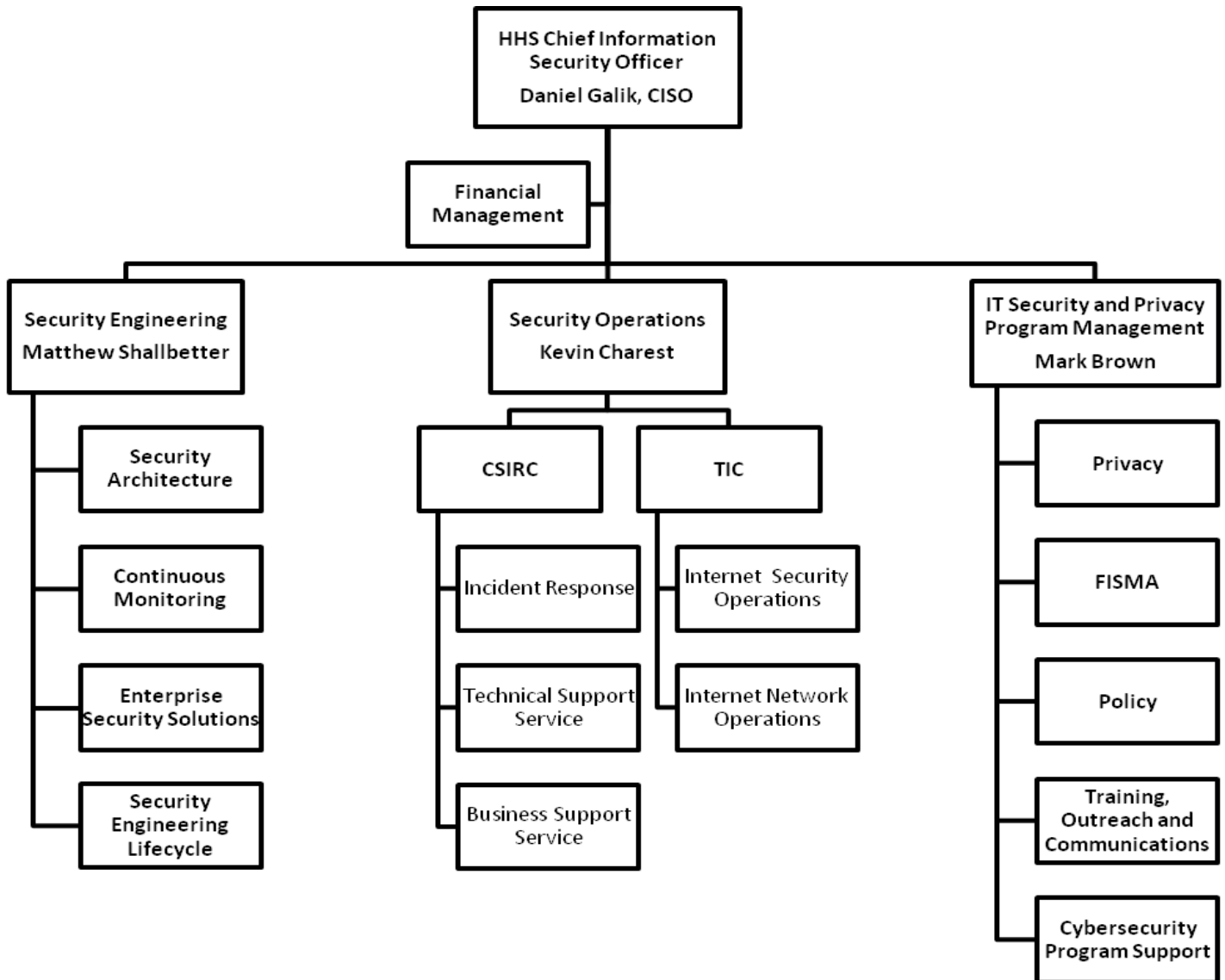
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# Organizational Charts

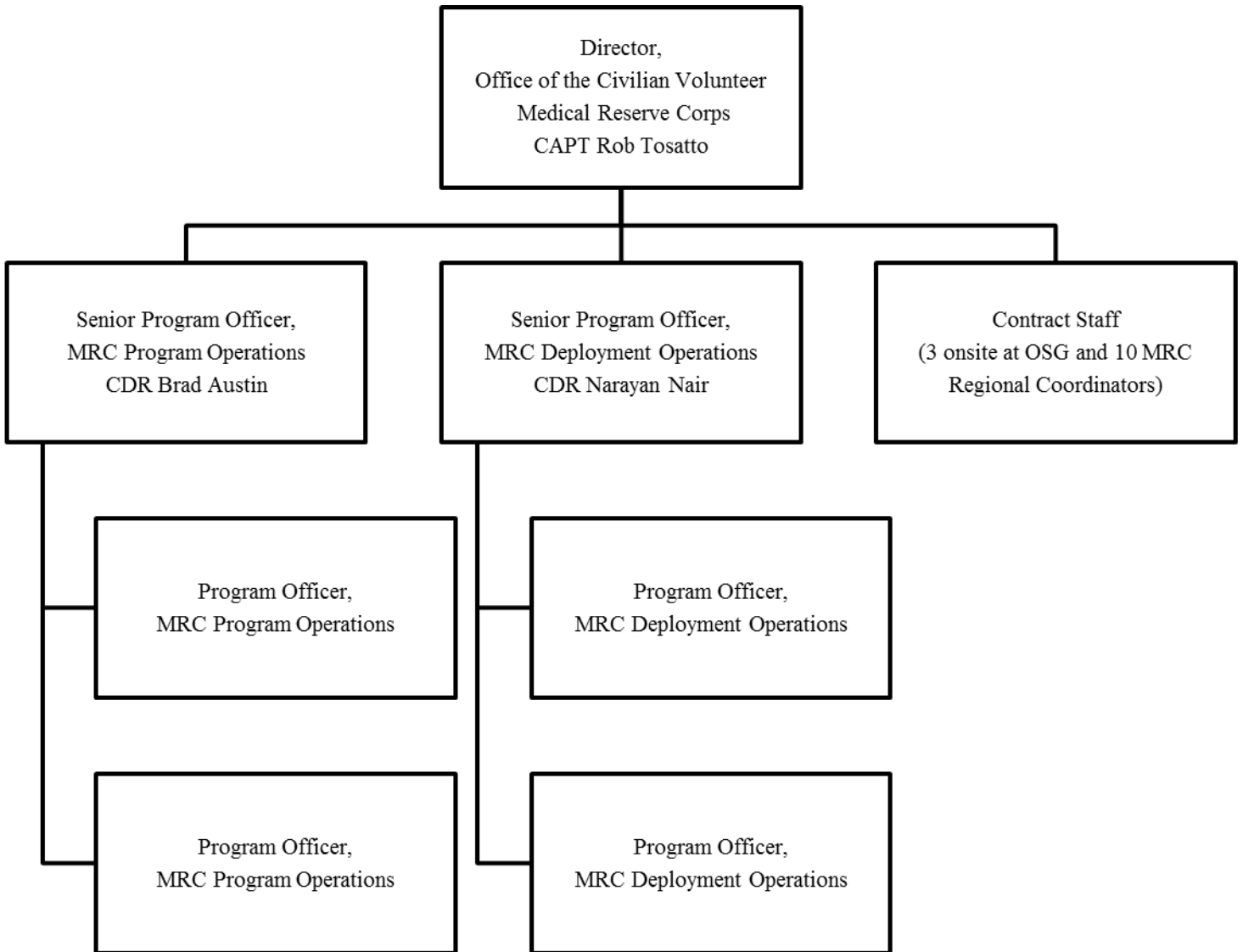
## Office of the Assistant Secretary for Preparedness and Response



# Cybersecurity

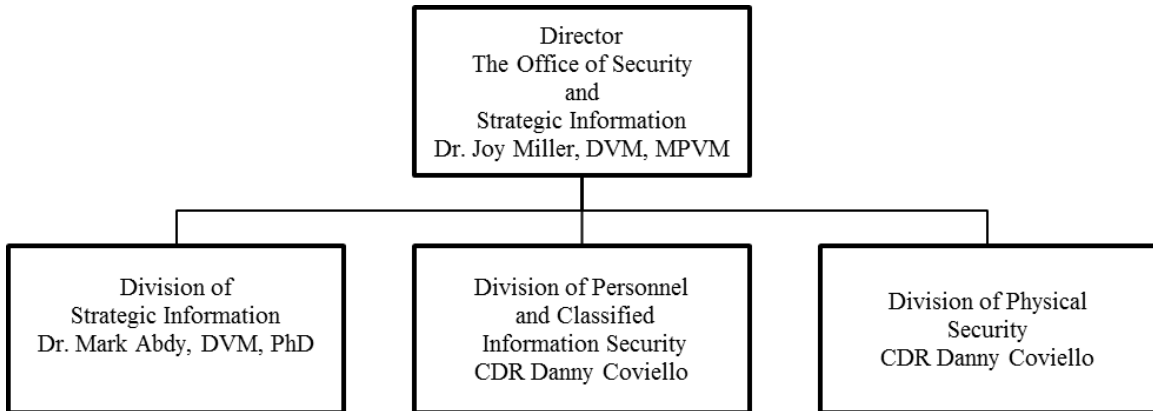


# Civilian Volunteer Medical Reserve Corps





# Office of Security and Strategic Information



## Overview of Budget Request

The FY 2013 request for the Public Health and Social Services Emergency Fund (PHSSEF) is \$1,057,262,000 and 628 FTE. This represents a program level increase of \$74,032,000, and no change in FTE, relative to the FY 2012 Enacted Level. These funds will provide the necessary resources to:

- Support a comprehensive program to prepare for the health and medical consequences of bioterrorism and other public health emergencies;
- Maintain the Department's counter-intelligence program;
- Maintain the Department's cyber-security efforts; and
- Support the Department's pandemic influenza activities.

The budget justification which follows represents funds requested within the Office of the Secretary (OS) for the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Assistant Secretary for Administration (ASA), and the Office of the Assistant Secretary for Health (OASH). This justification also requests funding for the Department's Pandemic Influenza Initiative, and Security and Strategic Information (SSI).

### *Programmatic Increases (relative to the FY 2012 Enacted level):*

- Assistant Secretary for Preparedness and Response (+\$56 million, \$982 million total) to support the advanced development of medical countermeasures, and to enhance community preparedness for public health events. This request reflects an increase of budget authority for BARDA.
- HHS Lease Renewals (+\$17 million, \$17 million total), for costs associated with procuring new long term leases, which will minimize the Department's rental costs in the out years.

### *Programmatic Decreases (relative to FY 2012 Enacted level):*

- Hospital Preparedness Program, ASPR (-\$120 million, \$255 million total) to support recent program alignment between the Department's preparedness programs will reduce administrative costs and accrue savings to both the Department and program grantees. The Hospital Preparedness Program would also provide for competitive grant awards to innovative healthcare coalitions, which will further allow the program to target funds to those areas most in need.

## Overview of Performance

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 – is vital to national security.

ASPR plans to achieve its mission through implementation of a new strategic plan, consisting of six Core ASPR Goals, which will serve as the framework for the development of a streamlined performance management process. ASPR's vision for performance management includes the development of data driven and evidence-based measures that support evaluation and accountability, as well as the development of standards to gauge the effectiveness of programs and progress towards goals.

In FY 2013, ASPR will revise or discontinue 20 performance measures, add one new measure, and retain five key measures. ASPR's strategic focus will turn towards the development and implementation of new capability-based performance measures which will support monitoring for purposes of both accountability and needed improvements in preparedness, response, and recovery efforts. Performance information included in the current budget justification effectively supports the budget request while also demonstrating key benefits to the public.

Measures support ASPR's goals to:

- Work to reach the fullest capabilities of the public health and responder community,
- Develop and procure medical countermeasures,
- Build community resilience,
- Ensure the healthcare infrastructure is able to meet anticipated and unanticipated needs, and
- Recognize our interdependence and solidarity with the rest of the world.

The HHS Cybersecurity Program's Computer Security Incident Response Center (CSIRC) became operational in FY 2011. In FY 2013, Cybersecurity will progress upon this achievement by improving Asset Management, Configuration Management, and Vulnerability Management across the Department in support of the President's priority cybersecurity initiative to fully implement automated security continuous monitoring. In FY 2013, the final stages of the Trusted Internet Connection (TIC) will also be completed and HHS will have consolidated its Internet traffic while fully implementing the Department of Homeland Security's Einstein security monitoring solution into the Department's TIC implementation. TIC is also a Presidential priority program for cybersecurity which will enhance the security of data that makes use of the Internet, by monitoring for intrusions and malicious activity.

**PHSSEF FY 2013 Budget by HHS Strategic Goal**  
(Dollars in Millions)

<b>HHS Strategic Goals</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013 PB</b>
<b>1 Strengthen Health Care</b>			
1.A Make coverage more secure for those who have insurance and extend affordable coverage to the uninsured			
1.B Improve health care quality and patient safety			
1.C Emphasize primary & preventative care linked with community prevention			
1.D Reduce growth of health care costs while promoting high-value, effective care			
1.E Ensure access to quality, culturally competent care for vulnerable populations			
1.F Promote the adoption and meaningful use of health information technology			
<b>2. Advance Scientific Knowledge and Innovation</b>			
2.A Accelerate the process of scientific discovery to improve patient care			
2.B Foster innovation at HHS to create shared solutions			
2.C Invest in the regulatory sciences to improve food & medical product safety			
2.D Increase our understanding of what works in public health and human services			
<b>3. Advance the Health, Safety and Well-Being of the American People</b>	<b>640</b>	<b>569</b>	<b>625</b>
3.A Promote the safety, well-being, resilience, and healthy development of children and youth			
3.B Promote economic & social well-being for individuals, families and communities			
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults			
3.D Promote prevention and wellness			
3.E Reduce the occurrence of infectious diseases			
3.F Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies	640	569	625
<b>4. Increase Efficiency, Transparency and Accountability of HHS Programs</b>	<b>35</b>	<b>0</b>	<b>17</b>
4.A Ensure program integrity and responsible stewardship of resources	35	0	17
4.B Fight fraud and work to eliminate improper payments			
4.C Use HHS data to improve American health and well-being of the American people			
4.D Improve HHS environmental, energy, and economic performance to promote sustainability			
<b>5. Strengthen the Nation's Health and Human Service Infrastructure and Workforce</b>			
5.A Invest in HHS workforce to meet America's health and human service needs today & tomorrow			
5. B Ensure that the Nation's healthcare workforce meets increased demands.			
5.C Enhance the ability of the public health workforce to improve health at home and abroad			
5.D Strengthen the Nation's human service workforce			
5.E Improve national, State & local surveillance and epidemiology capacity			
<b>TOTAL</b>	<b>675</b>	<b>569</b>	<b>642</b>

\*Table reflects PHSSEF Budget Authority

**All Purpose Table**  
(dollars in thousands)

**Public Health and Social Services Emergency Fund**

	FY 2011	FY 2012	FY 2013
	<u>Actual</u>	<u>Enacted</u>	President's <u>Budget Request</u>
<b>Assistant Secretary for Preparedness and Response</b>			
Preparedness and Emergency Operations.....	\$30,263	\$29,583	\$24,647
National Disaster Medical System.....	52,404	52,735	52,390
Hospital Preparedness.....	374,809	374,650	254,500
ESAR-VHP.....	5,748	4,989	500
Medical Countermeasure Dispensing.....	--	--	5,000
Biomedical Advanced Research and Development....	387,426	415,000	546,671
Strategic Investor.....	--	--	50,000
Policy and Planning.....	19,219	15,674	15,164
Operations.....	43,549	32,981	32,991
Co-Located Office Facility.....	--	--	--
<i>Subtotal, ASPR Program Level.....</i>	913,418	925,612	981,863
<b>Assistant Secretary for Administration</b>			
CyberSecurity.....	56,680	39,924	40,000
<b>Office of Public Health and Science</b>			
Medical Reserve Corps .....	11,925	11,247	10,971
<b>Office of the Secretary</b>			
Office of Security and Strategic Information.....	7,428	6,448	7,428
Pandemic Influenza.....	65,447	--	--
Parklawn Replacement.....	34,930	--	--
HHS Lease Replacement.....	--	--	17,000
<b>Total, PHSSEF Program Level.....</b>	<b>\$1,089,828</b>	<b>\$983,231</b>	<b>\$1,057,262</b>
<b>Less funds from other Sources</b>			
Shift of BioShield balances to other purposes.....	(415,000)	(415,000)	(415,000)
<b>Total, PHSSEF Budget Authority.....</b>	<b>\$674,828</b>	<b>\$568,230</b>	<b>\$642,262</b>

## **FY 2013 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, [\$569,452,000] \$625,262,000; of which [\$10,000,000] \$5,000,000 shall remain available until [September 30, 2014,] expended to support emergency operations and of which \$50,000,000 shall remain available until expended 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; and of which up to \$5,000,000 shall remain available through September 30, 2015 to support the 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 \$415,000,000 shall be available for expenses necessary to support advanced research and development pursuant to section 319L of the PHS Act, and other administrative expenses of the Biomedical Advanced Research and Development Authority to support additional advanced research and development: Provided, That funds provided under this heading for the purpose of acquisition of security countermeasures may be used and shall be in addition to any other funds available for such purpose: Provided further, That products purchased with funds provided under this heading may, at the discretion of the Secretary, be deposited in the Strategic National Stockpile pursuant to section 319F-2 of the PHS Act.

In addition, for expenses necessary for replacement of building leases and associated renovation costs for Public Health Service agencies and other components of the Department of Health and Human Services, including relocation and fit-out costs, \$17,000,000, to remain available until expended.

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, \$625,262,000;”*

This language provides general authority for the Department to prepare for and respond to public health emergencies. In particular, this provides most of the total funding for ASPR, MRC, and SSI and Cybersecurity.

*“of which \$5,000,000 shall remain available until expended to support emergency operations”*

This language provides a subset of response funding with multiyear availability.

*“and of which \$50,000,000 shall remain available until expended 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 language provides funds for the Strategic Investor, to advance medical countermeasure development.

*“and of which up to \$5,000,000 shall remain available through September 30, 2015 to support the delivery of medical countermeasures.”*

This language provides funds to ASPR for medical countermeasure delivery.

*“From funds transferred to this account pursuant to the fourth paragraph under this heading in Public Law 111-117, up to \$415,000,000 shall be available for expenses necessary to support advanced research and development pursuant to section 319L of the 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 making funds currently available in the BioShield Special Reserve Fund available for advanced development activities as well.

*“Provided, That funds provided under this heading for the purpose of acquisition of security countermeasures may be used and shall be in addition to any other funds available for such purpose: Provided further, That products purchased with funds provided under this heading may, at the discretion of the Secretary, be deposited*

This language provides BARDA with procurement authorities for security countermeasures.

*in the Strategic National Stockpile pursuant to section 319F-2 of the PHS Act.”*

*“In addition, for expenses necessary for replacement of building leases and associated renovation costs for Public Health Service agencies and other components of the Department of Health and Human Services, including relocation and fit-out costs, \$17,000,000, to remain available until expended.”*

This language provides for costs associated with procuring long term replacement leases that will minimize the Department’s rental costs in the out years and provide flexibility to allocate resources as space needs evolve and as the General Services Administration seeks reimbursement from the Department.



## AMOUNTS AVAILABLE FOR OBLIGATION

(Dollars in Millions)

	<b>FY 2011 Actual</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 Request</b>
Annual Appropriation	\$634,908,080	\$558,251,969	\$433,591,000
Multi-Year Appropriation	\$4,990,000	\$9,978,256	\$191,671,000
Subtotal Multi-Year Appropriations	\$4,990,000	\$9,978,256	\$191,671,000
No-Year Appropriation	\$34,930,000	\$0	\$17,000,000
Supplemental (P.L. 111-32)	\$0	\$0	\$0
Rescission (P.L. 111-226)	\$0	\$0	\$0
Subtotal No-Year Appropriations	\$34,930,000	\$0	\$17,000,000
Total, adjusted budget authority	\$674,828,080	\$568,230,225	\$642,262,000
Unobligated balance, start of year	\$5,447,258,089	\$3,396,229,565	\$1,416,045,565
Unobligated balance, end of year	\$3,396,229,565	\$1,416,045,565	\$92,248,000
Unobligated balance, lapsing	\$0	\$0	\$0
Total Obligations	\$2,725,856,604	\$2,548,414,225	\$1,966,059,565

## SUMMARY OF CHANGES

2012 General funds appropriation	983,230
Total adjusted budget authority	983,230
2013 Request - General funds	1,040,265
Total estimated budget authority	1,040,265
<b>Net Changes</b>	<b>57,035</b>

	FY 2012 Enacted Base		FY 2013 Request	
	FTE	Amount	Change From Base FTE	Amount
<b><u>Increases:</u></b>				
<b><u>A. Built-In:</u></b>				
1. Full-Time Permanent	544	\$50,986	2	\$11,125
2. Other than full-time permanent	0	\$7,999	0	\$1,877
3. Other Personnel Compensation	0	\$61	0	\$1
4. Military personnel	82	\$9,182	0	\$2,050
5. Civilian personnel benefits	0	\$16,869	0	\$3,460
6. Travel and transportation of persons	0	\$6,968	0	\$1,015
7. Transportation of things	0	\$471	0	\$128
8. Rental payments to GSA	0	\$12,694	0	\$1,450
9. Communications, utilities, and miscellaneous charges	0	\$1,284	0	\$11
10. Printing and Reproduction	0	\$38	0	\$8
11. Advisory and Assistance Services	0	\$138,032	0	\$44,856
12. Other services from non-Federal sources	0	\$28,798	0	\$6,075
13. Other goods and services from Federal sources	0	\$103,837	0	\$22,355
14. Operation and maintenance of facilities	0	\$5,660	0	\$1,826
15. Research & Development Contracts	0	\$11,802	0	\$3,775
16. Operation and maintenance of equipment	0	\$39,600	0	\$708
17. Supplies and materials	0	\$830	0	\$256
18. Equipment	0	\$1,326	0	\$429
19. Land and Structures	0	\$12	0	\$5
<b>Subtotal, Built-In Increases</b>	<b>626</b>	<b>+\$436,449</b>	<b>2</b>	<b>+\$101,410</b>
<b><u>B. Programs:</u></b>				
<b>Subtotal, Program Increases</b>			<b>0</b>	<b>\$0</b>
<b>Total Increases</b>	<b>626</b>	<b>+\$436,449</b>	<b>2</b>	<b>+\$101,410</b>
<b><u>Decreases:</u></b>				
<b><u>A. Built-In:</u></b>				
1. Other purchases of goods and services from Government accounts	0	\$3,419	0	-\$917
2. Subsistence and support of persons	0	\$994	0	-\$156

	<b>FY 2012 Enacted Base</b>		<b>FY 2013 Request Change From Base</b>	
3. Grants, subsidies, and contributions	0	\$542,368	0	-\$43,302
<b>Subtotal, Built-In Decreases</b>	<b>0</b>	<b>+\$546,781</b>	<b>0</b>	<b>-\$44,375</b>
<b><u>B. Programs:</u></b>				
<b>Subtotal, Program Decreases</b>			<b>0</b>	<b>\$0</b>
<b>Total Decreases</b>	<b>0</b>	<b>+\$546,781</b>	<b>0</b>	<b>-\$44,375</b>
<b>Net Change</b>	<b>626</b>	<b>+\$983,230</b>	<b>2</b>	<b>+\$57,035</b>

**Budget Authority by Activity**  
(Dollars in thousands)

	FY 2011		FY 2012		FY 2013	
	<u>Actual</u>		<u>Enacted</u>		<u>President's Budget</u>	
	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>	<u>FTE</u>	<u>Amount</u>
Bioterrorism and Emergency Preparedness	617	\$574,451	620	\$568,230	620	\$625,262
Pandemic Influenza	8	65,447	8	--	8	--
Buildings and Facilities	--	<u>34,930</u>	--	--	--	<u>17,000</u>
<b>TOTAL</b>	625	\$674,828	628	\$568,230	628	\$642,262

## Authorizing Legislation

	FY 2012 Amount <u>Authorized</u>	FY 2012 <u>Enacted</u>	FY 2013 Amount <u>Authorized</u>	FY 2013 President's <u>Budget</u>
Pandemic and All-Hazards Preparedness Act, 2006 and the Public Health Security and Bioterrorism Preparedness and Response Act, 2002		\$983,230,225		\$1,057,262,000

## Appropriations History

	<b>Budget Estimate to Congress</b>	<b>House Allowance</b>	<b>Senate Allowance</b>	<b>Appropriation</b>
<b><u>FY 2004</u></b>				
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
<b><u>FY 2005</u></b>				
Appropriation	61,456,000	61,456,000	61,456,000	161,456,000
Rescissions				-1,389,984
Supplemental Appropriation				60,000,000
<b><u>FY 2006</u></b>				
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
<b><u>FY 2007</u></b>				
Appropriation	218,413,000	160,475,000	166,907,000	602,200,000
Supplemental Appropriation				99,000,000
<b><u>FY 2008</u></b>				
Appropriation	1,729,211,000	1,705,382,000	1,674,556,000	729,295,000
<b><u>FY 2009</u></b>				
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
<b><u>FY 2010</u></b>				
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
Rescission (111-226)				-6,630,393
<b><u>FY 2011</u></b>				
Appropriation	1,041,694,000		1,050,795,000	674,828,000
<b><u>FY 2012</u></b>				
Appropriation (PL 112-74)	595,023,000	543,114,000	574,452,000	569,452,000
Rescission (PL 112-74)				-1,076,264
<b><u>FY 2013</u></b>				
Estimate	642,262,000			

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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY2012
Program Level	913,418	925,611	981,863	56,252
Budget Authority	498,418	510,611	566,863	56,252
FTE	481	550	550	0

The Office of the Assistant Secretary for Preparedness and Response’s (ASPR’s) mission is to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies and disasters. ASPR’s vision is a nation prepared to prevent, respond to and reduce the adverse health effects of public health emergencies and disasters. Both its mission and vision reflect the essential role ASPR plays within the nation’s public health preparedness and emergency response arena.

ASPR is requesting a total of \$981,863,000 for the FY 2013 budget, an increase of +\$56,252,000 above the FY 2012 Enacted.

The request includes:

- \$597 million, an increase of +\$182 million over the FY 2012 Enacted, to support BARDA. \$50 million of this request will support the Strategic Investor (SI) initiative. The SI will 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 USG. The SI will target priority countermeasures for advanced development of next-generation anthrax vaccines and therapeutics, diagnostics for radiological exposure, and broad spectrum antimicrobials with clear biothreat indications.
- \$332 million, a decrease of -\$124 million below the FY 2012 Enacted, to support federal, state and local capacity and capabilities in emergencies. Funds will also support the Hospital Preparedness Program (HPP) which focuses 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 and private partnerships, and utilizing exercises as a major component of the evaluation of the program. Funds will be used to transform the HPP grant from a solely formula-based award to states for building preparedness capacity, to a two-pronged grant program that includes a competitive component to drive innovation among healthcare coalitions, and a modest formula grant to States to sustain preparedness capacity and support healthcare coalitions and their partners. In addition, HPP will further advance ASPR’s efforts to integrate state and local public health and medical surge capability, building on the work done with CDC to align the HPP and Public Health Emergency Program grants. A total of \$5 million will support responses to National Special Security Events (NSSEs) and other planned and

unplanned emergencies. Included in this total is support for the National Disaster Medical System (NDMS), which provides for medical response assets, teams, supplies.

- \$50 million, a decrease of -\$13 million below the FY 2012 Enacted for enhancement of the ASPR-wide for domestic and international policy formulation, analysis, and coordination. The request supports the work of the Office of Policy and Planning as well as Operations in the coordination and implementation of the *National Health Security Strategy (NHSS)*, and continues the related research agenda and evaluation framework, as well as activities identified in the HHS Implementation Plan to support the *National Strategy for Countering Biological Threats*. Funds also support the ASPR Strategic Plan goal of “Improve the management of ASPR and investment in its people,” by implementing decisions systems for large scale acquisitions, taking advantage of efficiencies through information technology and expanding ASPR’s commitment to the management discipline of continuous quality improvement, including improved operations through the Secretary’s Program Integrity Initiative.



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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	30,263	29,583	24,647	-4,936
FTE	79	89	89	0

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#8 (ESF #8)*: preparedness and response to the public health and medical consequences of disasters, including terrorist incidents involving weapons of mass destruction. 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, temporary assistance to states, and during National Security Special Events (NSSEs) and 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. As such, the Office of Preparedness and Emergency Operations (OPEO) within ASPR is required to build and maintain an effective planning, coordination, and response capability, including significant logistics capabilities, for public health and medical emergencies. 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 Regional Emergency Coordinators (REC) who are the regionally-based public face of ASPR/OPEO for disaster preparedness, response, and recovery. They work with states and other ESF #8 partners to understand the specific needs of cities, regions, states, territories, and tribes, and also to promote a coordinated effort between HHS and other stakeholders in response to emergencies. Through the Secretary's Operations Center (SOC), the Incident Response Coordination Team program (IRCT), the National Disaster Medical System (NDMS), the RECs, and the Hospital Preparedness Program (HPP), ASPR directs and coordinates all of the federal public health and medical assets associated with an ESF #8 response. The RECs assume key leadership roles in the IRCT structure. This requires the skill and ability to quickly integrate into an emerging response; rapidly assess the situation; help define requirements; understand plans, capabilities and capacities of local partners and communicate effectively with federal, state, local and tribal partners on ESF #8's expected 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.

## Preparedness, Planning, Operations, and Infrastructure Coordination Logistics (LOGS)

During FY 2011, OPEO-Logistics deployed or pre-positioned over 200 tons of medical equipment and supplies in support of several NSSEs and natural disasters that included, but were not limited to, Hurricane Irene, Tropical Storm Earl, the Haiti Cholera Outbreak, the State of the Union Address, the Pacific Basin Earthquake Tsunami, the Peace Officers Memorial Day, the Cherry Blossom Festival, the devastating tornadoes that impacted Joplin, Missouri, and the National Level Exercise (NLE).

OPEO-Logistics also developed, coordinated, and implemented a National Warehouse Regionalization Plan to consolidate and restructure medical storage facilities across the nation to improve readiness and national preparedness. Through cooperative planning efforts with state partners, OPEO-Logistics conducted numerous Federal Medical Station (FMS) site visits and logistics planning workshops with state partners to improve their logistics resiliency and planning.

## Critical Infrastructure Protection (CIP)

The HHS/ASPR Critical Infrastructure Protection (CIP) Program advances Goal 1 of the ASPR Strategic Plan and fulfills HHS's responsibilities under Homeland Security Presidential Directive 7 (HSPD-7) by implementing a public-private partnership to increase the resilience of the Healthcare and Public Health Sector. CIP works closely with a Sector Coordinating Council (SCC) of private sector partners and a Government Coordinating Council (GCC) of their counterparts in State, local, Tribal, Territorial (SLTT), and federal government, holding semi-annual joint meetings and coordinating four joint SCC/GCC workgroups. CIP and its partners have co-written and continue to update a Sector-Specific Plan, detailing how they will work collaboratively to protect the Sector from all hazards. They also collaboratively develop a Sector Annual Report to document the progress of the partnership.

In FY 2011, the partnership embarked on a new analytical process, led by the Sector's Risk Management Workgroup, to identify the infrastructure most critical to the functioning of the Healthcare and Public Health system. The resulting list will serve as the basis for risk mitigation activities, including voluntary security site assessments and security clearances for facility owner/operators. Some facilities will qualify for a new voluntary pilot project that is currently underway with the Department of Energy to install systems that will enable the passive monitoring of power supply for critical facilities and instantly identify power disruptions and/or activation of generators. During an emergency response CIP will develop "infrastructure of concern lists" to be shared with RECs and State and local responders in order to prioritize response measures to protect those facilities. Data from the power monitoring pilot will also be shared instantaneously with federal and state partners, so that actions may be taken to support power restoration for critical facilities.

The CIP information sharing program assists all partners in identifying risks to the Sector and measures they may take to protect their organizations. It is guided by the Sector's Information Sharing Workgroup, and focuses on disseminating information in the classified, For Official Use Only (FOUO) and unclassified environments. To facilitate classified information sharing, CIP in

coordination with the HHS Office of Security and Strategic Information (OSSI) has offered each state health department three HHS-sponsored security clearances. CIP has received a total of thirty-six security applications thus far. Out of the thirty-six, seven have now been granted a secret level clearance. The remaining twenty-nine applicants are still processing their packages and are at various stages of the security clearance process. CIP is working with the Association of State and Territorial Health Officials (ASTHO) to reach out to states that do not have cleared personnel within the health department in order to encourage their participation in the program.

CIP provides at least four classified briefings annually to SLTT and private sector partners. The next briefing will occur immediately prior to the Public Health Preparedness Summit in Anaheim on February 21, 2012. CIP is also coordinating the dissemination of secure telecommunications equipment to health departments to enable real-time communications on threats. For threat information at the For Official Use Only (FOUO) level, CIP maintains a Web portal for the Sector on the Homeland Security Information Network (HSIN). There are currently 1,600 vetted Healthcare and Public Health Sector partners with access to HSIN. During national emergencies, CIP announces conference calls through HSIN which bring these partners together to discuss the ongoing response and identify private sector needs and questions. CIP also maintains a cadre of private sector liaison officers (LNOs) who are trained in emergency operations protocols and are available to assist with two-way information sharing with the Sector from a seat at the Secretary's Operations Center.

When specific threats are identified that have potential impact on the healthcare and public health sector, CIP disseminates that information through classified and unclassified channels. In response to recent threat information regarding the potential terrorist use of toxins and poisons, CIP worked with SLTT and private sector partners to develop three unclassified fact sheets for different audiences in the sector. The three fact sheets were tailored to meet the needs of healthcare providers, public health professionals and epidemiologists, and laboratory professionals. The fact sheets identify the potential threat, describe where to find additional information, and provide procedures to follow if the threat is encountered. The Program worked with state and local partners in the classified setting to develop the fact sheets, which were shared with every hospital, state health departments, and other partners. Other products developed this year by the CIP partnership include a Sector Cyber Security Primer from the Cyber Security Work Group, a fact sheet on preparing for water supply disruptions from the Research and Development Work Group, and a communications flow chart from the Information Sharing Work Group. In CY 2012, CIP plans to increase the development of fact sheets to assist the private sector in preparing for infrastructure-related emergencies and to initiate a webinar series to disseminate more detailed information on specific threats and protective measures.

### Continuity of Operations (COOP)

The Continuity of Operations (COOP) Program is responsible for leading the effort to ensure the continuation of the entire Department's essential functions during all hazards in accordance with Federal and Presidential Directives. In addition, the COOP Program serves the Office of the Secretary (OS), its Staff Divisions (STAFFDIVs), and its Operating Divisions (OPDIVs) by developing and managing the Department's COOP program as well as the day-to-day operations and implementation of the OS Continuity Program. In FY 2011, the COOP program designed,

developed, and held multiple continuity “Tests, Training and Exercise” events. In addition to our own internal exercises, HHS actively participated in the White House led annual continuity exercise, known as Eagle Horizon 2011 (EH-11), in June 2011 as required by HSPD-20. In the same fashion, the COOP program, with the support of the Departments’ senior leadership, has an even more robust Tests, Training & Exercise schedule laid out for FY 2012, for which planning and development is underway. The COOP program has begun to implement a 12-Month Strategic Plan to bring the HHS components’ numerous COOP programs under one umbrella as a single and unified program. This allows us to implement a comprehensive Department-wide continuity program while eliminating redundancies and addressing gaps in a cost-effective manner. In addition, the COOP program has taken lead oversight of the National Communications System 3-10 (NCS 3-10) program for the Department. This also allows us to develop and maintain a strong redundant communications capability while saving costs.

### Regional Emergency Coordination

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 RECs 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 gave HHS useful “lessons learned” to expand response capabilities and to work with state and local partners to fill identified gaps and become more resilient. For example, exercises with the state of North Dakota regarding flooding provided information to the state allowing it to modify its plans and, ultimately, become less dependent on federal support. OPEO continues these critical efforts in a variety of ways. OPEO RECs deploy during various responses, either within their own regions or in other regions depending on the event and need. During these responses lessons are gathered and applied to further preparedness and response planning across the states. Using ongoing gap analysis studies with the states, OPEO works to identify needs that would be unmet during a public health emergency and response. Potential solutions to those gaps are then identified by working with local, state, and federal partners, and the private sector, stressing wherever possible the states’ ability to fill gaps on their own or through mutual assistance.

### Response Operations

OPEO continues to enhance its information analysis and decision-making capability by providing sophisticated analytical decision support for OPEO and ASPR leadership, while serving as a model for other federal, state, and local entities. The Fusion Cell, a mix of analysts, public health specialists and epidemiologists, facilitates active use of information by improving capture, analysis and interpretation of information (e.g., Medmap, electronic medical record utilization, qualitative analysis, international assessments) in order to make timely, well-informed decisions which enable better action. Coupled with an innovative and comprehensive Disaster Medical Information Suite that captures real-time medical encounter information on all patient encounters during a response, OPEO has an unprecedented ability to adjust its personnel and resources to meet the needs in the field. These systems deliver a common operating picture

which enables a dynamic ESF #8 response, and which provides definitive and actionable information to incident managers. OPEO is also developing a methodology to assess risks prior to an incident, based on credible threats/hazards and vulnerabilities, by identifying technical and analytical approaches to identify indications and warnings (e.g., social media, Gobbler, MetaCarta, ED project, data stream/system evaluation, med intelligence). Furthermore, it is developing approaches for predictive analytics, assessing ways in which people exchange critical information before, during and after a public health incident to identify approaches to incorporating these exchanges in everyday practice. The program held Fusion Forums in June, July, and November 2011 as a way to engage stakeholders in discussions about uses of (and requirements for) innovative technologies for public health situational awareness. The audience for these forums was a mix of federal, state, tribal and territorial partners, as well as academia, non-profits, and the private sector. The focus of the forums was biosurveillance indicators and warnings in June, uses of social media for public health situational awareness in July, and use of emerging technologies in November. Working with local, state, federal, and private sector partners is key to providing the correct information. This information informs our reports to the National Operations Center, our liaison officers who are working with FEMA, and our future operations.

OPEO continues to enhance its coordination and communication capabilities by making continuous improvements to the Secretary's Operation Center. In addition to hardware and software updates, which will eliminate technological limitations, workflow analysis was conducted to increase space and determine additional requirements to operate the SOC more efficiently during an event or exercise.

### International Response Operations

OPEO has enhanced its international response capabilities by creating an international response program to coordinate efforts with DoS, USAID, DoD and other federal and international entities. Significant effort has gone into developing International Response Framework guidance and metrics (including the health services response annex) with the goal of improving the HHS range of response capabilities for cross-border and global health security, situational awareness, disaster response and humanitarian assistance, through international and U.S. interagency collaborations. A major section of the program focuses on stability operations for international disasters or conflict areas, and is supported by DoS resources. This program 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. OPEO leads the Department's efforts to provide and train technical experts, who can be deployed directly into unstable environments. This program collaborates with partners to develop culturally appropriate criteria for at-risk regions and countries with failing healthcare infrastructure indicators as well as develop planning and logistics support. International experience, training and deployment improve OPEO situational awareness and response to external health threats for an increasingly diverse U.S. population.

### 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 300 and 400 curriculum, and that the IRCTs have advanced and ongoing training such as the Incident Management Team All Hazards Section Chief training from the Emergency Management Institute . Training and exercise activities include the development of Presidential-level, national-level and departmental quarterly exercises, as well as exercises designed to enhance the abilities of our Emergency Management Group (EMG) to lead response operations during an event. Early in 2011, TELL, in support of HHS and the USG, developed and led a national Tier II exercise titled Dark Zephyr Exercise. It was designed to test the nation’s ability to respond to and begin recovery from an aerosolized anthrax release within the continental United States. This was a series of exercises beginning with state and local governments participation in San Francisco, through an Assistant Secretary level exercise and culminating with a tabletop exercise at the White House. The Dark Zephyr Exercise was both unique and innovative in its approach to examining the nation’s preparedness for threats of this type. In the 10 years since the 2001 anthrax attacks, aerosolized anthrax exercises have primarily focused on the mass prophylaxis effort in the first 48-72 hours of a response. The Dark Zephyr Exercise took the unique approach of starting the exercise 72 hours after detection of an anthrax release. This approach allowed government officials at all levels to begin to understand and plan for the difficult decisions and resource requirements needed to respond to an event of this type. To execute this level of an exercise required multiple collaborative meetings and workshops with local, state and federal government – all with TELL providing the leadership, the exercise design, the concept development, and the planning conferences, in addition to the exercises themselves.

In addition, the TELL team in OPEO leads the lessons learned and corrective action process for all events and incidents including training events and international deployments. TELL also supports the other offices in ASPR by leading exercises and through a rigorous ‘after action’ process to identify lessons learned. Projects receiving TELL support include:

- 1) Office of Planning and Policy efforts on pandemic influenza strategies and policies and the coordination of ESF #8 policy response; and
- 2) BARDA review of lessons from contracting and procurements, as well the development of appropriate logistics and transportation networks required to move medical countermeasures developed through private industry.

OPEO has begun the process of developing training requirements through the OPEO Response Training Guidelines and Course catalog to ensure it has a sufficient, culturally competent, and proficient public health, healthcare and emergency management workforce. OPEO, working with NDMS leadership, has defined a course of action that will unify the Disaster Mortuary Response Team (DMORT)/ Family Assistance Team (FACT) leadership, streamlining two separate teams working together on a mission.

#### National Special Security Events (NSSEs)

OPEO’s RECs lead coordination with state and local entities and with 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 the 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, developing interagency concepts of operations, resource typing of these capabilities, event planning, deployment of teams, and providing required logistical, travel, and equipment support. These planning and response activities focus on five overarching goals:

- 1) Save and sustain lives,
- 2) Protect the public's health,
- 3) Assure the integrity of medical infrastructure,
- 4) Maintain situational awareness, and
- 5) 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. Additionally, support is provided as requested to other events such as the Democratic National Convention (DNC), Republican National Convention (RNC), 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 2011, OPEO responded to NSSEs such as, the World Equestrian Games, New Years Day celebrations, the State of the Union Address, the Battle of First Manassas Celebration, and support for the 10<sup>th</sup> anniversary of 9/11. The State of the Union requires a different type of response than other OPEO response events in that it combines Continuity of Operations (COOP) and response, in which an ensured continuity capability of government functions is created that is not necessary in other events. Other events OPEO provided support for include the Peace Officers Memorial Day ceremony and the annual Cherry Blossom Festival. Responses to many of these events serve a dual purpose, as they also allow OPEO responders (NDMS, U.S. Public Health Service Office of Force Readiness and Deployment [OFRD], and other partners) to work and train together in preparation for future public health emergency events. For 2012, we will support our traditional events like the State of the Union but will also have the two national political conventions (the DNC and the RNC) in North Carolina and Florida. Significant operational planning is already being done to include OPEO senior leadership with the county, state and US Secret Service officials. The DNC and RNC will pose potential challenges for the upcoming year because both are in the same region (Region IV – Charlotte and Tampa) and they will be held during the peak period of the hurricane season in prone states.

### Preparedness Planning

OPEO leads planning activities required to develop and use data-based plans and tools to foster resilient communities that can respond to and quickly recover from disasters. OPEO also supports planning activities required to fulfill ASPR's responsibilities under ESF #8 of the NRF, PPD #8, and Homeland Security Presidential Directives (HSPDs) -10 and -21. This is accomplished through integrating preparedness activities across the tiers of response (federal, regional, state/territorial, and local). This includes regional planning for pre-staging FMS, especially in high-risk areas of the country. The FMS project supports ASPR/OPEO, in collaboration with CDC, in meeting the mandates set forth above to develop a federal asset to

provide over 30,000 patient beds. OPEO is also enhancing mass casualty care capability by the following:

- 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), Chemical Emergency Medical Management (CHEMM) and the State and Local Planners Playbook for Medical Response to a Nuclear Detonation that provide key principles of medical and public health response and guidance on diagnosis and treatment of radiation, nuclear, and chemical exposure for healthcare providers;

Following the 2011 earthquake in Japan, a nuclear power plant was damaged and radioactive material was released. Analysis of the utilization of the REMM website indicated a sharp spike in number of pages viewed, number of visitors, and the number of people who downloaded the mobile phone application. REMM was a handy source of information about the consequences of a radiation incident.

- 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 and expertise anticipated to be in short supply during disasters. For example, we have established relationships with experts in radiation response, as well as those experienced in chemical or toxin incidents.

Other mass casualty preparedness planning activities include initiatives to promote the development of subject matter expertise and decision support tools for chemical, biological, radiological and nuclear (CBRN) incidents. The use of REMM and radiation subject matter experts during the response to the Japan earthquake is one example of how we are building tools and expertise in support of 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 challenging issues regarding modeling; decision-making and triage under scarce resource conditions; response plans that seamlessly link government and non-government responders at the national level; and medical countermeasures and distribution schemes to save as many lives as possible. In FY 2011, OPEO conducted conferences on improvised explosive devices (IED) preparedness in two cities (New York and Seattle); these conferences involved local emergency responders, EMS, hospitals, public health agencies, law enforcement, and other partners. PPD -8 charges the federal government with strengthening national security and resilience through systematic preparedness. These activities support the core capabilities that have been identified as part of PPD-8. Metrics to measure progress toward achieving national public health, medical and fatality preparedness are being developed.



Funding History:

FY 2008	\$13,863
FY 2009	\$18,813
FY 2010	\$29,647
FY 2011	\$29,587
FY 2012	\$29,583

Budget Request:

The FY 2013 request for Preparedness and Emergency Operations is \$24,647,000, the same as the FY 2012 Enacted level. The request includes \$5,000,000 in no-year funding to prepare for and respond to non-Stafford Act National Special Security Events (NSSEs) and other planned and unplanned events. Funding for NSSE was first requested in FY 2010 and supports the activation of response teams for the State of the Union, the Olympics, large sporting events, and unplanned events. This flexible funding source has clearly demonstrated its value in mounting a quick response to save and sustain lives. NSSE has available some remaining funds from prior year appropriations. Those balances and this FY 13 request will cover upcoming events, such as the inauguration.

OPEO regional staff will continue assisting in testing of the integrated plans to prepare for and respond to public health emergencies. Real events, exercises and studies, will form the foundation of corrective action planning that includes advanced data systems to track preparedness and response. OPEO will continue efforts to enhance situational awareness and information sharing among all levels of government and the private sector, in both the classified and unclassified domains.

Funds will support regional and interagency coordination to provide federal public health and medical support to communities during a response. The request includes funding for deployment support and cache management to maintain regional readiness and preparedness planning activities, such as conducting national-level gap analyses, performing regional readiness exercises, and developing regional playbooks and web-based training modules. Funding will also be directed to preparedness planning and response operations to continue to identify requirements for the public health and medical needs using a “whole community” approach and to help quantify the assets and other capabilities needed to meet ASPR’s preparedness and response mission as the lead for ESF #8.

In FY 2013, the Logistics Program will continue to provide support for cache maintenance, medical and pharmaceutical supplies, information technology and communications capabilities to ensure all equipment caches will sustain deployed National Disaster Medical System and other ESF #8 emergency response personnel throughout the full spectrum of emergent care in the field. The Logistics program will also continue its regionalization efforts to streamline ASPR’s and the Department’s logistics capabilities and facilities across the nation by evaluating and right-sizing the Department’s medical treatment resources and pre-positioning critical medical supplies and treatment resources in high-risk areas throughout US and its territories. The program will continue to pursue new “GREEN” technology initiatives throughout its

procurement process, facilities and vehicle fleet to reduce greenhouse emissions contributing to energy conservation and environmental quality. The program will also expand its collaboration and coordination with federal, non-government, and private sector partners to share best-practices and gain efficiencies in resource utilization to enhance Department's capability to logistically respond to a domestic or international response.

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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	52,404	52,735	52,390	-345
FTE	69	77	77	0

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 an 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 services which include 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 healthcare, transportation assets and medical care resources during evacuation. It also includes movement of those patients from definitive care to a final disposition or 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.

In a 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.

NDMS teams have been successfully deployed to dozens of missions each year (such as the State of the Union, hurricanes, flooding, and tornadoes), providing significant support in all three key functions described above.

The ESF #8 Integrated Training Summit (formerly NDMS Training Summit) is an annual event with attendance exceeding 3,000 participants. The summit brings together federal (including DoD and VA), 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 incorporates specialized trainings for Incident Response Coordination Team (IRCT) personnel, OPEO logistics, and the DoD for aero-medical evacuation. Further, as the FY 2012 Summit plans progress, we are working with CDC to combine the Summit with the annual CDC Public Health Preparedness Conference.

The OPEO NDMS Program Development Branch (PDB) and the NDMS Chief Medical Officer Program (CMO) lead the effort within HHS to develop an integrated, scalable and deployable healthcare delivery by conducting a thorough review of after action reports and other literature, obtaining input from subject matter experts, and conducting evidence-based research. Using these tools, PDB and CMO are working, for example, to reduce variables such as the time to deploy to the site and effective deployment in stages rather than large groups.

NDMS is taking a proactive stance towards ensuring the safety and health of deployed HHS personnel. The CMO program has developed an innovative hazard and risk communication and mitigation plan for every deployment. In conjunction with a professional safety officer, mission-specific guidance is generated and customized every time OPEO response personnel operate in the field, both for training and response. Several other agencies are considering using the NDMS safety program as a model for their response operations as well.

In FY 2011, the Joint Patient and Tracking teams (JPATs) proved beneficial in their support of the DoD and VA Federal Coordinating Centers (FCC). This beneficial support was evident during the 2010 Haiti Response when teams were deployed and in the 2011 National Level Exercise during which the scenario was a massive earthquake in the New Madrid Seismic Zone.

Through the active recruitment of medical professionals throughout the country, NDMS has been capable of enriching 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 at the forefront of their medical communities and 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.

The NDMS mission has grown substantially since 2005 and NDMS remains the only system able to mesh federal response with civilian infrastructure and human capital assets. NDMS implemented a standardization and regionalization plan in July 2010, and as a result, was able to close/consolidate a total of 19 facilities throughout the Nation as of September 2011. Additionally, a second Mission Support Center in Texas was established to enhance training, readiness, and response in the Central Corridor of the United States (with a third one on track for occupation in FY 2013 in California for the Western Corridor). Also, cache management operations were standardized throughout the United States by centralizing packaging standards and execution in Regional facilities and Mission Support Centers. This function is now performed by two ASPR entities vice 33 decentralized teams. Due to improved standardization of its medical materiel and regionalization of warehouses, NDMS is able to respond more

quickly to public health emergencies. The standardization and regionalization has made response assets less vulnerable to geographic hazards (i.e., earthquakes, floods, etc.) which would hamper the ability to move supplies in order to meet the deployment goal of response assets on site within 12 hours of a public health emergency. NDMS will be a nimble and flexible response asset to the nation during public health emergencies.

Funding History:

FY 2008	\$42,464
FY 2009	\$45,965
FY 2010	\$52,493
FY 2011	\$52,404
FY 2012	\$52,735

Budget Request:

The FY 2013 request for the National Disaster Medical System is \$52,390,000, -\$345,000 below the FY 2012 Enacted level. Funding will support central headquarters operations, regional emergency coordination, as well as medical response assets, including teams, supplies, and equipment (e.g., 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.

FY 2013 funding includes logistics support for cache maintenance, including medical and pharmaceutical supplies and 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 to Haiti. 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 will continued to be streamlined to maximize critical skill sets and specialized surgical skill sets, share overhead costs, 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, when appropriate, smaller to meet both current and future mission requirements.

FY 2013 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. Such teams include Disaster Medical Assistance Teams (DMAT),

Disaster Mortuary Operational Response Teams (DMORT), National Veterinary Response Teams (NVRT), and other NDMS Specialty Teams located across the country.

Funding will be used for 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 concepts of operations.

Historically, NDMS has emphasized the ‘response’ portion of NDMS—the team building, training, cache development, etc. NDMS’ two other major parts are Patient Transportation and Definitive Care. Over the past several years, these components have been major concerns of our state partners. Funding requests in FY 2013 include development and training (with exercises) of those two critical portions of NDMS. Improvements made to both areas include the revision of the NDMS-Hospital MOU and to expanding the patient movement capability. The NDMS MOU with hospitals for definitive care has been revised to reflect changes in the operational capacity of OPEO and in response to hospitals’ issues regarding patient discharge to their home of record. The MOU now places patient return responsibility upon OPEO and outlines the support HHS will provide in that capacity. Patient movement has improved as NDMS has developed critical care teams that can manage patients at the aerial point of embarkation (APOE) and established a national ambulance contract with FEMA. Patient movement issues are discussed and resolved by the OPEO-led Senior Leaders Council for Patient Movement, of which OPEO conceived and implemented with our ESF #8 partners.

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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	378,557	379,639	255,000	-124,639
FTE	34	37	37	0

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

Program Description and Accomplishments:

The Hospital Preparedness Program (HPP) provides leadership and funding through grants to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Since its move to ASPR in 2007 from the Health Resources and Services Administration (HRSA), the program has continued to build medical surge capacity and capability, as well as enhance overall preparedness and response capabilities of hospitals, other healthcare organizations (HCO), and healthcare systems. HPP has strengthened federal, state, local, territorial, tribal and regional partnerships to improve overall medical surge preparedness nationally. The program continues to focus on strengthening the capability of individual hospitals and other HCOs. In addition, the building and sustainment of state-based, efficient Healthcare Coalitions (HCC) that maximize the ability of multiple HCOs to surge collectively and enable appropriate patient care during a disaster continue to be improved through the program. These HCC are a cornerstone for HPP and an integral component for community-wide planning for healthcare resiliency. The capabilities supported through the program include, but are not limited to, interoperable communications, bed and resource tracking systems, the 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 training and exercises to promote seamless preparedness integration across the local, state, regional, and federal tiers of healthcare asset management.

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. The HPP staff has developed relationships with awardees and sub-recipients at the state, local, and healthcare system level, which enable medical surge capacity and capability during a response. HPP headquarters and field staff provide technical assistance and real-time situational awareness to the rest of OPEO, making it possible to more effectively leverage and connect all ASPR programs and assets and enhance overall hospital, HCO, and healthcare system response to medical and public health emergencies. For instance, during hurricane Irene, HPP Field Officers deployed and were able to supply HCO-specific situational awareness information in a timely fashion through their liaison abilities and knowledge of grant-funded assets.

The program also supports the activities of the HPP Program Evaluation Section (PES), the Emergency Care Coordination Center (ECCC), the Healthcare and Public Health Sector Critical Infrastructure Protection (CIP) Program, and the Recovery Coordination Office (RCO). The 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 PD #7.

PES was established to evaluate the HPP program and grant recipients. Since 2010, PES has played a key role in aligning the measures and metrics used by the HPP and PHEP to assess healthcare systems and public health preparedness, and to minimize redundancies and the administrative burden of reporting and data collection on our awardees. PES is critically engaged in creating meaningful HPP and HPP-PHEP joint measures that support and test the revised capabilities, developing an IT system to better serve both public health and healthcare preparedness program's technology needs, and creating a grant evaluation framework that encompasses both programs.

In partnership with PHEP, PES is committed to quality improvement in the areas of performance measurement, analysis, study designs, and information technology systems necessary to critically examine and automate healthcare preparedness assessment. PES translates analytical findings into information that decision-makers need to make improvements. Levers for program improvement in which PES may become involved include program planning, funding criteria related to benchmarks, and performance measurement. PES has a history of using HPP data and its analysis to support awardees and inform future program directions.

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 PD #21 and was launched as a direct response to the 2006 Institute of Medicine Series of Reports titled *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 of 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 maximum 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). The optimization of the ECS for routine patient care operations is fundamental to a prepared and resilient community. For example, if a region's emergency departments are overcrowded with boarded patients on a day to day basis, it will likely have a reduced capability to respond to a mass casualty incident that results in a surge of patients. Situated within ASPR, the ECCC is ideally positioned to address this critical issue within the medical community by bringing together key stakeholders and promoting both collaboration and the development of an evidence base to inform next steps. The ECCC distributed a multi-year strategic plan in 2011 that outlines the priorities of the Center and crosswalks the strategy with the strategic plans of both ASPR and HHS.

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 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 HPP Grant Guidance to help states develop more comprehensive strategic planning and streamline 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 DHS 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.

ASPR has made great strides through our grant alignment effort with CDC to streamline and improve the effectiveness of both the HPP and PHEP programs. In FY 2012, there will be a single Funding Opportunity Announcement for the programs, and a single application interface for grantees, in effect establishing a virtual one-stop-shop and eliminating an administrative layer for grantees. These alignments have led to greater administrative efficiency for grants management by consolidating federal HPP Field Project Officers locating them close to grantees in the regions, and effectively reducing management costs for HPP by up to 10 percent.

The HPP Grant Program developed new evidenced-based performance measures for grantees in FY 2008 that reflect the requirements of Pandemic and All-Hazards Preparedness Act (PAHPA), and continues to refine those measures for FY 2013 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 was made in achieving core HPP tenants. 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 healthcare system is more prepared to respond to disasters because of the funding that has been provided through this cooperative agreement program. Recently, the HPP Grant Program released *From Hospitals to Healthcare Coalitions: Transforming Health Preparedness and Response in Our Communities*. This is the program's first state-by-state report and identifies advances states have made in preparing hospitals for all types of disasters. The report also discusses the next steps the program will take to boost community resilience.

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:

Oklahoma Tornadoes: Oklahoma had approximately 35 tornadoes touch ground, affecting central, northwest and southwest Oklahoma. These storms caused significant damage in these areas. Shelter in Place was demonstrated as hospitals secured patients throughout the storms and tornadoes. Interoperable communications were critical as power sources were out; hospitals were able to report situational reports via multiple alternative communications devices. Partnerships and coalitions allowed a regional approach to response operations and the management of critical resources. HAvBED bed-tracking was utilized to assist in evacuating to other facilities or for emergency department surge.

Missouri National Level Exercise (NLE) and Tornado: Missouri planned for three years for a national level exercise to test a few of their HPP capabilities including deploying the 60-bed Mobile Medical Unit, HAvBED reporting, interoperable communications, evacuation, fatality management and activation of their state ESAR-VHP system called Show-Me-Response.

Shortly after the completion of their exercise, the southwestern part of Missouri in Joplin was hit with an EF-5 tornado with winds up to 200 miles per hour. The tornado destroyed roughly 30 percent of Joplin's infrastructure including St. John's Regional Medical Center, a 370-bed hospital. Med Sleds funded through the Hospital Preparedness Program assisted staff in evacuating 183 patients down as many as eight flights of stairs.

The state, with the assistance of the Missouri DMAT and the National Guard, deployed the 60-bed mobile hospital, which was deployed during the NLE, to Joplin to support a full array of services including emergency, surgery, imaging, lab and inpatient care. HPP grants contributed significantly to the purchase of this portable facility.

The state's mobile medical and communication trailers were deployed from different regions of Missouri to help provide redundant forms of communication. Interoperable

communications capabilities were demonstrated as healthcare facilities and emergency operations centers were able to provide situational reports. Local responders treated 500 patients in emergency departments and 400-600 patients in established triage areas within 12 hours of the incident.

As a result of the tornado approximately 160 people died, and 713 were injured. Impacted facilities included dental offices, dialysis facilities, long term care facilities, and childcare facilities. The 183 patients that were evacuated from St. John's were transferred to 42 hospitals in 4 states, including a neighboring hospital that was not directly affected by the tornado. HPP funds were used to help the hospitals prepare for an emergency by putting plans in place and exercising those plans. The Incident Command Structure was used, and had Memorandums of Understanding in place to ensure roles were determined in advance.

States are not eligible to receive CDC Public Health Emergency Preparedness Program funding unless they participate in ESAR-VHP. The 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 healthcare 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 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. Currently, all fifty states and the District of Columbia have fully operational ESAR-VHP systems. There are over 189,700 registered ESAR-VHP volunteers.

In FY 2011, ASPR awarded two new and 24 non-competing continuation grants 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), Drug Enforcement Administration (DEA), 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 U.S. Public Health Service Commissioned Corps (USPHS), and the MRC to conduct the Integrated Medical, Public Health, Preparedness, and Response Training Summit. In addition to a joint ESAR-VHP and MRC state coordinators meeting, the Summit provided a forum for training, discussion, information sharing, and networking with public health and response partner organizations.

In FY 2011, the ESAR-VHP maintained the national website to elevate the awareness of the ESAR-VHP program and encourage health professionals to register for ESAR-VHP in their states. The national website is a central location for potential volunteers to learn about ESAR-

VHP. Following the tornado in Joplin, Missouri, over 4,000 volunteers registered with Missouri's ESAR-VHP system called Show-Me-Response. Out-of-state health professionals were directed to the national ESAR-VHP website to register with their state ESAR-VHP programs.

In FY 2011, state ESAR-VHP programs deployed volunteers to support local and state response activities, including flu vaccinations, tornadoes, wildfires, floods, and hurricanes. For example:

#### Tennessee Floods

In May 2011, Tennessee used their ESAR-VHP system (TN Volunteer Mobilizer) to request assistance within two regions for flooding. Five hundred fifteen volunteers were activated. Support and medical volunteers were deployed. Support volunteers were used for sandbagging, call center staffing, and operation of heavy equipment. Medical volunteers provided assistance in first aid stations and shelters.

#### Hurricane Irene and Tropical Storm Lee

Following Hurricane Irene, North Carolina deployed State Medical Assistance Teams comprised of EMS and hospital-based responders. Sixty-eight volunteers served in special medical needs shelters and medical clinics for a period of 4-6 days. New Jersey volunteers assisted and supported Hurricane Irene response activities in local jurisdictions, including staffing local mass care shelters and an evacuation center. Virginia deployed 71 physician, registered nurse, licensed practical nurse, mental health, and general support volunteers to support medical needs shelters, pet shelters, response preparations, and health department operations centers. Deployment ranged from 2-54 hours per volunteers and volunteers provided 1,190 hours of support. Massachusetts activated local volunteers for assistance in shelters to provide medical care and general shelter staffing. New York respiratory therapists were deployed to manage evacuated nursing home patients on ventilators. Volunteers were augmented to aid nursing home staff who over-bedded in order to receive patients from evacuated nursing homes. Medical personnel provided medical support in evacuation shelters, and registered nurses staffed clinics for tetanus shots. Rhode Island deployed 25 volunteers to conduct functional assessments in general population shelters.

During FY 2011, the ESAR-VHP program coordinated the development of a HHS Volunteer Playbook and Federal Protocol for deploying civilian volunteers in a national emergency. The HHS Volunteer Playbook includes documentation on all HHS civilian volunteer pools available for federal deployment during a large scale national emergency. It includes information on volunteers' roles and responsibilities, triggers for activation, strategic public messaging, and volunteer hiring and deployment procedures. The Federal Protocol outlines the process for deploying ESAR-VHP and Medical Reserve Corps (MRC) volunteers during a Federal response. The program continued 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 identified the technical and business requirements for a web application to allow states to transmit volunteer information, i.e., credentials, to other states and healthcare facilities. The web application will be launched in FY 2012. 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, and 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 and six state ESAR-VHP programs participated in 2011 National Level Exercise.

Funding History:

FY 2008	\$416,979
FY 2009	\$385,056
FY 2010	\$417,400
FY 2011	\$380,557
FY 2012	\$379,639

Budget Request:

The FY 2013 request for Hospital Preparedness is \$255,000,000 a decrease of -\$124,639,000 from the FY 2012 Enacted level. This request includes \$500,000 for ESAR-VHP, a reduction of \$4,491,000 below the FY 2012 Enacted level. All fifty states and the District of Columbia have fully operational ESAR-VHP systems. FY 2012 will be the last year of the project period for the current ESAR-VHP grants. Grants will be discontinued in FY 2013. Funding for state access to national data sources for credentials verification and for the participation of state and territorial ESAR-VHP personnel in the Integrated Training Summit will be discontinued. The funding requested for ESAR-VHP will support existing staff that will provide technical expertise and support to states and other partners. These staff may in part be funded by the HPP grant, allowing continued support to their target audience.

The remaining funding requested will be directed toward the Hospital Preparedness Program, including formula grant awards to states, cities and territorial public health departments to maintain core state and hospital-based systems essential to a prepared healthcare response including interoperable communications, bed and resource tracking systems, National Incident Management System (NIMS) and other capabilities-based education and training, and HSEEP-based exercises to promote seamless preparedness integration across the local, state, regional, and federal tiers of healthcare asset management.

In support of the National Preparedness Goal, the Hospital Preparedness Program grants to states will also promote allocating a portion of all state grant awards to healthcare coalition development emphasizing and/or sustaining three key areas: 1) a risk-based methodology, 2) a capability approach consistent with Presidential Policy Directive #8, and 3) evidence-based metrics for evaluation. Part of the funding for HPP, \$15 million of the total, will be allocated via competitive grant. These new Hospital Preparedness Program risk-based allocations will be informed by the state's risk of specific threats and vulnerabilities, taking into account sub-state regional variations to include concrete, measurable, and prioritized objectives to mitigate that risk.

Funding allocations to healthcare coalitions through a state's grant award will enable targeted healthcare coalition development at the sub-state regional level to improve medical surge

capability and community resilience, in harmony with the National Health Security Strategy, in concert with the HHS/ASPR Medical Surge Capacity and Capability Handbook framework, and in support of independent expert coalition research.

In support of the National Preparedness Goal, health preparedness capabilities will be further defined and developed for specific types of incidents that pose the greatest risk to the security of the Nation, and they will emphasize actions aimed at achieving an integrated, dual-use, layered, and all-of-Nation preparedness approach that optimizes the use of available resources. Healthcare coalition development through targeted state grant award allocations, a core component of the medical surge capability, is a cornerstone of HPP and seamlessly integrates into the National Preparedness Goal and its components.

As defined in PPD #8, the National Preparedness System (NPS) will include a comprehensive approach to assess national preparedness that uses consistent methodology to measure the operational readiness of national capabilities at the time of assessment, with clear, objective and quantifiable performance measures, against the target capability levels identified in the national preparedness goal. Assessment strategies for evaluating state grant award-based healthcare coalition allocation results will be congruent with the NPS, and will include the development of objective deliverable measures to gauge healthcare coalition operational success, and improve local and regional resilience. This will occur through an independent review of specific quantitative and qualitative data sources.

In FY 2013, 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 and private partnerships, and using 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., within 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, healthcare systems, and HCOs to report available assets in support of seamless preparedness and response across the tiers of healthcare asset management. Continued support also will be provided for evaluation activities, such as review and revision of current performance measures, development of profiles of state healthcare 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 healthcare system's ability to respond when the infrastructure surrounding the healthcare 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), the Critical Infrastructure Protection (CIP) program for the Healthcare and Public Health Sector, and the Recovery Coordination Office (RCO). PES evaluates the HPP program and overall healthcare systems preparedness. The CIP program includes collaboration with federal, state, local, territorial, tribal, and private sector

stakeholders on a range of activities to enhance the resiliency of the sector, including information sharing, threat risk assessments and participation in exercises. In FY 2013, the CIP program will continue to focus on initiatives essential to meeting the requirements of NIPP and building partnerships with local, state, and regional stakeholders under the NIPP framework. A primary area of focus will continue to be the sharing of threat analysis and risk mitigation information with private sector partners by means of a secure web portal, production and dissemination of fact sheets, and quarterly classified briefings.

Outputs and Outcomes:

Measure	Most Recent Result	FY 2011 Target	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2011
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	N/A	60%	N/A
2.4.4: Enhance State and Local Preparedness: Improve efficiencies in the administration of public health and medical preparedness programs through the implementation of a joint funding opportunity announcement encompassing the two HHS preparedness programs.	N/A	N/A	N/A	100%	N/A

**Discontinued Performance Measures (2.4.2 A-E and 2.4.3)**

**Measure 2.4.2.A:** Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states demonstrating ability to report hospital bed data: % of states demonstrating ability to report hospital bed data (Outcome).

<b>FY</b>	<b>Target</b>	<b>Result</b>
2012	Discontinued	N/A
2011	100%	Dec 31, 2012
2010	90%	Dec 31, 2011
2009	80%	100% (Target Exceeded)
2008	60%	100% (Target Exceeded)

**Measure 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)

<b>FY</b>	<b>Target</b>	<b>Result</b>
2012	100%	Dec 31, 2013
2011	100%	Dec 31, 2012
2010	98%	Dec 31, 2011
2009	95%	100% (Target Exceeded)
2008	60%	89% (Target Exceeded)

**Measure 2.4.2.C:** Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states demonstrating development of Fatality Management Plans: % of states demonstrating development of Fatality Management Plans (Outcome)

<b>FY</b>	<b>Target</b>	<b>Result</b>
2012	Discontinued	N/A
2011	100%	Dec 31, 2012
2010	85%	Dec 31, 2011
2009	70%	96% (Target Exceeded)
2008	60%	58% (Target Not Met)



**Measure 2.4.2.D:** Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states demonstrating development of Hospital Evacuation Plans: % of states demonstrating development of Hospital Evacuation Plans (Outcome)

<b>FY</b>	<b>Target</b>	<b>Result</b>
2012	Discontinued	N/A
2011	100%	Dec 31, 2012
2010	90%	Dec 31, 2011
2009	85%	96% (Target Exceeded)
2008	60%	82% (Target Exceeded)

**Measure 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)

<b>FY</b>	<b>Target</b>	<b>Result</b>
2011	51.1 per 1 million dollars	Apr 30, 2013
2010	34 per 1 million dollars	Apr 30, 2012
2009	22.69 per million dollars	46.9 per million dollars (Target Exceeded)
2008	15.13 per million dollars	25.8 per million dollars (Target Exceeded)

#### **Data Source and Validation for Hospital Preparedness Program**

<b>Measure</b>	<b>Data Source</b>	<b>Data Validation</b>
2.4.2.A 2.4.2.B 2.4.2.C 2.4.2.D	Reports from states and health care facilities; after action reports and corrective action plans; Memoranda of Understanding among coalition partner; minutes of meetings. Sector Specific Plan (SSP) for the Healthcare and Public Health Sector: An element of the National Infrastructure Protection Plan (NIPP).	Observation of exercises and drills; data reported to the SOC. The SSP initial draft was cleared through the Executive Secretary's process and all commentary from the department was included and was reviewed by private sector partners. Changes were made after the 2005 changes to the NIPP. The final NIPP was published in early 2006 and final revisions were be made to the SSP to ensure full compliance with the NIPP. The SSP was forwarded to DHS within 180 days and the tasks associated with the SSP are being

Measure	Data Source	Data Validation
		scheduled in partnership with the private and government sector partners.
2.4.3	Data are based on the applications submitted.	Data are self-reported
2.4.4	Joint Funding Announcement	Data are self-reported

## Discretionary State/Formula Grants

### Hospital Preparedness Program

STATE/TERRITORY	FY 2011 Actual	FY 2012 Enacted	FY 2013 President's Budget	Difference +/- 2012
Alabama	\$5,386,508	\$5,305,549	\$3,372,987	(\$1,932,562)
Alaska	\$1,211,937	\$1,193,722	\$918,578	(\$275,144)
Arizona	\$7,051,765	\$6,945,777	\$4,352,062	(\$2,593,715)
Arkansas	\$3,486,575	\$3,434,172	\$2,255,935	(\$1,178,237)
California	\$28,666,533	\$28,235,675	\$17,060,308	(\$11,175,367)
<i>City of Chicago</i>	\$3,520,199	\$3,467,290	\$2,275,704	(\$1,191,586)
Colorado	\$5,550,503	\$5,467,079	\$3,469,407	(\$1,997,672)
Connecticut	\$4,223,889	\$4,160,404	\$2,689,434	(\$1,470,970)
Delaware	\$1,406,825	\$1,385,680	\$1,033,161	(\$352,519)
District of Columbia	\$1,558,756	\$1,535,328	\$1,122,488	(\$412,840)
Florida	\$19,720,658	\$19,424,257	\$11,800,646	(\$7,623,611)
Georgia	\$10,449,266	\$10,292,214	\$6,349,599	(\$3,942,615)
Hawaii	\$1,865,852	\$1,837,808	\$1,303,043	(\$534,765)
Idaho	\$2,058,131	\$2,027,197	\$1,416,092	(\$611,105)
Illinois	\$11,113,877	\$10,946,835	\$6,740,352	(\$4,206,483)
Indiana	\$7,208,168	\$7,099,829	\$4,444,019	(\$2,655,810)
Iowa	\$3,668,490	\$3,613,353	\$2,362,891	(\$1,250,462)
Kansas	\$3,436,853	\$3,385,197	\$2,226,701	(\$1,158,496)
Kentucky	\$4,968,989	\$4,894,305	\$3,127,510	(\$1,766,795)
<i>LA County</i>	\$11,069,920	\$10,903,539	\$6,714,507	(\$4,189,032)
Louisiana	\$5,055,790	\$4,979,801	\$3,178,543	(\$1,801,258)
Maine	\$1,904,184	\$1,875,564	\$1,325,579	(\$549,985)
Maryland	\$6,466,757	\$6,369,562	\$4,008,112	(\$2,361,450)
Massachusetts	\$7,339,572	\$7,229,258	\$4,521,276	(\$2,707,982)
Michigan	\$11,226,706	\$11,057,969	\$6,806,689	(\$4,251,280)
Minnesota	\$5,990,088	\$5,900,057	\$3,727,858	(\$2,172,199)
Mississippi	\$3,592,473	\$3,538,478	\$2,318,197	(\$1,220,281)
Missouri	\$6,707,932	\$6,607,112	\$4,149,908	(\$2,457,204)
Montana	\$1,503,679	\$1,481,079	\$1,090,106	(\$390,973)
Nebraska	\$2,378,867	\$2,343,113	\$1,604,666	(\$738,447)
Nevada	\$3,151,521	\$3,104,154	\$2,058,942	(\$1,045,212)
New Hampshire	\$1,897,087	\$1,868,574	\$1,321,407	(\$547,167)

<b>STATE/TERRITORY</b>	<b>FY 2011 Actual</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 President's Budget</b>	<b>Difference +/- 2012</b>
New Jersey	\$9,769,919	\$9,623,077	\$5,950,181	(\$3,672,896)
New Mexico	\$2,576,778	\$2,538,049	\$1,721,026	(\$817,023)
New York	\$12,285,085	\$12,100,440	\$7,428,955	(\$4,671,485)
<i>New York City</i>	\$9,227,897	\$9,089,202	\$5,631,503	(\$3,457,699)
North Carolina	\$9,910,111	\$9,761,162	\$6,032,606	(\$3,728,556)
North Dakota	\$1,175,614	\$1,157,945	\$897,222	(\$260,723)
Ohio	\$12,695,478	\$12,504,665	\$7,670,243	(\$4,834,422)
Oklahoma	\$4,302,943	\$4,238,270	\$2,735,913	(\$1,502,357)
Oregon	\$4,432,087	\$4,365,473	\$2,811,842	(\$1,553,631)
Pennsylvania	\$13,718,265	\$13,512,079	\$8,271,583	(\$5,240,496)
Rhode Island	\$1,634,345	\$1,609,781	\$1,166,930	(\$442,851)
South Carolina	\$5,091,363	\$5,014,840	\$3,199,459	(\$1,815,381)
South Dakota	\$1,330,796	\$1,310,794	\$988,460	(\$322,334)
Tennessee	\$6,916,279	\$6,812,327	\$4,272,405	(\$2,539,922)
Texas	\$25,477,218	\$25,094,295	\$15,185,173	(\$9,909,122)
Utah	\$3,209,463	\$3,161,225	\$2,093,009	(\$1,068,216)
Vermont	\$1,162,908	\$1,145,429	\$889,752	(\$255,677)
Virginia	\$8,620,629	\$8,491,061	\$5,274,465	(\$3,216,596)
Washington	\$7,295,589	\$7,185,936	\$4,495,417	(\$2,690,519)
West Virginia	\$2,432,140	\$2,395,585	\$1,635,987	(\$759,598)
Wisconsin	\$6,403,834	\$6,307,584	\$3,971,117	(\$2,336,467)
Wyoming	\$1,047,196	\$1,031,457	\$821,720	(\$209,737)
<b>Subtotal</b>	<b>\$345,554,287</b>	<b>\$340,360,606</b>	<b>\$214,291,675</b>	<b>(\$126,068,932)</b>
Indian Tribes	\$0	\$0	\$0	\$0
Migrant Program	\$0	\$0	\$0	\$0
American Samoa	\$311,460	\$306,779	\$286,135	(\$20,644)
Guam	\$423,819	\$417,449	\$352,196	(\$65,253)
Marshall Islands	\$309,956	\$305,297	\$285,251	(\$20,046)
Micronesia	\$364,903	\$359,419	\$317,556	(\$41,863)
Northern Mariana Islands	\$330,888	\$325,915	\$297,557	(\$28,358)
Palau	\$270,951	\$266,879	\$262,319	(\$4,560)
Puerto Rico	\$4,673,295	\$4,603,055	\$2,953,658	(\$1,649,397)
Virgin Islands	\$365,616	\$360,121	\$317,975	(\$42,146)
<b>Subtotal</b>	<b>\$7,050,888</b>	<b>\$6,944,913</b>	<b>\$5,072,647</b>	<b>(\$1,872,266)</b>
<b>Total States/Territories</b>	<b>\$352,605,175</b>	<b>\$347,305,519</b>	<b>\$219,364,322</b>	<b>(\$127,941,198)</b>
Technical Assistance	\$0	\$0	\$0	\$0

<b>STATE/TERRITORY</b>	<b>FY 2011 Actual</b>	<b>FY 2012 Enacted</b>	<b>FY 2013 President's Budget</b>	<b>Difference +/- 2012</b>
State Penalties	\$0	\$0	\$0	\$0
Contingency Fund	\$0	\$0	\$0	\$0
Other Adjustments (competitive awards)	\$0	\$0	\$15,000,000	\$15,000,000
<b>Subtotal Adjustments</b>	<b>\$0</b>	<b>\$0</b>	<b>\$15,000,000</b>	<b>\$15,000,000</b>
<b>Total Resources</b>	<b>\$352,605,175</b>	<b>\$347,305,519</b>	<b>\$234,634,322</b>	<b>(\$112,671,197)</b>

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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	0	0	5,000	5,000
FTE	0	0	0	0

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 (HHS) 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 a National Postal Model for other cities interested in utilizing a quick strike residential delivery system through the USPS to deliver medical countermeasures for a biological attack.

ASPR 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 National Postal Model 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 350 U.S. postal workers who could be called upon to deliver antibiotics to 23 zip codes in Louisville, Kentucky 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 protection equipment, and the Postal volunteers 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. Prior to 2011, these home Medkits had to be replaced every year and the postal workers and their families had to be screened again by medical providers if there had been changes to their health status. This “refresh” of the home Medkits was completed on schedule, with a few exemptions. Through collaboration with the Food and Drug Administration (FDA), future refresh activities will only occur upon expiry of the medication or when there is a change in the health status of the postal volunteer or his/her household members. A table top exercise was conducted in Minneapolis-St. Paul in January 2011 and a full scale exercise will be conducted in the Spring 2012. Conducting robust exercises ensures that 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. This year, using FY 2010 funding still available, four new cities were added to the program after they successfully competed for funding through a cooperative agreement funding opportunity. The funds will support postal model planning as well as four tabletop exercises in the cities who received the funding: Louisville, San Diego, Boston and Philadelphia.

Funding History:

FY 2008	\$0
FY 2009	\$0
FY 2010	\$9,998
FY 2011	\$0
FY 2012	\$0

Budget Request:

The FY 2013 request is \$5,000,000, an increase of +\$5,000,000 above the FY 2012 Enacted level. For FY 2013, funding will support the continued implementation of the National Postal Model. Work will continue with the pilot cities: Minneapolis/St Paul and Louisville, and the

recent awardees of the 2011 Cooperative Agreement: Philadelphia, Boston and San Diego. The after action reports for the four Table Top Exercises and one Full Scale Exercise that was conducted in FY 2012 will be analyzed to further refine program implementation in the existing cities and to define future directions for new cities joining the program. ASPR plans to add two new cities and conduct tabletop exercises with each of the new cities. One of the four cities that will conduct a table top exercise in FY 2012 will be funded to conduct a full scale exercise. Funds will also be used to support USPS and HHS programmatic costs, and to provide resources to maintain the operational readiness in the five cities which will have tested their operational capability in FY 2012.

Outputs and Outcomes:

**Program Medical Countermeasure Dispensing**

**Agency Long-Term Objective:** Enhance State and Local Preparedness

**Table 1: Measure ID 2.4.10:** Expansion of the Cities Readiness Initiative USPS Strike Teams in up to 15 cities (Outcome)

FY	Target	Result
2013	2 Cities	N/A
2012	As the result of budget constraints, there are no expectations for continued expansion beyond the current fiscal year.; therefore, only the original pilot city and 4 awardees will possess this capability but may be unable to sustain it	As the result of budget constraints, there were no expansions this fiscal year.; therefore, only the original pilot city and 4 awardees possess this capability but may be unable to sustain it. (Target Met)
2011	5 total cities	There is 1 operational city (Minneapolis –St. Paul MN, that received a grant award for full scale exercise) and 4 cities (Boston, MA, Philadelphia, PA, San Diego, CA and Louisville, KY) who received grant awards for continued operational planning efforts into FY 2012. (Target Met)
2010	4 cities	One city is operational (Minneapolis-St. Paul, MN) while one city is still in planning (Louisville). Activity is continuing.  (In Progress)

**Table 2: Data Source and Validation for Medical Countermeasure Dispensing Program**

Measure ID	Data Source	Data Validation
2.4.10	Analysis of state and local preparedness plans and plan with specific emphasis on the medical countermeasure dispensing component	Interagency review by appropriate subject matter experts, field testing of strategies and messages during developing incidents and major exercises



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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	387,426	415,000	596,671	181,671
FTE	94	108	108	0

Allocation Method: Direct Federal/intramural; contracts; grants

Program Description and Accomplishments:

The mission of the Biomedical Advanced Research and Development Authority (BARDA) is to develop and provide medical countermeasures (MCM) that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) disasters, pandemic influenza, and emerging infectious diseases. As a division within ASPR, BARDA supports ASPR’s mission to “Lead the country in preparing for, responding to, and recovering from health effects of emergencies and disasters by supporting our communities’ ability to withstand adversity, strengthening our health and response systems, and enhancing national health security.”

BARDA was established by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA), which was signed into law on December 19, 2006. Title IV of PAHPA established BARDA within HHS to accelerate the development of MCMs. BARDA fulfills its mission by providing funding and core service assistance for advanced research and development, building and maintaining national stockpiles and domestic manufacturing infrastructure, innovation of platform technologies, and strategic initiatives that result in re-purposed or multi-purpose products.

Since its inception in 2007, BARDA has supported more than seventy CBRN medical countermeasure product candidates with advanced research and development funding. Twenty three new medical countermeasure candidates for CBRN threats were added in FY 2011 to the existing MCM portfolios. Additionally, in FY 2011 BARDA established an animal studies network with twelve laboratories to provide core service assistance to manufacturers for the development of animal models and conducting good laboratory practices (cGLP) animal challenge studies for MCMs to CBRN threats. In FY 2012, BARDA expects to expand its portfolio of CBRN MCMs to at least eighty product candidates by adding new MCMs primarily in the areas of broad spectrum antimicrobials, acute radiation syndrome therapeutics, biodosimetry devices, and chemical antidotes.

Since 2004, nine medical countermeasures have been acquired through Project BioShield with the most recent being a smallpox antiviral drug in FY 2011. For FY 2012 and 2013, four areas are highlighted for support under Project BioShield, and include: (1) replenishment of expiring and unlicensed products, including anthrax antitoxins and smallpox vaccine; (2) acquisition of anti-neutropenia drugs for radiological and nuclear threats and anti-convulsive drugs for high-

volatility chemical agents; (3) animal studies supporting licensure of MCMs acquired under Project BioShield (anthrax and botulinum antitoxins; anthrax and smallpox vaccines) under the FDA Animal Rule, and (4) optimization of products for better logistical distribution and easier administration. The cost of these efforts is estimated at \$0.9 -1.1 billion and coupled to offsets for BARDA Advanced Research and Development (ARD) program support in FY 2012 and FY 2013 will deplete the remaining balance of funds in the Special Reserve Fund before the end of FY 2013.

The 2010 PHEMCE Medical Countermeasure Review identified remaining gaps in developing, acquiring, licensing, and making available medical countermeasures, and recommended multiple initiatives and enhancements. Two of these initiatives—the Centers for Innovation in Advanced Development and Manufacturing (CIADM) and the Medical Countermeasure Strategic Investor (SI)—are led by BARDA. Furthermore, several improved business practices—in-process reviews and case management of MCM projects—that are led by ASPR are conducted in full collaboration with enterprise partners (BARDA, FDA, NIH, CDC, DoD) early in the product development process and at staff and senior leadership levels. Lastly, through the leadership of the ASPR, the PHEMCE conducts annual portfolio reviews of the major medical countermeasure threat areas— anthrax, smallpox, radiological and nuclear threats, and pandemic influenza—to identify progress, challenges, and obstacles, to discuss remedies, and to assign responsibilities and timelines for implementation of actions for the development, acquisition, licensure, distribution, and administration of these medical countermeasures. Together, these initiatives and enhancements embody a more coordinated and comprehensive strategy for BARDA to develop and provide medical countermeasures for the nation.

#### *Chemical, Biological, Radiological, and Nuclear (CBRN) Threats*

As mandated by PAHPA, BARDA supports the advanced development of medical countermeasures against CBRN threats as well as pandemic influenza and emerging infectious diseases. In FY 2009, BARDA issued its first Broad Agency Announcement (BAA). A BAA is the major mechanism for BARDA to express its intentions and solicit proposals to support advanced research and development of CBRN medical countermeasures. Under this original BAA, special instructions were issued for anthrax vaccines, anthrax antitoxins and therapeutic countermeasures for skin and lung injury associated with acute radiation syndrome (ARS), and bioassays and biodosimetry devices to measure exposure levels in persons after a nuclear or radiological event. In FY 2010, BARDA renewed the BAA for CBRN medical countermeasures and issued special instructions for the support of broad spectrum antimicrobial drugs having efficacy against biothreats and public health infections including antibiotic-resistant strains of community- and hospital-acquired bacteria pathogens. The third iteration of this BAA was issued in FY 2011 and serves as a pivotal mechanism for meeting BARDA’s mission with regard to CBRN MCMs.

In the anthrax MCM portfolio, BARDA has invested in the development and acquisition of three major MCM types (vaccines, antitoxins, and antibiotics) since 2004. In FY 2007, support for the development and acquisition of a next generation rPA anthrax vaccine candidate using an *E. coli* expression system under a Project BioShield contract was discontinued due to the instability of the product and failure to meet project milestones within planned timelines. In FY 2010,

BARDA supported the expansion of domestic manufacturing capacity for the only currently licensed anthrax vaccine (BioThrax) and advanced development of three next-generation anthrax rPA vaccine candidates. In FY 2011, BARDA awarded a contract to support advanced development of another next generation anthrax rPA vaccine candidate that utilizing an adenovirus-vector platform technology for intranasal vaccine administration. In FY 2012, BARDA and HHS partners (FDA, NIH, and CDC), will continue to determine whether antigen- and dose-sparing strategies with licensed anthrax vaccine are feasible to expand the existing anthrax vaccine stockpile and whether adjuvants formulated with anthrax vaccines will be needed to accomplish this goal. In FY 2011, BARDA also continued support for the development of three anthrax antitoxin therapeutic candidate products that may have greater product stability and efficacy and easier storage and administration to the patient (e.g., lyophilized antitoxin product). BARDA is leading an interagency effort in FY 2011-12 to determine the feasibility of utilizing antibiotics (in the form of MedKits) for expanded usage, including personal home use.

Under the smallpox MCM portfolio, BARDA has invested in the development and acquisition of vaccine candidates and antiviral candidate products since 2007. In FY 2010, BARDA awarded a contract to develop an enhanced formulation of the smallpox MVA vaccine for immunocompromised individuals that is currently in the Strategic National Stockpile (SNS) and available for use during a declared emergency. The lyophilized formulation will increase the shelf-life of the product and decrease lifecycle costs. In FY 2011, BARDA awarded contracts for advanced development and acquisition of smallpox antiviral drugs to treat individuals infected with the variola virus, the causative agent of smallpox. These awards reaffirmed the USG's commitment to develop and acquire two smallpox antiviral drugs to mitigate possible drug resistance. One of the smallpox antiviral drug candidates development was deemed mature enough for product acquisition in FY 2011 under Project BioShield with initial product delivery expected in FY 2013. The other smallpox antiviral drug candidate transitioned from NIH to BARDA in FY 2011 for advance development support. Finally, in FY 2011, BARDA supported the development of a live, attenuated smallpox vaccine, for which there is only one manufacturer. To decrease the risk associated with a single manufacturer, BARDA has invested in animal studies to determine if this new vaccine candidate has comparable efficacy to the current licensed vaccine. The candidate product is already licensed for use in Japan, and these studies will allow BARDA to assess the potential of this vaccine candidate.

In the MCM portfolio for other biotreats (e.g., plague, tularemia, typhus, glanders, viral hemorrhagic fever, etc.), BARDA adopted a unique and productive strategy to support development of broad spectrum antimicrobials against biotreats and multi-drug resistant community- or hospital-acquired pathogens to re-energize a dormant antibiotic industry and make new products available. Although there are antibiotics on the market that can treat most of the biotreat bacterial pathogens, more effective and longer lasting antibiotics without serious side effects are desired. Further emergence of multi-drug resistance in biotreat pathogens naturally or intentionally may occur. Lastly the abundance of multi-drug resistant pathogens, which has persisted for more than two decades as a major problem in public health, may appear as secondary bacterial infections and exacerbate the injuries and illnesses suffered in CBRN events. To address this complex problem, in FY 2010, BARDA awarded its first contract for the advanced development of a new broad spectrum antibiotic, a new cephalosporin with indications

for treatment 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 usage. BARDA awarded a contract in FY 2011 to a large fully-integrated pharmaceutical company for the advanced development of a new class of antibiotics; this award marked the first large pharmaceutical company that has partnered with BARDA to develop drugs against CBRN threats. In FY 2012, BARDA anticipates supporting development of several new antibiotic candidates that represent entirely new classes of broad spectrum antimicrobials to treat both biothreat-caused infections as well as public health infectious diseases.

Since 2009, in the radiological and nuclear medical countermeasures portfolio, BARDA has supported early-stage development of therapeutic small molecule drugs, cell therapies, and biologicals, as well as the biodosimetry devices and bioassays, to address the multiple illnesses associated with acute radiation syndrome (ARS). To support early development of a wide variety of therapeutic medical countermeasures for neutropenia associated with acute radiation syndrome, BARDA supported ten new product candidates in FY 2010. An additional nine product candidates were added to the portfolio in FY 2011 to treat skin, lung, or gastrointestinal injury associated with acute radiation syndrome. In FY 2012, BARDA anticipates expanding slightly the size of the overall portfolio, by down-selecting poor product candidates, maintaining support for promising candidates already in the portfolio, and adding several new candidates to maintain a robust and diverse early development product portfolio. Since many of these candidate products may have clinical indications in the commercial market, including treatment of cancer and adverse events from radiation therapy and chemotherapy, advanced development costs of these product candidates may be shared more with manufacturers. Further, special emphasis will be accorded in FY 2012 to support the development of new skin-replacement therapies to treat thermal burn patients following radiation or other burn events. Special instructions to an existing Broad Agency Announcement for proposals to develop cell-based therapies as skin replacement to treat thermal burns following radiation exposure will be posted in FY 2012. Keeping with the HHS commitment to develop and provide drugs for special populations including children, BARDA supported in FY 2011 the development of a pediatric formulation of Prussian Blue, a de-corporation drug to remove radionuclides from affected persons.

In FY 2010, ten biodosimetry devices and bioassays were supported for early development of products as point-of-care and high-throughput diagnostics to ascertain the level of radiation exposure in persons following an ionizing irradiation event. In FY 2011, support was provided to seven of the existing product candidates and to one new product candidate that measures radiation absorbed in the teeth. One of the highlights in FY 2011 was the passage of one product candidate beyond the biomarker feasibility stage. To compensate for the down-selection of product candidates that fail for performance or are not feasible for mass casualty radiological events, BARDA anticipates adding several new candidates in FY 2012 to maintain a critical mass of products in the biodosimetry product portfolio at the early-stage of development. This down-selection occurred in FY 2011, as support for three of the original ten biodosimetry device candidates was discontinued due to poor performance, as milestones were not reached within the stated timelines. As a result, BARDA supported a total of eight candidate devices in FY 2011.

The biodosimetry and ARS therapeutic development contract awards were managed in FY 2011 under new BARDA oversight and decision practices that included an interagency in-process review to evaluate progress and determine whether funding should continue as recommended under the PHEMCE Medical Countermeasure (MCM) review.

In FY 2011, BARDA reached a milestone by establishing a new product portfolio—chemical antidotes—through its support for the development of two new products, galantamine and amyl nitrite. These candidate products are indicated for the treatment of persons exposed to highly volatile chemical nerve agents and cyanide poisons, respectively. One of these products is already approved by the FDA for another clinical indication. The ability of BARDA to “repurpose” already approved drugs for chemical and radiological/nuclear threats provides the potential to decrease development and lifecycle-maintenance costs, and ensure greater likelihood of product and company sustainability and stability. With DHS’s issuance of a Material Threat Determination for chemical threats in FY 2011 and subsequent product requirements set by ASPR to address the medical consequences of chemical events, BARDA anticipates supporting the development of additional new chemical antidote product candidates to treat exposure to volatile and non-volatile chemical agents in FY 2012.

In FY 2012, BARDA plans to acquire cytokine therapeutics under Project BioShield (PBS) to treat neutropenia, which is the first illness to appear following exposure to high-levels of ionizing radiation. Many of these anti-neutropenic drug products are licensed in the U.S. and elsewhere for oncology indications and represent medical countermeasures mature enough for product acquisition under Project BioShield. Additionally, BARDA expects to acquire in FY 2012 an anti-convulsive drug under Project BioShield which is already approved by the FDA for another clinical indication. This product was supported by BARDA in the RAMPART study at NIH in which 13% of the cohort was pediatric patients, again addressing the PAHPA-mandate to develop MCMs for at risk-individuals. Further support from the Special Reserve Fund for Project BioShield will be utilized in FY 2012 and 2013 to replenish expiring inventories of unlicensed anthrax antitoxins and smallpox vaccine to maintain a readiness level for these threats. Funding will be provided in FY 2012 for pivotal animal studies supporting licensure of anthrax and botulinum antitoxins and anthrax and smallpox vaccines under the Animal Rule and acquired already under Project BioShield. Lastly support will be extended in FY 2012 to optimize the formulations of anthrax antitoxins and smallpox vaccines for better logistical distribution and easier administration.

### *Product Innovation*

In FY 2009, BARDA formally addressed the PAHPA mandate to foster product innovation by establishing an Innovations Program. This program was designed to identify and support novel technological tools and capabilities that will enable the nation to meet the challenge of developing, manufacturing, testing, and delivering medical countermeasures for the large number and wide range of public health threats that could precipitate an emergency response. The focus of the BARDA Innovations Program is to create a more diversified and adaptable medical countermeasure enterprise by nurturing products that have greater utility, such as those for broad-spectrum or multiple disease indications, and by developing technologies that make the development and manufacturing pipeline faster, more efficient, and less expensive using

standardized platform and template approaches. Several of these projects are developing new ways to formulate medical countermeasure products (e.g., lyophilization and adjuvants) that may result in greater supply and significantly lower lifecycle management costs with regard to product acquisition, storage, and distribution. The program supported eight projects and products contracts in FY 2010. BARDA supported product stability and dose-sparing innovations on existing vaccine products using lyophilized formulations with novel adjuvants. Also, BARDA funded multiplex-PCR diagnostic platforms capable of detecting multiple biothreats including influenza viruses, anthrax spores, and other pathogens in clinical samples. Other projects included the development of new lot-release sterility assays for vaccines, the optimization of high-production vaccine virus seed strains for influenza, and a system for *in vitro* immunity testing. These initiatives address specific technological gaps that were noted in both the MCM review and the President's Council of Advisors on Science and Technology (PCAST) report on Pandemic Influenza Vaccine Production. The goal of the Innovations program is to maintain a dynamic portfolio of projects that allow for the evaluation and advancement of promising technologies through short-term (one to three years) contract funding. Successful technologies may then be in a position to attract further support from other BARDA programs or from private sources. Continuation of these projects in FY 2012 is anticipated.

#### *Animal Studies*

In FY 2011, BARDA awarded seventeen service contracts to establish a network of contractors that can perform animal studies and assays under cGLP to address a capacity gap among federal agencies working on CBRN MCMs. cGLP animal studies are an absolute requirement to support regulatory approval of medical countermeasures. These studies refine current animal models and create new models to better understand the pathogenesis of disease caused by various threat agents and product efficacy. These contracts address an important gap identified in the portfolio reviews. BARDA anticipates utilization of these laboratories in FY 2012 to assist with animal model development and animal challenge studies for smallpox antiviral drugs, anthrax vaccines with adjuvants, antibiotics for glanders and melioidosis, and other MCMs.

#### *Centers for Innovation in Advanced Development & Manufacturing (CIADM)*

The CIADM initiative was created to establish public-private partnerships that build, maintain, and operate U.S.-based infrastructure capable of facilitating MCM product development, ensure domestic vaccine manufacturing surge capacity, and provide workforce development training programs. Two or three contract awards using pandemic influenza supplemental appropriations are expected during FY 2012 for the first phase of this initiative—construction or retrofitting, commissioning and validation of facilities. The Centers will provide: (1) core services for advanced development and manufacturing of CBRN vaccines and biological products on a routine day-to-day basis; (2) additional rapid and flexible domestic vaccine manufacturing surge capacity for pandemic influenza or other known or unknown pathogen outbreaks in an emergency using modern and next generation technologies; and (3) a workforce development training program to enhance and maintain the U.S.-based ability to produce these MCMs

### Funding History:

FY 2008	\$110,875
FY 2009	\$285,688
FY 2010	\$320,111
FY 2011	\$387,426
FY 2012	\$415,000

### Budget Request:

The FY 2013 request for BARDA is \$596,671,000; an increase of +\$181,671,000 over the FY 2012 Enacted level. Funds are requested to be authorized for both development and acquisition of MCMs. The request includes \$60,736,000 for BARDA operations including activities which had been supported through ARD, PBS, and pandemic influenza funding. The request will also fund the Strategic Investor initiative from new budget authority at a level of \$50,000,000.

Funding in FY 2013 will be used to support the following efforts:

- Development, innovation, and evaluation of candidate MCMs with the long-term potential to qualify through the BARDA advanced research and development programs for acquisition as a MCM for the SNS or utilization prior to, during, and after CBRN threat events or become available in the commercial market if needed during an event;
- The establishment of the HHS Secretary's Strategic Investor initiative to provide focused investment for MCM gaps and business management assistance to MCM developers;

Funding will support the advanced development of the highest-priority MCMs among the thirteen CBRN threats identified in the PHEMCE Strategy and Implementation Plans and the Secretary's MCM Review. BARDA will manage the advanced research and development of promising CBRN MCM products from proof-of-concept Phase 1 clinical studies through (1) scale-up manufacturing process development and validation, (2) Phase 2 and 3 human clinical studies, and (3) pivotal animal challenge efficacy studies towards FDA regulatory approval and availability for delivery to the SNS or direct usage in an event.

FY 2013 marks a major crossroads for appropriations to support the preparedness and response mission of BARDA at multiple levels. With the forecasted depletion of the Special Reserve Fund that has supported acquisitions of MCMs under Project BioShield since 2004 and funded BARDA ARD programs since FY 2008, the FY 2013 budget reflects a careful balance of these prioritized ARD and Project BioShield programs by requesting the authority to use unobligated balances in the SRF for both development and acquisition of CBRN MCMs.

### *Chemical, Biological, Radiological, and Nuclear Threats*

Requested funding for the anthrax MCM portfolio will support continued advanced development of enhanced licensed anthrax vaccine with adjuvants, next generation anthrax vaccine candidates, and anthrax monoclonal antitoxin on existing BARDA contracts. The funding will

allow candidate next generation anthrax vaccine and antitoxin therapeutics under development to progress toward regulatory approval and availability for acquisition under Project BioShield in the coming years or to a point for which data do not support further development of the products. The FY 2013 portfolio of these anthrax medical countermeasures is at sufficient size and promise to create the critical mass to meet response requirements.

Under the smallpox MCM portfolio, BARDA will continue to fund existing contracts in FY 2013 for development of vaccines and antiviral drugs for smallpox. The ongoing programs will provide support for the development of a second smallpox antiviral drug and enhancements to the first drug that is expected to be in the stockpile by the end of FY 2013; these enhancements will include extended shelf-life, less cold chain dependency, decrease life-cycle costs and expand ease of use in severely ill individuals. Ongoing support to enhance the current smallpox vaccine for immunocompromised individuals will continue. In FY 2012 and subsequent years, smallpox vaccine for immunocompromised persons in the SNS will begin to expire and require replenishment. BARDA will utilize the SRF to replenish expiring doses, support additional studies required by the FDA and stockpile bulk drug intermediate to enhance our preparedness.

For other biothreat MCMs, funds are requested in FY 2013 for development of broad spectrum antimicrobial drugs with multi-purpose use to treat infections resulting from biothreats such as anthrax, plague, and tularemia, and especially enhanced antibiotic-resistant forms of these bacterial threat agents and from antibiotic-resistant bacterial strains in community- and hospital-acquired infections. Funding will support further product development of antibiotic candidates primarily under existing contracts within BARDA or transitioned from NIH or DoD. In FY 2013, BARDA expects to add two or three new candidates to its broad spectrum antimicrobial portfolio for advanced development of antimicrobial drugs, which utilize new mechanisms of action. Additionally, BARDA expects to support development of several new broad spectrum antiviral drugs in early-stage development for treatment of viral hemorrhagic fever; this will mark a milestone for BARDA, as MCMs will be under development or already acquired for all of the threats determined by DHS for the U.S. civilian population.

In the radiation/nuclear MCM portfolio, funding will support the advanced development of therapeutics under existing BARDA contracts to address illnesses associated with acute radiation syndrome. The requested funding level will support additional development of therapeutic candidate products in BARDA's diverse product pipeline for the seven illnesses resulting from injuries caused by radiological or nuclear events. Funds will allow for further development of physical biodosimetry devices to measure radiation exposure after an incident. FY 2013 funding addresses the transition of promising Acute Respiratory Syndrome (ARS) therapeutic and biodosimetry devices from early to advanced development. It is critical for HHS to have the ability to ascertain which individuals were actually exposed to the threat agent to ensure that the limited critical MCMs are given only to those who will truly benefit from them. BARDA will work with our HHS and Department of Defense partners to ensure priorities are aligned across the PHEMCE and that costs for development of the diagnostic devices are shared.



As mentioned above, BARDA will issue special instructions under the Broad Agency Announcement (BAA) for products to address thermal burns in FY 2012. In FY 2013, BARDA expects to support development of two to four new product candidates for thermal burns. These products may be either definitive care products such as skin-replacement cell therapies or point-of-care products such as antibiotic-impregnated wound wrappings.

With the issuance of a Material Threat Determination for chemical threats by DHS in FY 2011 and a PHEMCE-set product requirement, BARDA will expand in FY 2013 the current portfolio of chemical antidote candidate products to address this high priority threat. BARDA will continue to fund the development of candidates on existing contracts and award new contracts for promising novel chemical drug antidote candidates as they are identified in FY 2013.

Funding will continue support of BARDA's Innovation Program to promote innovation of medical countermeasures and diagnostics having all-hazards or multi-purpose potential. In FY 2013, three or four new projects will be added to the portfolio as other projects end. Efforts will be prioritized to address specific technological needs and opportunities that may contribute to the success of BARDA's mission, such as the testing of new and existing small molecule products that can modulate host immunity to provide broad spectrum therapeutic or prophylactic value in the face of known or unknown biothreats.

Within the animal studies program, requested funding will support studies under the contracts awarded in FY 2011. BARDA will prioritize animal studies to support natural history and efficacy for multiple candidates. The data will be owned by the USG and can be shared with multiple developers to decrease the cost and time associated with each contractor needing to show supportive data under the FDA Animal Rule. 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 2013 will see expansion of this network and testing of prioritized MCMs and threat agents, especially for therapeutic drugs for radiation and nuclear threats and antidotes to non-volatile chemical agents.

The requested funding in FY 2013 will support, if needed, initial operational costs incurred at the new Centers of Innovation for Advanced Development and Manufacturing (CIADM), which will most likely be the facilities that have completed retrofitting and validation. This new MCM initiative establishes public-private partnerships that build, maintain, and operate U.S.-based facilities that provide routine core services such as advanced development and manufacturing of vaccines and biologics to counter CBRN threats. The funding request will cover the operational expenses incurred for core services towards advanced development and manufacturing CBRN MCMs in one of these retrofitted facilities. Additionally, technology transfer of the manufacturing processes for pandemic influenza vaccines will occur in FY 2013 to produce vaccines in an emergency. Funding in FY 2013 will support the initial start-up operational costs for the development and manufacturing activities, if a retrofitted manufacturing facility becomes operational.

The FY 2013 President's Budget requests funds for the HHS MCM Strategic Investor program. The FY 2012 Request included funds to establish the SI program, however this request is for

new budget authority. The SI program goal is to strategically provide both financial and business support to companies that may develop and provide MCMs against remaining MCM gaps.

The SI will be designed to invest in companies that have a viable commercial future and will expedite the evolution of the MCM pipeline in directions consistent with the Secretary’s MCM Review, which called for an independent strategic investment firm for innovation in MCM, and will be directed to fill specific gaps in the MCM development pipeline and stockpiles. It will serve as a professional scouting or “informed consumer” capability for the federal government; looking for the best value and interacting with these companies in ways that the federal government could not. 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 HHS’ requirements and would receive information in return regarding the status of the effort toward the Department’s objectives. Key gaps in medical countermeasure discovery and development programs will be identified in the annual PHEMCE portfolio reviews and translated to specific action items that the Strategic Investor program may be able to address better than existing early and advanced development programs among PHEMCE partners.

Outputs and Outcomes:

2.4.13: Increase the number of new CBRN and emerging infectious disease medical countermeasures under EUA or licensed (Outcome)

	FY 2011	FY 2012	FY 2013
<b>Target</b>	<p>Awards contracts for the advanced development of recombinant-based influenza vaccines.</p> <p>Initiate clinical study to determine the safety of an anthrax vaccine.</p> <p>Issue RFP to establish Centers of Innovation for Advanced Development and Manufacturing</p> <p>Issue RFP to establish a network of domestic vaccine and biologics manufacturers</p>	<p>. FY 2012 targets are:            CBRN Licensed= 0;            EUA= +1; Pan            Flu/EID Licensed= +1;            EUA= 0</p>	<p>FY 2013 targets are:            CBRN Licensed= +0;            EUA= +3; Pan Flu/EID            Licensed= +3; EUA= +0</p>
<b>Result</b>	<p>Awarded contract for Recombinant-based flu vaccines.</p> <p>Started large clinical studies to evaluate safety H5N1 vaccines.</p> <p>Issued RFP to establish Centers of Innovation for Advanced Development and Manufacturing. Proposals received and are under evaluation.</p> <p>Issued RFI issued to discern the capabilities of US vaccines and biologics manufacturing which will inform the subsequent RFP.</p>	N/A	N/A
<b>Status</b>	Target met		

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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	18,327	15,674 <del>3</del>	15,164 <del>5</del>	-510 <del>8</del>
FTE	48	55	55	0

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

Program Description and Accomplishments:

The Office of Policy and Planning (OPP) advises the ASPR on policy options and strategic planning to support, strengthen and sustain health and emergency response systems that enable the Department’s domestic and international public health emergency preparedness and response activities. OPP has in-house staff with science-policy expertise who write medical countermeasure requirements and related policy papers for a wide range of chemical, biological, radiological, nuclear (CBRN) threats, emerging infectious diseases and pandemic influenza, requiring the focused application of scientific and analytical skills over a significant period of time. This work is done in collaboration with key stakeholders throughout the federal government as well as in state and local governments, the private sector and the general public. OPP also provides in-house subject matter expertise and coordination of HHS-wide and U.S. Government stakeholders to bolster health security-related policy and planning efforts that support implementation of the *National Health Security Strategy* (NHSS). This includes the coordination, analysis and implementation of relevant laws (e.g., Pandemic and All-Hazards Preparedness Act [PAHPA]) and regulations, proposed policies, Departmental and national strategies, presidential directives, executive orders, and the development of requirements and strategies for medical countermeasure research, development, acquisitions, and utilization.

In December 2009, the Department issued its first quadrennial NHSS as directed by PAHPA. The NHSS represents the Department’s foundational comprehensive strategy focusing specifically on the nation’s goal of protecting public health in the case of an emergency. The purpose of the NHSS is to guide the nation’s efforts to minimize the effects associated with potentially large-scale incidents that put the well-being of the 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, able to effectively respond 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 oversees and coordinates the implementation of the NHSS, which takes a “systems approach” to health, recognizing that many interrelated systems are needed to support the health of individuals and communities as well as protect them and support their recovery after an

incident. These interrelated systems include traditional healthcare, public health, and behavioral healthcare systems, as well as those systems that address elements essential to maintaining public health, such as clean water, food, housing, the environment, and access to healthcare.

OPP provides leadership in international programs, initiatives, and policies that enhance U.S. and global public health emergency preparedness and response. It supports goals, objectives, and implementation plans derived from national and international strategies, agreements, and initiatives, including the World Health Organization's International Health Regulations (2005), the Global Health Security Initiative (GHSI), the North American Leaders Summit (NALS), the North American Plan for Animal and Pandemic Influenza, and the Beyond the Border Initiative. OPP also engages with cross-border and international partners to build capacity for pandemic influenza preparedness and response through strategic programs in developing countries, and coordinates the notification of potential Public Health Emergencies of International Concern to WHO.

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 requirements. OPP has examined ways to strengthen biosafety and oversight of research facilities; developed policies to mitigate risks posed by the misuse of technologies related to the synthesis of nucleic acids; and supported U.S. Government efforts to strengthen pathogen security. OPP coordinates the transparency, participation, and collaboration of the Department across the U.S. Government 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 implement policies and practices addressing the functional needs of children and other at-risk individuals, the behavioral health needs of disaster survivors and responders, and community resilience. OPP also provides policy and strategic direction for the NHSS objective of promoting an effective medical countermeasure enterprise, including implementation of recommendations in the Secretary's "Public Health Emergency Medical Countermeasures Enterprise Review," as well as supporting the end-to-end Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Through the PHEMCE, OPP leads the establishment of requirements for medical countermeasure research, development and acquisition, as well as related policies for their effective distribution, dispensing and administration. Additionally, OPP works to establish policies that support integrated and scalable health systems in support of the NHSS' second pillar. To that end, OPP engages in activities that encourage the widespread use of interoperable electronic health records, improve access to care, and align incentives. OPP works closely with the Hospital Preparedness Program, the Emergency Care Coordination Center, and other partners to promote strong public health, healthcare, and emergency response systems. Finally, OPP serves as the liaison between ASPR and the White House National Security Staff on a broad range of policy issues related to health security.

OPP's recent accomplishments include:

- Providing technical assistance and coordination to implement a behavioral health workforce protection and stress management framework for HHS responders;
- Developing medical countermeasure requirements for CBRN and improvised nuclear device threats; requirements have been approved recently for botulism, improvised nuclear device and nerve agents;
- Coordinating the notification of 39 potential Public Health Emergencies of International Concern to WHO;
- Coordinating the policy aspects of the response to the Haiti earthquake, the Deepwater Horizon oil spill, and the Japanese earthquake and tsunami;
- In coordination with the U.S. Department of Agriculture, establishing and managing the Federal Experts Security Advisory Panel, as directed by *Executive Order 13546*;
- Promoting transparency and broader awareness about the evolving nature of biological agents that can be hazardous, and how to handle and use these agents safely and securely (<http://www.phe.gov/s3>);
- Supporting the World Health Organization (WHO) Advisory Committee on Variola Virus Research (ACVVR);
- Serving as the liaison between ASPR and the White House National Security Staff (NSS) on a broad range of policy issues related to both domestic and international health security;
- Reviewing Public Readiness and Emergency Preparedness (PREP) Act policy issues and developing recommendations for presentation to the Secretary;
- Coordinating the NBSB development of recommendations for the use of anthrax vaccine in pediatric populations;
- Obtaining key stakeholder input for medical countermeasure (MCM) research, development, stockpiling and utilization focused on pediatric medical countermeasures, conducting public meetings on distribution and dispensing of antibiotics during an anthrax attack and an expert workshop on clinical diagnostics for intentional biological threats, and sponsoring an Institute of Medicine study on prepositioning of antibiotics for anthrax;
- Co-chairing the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group and producing recommendations to better address the disaster-related needs of children;
- Completing the HHS Disaster Behavioral Health Concept of Operations to support federal disaster behavioral health preparedness, response, and recovery;
- Implementing Secretarial priorities from the HHS Health Disparities For Minorities and Health Disabilities Plans to advance the health, safety, and well-being of the American people;
- Co-sponsoring a national EMS stakeholder listening session to receive input on departmental priorities for the support and integration of EMS into the health care system;
- Working to strengthen and build integrated, scalable health and emergency response systems into OPP's strategic policy activities;
- Leading the development of the HHS International Public Health and Medical Emergency Policy and Assistance Framework to support the Departmental response to international public health emergencies;
- Leading the development of the *Strategic Policy Framework for Responding to International*

*Requests for Public Health Emergency Medical Countermeasures from HHS Stockpiles*, which will guide U.S. Government receipt, evaluation, and response to international requests for emergency medical countermeasures;

- Leading the HHS engagement in the Global Health Security Initiative (GHSI), including coordinating international preparedness efforts to address chemical, biological, radiological and nuclear threats, as well as pandemic influenza;
- Leading the successful trilateral and multi-sectoral revision and launch of the 2011 North American Plan for Animal and Pandemic Influenza (NAPAPI), incorporating lessons learned from the 2009 H1N1 pandemic;
- Leading and managing a strategic U.S. Border states cross-border program with Mexico and Canada that contributed to the detection of the first two confirmed U.S. cases of 2009 H1N1;
- Co-leading with CDC the Strategic National Stockpile (SNS) Annual Review, and coordinating the PHEMCE, including activities of the threat-specific Working Groups, Integrated Program Teams (IPT), Enterprise Executive Committee (EEC) and the Enterprise Senior Council (ESC); and
- In coordination with other stakeholders, conducting examinations of existing processes and tools used to provide funding to end-users during a public health emergency response, providing recommendations to improve the Department's financial preparedness to respond to emergencies.

Funding History:

FY 2008	\$19,057
FY 2009	\$18,877
FY 2010	\$19,008
FY 2011	\$18,327
FY 2012	\$15,674

Budget Request:

The FY 2013 request for the Office of Policy and Planning is \$15,164,000, a decrease of -\$510,000 below the FY 2012 Enacted level. The FY 2013 request reflects a reduction in the level of support for cross-border public health preparedness activities by eliminating funding for grants which address the detection of infectious diseases at our borders.

OPP will implement and monitor progress towards the community resilience goal of the NHSS, as well as the Strategy's objectives related to informed communities and post-incident health recovery, to the extent feasible given budgetary constraints. OPP will develop and implement the next NHSS as required by PAHPA. ASPR will prioritize some of the requirements detailed in the NHSS Implementation Plan, including efforts to integrate health care organizations into coalitions; to address the needs of at-risk individuals, including children, and the behavioral health needs of disaster survivors and responders; to develop ethical processes for the allocation of scarce resources during a public health emergency or disaster; to build initiatives to exercise, measure, and report the ability to surge during a public health emergency or disaster; and to cultivate and promote solutions to barriers to forming health care coalitions. In FY 2013 OPP will contribute to ASPR's efforts to develop metrics to assess emergency care and emergency

preparedness at facility and regional levels, to quantify and report access to emergency care and system stress, and to support efforts to test facility and health coalition surge capacity.

OPP will organize and participate in international engagement activities relied upon by ASPR, HHS, U.S. Government interagency, and international partners. OPP will develop policies and procedures for the U.S. Government's provision and receipt of international assistance during public health and medical emergencies. Furthermore, OPP will continue to work with HHS and international stakeholders to identify and address barriers to the international sharing of medical countermeasures through support of the next phase of the WHO Global Action Plan (GAP II), implementation of the North American Plan for Animal and Pandemic Influenza (NAPAPI), and implementation of the Pandemic Influenza Preparedness (PIP) Framework. In close collaboration with the DHS Office of Health Affairs, OPP will oversee the coordination and implementation of HHS deliverables in support of the Beyond the Border Initiative Action Item on Health Security, contingent upon availability of funding. The FY 2013 request will assist OPP in supporting ASPR efforts to enhance international public health emergency preparedness and to provide limited support to U.S. states for cross-border public health preparedness activities.

The FY 2013 request does not include support for the World Health Organization (WHO) Advisory Committee on Variola Virus Research (ACVVR). OPP provides support to fulfill the goals of the WHO ACVVR, which advises on the need for continued research, reviews proposals for research involving viable Variola virus (the causative agent of smallpox), and reviews the progress of such research. OPP has implemented the ASPR-Centers for Disease Control and Prevention (CDC) interagency agreement (IAA) that provides ASPR financial support to the WHO Committee via the CDC.

However, within the context of the FY 2013 budget, it is necessary to identify the highest priority activities to support. OPP has recently experienced an expansion of current responsibilities and has assumed a number of additional tasks related to our core responsibilities in biosafety and biosecurity. OPP continues to serve as the focal point within ASPR for activities related to biosafety, biocontainment, and biosecurity (biorisk management). ASPR also serves as chair of the newly established Interagency Biorisk Management Working Group and the Interagency Biosafety and Biosecurity Outreach Sub Working Group. The functions of these working groups are to help coordinate trans-federal efforts to strengthen biorisk management, and support outreach and education on related topics. In addition, ASPR is chair of the Federal Experts Security Advisory Panel, which is working to enhance the security of select agents and toxins; is supporting efforts to address dual use research issues, including the development of U.S. Government policy related to dual use research; and is supporting a range of efforts on international bioengagement.

ASPR continues to support, in principle, the mission and goals of the WHO ACVVR, but must redirect funding for the WHO ACVVR to meet current and future demands regarding the expanded portfolio in domestic biorisk management and international bioengagement, which are priorities of the Administration. Redirection of funding is necessary to meet current policy and operational priorities while assuming a substantially expanded scope of responsibilities.

With the FY 2013 request, OPP will provide support for ASPR-led outreach activities, such as roundtables and workshops, to obtain the stakeholder input critical to developing sound requirements and policies. In addition, OPP will continue to develop medical countermeasure requirements and policies for the very highest priority threats and for other threats as resources allow.

Outputs and Outcomes:

Measure	Most Recent Result	FY 2011 Target	FY 2013 Target	FY 2013 +/- FY 2012
2.4.9: Establish and improve awareness of the ASPR strategy for preparedness and response (Outcome)	FY 2012: The NHSS Implementation Plan is in final Departmental clearance and the ASPR 2011-2015 Strategic Plan is published and in the implementation/action planning phase.	Publish the first NHSS Implementation Plan by March 2011. (Target not met)	Move toward goal of publishing the second <i>National Health Security Strategy</i> .	N/A
2.4.10: Strengthen coordination and development of public health and medical emergency preparedness, response and recovery policy for the department: % of OPP assigned NHSS Implementation Plan activities fully executed according to established timelines and measures.	n/a	n/a	90%	n/a



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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Budget Authority	36,651	32,981	32,991	10
FTE	157	181	181	0

Allocation Method: Direct Federal/intramural; contracts

Program Description and Accomplishments:

The Operations activity supports funding for the ASPR Immediate Office, 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 ASPR Immediate Office (IO) provides overall leadership and strategic management of all of ASPR components. The IO will be implementing ASPR's newly released five-year strategic plan and coordinating ASPR's efforts to set short and long-term goals, objectives and targets for meeting preparedness priorities. The IO also supports the ASPR's role as principal advisor to the Secretary of HHS on all matters related to public health and medical emergency preparedness and response.

COO supports all of ASPR through Communications and Public and Media Affairs, Workforce Development, Facility Operations, Records and Information Management, Technology Management, Information Technology Integration, Logistics and Emergency Travel (both operational and for the HHS regions), Legislative Coordination, and Executive-Secretary level correspondence support. In addition, COO provides the facility, logistics, and infrastructure and information technology support services necessary to maintain the day-to-day operations of ASPR. COO also prepares outreach guidance, maintains web-based capabilities to support resilient communities and informed individuals, and supports all external communications, including legislative and executive branch inquiries. Finally, COO serves as the principal advisor to the ASPR on all legislative strategies to satisfy PAHPA, Project BioShield, and other legislative requirements.

In FY 2011, COO strategically invested in internal management and operations to promote a more flexible and nimble organization able to adapt to threats impacting public health. COO prioritized attracting and retaining a next generation workforce capable of adapting to new challenges, ensured staff had the tools necessary to complete objectives, and fostered efforts to promote increased employee morale and overall job satisfaction. A workforce survey completed in FY 2011 demonstrated how successful workforce initiatives have been in improving morale throughout the organization. COO also strengthened organizational engagement and communication with key audiences through strategic external outreach and promotion initiatives, including working closely with Congress and federal partners on the reauthorization of PAHPA, and the day-to-day maintenance and operation of the PHE.gov website, which serves as an

efficient one-stop shop for public health and medical emergency preparedness, response, and recovery information from all ESF #8 partners. In FY 2011, COO also supported implementation of an ASPR-wide quality improvement program by hosting Lean Six Sigma (LSS) training sessions to improve performance, reduce operational costs, and accelerate schedules across the organization.

Building on FY 2011 activities, COO completed a workforce analysis project. Findings will be included in classification, job selection, and technical document reports. These reports are undergoing review and are anticipated to be final in February 2012. Using the results from the project, COO will implement recommended actions to ensure workforce expectations meet demands. COO also provided leadership and management training sessions to ensure supervisors have adequate tools and techniques to effectively move the organization forward. Also in FY 2012, to support enhanced correspondence and ensure documents are protected, COO invested in the integration of the SWIFT Correspondence system to Sharepoint 2010 and is supporting a failover back-up capability for all documents. To promote and foster collaboration among organizational divisions, in FY 2012 COO will execute the final phase of a long-term housing consolidation strategy for *Federal Office Building 8* that will facilitate the physical move of 700+ staff from five geographically separated buildings into one consolidated facility.

Acquisition Management, Contracts, & Grants (AMCG) provides ASPR with acquisition, contracts, and grants management support to each office within ASPR: COO, OPP, OFPA, Immediate Office of the ASPR, BARDA, and OPEO; with particular focus on providing major systems acquisition support to BARDA and contractual support to OPEO. The Division of Acquisition Program Support (APS) within AMCG provides a wide range of program management support to the ASPR as well as direct program support to BARDA and OPEO that includes Earned Value Management Systems (EVMS) Decision Gate, In-Process Reviews (IPR) of contracts, auditing and cost analysis, and Milestone Decision Reviews. Additionally, functional support activities of APS include requirements analysis for Statement of Work (SOW)/Statement of Objectives (SOO)/Performance Based Statement of Work (PBSOW), acquisition strategy development, acquisition planning, and tracking contractual milestone dates with measurable success criteria. AMCG serves as ASPR's focal point for management and leadership of acquisition policy and administration of grants, cooperative agreements, and other transaction authority agreements.

On behalf of the ASPR, the Office of Financial Planning and Analysis (OFPA) 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. OFPA also ensures that ASPR's financial resources are aligned to its strategic priorities. OFPA carries out its responsibilities by formulating, monitoring, and evaluating ASPR budgets and financial plans that support program activities and ensures the efficient execution of ASPR financial resources. In coordination with BARDA and other partners in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), OFPA is working to develop multi-year budget projections that will help inform resource allocation for MCMs in the out-years. OFPA also oversees emergency Administration and Finance (A&F) operations which provide Stafford Act expertise, financial tracking, and emergency administrative functions that directly support HHS responders and stakeholders. When the HHS Emergency Management Group (EMG) is activated

as Emergency Support Function Eight (ESF #8) under the National Response Framework, A&F integrates with the EMG under the structure of the Incident Command System. Through A&F, OFPA works closely with the FEMA and other response partners to ensure funding authorized under the Stafford Act or other reimbursable funding sources is available for HHS emergency operations and that related expenditures are accounted for within 90 days of the end of operations and procurement.

In addition, OFPA ensures accountability and effectiveness of ASPR's financial programs and operations by establishing, assessing, correcting, and reporting on internal controls, as required under OMB Circular A-123. OFPA also serves as the lead for meeting ASPR's goals in support of the Secretary's Program Integrity initiative. It coordinates cross disciplinary reviews of ASPR's high-impact, high-visibility programs to identify risks to mission completion and develop strategies to ensure effective and efficient operations. In FY 2011 ASPR completed Program Integrity risk assessments of its CBRN, Pandemic Influenza and Hospital Preparedness programs. In FY 2012, ASPR will implement risk reduction activities for these programs and assessing other mission specific programs. OFPA also has developed a financial management tool to streamline budget execution and monitor all levels of expenditures. Recent enhancements of the tool include an executive dashboard that provides real-time reports on status of funds and cycle times for executing financial transactions. In FY 2012, a staffing module will be deployed that will track salaries and expenses supporting ASPR's workforce.

Funding History:

FY 2008	\$34,364
FY 2009	\$36,950
FY 2010	\$36,948
FY 2011	\$36,651
FY 2012	\$32,981

Budget Request:

The FY 2013 request is \$32,991,000, equal to the FY 2012 Enacted level. 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, quality improvement, and strategic human capital management initiatives. Funding will continue to support the development of short and long-term policy and strategic objectives, including implementation of mandates included in a reauthorized PAHPA and any other relevant legislative initiatives, and of strategic communication including programming support for the HHS-TV studio which provides 24-hour emergency health preparedness information to the public.

Outputs and Outcomes:

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

<u>Measure</u>	Most Recent Result	FY 2012 Target	FY2013 Target	FY 2013 +/- FY 2012
<p>2.4.8: Improve strategic communications effectiveness. (Outcome)</p>	<p>FY 2012: Maintained and continued to improve 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)</p> <p>Supporting an effective communications strategy continue to implement the ASPR Quality Improvement initiative to strengthen organizational communications and improve performance; participate in the Organizational Strategic Implementation Plan working group to promote implementation of measures included in the ASPR Strategic Plan; promoting a leadership and mentoring culture within the organization; and implementation of a coordinated and systematic decision process and standard operating procedure for program, policy and procurement actions. (Target Met)</p>	<p>Continue to implement the ASPR strategic communications plan. Maintain and improve ASPR's central infrastructure for public web communications and interagency collaboration.</p>	<p>Continue efforts toward effective and strategic communications, including implementation of the Quality Improvement initiative and improve ASPR's central infrastructure for public web communications and interagency collaboration.</p>	<p>N/A</p>

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

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY2012
Budget Authority	56,680	39,924	40,000	76
FTE	19	30	30	0

Allocation method: Contracts and Direct Federal/Intramural

Program Description and Accomplishments:

The HHS Cybersecurity 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 Cybersecurity 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 Cybersecurity 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 2012 and FY 2013, the Department will shift emphasis to efforts that will enhance the automation of the continuous security monitoring of our operational systems. As computer systems and the attacks against our systems become more sophisticated and persistent, HHS will rely heavily on automated tools to more quickly measure the security compliance and operational security status of all of our computer systems, following the direction and continuous monitoring strategy prescribed by DHS.

The HHS Cybersecurity Program has established the HHS Computer Security Incident Response Center (CSIRC), which includes the security technologies that provide an enterprise-wide

capability to monitor the Department's computers and networks for security incidents and attacks. Full operational capability (FOC) was achieved for the CSIRC in late 2011. HHS plans to continue to expand CSIRC capabilities in FY 2013 to enable the Department to better determine the overall enterprise security risk posture of our operational IT systems, by maintaining and upgrading our secure Internet gateways, intrusion detection systems, network security forensics and analysis, and other enterprise security technologies throughout the Department. Security operations centers (SOCs) were established or upgraded at the operating divisions (OPDIVs) that now enable the Department and the OPDIVs to quickly share security incident information and better coordinate our responses to attacks. In FY 2011, the Department also achieved DHS targets prescribed for the implementation of Domain Name Systems Security (DNSSEC) upgrades to our network infrastructure.

HHS Cybersecurity Program efforts in FY 2012 and 2013 will include the engineering and implementation work necessary to implement the Department of Homeland Security (DHS) Trusted Internet Connections (TIC) and Einstein monitoring initiatives, which will enable the Department to meet our obligations specified in the DHS TIC and Einstein service level agreements (SLA). Building upon design work completed in FY 2011, the Department has ordered the technology that will enable HHS to consolidate Internet connections to three locations in late FY 2012 and early FY 2013, while adding the special monitoring technologies provided by DHS known as Einstein. The implementation of TIC is a top priority for the Department in FY 2012.

The HHS Cybersecurity 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 HHS Cybersecurity 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 2011, using the 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 updated its Department-wide IT security policies and processes to conform to the latest Federal guidance. The Department will issue guidance in FY 2012 to address security for cloud computing, relying on the evolving OMB guidance for cloud computing known as FedRAMP (Federal Risk and Authorization Management Program). The Department also submitted its security continuous monitoring plan to DHS in June 2011 that provides details on how the Department will implement the core components of security continuous monitoring throughout the Department by October 1, 2012. This will also be one of the high priority efforts that the Department plans to focus attention on in FY 2012. Efforts in FY 2013 will continue implementation of the remaining components of security continuous monitoring. Department-wide licenses were also 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).

Funding History:

FY 2008	\$8,906
FY 2009	\$8,906
FY 2010	\$27,040
FY 2011	\$56,680
FY 2012	\$39,924

Budget Request:

The FY 2013 request for the HHS Cybersecurity Program is \$40,000,000, slightly above the FY 2012 Enacted level. The FY 2013 request will enable the HHS Cybersecurity Program to continue to provide management and oversight of the Department's IT Security Program, to ensure compliance with the requirements of FISMA, and also to sustain the security investments made in FY 2010 and FY 2011 including the FY 2011 supplemental increase.

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 security engineering, and ongoing maintenance and operations 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.

FISMA Program Management (\$13.2 M): The request will allow the HHS Cybersecurity 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.

Computer Security Incident Response Center (CSIRC); and Security Incident Response & Situational Awareness (\$11.8 M): Full operational capability (FOC) for all CSIRC components was achieved by September 30, 2011, and the CSIRC is operating out of its own leased facility near CDC offices in Atlanta. CSIRC will continue enhancements while operating at FOC in FY

2013. 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. The CSIRC will be operating at FOC in FY 2013 and this will enable the Department to sustain a very robust capability to defend against computer attacks, and also better detect and respond to any attacks.

The President's Budget invests in security technologies including enterprise network intrusion detection and prevention solutions, network traffic analysis tools, Security Information and Event Management (SIEM) solutions, 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 use of security technologies that allow the protection mechanisms used by our systems and data to keep pace with those threats. 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.

Trusted Internet Connection (TIC) (\$10.7 M): Initial procurement of technologies to support TIC and Einstein implementations began in late FY 2011. 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 implementation of three TIC sites in FY 2012 will allow the Department to align with the Department of Homeland Security initiatives for providing greater security in the government's internet connections as well as facilitating the necessary infrastructure to implement Einstein for the entire Department expanding from the three OPDIVs where Einstein is currently installed. Additionally, the security solution suite at the three TIC sites will allow the Department to provide redundancy and failover capability in the event of failure of the security infrastructure at any OPDIV in real-time – this includes firewalls, Intrusion Detection Systems (IDS), netflow analysis, and Security Information and Event Management (SIEM). Finally the TIC will provide core capabilities for the Department's continuous monitoring plan. In FY 2013, the Department will require funds to operate and maintain the three TIC sites, and complete the cutover to TIC of any remaining complex circuits that were not cutover in FY 2012.

Endpoint Protection Security Tools (\$4.3 M): As threats continue to evolve from new variations of malicious software that attackers are using, HHS will continue to enhance the IT security at the Operating Divisions by pursuing and sustaining a number of high impact investments that will better enable us to keep pace in addressing and correcting new and any 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 2013 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:

The new performance measures directly correspond to the White House priority cybersecurity initiatives to implement automated security continuous monitoring, and to implement the Trusted Internet Connections initiative. The first three performance measures measure progress for the fundamental capabilities of continuous monitoring, and the boundary protection measure aligns with the implementation of TIC, which will add to the capabilities in place for the HHS CSIRC. Specifically, new measures were created to track the progress of continuous monitoring, TIC, and the HHS CSIRC.

<b>Measure</b>	<b>Year and Most Recent Result /Target for Recent Result / (Summary of Result)</b>	<b>FY 2012 Target</b>	<b>FY 2013 Target</b>	<b>FY 2013 Target +/-FY 2012 Target</b>
Asset management: Percentage of IT assets that provide detailed asset inventory information e.g. IP address, machine name, OS, patch level, using security continuous monitoring automated tools.	FY 2011: <u>41.5%</u> Target: <u>N/A</u> (New measure)	<u>80%</u>	<u>95%</u>	<u>+15%</u>
Configuration management: Percentage of IT assets covered by an automated capability that provides visibility at the Department/OPDIV level into asset system security configuration information (e.g. comparison of agency baselines to installed configurations).	FY 2011: <u>42%</u> Target: <u>N/A</u> (New measure)	<u>80%</u>	<u>95%</u>	<u>+15%</u>
Vulnerability management: Percentage of IT assets covered by automated vulnerability management, using security continuous monitoring automated tools.	FY 2011: <u>65.4%</u> Target: <u>N/A</u> (New measure)	<u>80%</u>	<u>95%</u>	<u>+15%</u>
Boundary protection: Percentage of HHS network connections to the Internet in compliance with TIC implementation requirements.	FY 2011: <u>0%</u> Target: <u>N/A</u> (New measure)	<u>50%</u>	<u>90%</u>	<u>+40%</u>

**Office of Public Health and Science**  
**Medical Reserve Corps**

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY2012
Budget Authority	11,925	11,247	10,971	-276
FTE	7	7	7	0

Authorizing Legislation: Pandemic and All-Hazards Preparedness Act

Allocation Methods: Direct Federal; Contract; and Cooperative Agreement

Program Description and Accomplishments:

The Division of the Civilian Volunteer Medical Reserve Corps (DCVMRC) was established by the Office of the Surgeon General (OSG), within the HHS Office of the Assistant Secretary for Health (OASH), in March 2002. The Medical Reserve Corps (MRC) began as a demonstration project, and was subsequently authorized by Congress in the 2006 Pandemic and All-Hazards Preparedness Act.

The MRC 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. As of December 2011, there are over 970 MRC units in all 50 states, Washington, DC, Guam, Palau, American Samoa, Puerto Rico, and the US Virgin Islands, with more than 200,000 volunteers.

MRC units are organized and utilized locally to meet the needs in their community. In addition to emergency preparedness and response activities, they are strongly encouraged to contribute to local public health initiatives, such as those meeting the priorities of the HHS Secretary, Assistant Secretary for Health and the Surgeon General.

The DCVMRC functions as a clearinghouse for information and guidance to help communities establish, implement, and sustain local Medical Reserve Corps 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.

The MRC program has seen significant growth since its development, both in the number of units and in the number of volunteers; however, the rate of growth has begun to decrease.

	<b>New MRC Units</b>	<b>Total Number of MRC Units</b>	<b>Total Number of Volunteers</b>
FY02	42	42	(Inception)
FY03	124	166	2,602
FY04	51	217	32,563
FY05	106	321	55,110
FY06	166	483	93,714
FY07	245	710	145,976
FY08	103	787	168,996
FY09	90	856	189,245
FY10	101	940	210,114
FY11	45	967	202,801

The MRC remains a strong, viable network of volunteers that are assisting their communities on a regular/daily basis. The following table provides a summary of the type and number of activities reported by MRC units (Note – the H1N1 pandemic caused substantially increased numbers of public health and response activities in FY10):

<b>Activity Focus</b>	<b>FY09</b>	<b>FY10</b>	<b>FY11</b>
Administrative	921	1,054	1,866
Preparedness	1,576	1,496	1,695
Public Health	1,121	2,819	1,845
Response	774	1,834	997
Training	2,076	2,241	2,951
<b>Total</b>	<b>6,468</b>	<b>9,444</b>	<b>9,354</b>

Funding History:

FY 2008	\$9,578
FY 2009	\$12,344
FY 2010	\$12,581
FY 2011	\$11,925
FY 2012	\$11,247

Budget Request:

The FY 2013 budget request of \$10,971,000 is \$276,000 less than the FY 2012 Enacted Level. In FY 2013, the DCVMRC will strive to maintain the current level of support and services for MRC units at the local level.

DCVMRC will continue its work to support local MRC units through a variety of strategic and cost effective methods, including:

- Cooperative agreement with the National Association of County and City Health Officials (NACCHO). The original cooperative agreement was in place for FY 2006-2009, and has been continued each year since, at approximately \$6 million. Activities under this cooperative agreement include providing “Capacity-building Awards” directly to MRC units, providing logistical and other support for regional and national MRC meetings, 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.

- A contract providing local MRC units with technical assistance, guidance documents, and annual technical assistance assessments. This contract also supports communications with MRC leaders and stakeholders, the MRC website ([www.medicalreservecorps.gov](http://www.medicalreservecorps.gov)), a Geospatial Information System, a database of MRC unit profiles, promotional materials, and outreach.
- An 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 comprehensive online learning management resource offered (free-of-charge) to all MRC units.
- An Interagency Agreement with the OASH Regional Health Administrators to support MRC operations in the ten HHS Regions as the regional offices each provide support for various MRC projects and general operational needs.

## Office of Security and Strategic Information

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY2012
Budget Authority	7,428	6,448	7,428	980
FTE	28	31	33	2

Allocation Method: Direct Federal

Program Descriptions and Accomplishments:

The Office of Security and Strategic Information (OSSI) functions to provide security, intelligence, and counterintelligence expertise to protect the Department’s personnel, critical infrastructure and systems, and to safeguard our national security interests from insider and external threats. OSSI is headed by a Deputy Assistant Secretary for Security who serves as the Secretary’s Senior Intelligence Official and reports directly to the Deputy Secretary on intelligence and counterintelligence issues. On a day-to-day basis, OSSI works under the supervision and authority of the Assistant Secretary for Administration. 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 Homeland Security Council and National Security Council committees and workgroups, and on interagency committees and councils both inside and outside the Intelligence Community. OSSI serves as a representative of and principal advisor to the Secretary and Deputy Secretary on issues concerning national security, strategic information, 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.

OSSI Divisions:

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 works 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 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.

DSI is responsible for reviewing and approving all requests for visits by foreign nationals to

HHS properties. This includes the implementation of a Department-wide foreign visitor policy, 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.

The COMSEC team within the OSSI chain, is responsible for HHS Secure Communications, and for:

- Planning and supporting the senior management the ongoing and continued development of an infrastructure of sensitive and classified communications among HHS components. The infrastructure developed includes SIPRNET, JWICS, and HSDN, which are Controlled Unclassified Information systems of communication with the intelligence communities.
- Ensuring 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).
- Deploying COMSEC equipment and personnel to support HHS Continuity of Operations Plan (COOP) requirements to have secure and reliable voice and data transmission, planning and training.
- 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.

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:

- Final 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 leveled off to over 4,000 cases adjudicated per year due to the implementation of HSPD-12.

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 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.

Funding History:

FY 2008	\$3,263
FY 2009	\$3,263
FY 2010	\$4,893
FY 2011	\$7,428
FY 2012	\$6,448

Budget Request:

The FY 2013 request for OSSI is \$7,428,000, an increase of \$980,000 above the FY 2012 enacted appropriation. OSSI will be able to maintain operational tempo and national security requirements. This budget request will provide the necessary support to the HHS Foreign Visitor program, and the necessary personnel needed to implement the HHS Foreign Travel briefs which are critical to the security and infrastructure protection missions of the Department. The request will also fund the Cyber Analysis Counter Intelligence initiatives necessary to support the Secretary and the missions of HHS. The budget request will result in OSSI realizing its mission goals in fulfilling the numerous presidential directives, and national security directives and requirements and will result in affecting the many of the scientific and Public Health and Secretarial objectives/goals.

**Background**

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

Cyber threat analysis and Counter Intelligence (CI) 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 CI 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.

### **The 2013 Budget Request Supports**

#### **HHS Foreign Travel Briefs**

OSSI requests funds to continue the development and maintenance of the HHS foreign travel briefings and monitoring. The CI program would use existing GovTrip software to identify personnel requiring foreign travel briefings, but OSSI requires funding to develop training modules and conduct briefings for personnel. Focus of the program would be to provide security and counterintelligence briefings to key personnel who hold national security clearances in an effort to raise awareness of the threats and mitigate the vulnerabilities related to overseas travel.

#### **Activities Requirement**

HHS provides for more than 10,000 trips per year overseas by HHS employees. OSSI supports this mission through:

- The development and execution of a policy that provides traveler awareness services including pre- and post-travel briefings. The policy and follow on program will also address trip reporting requirements and information sharing criteria.
- Disseminating foreign travel briefs for personnel.
- Developing and briefing all official, and if requested unofficial, travelers on HHS travel requirements consistent with developed policy. Timely, accurate, and continually updated briefings will be provided for the traveler at the Unclassified up to TS/SCI level as appropriate. The briefings will be tailored to address relevant issues in pre- and post-travel contact sessions.
- Providing pre- and post-travel contact procedures to facilitate information exchanges between official HHS travelers and communities of interest.
- Developing and implementing procedures that are consistent with HHS policy and the HHS Secretary's direction. Information sharing procedures will be developed and codified to encourage sharing of relevant traveler experiences between HHS and US Government communities of interest.

- Developing a Post Travel instruction and expectation sheet that clearly defines the roles and expectations for HHS official travelers. The operating guidelines for the program will be consistent with applicable HHS policy and direction.
- Conducting post-travel interviews to facilitate the maximum amount of information about the activities of interest without requiring a second round of interviews.
- The execution of a timely and efficient post-travel contact program that allows HHS travelers an opportunity to document relevant post-travel experiences to both HHS (to better prepare future HHS travelers) and relevant US Government information sharing partners.
- Providing formalized scheduling and contact procedures.
- Developing and executing efficient and timely contact procedures for HHS travelers on a pre-and post-travel basis.
- Providing information-sharing, which has been very valuable to the USG at large.
- Developing timely and efficient processes for ensuring that HHS traveler experiences and trip reporting continues to be shared with relevant US Government information sharing partners.

#### Foreign Visitor Tracking System

The HHS program provides for capabilities with existing CI programs and Operations This Oracle based web browser system meets all accreditations and FISMA requirements. It has been in existence since 2005. Current Federal customers include US Army at Redstone Arsenal, USAF at Egland AFB, NASA, and most recently, National Institutes of Health (NIH). The system tracks credentials and personnel. It makes temporary badges for visitors and passes (you can design them however you want to).The system screens all terrorist watch group lists, FBI terrorist watch lists, “OFAC” lists, INTERPOL list, etc. The program Screens all known organizations and subordinate organizations affiliated with criminal and terrorist organizations. The system checks the State Department’s list of countries listed as Sponsors of State Terrorism.

- It also allows us to add or subtract countries as we see fit. The system can easily “handshake” with other visitor management systems.
- Can track individual visitors and maintains a log of their visits to multiple locations. The system can export reports as needed. Usually exports reports in an Excel format. The system can be set up for requests to be approved at multiple levels based on where the visitor is from, and where they plan on visiting.
- The system can be configured to reject a request if the purpose of the visit has not been articulated.
- The system uses “soundex” technology to conduct searches. In other words, if you search for “Mr. Little” it will also search for “Lyttle”, “Liddle”, etc.
- Capability exists for off-site hosting.

#### Cyber Threat Analysis

Our nation’s adversaries develop and launch sophisticated strategies to conduct cyber attacks on information technology systems (logical intrusions) and elicit personnel and systems for sensitive information (physical intrusions). These adversaries, who target a wide variety of

USG businesses and Federal Departments, represent an advanced persistent threat. USG-wide efforts to counter these cybersecurity and counterintelligence threats are only as strong as the weakest link. National Cybersecurity and Counterintelligence executives conclude that to avoid being detected, our adversaries rely on inadequate detection and response capabilities, unclear reporting mechanisms and security procedures, and lack of security awareness among the federal workforce. These known vulnerabilities necessitate that HHS develop programs to protect our personnel, sensitive IT systems and critical infrastructure. To assist in building such a program, the Office for Security and Strategic Information (OSSI) requires funding to implement and effectively manage activities related to cybersecurity analysis and counterintelligence. OSSI requires funding for support in the following program areas:

#### Cyber Threat Analysis Support

Cyber Threat Analysis will continue to build upon the following capabilities.

- Serves as the Department's "information broker" for cyber threat information by routinely disseminating cyber threat information to senior management, CSIRC, and OpDivs
- Consolidate and analyze information and information from the Computer Incident Response Center (CIRC), Operating Divisions, Intelligence Community, and U.S. Government agencies to produce a comprehensive, all-source threat picture of the Department's assets including critical infrastructure
- Produces comprehensive cyber threat assessments and analysis regarding State and non-State entities that may pose a threat to the Department's IT infrastructure for the Department's systems and management staff

The FY 2013 Budget would provide funds for updates to HHS secure IT systems, including JWICS, SIPRNET and HSDN, which are used to monitor intelligence on cyber threat activities prior to a cyber intrusion and to facilitate communication and dissemination of intelligence during an intrusion. OSSI requires software tools to analyze cyber intrusion events and to provide guidance to HHS cybersecurity detection, mitigation, and response teams. In addition, OSSI requires support to manage the Department's foreign visitor database and develop training programs

The Budget would also provide support for personnel to conduct cybersecurity analysis, monitor and maintain foreign visitor databases, and provide travel briefings and intelligence support to counterintelligence activities.

#### Physical Security (PERSEC) Program

The FY 2013 Budget would provide funds for the Security Manager Program initial cost, which supports Office of Personnel Management (OPM) mandates for electronic communication of all personnel security information for all HHS personnel and the transfer of manual records to electronic records for e-adjudication and storage security.

## Pandemic Influenza

Dollars in Thousands

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY2012
Budget Authority	65,447	0	0	0
FTE	8	8	8	0

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

Program Description and Accomplishments:

HHS has made significant progress in enhancing pandemic preparedness and response capabilities for our nation and our international partners, and has continued to work closely with states to enhance their pandemic preparedness. Over the past six years, substantial progress has afforded new influenza vaccines, antiviral drugs for the critically ill, more sensitive and faster rapid diagnostics, and much greater domestic vaccine manufacturing surge capacity. Since December 2005, HHS has been funding pandemic preparedness activities including: expanding and diversifying domestic vaccine production and surge capacity; enlarging H5N1 pre-pandemic vaccine and antiviral drug stockpiles; supporting advanced development of next-generation vaccines and antiviral drugs including cell culture, antigen sparing, and recombinant influenza vaccines; advanced development of point-of-care and high-throughput diagnostics; development and stockpiling of medical supplies such as masks, respirators and ventilators; improving state and local preparedness; expanding risk communication efforts; enhancing FDA’s regulatory science base; and expanding surveillance, research, and international collaboration efforts of CDC, NIH, ASPR and OGA. Many of these preparedness efforts were transformed in 2009-2010 during the H1N1 influenza pandemic into response measures and included pandemic influenza vaccines, expanded vaccine production, adjuvants for vaccines, new antiviral drugs, rapid diagnostics, and respirators.

Preparedness and response accomplishments include:

- As the next step in the overall strategy for providing more and better influenza vaccines sooner, ASPR has supported since 2005 the development of 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 2011-2012. Two of the original contracts were terminated due to the contractors’ decisions to go in a different business direction, loss of commitment to build a manufacturing facility in the U.S., or less than optimal clinical results. The remaining two cell-based influenza vaccine candidates are moving through the development pipeline. Unused funds for these contracts were used to support advanced development of recombinant-based influenza vaccines and antiviral drugs as well as other on-going pandemic influenza activities.

- Another step in the pandemic influenza vaccine strategy was to expand pandemic influenza vaccine capacity; ASPR supported the development of adjuvant technologies that are currently in late-stage development for H5N1 and H1N1 vaccines. Several of these adjuvants have demonstrated multifold antigen-sparing effects, broad immunity across virus strains, and significant long-lasting prime-boost effects. Together these products represent a major technological breakthrough for pandemic vaccine preparedness with possibilities for better seasonal influenza vaccines for select populations. Submission of licensure applications to the FDA by two manufacturers with pandemic influenza vaccines formulated with oil-in-water emulsion adjuvants are expected in 2012.
- A penultimate step in the pandemic influenza vaccine strategy has been supporting the advanced development of next generation recombinant- and molecular-based influenza vaccines towards U.S.-licensure with a commitment to build a domestic manufacturing facility having a capacity of at least 50 million pandemic vaccine doses within six months of pandemic onset and to lot release the first doses pandemic vaccine within 12 weeks of pandemic onset. Three contracts have been awarded (2009, 2011) with re-submission of licensure application to the FDA expected for one vaccine candidate in 2012. The other two vaccine candidates are in Phase 2 clinical trial studies.
- Three main activities were launched to expand domestic pandemic influenza vaccine manufacturing surge capacity and address the above strategic goal through public-private partnerships. These U.S.-based efforts included retrofitting of existing vaccine manufacturing facilities to fortify existing egg-based influenza vaccine capabilities, building new facilities for cell-based influenza vaccines, and the establishment of Centers of Innovation for Advanced Development and Manufacturing (CIADM) using flexible, innovative manufacturing processes with next generation influenza vaccine technologies. In 2007, HHS awarded two contracts to support retrofitting of existing domestic manufacturing facilities to increase domestic pandemic vaccine production and surge capacity. During the 2009 H1N1 pandemic, new fill-finished and bulk manufacturing lines at these retrofitted facilities came on line earlier than anticipated and provided significant amounts of H1N1 vaccine for the U.S. Full completion of the retrofitting from one of these projects was completed in 2011 for one manufacturer; completion of retrofitting of the bulk manufacturing facility on the other project is scheduled for 2012. HHS awarded a contract in 2009 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 has undergone validation and could provide at least 25% of the U.S. pandemic vaccine supply by October 2011, if needed. ASPR issued a solicitation in March 2011 for the establishment of the CIADMs with contract awards expected in 2012.
- During the 2009 H1N1 pandemic response, ASPR contracted with five U.S.-licensed influenza vaccine manufacturers to produce 186 million filled and finished doses of 2009 H1N1 vaccine for use in the U.S. and for international donation. The Department purchased sufficient ancillary supplies to vaccinate the H1N1 vaccine target groups in the U.S. population, including 340 million syringe/needle combinations for vaccine delivery and 8 million syringe/needle combinations for mixing of vaccine and adjuvant; every

vaccine dose was accompanied by the ancillary supplies during the H1N1 pandemic. As a contingency plan for mismatched vaccine or more virulent virus strains in the 2009 H1N1 pandemic, ASPR procured an additional 125 million doses of a new oil-in-water emulsion adjuvant, which were developed under HHS development contracts. As conditions did not warrant the usage of these adjuvants, these products will be stockpiled and remain available for future pandemics or other outbreaks. Clinical studies in 2009 with H1N1 vaccines administered with these adjuvants demonstrated a two to four fold antigen-sparing effect. Similar clinical studies with H5N1 vaccines administered with these adjuvants began in April 2011.

- To address the growing concerns of influenza antiviral drug resistance and the need for drugs to treat the critically ill, ASPR has supported parenteral antiviral drugs for critically ill persons with influenza, including peramivir since 2007, for advanced development towards regulatory approval; this drug is currently in pivotal Phase 3 clinical trials worldwide. Support for a second drug candidate that has longer lasting effectiveness was provided in 2011, and it is in Phase 2 clinical trials presently. Since there remains a paucity of influenza antiviral drugs with new mechanisms of actions and few combined drug studies have been done, solicitations will be issued in 2011 to support advanced development of additional influenza antiviral drugs with novel mechanisms of actions, easier usage, longer lasting, and possible co-administration with other influenza antiviral drugs.
- ASPR completed its goal of 50 million courses of influenza antiviral drugs for the federal stockpile in December 2007. In response to the 2009 H1N1 outbreak, 11 million antiviral drug treatment courses were deployed to the states in May 2009. ASPR replenished the federal stockpile with 13 million treatment courses in June 2009. Given concerns for the emergence of oseltamivir-resistant 2009 H1N1 virus strains and the disproportionate ill-effects of the 2009 H1N1 pandemic on children, an additional 16.1 million treatment courses of zanamivir and pediatric formulations of oseltamivir were procured for the federal stockpile in September 2009. To date, states have purchased 25.9 million treatment courses of antiviral drugs towards the federal subsidy goal of 31 million. The current national inventory of federal and state stockpiles of antiviral drugs is over 107 million treatment courses. Additionally, a small federal stockpile of peramivir was established during the 2009 H1N1 pandemic to treat critically ill persons under Emergency Usage Authorization. Over 1,200 persons received this drug during the H1N1 pandemic, and the remaining unused treatment courses are stored as a national stockpile.
- ASPR 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 ASPR met product requirements during Independent Government Evaluation in 2008 and underwent clinical development in early 2009. The first 2009 H1N1 clinical case in the U.S. was detected with the POC diagnostic device developed under HHS contractual support for product development.

- In 2008, ASPR completed clinical evaluation of a new 5-target PCR rapid diagnostic test for avian and seasonal influenza. This high-throughput assay test will be used in all U.S. public health laboratories and internationally at World Health Organization (WHO) reference laboratories.
- In 2006, ASPR purchased 104 million N95 respirators and 52 million surgical masks for the SNS. In response to the outbreak of 2009 H1N1, 80% of the stockpiled N95 respirators and 25% of surgical masks in the stockpile were deployed to the States.
- In 2007 and 2008, ASPR deployed teams of experts to help investigate suspected cases of human transmission of infection with influenza A in 12 countries in Asia, Africa, and Europe. ASPR also supports pandemic influenza preparedness activities in approximately 40 countries around the world.
- Through ASPR, the Department lead the efforts to develop several key pandemic policy documents including: the *Operational Framework for the International Deployment of 2009 H1N1 Influenza Vaccine from the U.S. Government to the World Health Organization (WHO)*; the *Strategic Policy and Operational Framework for Responding to International Requests for Public Health Emergency Medical Countermeasures from HHS Stockpiles*, a strategic policy and operational framework through which the U.S. Government will receive, consider, decide on, and respond to international requests for emergency medical countermeasures, including pandemic influenza vaccines and antiviral drugs; and, the HHS International Public Health and Medical Emergency Policy and Assistance Framework (IEPAF), which describes how HHS will launch a Department-wide international engagement effort in cooperation with other U.S. Government agencies and the United Nations in response to public health emergencies including pandemic influenza.
- ASPR led the trilateral cross-sector efforts to revise and finalize the 2011 North American Plan for Animal and Pandemic Influenza (NAPAPI), involving experts from the health, agriculture, security and foreign affairs sectors in Canada, Mexico and the United States and incorporating lessons learned in response to the 2009 H1N1 pandemic.
- ASPR led HHS' engagement in the Global Health Security Initiative (GHSI), including coordinating international preparedness for pandemic influenza, hosting two meetings of the GHSI Pandemic Influenza Working Group, and developing the H1N1 lessons learned presented to the GHSI Senior Officials and Ministers of Health during the GHSI Ministerial Summit in Mexico City.
- Management of strategic programs for public health emergency preparedness capacity building in developing countries that resulted in the inauguration of two BioSafety Level-3 laboratories in Mexico City and Panama City was led by ASPR. Both laboratories are expected to become members of the CDC Laboratory Response Network.
- The U.S. Government efforts to provide an official response to the WHO Review Committee *Report of the Functioning of the International Health Regulations (2005)* and



on *Pandemic Influenza A (H1N1) 2009* and the development of the document *Promoting Global Health Security: Government Guidance and Principles for U.S. Government Departments and Agencies to Strengthen IHR Core Capacities Internationally*, was led by ASPR as part of the National Security Staff Sub-IPC on Emerging Pandemic Threats.

- ASPR developed and implemented the standard operating procedure for the U.S. Government’s assessment and notification of potential Public Health Emergencies of International Concern to the World Health Organization (WHO) through the HHS Secretary’s Operations Center. This included the notification of several cases in the United States of novel human influenza viruses with pandemic potential.

Funding History:

FY 2008	\$66,177
FY 2009	\$8,026,091
FY 2010	\$340,591
FY 2011	\$65,447
FY 2012	\$0

Budget Request:

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

The Department makes no request in FY 2013 for Pandemic Influenza activities. Ongoing flu activities are being funded from existing balances and spent according to the approved flu spend plan submitted to the Congress in August 2010. Unobligated balances currently exist from the following appropriations: FY 2006 supplemental, FY 2009 appropriation, FY 2010 appropriation, and 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. One main activity related to the review, as mentioned above, is the establishment of Centers of Innovation for Advanced Development and Manufacturing 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. An RFP was issued in March 2011 and proposals have been received and are being reviewed. Initially, this program will be supported with \$478 million for the construction

of new or renovated facilities in the U.S. Funds for initial operations of a retrofitted facility in FY 2013 are included in the BARDA ARD budget request for FY 2013.

The Department made significant investments in FY 2011 on the advanced development of recombinant and molecular vaccines, antiviral drugs, and advanced antigen sparing technology (adjuvants) using remaining balances of unobligated funds from the pandemic influenza supplemental appropriations. In FY 2012 and 2013, acquisitions and other programmatic activities will be supported through the utilization of unobligated balances from the supplemental appropriations for pandemic influenza vaccines and antiviral drugs, and from recovered funds from existing contracts that were terminated for performance or successfully closed out.

In FY 2012 and FY2013, additional funding from the remaining balances will be obligated towards the three existing contracts to develop recombinant influenza vaccines for seasonal and pandemic influenza. This funding will support completion of pivotal Phase 3 clinical studies in support of FDA licensure. Funding on these contracts will deplete the funding allocated for vaccine advanced development. In FY 2012, additional funding will be provided on two existing contracts to support late-stage clinical trials of pandemic influenza vaccines formulated with adjuvants that provide dose- and antigen-sparing savings, but will deplete funds allocated to antigen-sparing vaccine technologies. In FY 2012, multiple new contract awards are expected for the advanced development of non-neuraminidase antiviral drugs and antibody therapies. These contracts will deplete the remaining unobligated funds for antiviral drug development.

ASPR continues to monitor existing contracts closely to determine the potential for additional recoveries. If recoveries are realized, investments would be made in the following areas: pre-pandemic vaccine stockpiling, maintenance of a fill-finish manufacturing network, and the advanced development of a universal influenza vaccine, novel adjuvants, and new antiviral drugs. In addition, ASPR remains committed to maintaining the capabilities that have been established through the rapid-diagnostic assay development and international vaccine manufacturing capacity programs.

**BUDGET AUTHORITY by OBJECT CLASS - DIRECT**

(Dollars in Thousands)

	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Personnel compensation:			
Full-time permanent (11.1)	50,986	62,111	11,125
Other than full-time permanent (11.3)	7,999	9,876	1,877
Other personnel compensation (11.5)	61	62	1
Military personnel (11.7)	9,182	11,232	2,050
Special personal services payments (11.8)	0	0	0
Subtotal, Personnel compensation	68,228	83,281	15,053
Civilian personnel benefits (12.1)	13,807	16,656	2,849
Military benefits (12.2)	3,062	3,673	611
Benefits for former personnel (13.0)	0	0	0
Total Pay Costs	85,097	103,610	18,513
Travel and transportation of persons (21.0)	6,968	7,983	1,015
Transportation of things (22.0)	471	599	128
Rental payments to GSA (23.1)	12,694	14,144	1,450
Communications, utilities, and miscellaneous charges (23.3)	1,284	1,295	11
Printing and reproduction (24.0)	38	46	8
Other Contractual Services:			
Advisory and assistance services (25.1)	138,032	182,888	44,856
Other services from non-Federal sources (25.2)	31,200	36,981	5,781
Other goods and services from Federal sources (25.3)	104,854	126,586	21,732
Operation and maintenance of facilities (25.4)	5,660	7,486	1,826
Research and development contracts (25.5)	11,802	15,577	3,775
Medical care (25.6)	0	0	0
Operation and maintenance of equipment (25.7)	39,600	40,308	708
Subsistence and support of persons (25.8)	994	838	-156
Subtotal, Other Contractual Services	332,142	410,664	78,522
Supplies and materials (26.0)	830	1,086	256
Equipment (31.0)	1,326	1,755	429
Land and Structures (32.0)	12	17	5
Investments and Loans (33.0)	0	0	0
Grants, subsidies, and contributions (41.0)	542,368	499,066	-43,302
One-time Appropriation for Treasury (43.0)	0	0	0
Refunds (44.0)	0	0	0
Total Non-Pay Costs	898,133	936,655	38,522
Total Budget Authority by Object Class	983,230	1,040,265	57,035

## SALARIES AND EXPENSES

(Dollars in Thousands)

	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
<b>Personnel compensation:</b>			
Full-time permanent (11.1)	50,986	62,111	11,125
Other than full-time permanent (11.3)	7,999	9,876	1,877
Other personnel compensation (11.5)	61	62	1
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Subsistence and support of persons (25.8)	994	838	-156
Subtotal, Other Contractual Services	332,142	410,664	78,522
Supplies and materials (26.0)	830	1,086	256
Land and Structures (32.0)	12	17	5
<b>Total Non-Pay Costs</b>	<b>341,745</b>	<b>421,690</b>	<b>79,945</b>
<b>Total Salaries and Expenses</b>	<b>426,842</b>	<b>525,300</b>	<b>98,458</b>

**DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT**

	FY 2011 Actual			FY 2012 Enacted			FY 2013 Budget Request		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Direct:	461	82	543	541	87	628	543	87	628
Reimbursable:	2	0	2	0	0	0	0	0	0
<b>FTE Total</b>	<b>463</b>	<b>82</b>	<b>545</b>	<b>541</b>	<b>87</b>	<b>628</b>	<b>543</b>	<b>87</b>	<b>628</b>

## Detail of Positions

	2011 Actual	2012 Enacted	2013 Estimate
Executive level I .....	--	--	--
Executive level II.....	6	5	5
Executive level III .....	--	--	--
Executive level IV.....	--	--	--
Executive level V.....	--	--	--
Subtotal .....	6	5	5
Total - Exec. Level Salaries	\$1,510,674	\$1,638,459	\$1,638,459
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	\$1,922,776	\$1,928,534	\$1,928,534
GS-15.....	104	105	105
GS-14.....	243	243	243
GS-13.....	77	78	78
GS-12.....	42	43	43
GS-11.....	23	25	25
GS-10.....	1	1	1
GS-9.....	13	13	13
GS-8.....	2	2	2
GS-7.....	9	10	10
GS-6.....			
GS-5.....	4	4	4
GS-4.....	1	1	1
GS-3.....			
GS-2.....			
GS-1.....			
Subtotal .....	519	525	525
Total - GS Salary	\$56,140,478	\$62,794,251	\$67,448,023
Commissioned Corps.....	87	87	87
Total Positions.....	623	628	628
Average ES level .....	3	2	2
Average ES salary.....	\$174,798	\$175,321	\$175,321
Average GS grade.....	13/5	13/7	13/7
Average GS salary.....	\$108,170	\$119,608	\$128,472
Average Special Pay (Commissioned Corps)	\$85,204	\$89,845	\$92,166

## **Significant Items for Inclusion in the FY 2013 Congressional Justification**

**The conferees direct the Biomedical Advanced Research and Development Authority to develop a plan to deliver recombinant anthrax vaccine to the Strategic National Stockpile by 2015 and brief the House and Senate Committees on Appropriations on such a plan not later than 60 days after enactment of this Act. (Senate Report 112-84)**

### Action To Be Taken:

The Department shares the committees' concern about the importance of procuring recombinant anthrax vaccine for the Strategic National Stockpile. The written plan is currently under development, and briefings will be scheduled for this winter and spring.