DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2015

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committees

Contents

We are pleased to present the FY 2015 Congressional Justification for the Public Health and Social Services Emergency Fund. This Budget request directly supports the Nation's ability to prepare for, respond to, and recover from the health consequences of naturally occurring and man-made threats. The submission includes the FY 2015 budget justifications for the Office of the Assistant Secretary for Preparedness and Response (ASPR); Pandemic Influenza; Cybersecurity, the Office of Security and Strategic Information (OSSI), and the Medical Reserve Corps (MRC), which is managed in the Office of the Assistant Secretary for Health (OASH).

As a nation, we must be prepared to effectively respond to global catastrophic events - whether man-made or naturally occurring. One of the primary responsibilities of ASPR is to ensure that safe and effective medical countermeasures (MCMs) 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; the distribution and administration of countermeasures to people in need; and the evaluation of the efficacy of these products.

HHS continues to invest in the development of promising countermeasures, technologies, and diagnostics to address a broad array of chemical, biological, radiological, and nuclear (CBRN) threats and pandemic diseases. Thus far, MCMs for anthrax and other bacterial threats, smallpox, chemical threats, radiation exposure, and botulism have been delivered to the Strategic National Stockpile. Research and development efforts are also underway for a variety of diagnostic platforms, smallpox therapeutics, and additional MCMs. In 2015, ASPR will continue efforts to protect at-risk populations and extend the utility of existing MCMs.

The MCM enterprise is just one component of a broader response strategy aimed at mitigating the effects of CBRN threats and pandemic disease events. To respond effectively to public health emergencies, the United States needs a health care system that is able to deliver coordinated and effective care that integrates the healthcare, public health, and emergency management systems. Building and sustaining strong local and regional healthcare coalitions is vital to improving communities' preparedness for responding to disasters and other major events.

The National Health Security Strategy supports this larger vision by guiding 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. National health security is only possible when our approaches are founded on a good base of scientific knowledge, farsighted strategic planning, and systematic practices for applying lessons learned and continuous improvement. Although major progress has been made, there is still much work to be done in planning for recovery and building communities' resilience.

The FY 2015 Budget requests $1.4 billion for ASPR, an increase of +$192 million above the FY 2014 Enacted level. Nearly three-quarters of the request is for continued investments in the advanced development and procurement of MCMs and diagnostics against CBRN threats and emerging diseases with pandemic potential. The FY 2015 Budget provides $415 million for ASPR's Biomedical Advanced Research and Development Authority and $415 million for Project BioShield. These investments will keep HHS on track to procure a dozen new CBRN MCMs by 2018. The FY 2015 Budget also provides $170 million for HHS' Pandemic Influenza activities in ASPR and the Office of Global Affairs. Among the important FY 2015 requests is funding for the initial advanced development of universal influenza vaccine candidates.

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 2015 request of $45 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 and ongoing operations for the Department of Homeland Security's Trusted Internet Connection (TIC) and Einstein initiatives, and enhancement of enterprise-wide capabilities to continuously monitor the Department's computers and networks for security incidents and attacks.

Approximately $8 million is included in the FY 2015 President's Budget for the MRC. The MRC is a national network of local groups of volunteers ready to respond to emergencies, reduce vulnerabilities, and build resiliency in local communities through prevention, preparedness and public health activities. Over the past ten years, the program has grown to more than 200,000 volunteers in over 900 units across the United States. 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.

The Budget includes $7 million the OSSI, which 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 protects the Department's people, assets, and information from internal or external security threats, and facilitates the integration of strategic information into policy and operational decisions to safeguard the nation's health and well-being. 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.

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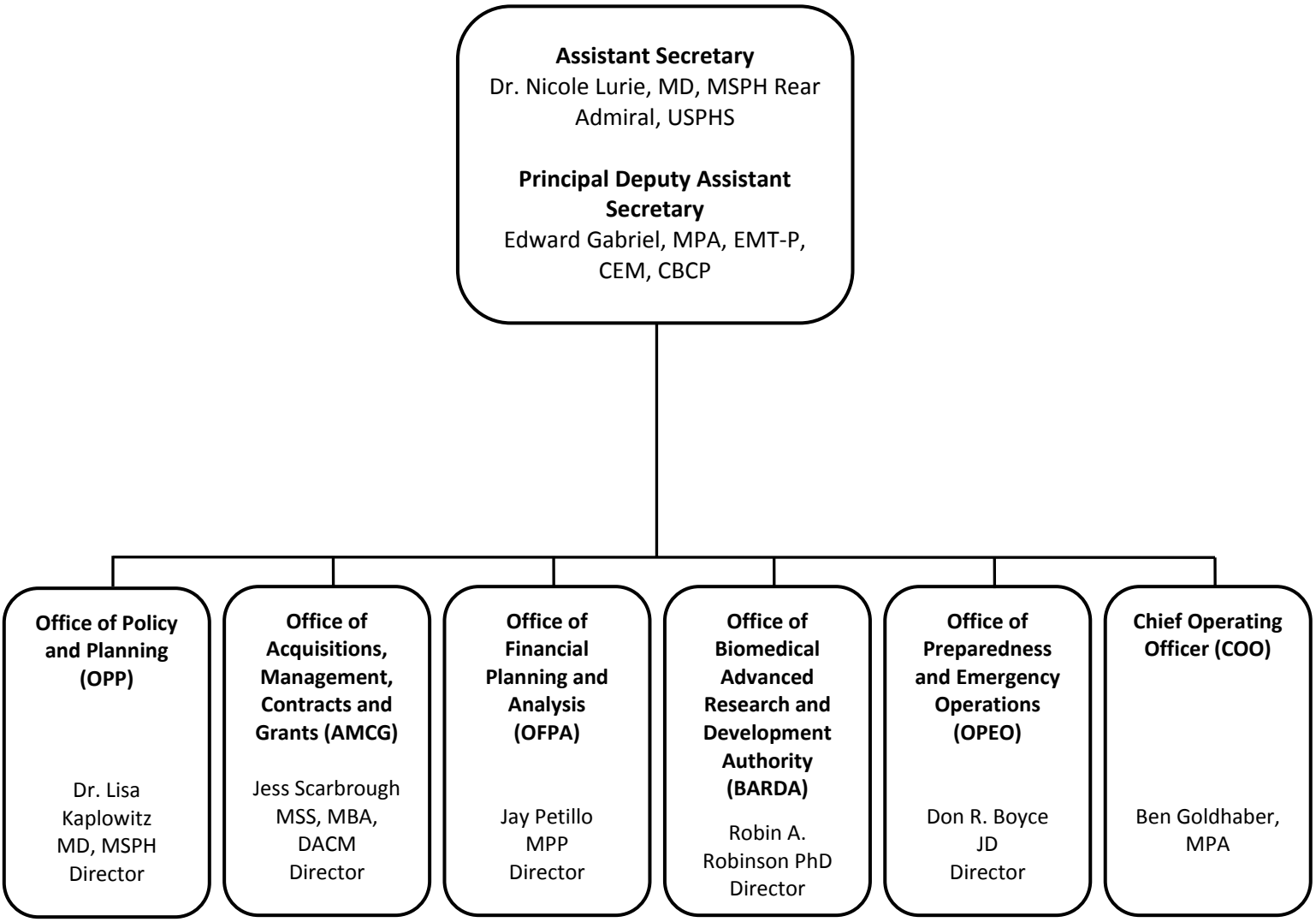
ORGANIZATIONAL CHARTS

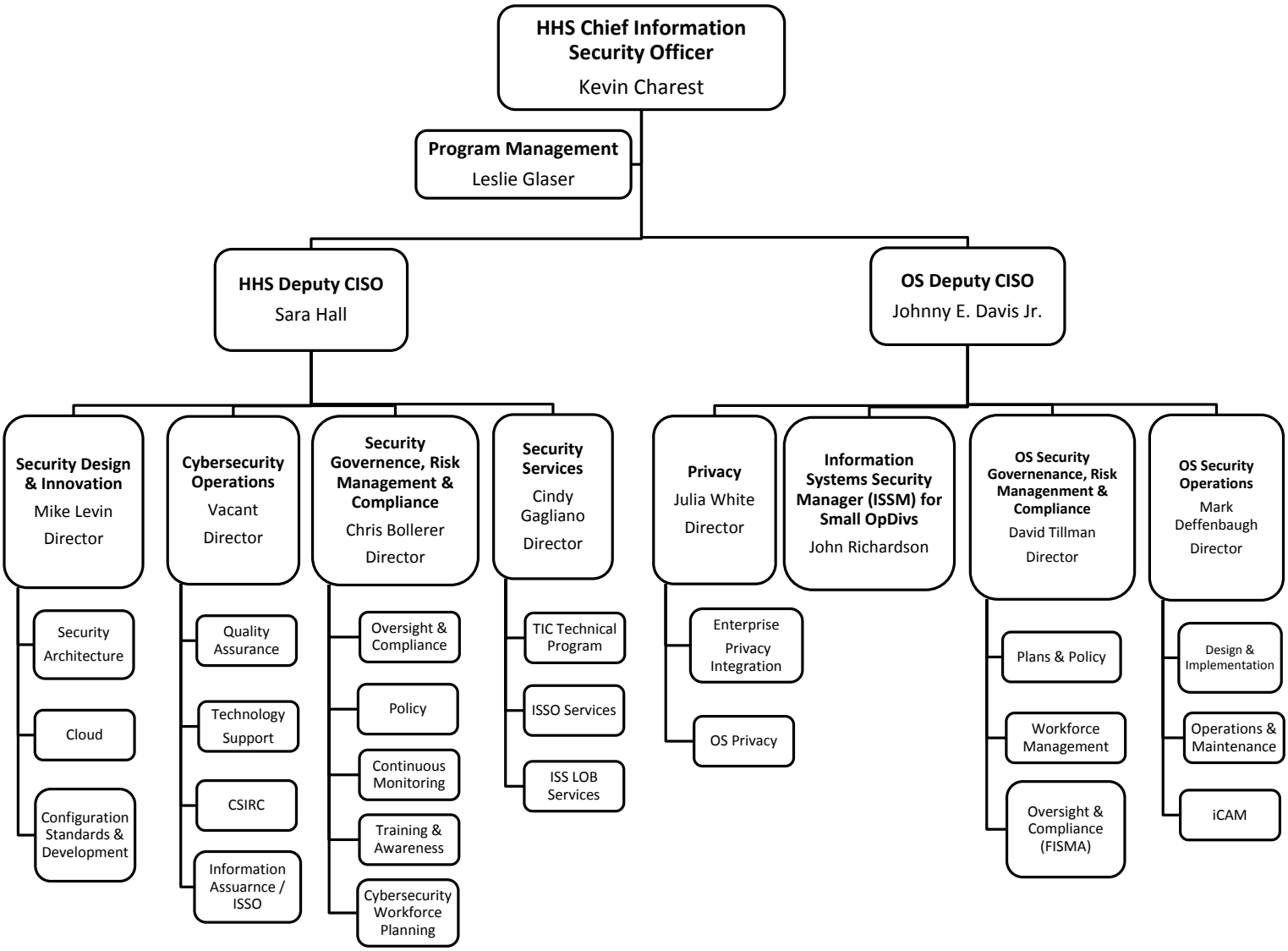
(See text version of charts)

Assistant Secretary for Preparedness and Response



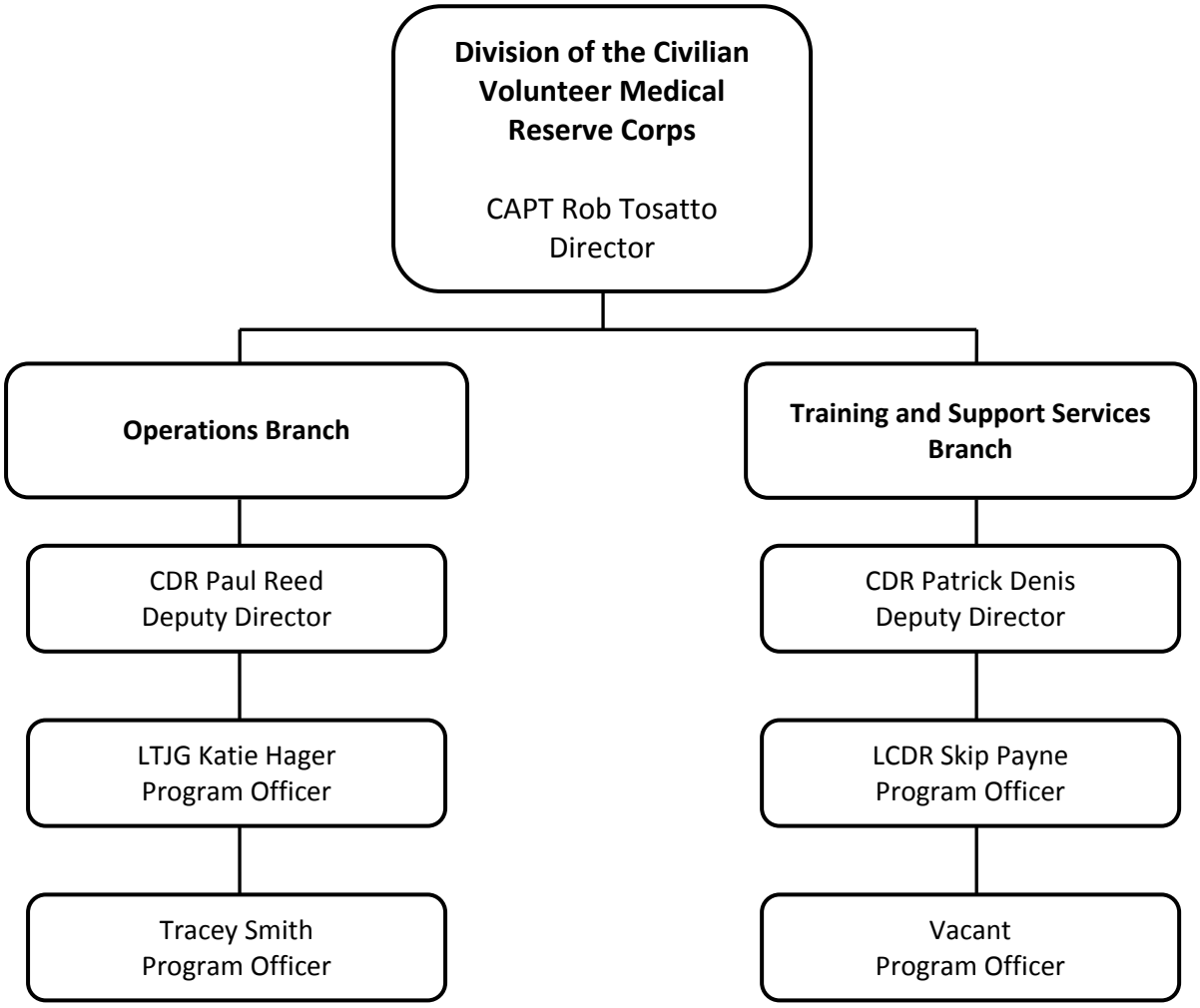
Cybersecurity

(See text version of charts)



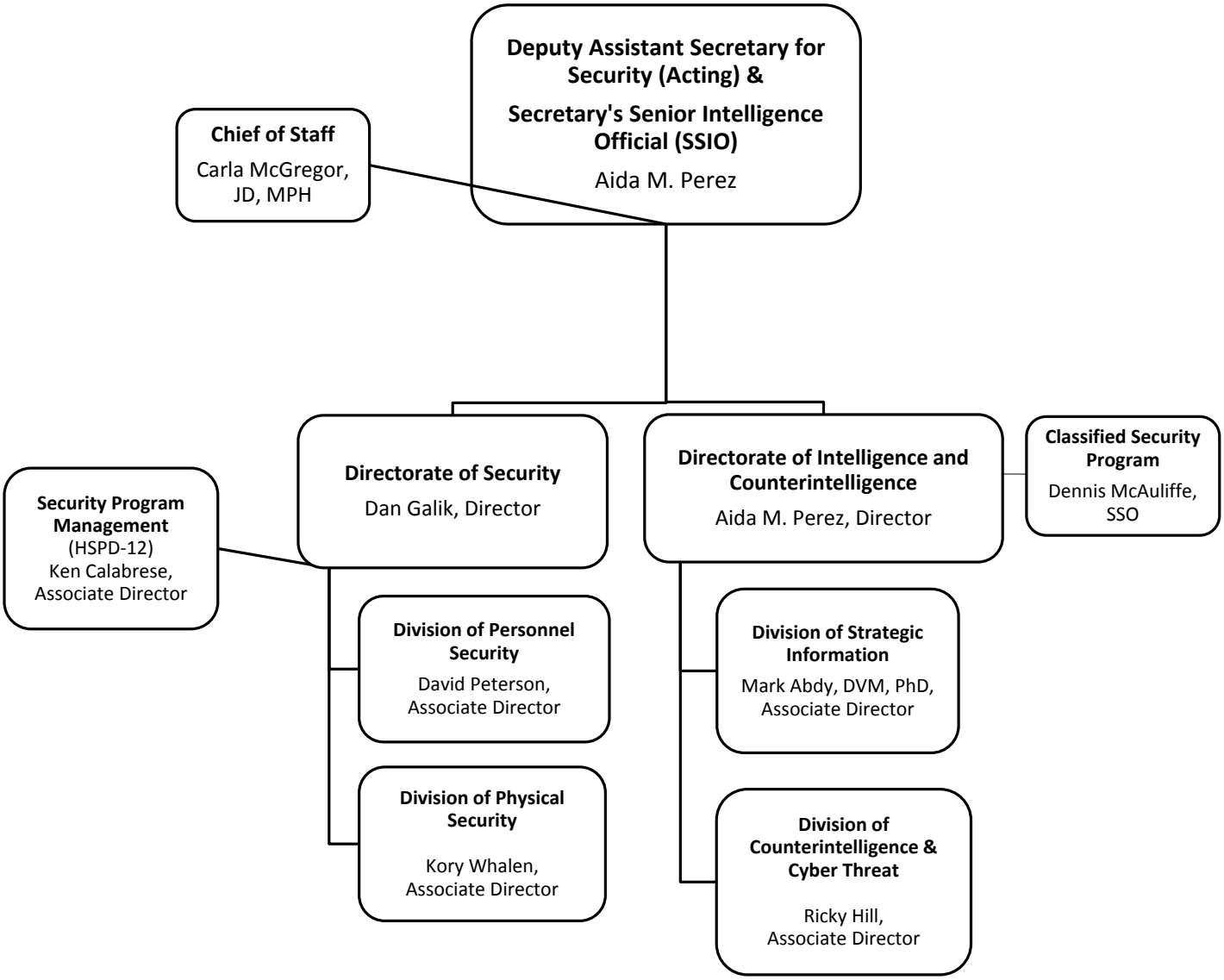
Civilian Volunteer Medical Reserve Corp

The Pandemic and All Hazards Preparedness Reauthorization Act of 2013 moved oversight and responsibility for the Civilian Volunteer Medical Reserve Corps to the Office of the Assistant Secretary for Preparedness and Response; this office is managed in the Office of the Assistant Secretary for Health (OASH).
(See text version of charts)



Office of Security and Strategic Information

OSSI coordinates Personnel, Physical, and Security Access Management services across the Department that are resourced by non-PHSSEF Funds.
(See text version of charts)



INTRODUCTION AND MISSION

The Office of the Assistant Secretary for Preparedness and Response (ASPR) is a leader in preparing America's communities to respond to and recover from public health and medical disasters and emergencies. These events include natural disasters, pandemic diseases, and man-made threats from chemical, biological, nuclear, and radiological (CBRN) agents. ASPR is a Staff Division in the Office of the Secretary, and the ASPR serves as the principal advisor to the Secretary on public health and medical emergency preparedness and response, including incidents covered by the National Response Framework. ASPR takes a collaborative approach to the Department's preparedness, response, and recovery responsibilities by working with Operational Divisions and Staff Divisions across the Department to coordinate preparedness and response activities. In addition, ASPR has operational responsibilities for the advanced research and development of medical countermeasures (MCMs) and for coordination of the Federal public health and medical response to such incidents.

ASPR's mission is to lead the country in preparing for, responding to, and recovering from the adverse 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. ASPR's Strategic Implementation Plan is guided by six major goals:

- **Goal 1 – Promote resilient communities, fostering a nation able to withstand and recover from public health emergencies.** ASPR's Hospital Preparedness Program (HPP) enabled Oklahoma to be better prepared for the EF-5 tornado that hit Moore in May 2013 because the state and local communities had tested their core preparedness capabilities. Similarly, responders to the Boston Marathon bombing have recognized the contributions of HPP in preparing the region's healthcare system for mass casualty events.

- **Goal 2 – Strengthen Federal public health and medical preparedness, response, and recovery leadership and capabilities.** ASPR's National Disaster Medical System deployed approximately 2,300 responders to support the response to Hurricane Sandy. The Division of Recovery in ASPR's Office of Emergency Management continues to work with partners to aid recovery in the New York and New Jersey communities devastated by the superstorm.

- **Goal 3 – Promote an effective medical countermeasures enterprise.** Since its inception in 2007, ASPR's Biomedical Advanced Research and Development Authority (BARDA) has supported advanced research and development of more than 85 CBRN and 50 pandemic influenza MCM product candidates. BARDA had procured 12 new MCMs since 2004 under Project BioShield. They are available in the Strategic National Stockpile for use against CBRN threats. Antitoxins for anthrax and botulism and cell- and recombinant-based influenza vaccines, all supported by BARDA, were approved by the Food and Drug Administration within the last year. BARDA also is leading the development and stockpiling of vaccines and the evaluation of new antiviral drug candidates in response to the current emergence of H7N9 influenza virus and a potential pandemic.

- **Goal 4 – Strengthen ASPR's leadership role in coordinating and developing public health and medical emergency preparedness, response, and recovery policy.** In FY 2013, ASPR coordinated the implementation of activities in the National Health Security Strategy Implementation Plan, as well as activities in the HHS Implementation Plan to support the National Strategy for Countering Biological Threats.

- **Goal 5 – Improve the preparedness and integration of health care delivery systems.** Even as HPP continues its focus on improving the preparedness of community healthcare coalitions, ASPR proposes in the FY 2015 President's Budget to dedicate $15 million to competitive awards that will test innovative models to help ensure community resilience.

- **Goal 6 – Improve management of the ASPR organization and investment in its people.** During FYs 2013 and 2014, ASPR is continuing to strategically invest in its internal management and operations to promote a more flexible and nimble organization that is better able to adapt to threats affecting public health. Notable quality improvements by ASPR include reducing the time it takes to produce hiring packages by 50 percent, streamlining the release of press announcements, improving the travel authorization process, more efficiently accounting for emergency responder staff salaries, and more timely procuring preparedness assets.

The Cybersecurity program, within the Office of the Assistant Secretary for Administration, coordinates all of the HHS information technology security efforts and works to ensure that automated information systems are designed, operated, and maintained with the appropriate information technology security and privacy data protections.

Funding for the Office of Security and Strategic Information provides strategic information and intelligence for the Department as well as physical and personnel security policy, security awareness, classified information communications security, and related medical, public health, and biomedical information matters. The Budget provides for coordination, convergence, and oversight of all aspects of integrating national security information, including classified and unclassified intelligence.

The mission of the Medical Reserve Corps (MRC) is to improve the health and safety of communities across the country by organizing and utilizing public health, medical, and other volunteers. MRC units are community-based and function as a way to locally organize and utilize volunteers who want to donate their time and expertise to prepare for and respond to emergencies and promote healthy living throughout the year. MRC volunteers supplement existing emergency and public health resources.

Pandemic Influenza funding supports HHS' efforts to prepare for and respond to a pandemic influenza outbreak. These funds support the development of next generation antivirals, ongoing activities to promote the development of rapid diagnostic assays for the diagnosis of pandemic influenza, and the accelerated development and production of influenza vaccine worldwide.

OVERVIEW OF BUDGET REQUEST

The FY 2015 Budget request for the Public Health and Social Services Emergency Fund (PHSSEF) is $1,437,813,000 and 765 FTE. This represents a program level increase of +$194,383,000, and +24 additional full time equivalent employees (FTE), relative to the FY 2014 Enacted level. These funds will provide the necessary resources to:

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

The Budget provides funds for programs within the Office of the Secretary, and specifically 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 activities.

Programmatic Increases (relative to the FY 2014 Enacted level):

- Assistant Secretary for Preparedness and Response (ASPR) (+$151 million, $1.2 billion total program level): Within ASPR, the Budget supports the advanced development of medical countermeasures (MCMs), and to enhance community preparedness and response for public health events. Notable activities include:

    - Project BioShield (+$160 million, $415 million total): FY 2015 funding will support the procurement of 12 novel MCMs against chemical, biological, radiological, and nuclear (CBRN) threats, including new procurements of artificial skin for thermal burn victims; antidotes for chemical threats; biodosimetry devices to determine the level of exposure to ionizing radiation; smallpox vaccine for use in at-risk individuals; additional doses of anthrax antitoxins to maintain current levels through this decade; and maintenance costs for a vendor-managed inventory of anti-neutropenia cytokines at the current level.

- Pandemic Influenza (+$55 million, $170 million total): The Budget continues to support the Department's efforts to prepare for and respond to a pandemic influenza outbreak through advanced development of candidates for a universal influenza vaccines, international and domestic preparedness and response activities to pandemic disease threats posed by viruses such as H7N9, advanced development of next-generation antiviral drugs, and annual sustainment costs for vaccine stockpiling and the fill and finish network.

- Office of Security and Strategic Information (+$1 million, $7 million total): The request provides funding to support the new Counterintelligence activities and the Foreign Visitor program, which provides the Department's overseas travelers with safety and security information.

- Cybersecurity (+$4 million, $45 million): The Budget supports operations costs for the Trusted Internet Connections, which consolidate internet traffic through as few secure web portals as

possible, allowing for enhanced monitoring and incident response capabilities. This program will significantly improve the Department's ability to detect and prevent cyberthreats.

Programmatic Decreases (relative to the FY 2014 Enacted level):

- Preparedness and Emergency Operations (-$3.3 million, $24.8 million total): The request provides $24,789,000 for Preparedness and Emergency Operations. This level is -$3.3 million below the FY 2014 Enacted level. The request supports the Office of Emergency Management's (OEM) ability to respond rapidly to a disaster or other public health or medical incident. The budget also supports OEM's coordination with the ten emergency response regions and state and local responders throughout the nation. The request includes $5 million in no-year funding to prepare for and respond to National Special Security Events like the President's annual State of the Union address, and other planned and unplanned events that are not eligible for assistance from the Federal Emergency Management Agency under the *Stafford Act*.

- Medical Countermeasure Dispensing (-$5.0 million, no funding is requested): For FY 2015, consistent with its core functions and ongoing mission, ASPR will continue to provide subject matter expertise to state and local governments specific to all-hazards emergencies impacting health and medical issues. If local or state jurisdictions decide to allocate resources to design or develop additional MCM distribution models, ASPR and the Department remain committed to offer support, share best practices, and assist the planning activities.

- Medical Reserve Corps (-$2 million, $9 million total): The Budget maintains support for local MRC units, while decreasing overhead and communications costs to the program.

- Departmental Lease Replacement (-$16 million, no funding is requested): Funding for FY 2015 lease replacement costs will be directly met within Operational and Staff Division budgets.

General Provisions:

- Multiyear Contracting Authority: The Budget includes authority for BARDA to utilize multiyear contracting authority, which provides flexibility to enter into long-term procurement contracts for MCMs, while operating within current year budget constraints. This authority was included in the FY 2014 Appropriations language.

BUDGET BY STRATEGIC GOAL

(Dollars in Millions)

HHS Strategic Goals	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget
1.Transform Health Care			
1.A Make coverage more secure			
1.B Improve health care quality and patient safety			
1.C Emphasize primary & preventative care, link to prevention			
1.D Reduce growth of health care costs promoting high-value			
1.E Ensure access to quality culturally competent care			
1.F Promote the adoption of health information technology			
2. Advance Scientific Knowledge and Innovation			
2.A Accelerate scientific discovery to improve patient care			
2.B Foster innovation at HHS to create shared solutions			
2.C Invest in sciences to improve food & medical product safety			
2.D Increase understanding of what works in health & services			
3. Advance the Health, Safety and Well-Being of the American People	**952**	**1,227**	**1,438**
3.A Ensure the children & youth safety, well-being & health			
3.B Promote economic & social well-being			
3.C Improve services for people with disabilities and elderly			
3.D Promote prevention and wellness			
3.E Reduce the occurrence of infectious diseases			
3.F Protect Americans' health and safety during emergencies	952	1,227	1,438
4. Increase Efficiency, Transparency and Accountability of HHS Programs	**16**	**16**	
4.A Ensure program integrity and responsible stewardship	16	16	
4.B Fight fraud and work to eliminate improper payments			
4.C Use HHS data to improve American health & well-being			
4.D Improve HHS environmental performance for sustainability			
5. Strengthen the Nation's Health and Human Service Infrastructure and Workforce			
5.A Invest in HHS workforce to help meet America's health and human service needs today & tomorrow			
5.B Ensure health care workforce meets increased demands.			
5.C Enhance the ability of the public health workforce to improve health at home.			
5.D Strengthen the Nation's human service workforce			
5.E Improve national, State & local surveillance capacity			
Total PHSSEF Program Level	**968**	**1,243**	**1,438**

ALL PURPOSE TABLE

(Dollars in Millions)

Activity	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Assistant Secretary for Preparedness and Response				
Preparedness and Emergency Operations	27.984	28.079	24.789	-3.290
National Special Security Events (non-add)	*9.376*	*5.000*	*5.000*	-
National Disaster Medical System	49.708	50.054	50.054	-
Hospital Preparedness	358.231	255.060	255.060	-
Hospital Preparedness Program (non-add)	*357.731*	*254.555*	*254.560*	*+0.005*
ESAR-VHP (non-add)	*0.500*	*0.505*	*0.500*	*-0.005*
Medical Countermeasure Dispensing	-	5.000	-	-5.000
Biomedical Advanced Research and Development Authority (BARDA)	415.000	415.000	415.000	-
Advanced Research and Development (non-add)	*350.000*	*355.000*	*335.000*	*-20.000*
Strategic Investor (non-add)	-	-	*20.000*	*+20.000*
BARDA Management (non-add)	*65.000*	*60.000*	*60.000*	-
Project BioShield	-	255.000	415.000	+160.000
Policy and Planning	14.877	14.877	14.877	-
Operations	31.304	31.305	31.305	-
Subtotal, ASPR Program Level (non-pan flu)	**897.104**	**1,054.375**	**1,206.085**	**+151.710**
Other Office of the Secretary				
Office of Security and Strategic Information	6.118	6.118	7.470	+1.352
Cybersecurity	37.884	41.125	45.270	+4.144
Medical Reserve Corps	10.672	10.672	8.979	-1.693
HHS Lease Replacement	16.131	16.131	-	-16.131
Subtotal, Other Office of the Secretary	**70.805**	**74.046**	**61.719**	**-12.328**
Pandemic Influenza				
No-Year Funding	-	83.000	140.000	+57.000
Annual Funding	-	32.009	30.009	-2.000
Subtotal, Pandemic Influenza	-	**115.009**	**170.009**	**+55.000**
Less Funds from Other Sources				
Use of Project BioShield Special Reserve Fund balances for BARDA	-415.000	-	-	-
Use of Public Health Service Evaluation Funding for ASPR Office of Policy and Planning	-	-	-14.877	-14.877
Subtotal, Less Funds from Other Sources	**-415.000**	-	**-14.877**	**-14.877**
Total, PHSSEF Budget Authority	**552.910**	**1,243.430**	**1,422.936**	**+179.506**
Total, PHSSEF Program Level	**967.910**	**1,243.430**	**1,437.813**	**+194.383**
FTE	**663**	**741**	**765**	**+24**

FY 2015 PROPOSED APPROPRIATIONS LANGUAGE

(Relative to FY 2014 Enacted)

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, **[**$857,290,000**]** *$837,927,000*, of which **[**$415,000,000**]** *$415,000,000* shall remain available through September 30, **[**2015**]** *2016*, 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**[**, and of which up to $5,000,000 shall remain available through September 30, 2016, to support the delivery of medical countermeasures and shall be in addition to any other amounts available for such purpose**]**: *Provided*, That funds provided under this heading for the purpose of acquisition of security countermeasures 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: *Provided further*, That $5,000,000 of the amounts made available to support emergency operations shall remain available **[**through September 30, 2016.**]** *until expended: Provided further, That, of the amounts made available to support advanced research and development, up to $20,000,000 shall be available for the purposes of establishing and funding, using for either such purpose contracts, grants, cooperative agreements, or other transactions as described in section 319L of the PHS Act (42 U.S.C. 247d-7e), a strategic investment corporation, which shall not be deemed to be a Federal agency for any purpose, to further the purposes of such section 319L to foster innovation in the development of medical countermeasures: Provided further, That, in addition to amounts provided herein, $14,877,000 shall be available from amounts available under section 241 of the PHS Act to supplement funds otherwise available for carrying out activities of the Office of the Assistant Secretary for Preparedness and Response.*

For **[**necessary**]** expenses *necessary* for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act), **[**$255,000,000**]** *$415,000,000*, to remain available until expended.

For *an additional amount for* expenses necessary to prepare for **[**and**]** *or* respond to an influenza pandemic**[**, $115,009,000**]** *or emerging infectious disease, including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools, $170,009,000*; of which **[**$83,000,000**]** *$140,000,000* shall be available until expended**[**, for activities including the

development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools**]**: *Provided* **[**further**]**, That*,* notwithstanding section 496(b) of the PHS Act, funds may be used for the construction or renovation of privately owned facilities for the production of pandemic influenza vaccines and other biologics, if the Secretary finds such construction or renovation necessary to secure sufficient supplies of such vaccines or biologics*: Provided further, That funds appropriated in this paragraph may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this paragraph*. **[**In addition, for expenses necessary for replacement of building leases and associated renovation costs for Public Health Service agencies and other components of HHS, including relocation and fit-out costs, $16,131,000, to remain available until expended.**]**

FY 2015 Proposed General Provisions

SEC. 222. (a) The Biomedical Advanced Research and Development Authority (BARDA) may enter into a contract, for more than one but no more than ten program years, for purchase of research services or of security countermeasures, as that term is defined in section 319F-2(c)(1)(B) of the Public Health Service Act (42 U.S.C. 247d-6b(c)(1)(B)), if—

(1) funds are available and obligated—

(A) for the full period of the contract or for the first fiscal year in which the contract is in effect; and

(B) for the estimated costs associated with a necessary termination of the contract;

and

(2) the Secretary determines that a multi-year contract will serve the best interests of the Federal Government by encouraging full and open competition or promoting economy in administration, performance, and operation of BARDA's programs.

(b) A contract entered into under this section:

(1) shall include a termination clause as described by subsection (c) of section 3903 of title 41, United States Code; and

(2) shall be subject to the congressional notice requirement stated in subsection (d) of such section.

APPROPRIATIONS LANGUAGE ANALYSIS

Language Provision	Explanation
[, and of which up to $5,000,000 shall remain available through September 30, 2016, to support the delivery of medical countermeasures and shall be in addition to any other amounts available for such purpose**]**	This language is removed since funds are not requested for this activity in FY 2015.
Provided further, That, of the amounts made available to support advanced research and development, up to $20,000,000 shall be available for the purposes of establishing and funding, using for either such purpose contracts, grants, cooperative agreements, or other transactions as described in section 319L of the PHS Act (42 U.S.C. 247d-7e), a strategic investment corporation, which shall not be deemed to be a Federal agency for any purpose, to further the purposes of such section 319L to foster innovation in the development of medical countermeasures:	This language provides funding for the Strategic Investor which provides capital to support development and manufacturing of high priority medical countermeasures throughout the industry.
Provided further, That, in addition to amounts provided herein, $14,877,000 shall be available from amounts available under section 241 of the PHS Act to supplement funds otherwise available for carrying out activities of the Office of the Assistant Secretary for Preparedness and Response.	This language provides the authority to support activities within the Office of the Assistant Secretary for Preparedness and Response using PHS evaluation funding.
For *an additional amount for* expenses necessary to prepare for **[**and**]** *or* respond to an influenza pandemic	This language clarifies that these funds are not the only HHS funds available for preparing for or responding to an influenza pandemic or emerging infectious disease.
or emerging infectious disease, including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools, $170,009,000; of which **[**$83,000,000**]** *$140,000,000* shall be available until expended**[**, for activities including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools**]**:	This language provides the authority to use FY 2015 appropriations to support preparation or response to other emerging infectious diseases in addition to pandemic influenza. The language noting the specific activities has been moved to make clear that annual funding as well as no-year funding may be used for these purposes, if needed.
Provided further, That funds appropriated in this paragraph may be transferred to other appropriation accounts of the Department of Health and Human Services, as determined by the Secretary to be appropriate, to be used for the purposes specified in this paragraph.	This language provides permissive authority to the Secretary to determine the appropriate circumstances for Pandemic Influenza funding to be transferred for use to other appropriation accounts within HHS.
[In addition, for expenses necessary for replacement of building leases and associated renovation costs for Public Health Service agencies and other components of HHS, including relocation and fit-out costs, $16,131,000, to remain available until expended.**]**	This language is removed since funds are not requested for this activity in FY 2015.

AMOUNTS AVAILABLE FOR OBLIGATION

(In Dollars)

Detail	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
Annual Appropriation	558,394,636	464,299,000	447,936,000
Rescissions	-1,116,790	-	-
Sequester Order	-27,422,236	-	-
Transfers	-2,453,452	-	-
Subtotal, Adjusted Annual Appropriation	**527,402,158**	**464,299,000**	**447,936,000**
Multi-Year Appropriation	9,981,100	425,000,000	420,000,000
Supplemental (PL 113-2)	195,000,000	-	-
Rescissions	-19,962	-	-
Sequester Order	-10,085,620	-	-
Transfers	-149,344,709	-	-
Subtotal, Multi-Year Appropriation	**45,530,809**	**425,000,000**	**420,000,000**
No-Year Appropriation	17,000,000	354,131,000	555,000,000
Rescissions	-34,000	-	-
Sequester Order	-834,854	-	-
Subtotal, No-Year Appropriation	**16,131,146**	**354,131,000**	**555,000,000**
Total, Adjusted Budget Authority	**589,064,113**	**1,243,430,000**	**1,422,936,000**
Unobligated balance, start of the year	2,348,685,387	851,191,693	128,244,802
Unobligated balance, end of the year	851,191,693	128,244,802	236,948,955
Total Obligations	**2,054,881,736**	**1,319,000,000**	**1,541,000,000**

SUMMARY OF CHANGES

(Dollars in Thousands)

FY 2014	
Total Estimated Budget Authority	1,243
(Obligations)	1,399
FY 2015	
Total Estimated Budget Authority	1,423
(Obligations)	1,636
Net Change	**+179.506**

Increases	**FY 2015 PB FTE**	**FY 2015 PB BA**	**FY 2015 +/- FY 2014 FTE**	**FY 2015 +/- FY 2014 BA**
Assistant Secretary for Preparedness and Response				
Project BioShield	-	415	-	160
Subtotal, ASPR Increases	**-**	**415**	**-**	**+160**
Other Office of the Secretary				
Cybersecurity	112	45	+24	+4
Office of Security and Strategic Information	33	7	-	+1
Departmental Lease Renewals	-	-	-	-16
Subtotal, Other Office of the Secretary Increases	**145**	**53**	**+24**	**-11**
Pandemic Influenza				
No-year Flu Funds	-	140	-	+57
Annual Flu Funds	5	30	-	-2
Subtotal, Pandemic Influenza	**5**	**170**	**-**	**+55**
Total Increases			**+24**	**+204**

Decreases	**FY 2015 PB FTE**	**FY 2015 PB BA**	**FY 2015 +/- FY 2014 FTE**	**FY 2015 +/- FY 2014 BA**
Assistant Secretary for Preparedness and Response				
Preparedness and Emergency Operations	111	25	-	-3
Medical Countermeasure Dispensing	-	-	-	-5
Subtotal, ASPR Decreases	**111**	**25**	**-**	**-8**
Other Office of the Secretary				
Medical Reserve Corps	7	9	-	-2
Subtotal, Other Office of the Secretary Decreases	**7**	**9**	**-**	**-2**
Total Decreases			**-**	**-10**

Net Change in Program Level			**+24**	**+195**

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Thousands)

Activity	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget
Bioterrorism and Emergency Preparedness	536,778	1,112,290	1,252,927
Pandemic Influenza	-	115,009	170,009
Buildings and Facilities	16,131	16,131	-
Total Budget Authority	**552,910**	**1,243,430**	**1,422,936**
Total FTE	663	741	765

AUTHORIZING LEGISLATION

(Dollars in Thousands)

Details	2014 Authorized	2014 Enacted	2015 Authorized	2015 President's Budget
Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)		1,243,430		1,422,936

APPROPRIATIONS HISTORY

(Dollars in Thousands)

Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
FY 2005				
Appropriation	61,456	61,456	61,456	161,456
Rescissions				-1,390
Supplemental Appropriation				60,000
FY 2006				
Appropriation	203,589	60,633	60,633	63,589
Rescissions				-636
Transfer to CMS				-43
Supplemental Appropriation				5,570,000
FY 2007				
Appropriation	218,413	160,475	166,907	602,200
Supplemental Appropriation				99,000
FY 2008				
Appropriation	1,729,211	1,705,382	1,674,556	729,295
FY 2009				
Appropriation	2,300,831	1,443,827	1,251,758	3,160,795
Supplemental Appropriation (PL 111-5)		900,000	870,000	50,000
Supplemental Appropriation (PL 111-32)				7,650,000
Transfer to CDC				-200,000
FY 2010				
Appropriation	2,678,569	2,100,659	2,621,154	3,770,694
Supplemental Appropriation (PL 111-212)				220,000
Rescission (PL 111-226)				-6,630
FY 2011				
Appropriation	1,041,694		1,050,795	674,828
Supplemental Appropriation (ARRA)		50,000	50,000	50,000
FY 2012				
Appropriation	595,023	543,114	574,452	596,452
Rescission (PL 111-226)				-1,076
FY 2013				
Appropriation	642,262			584,205
Transfer to CDC				-1,919
Transfer to OMHA				-629
Supplemental Appropriation	800,000	800,000	800,000	800,000
Transfer to ACF – SSBG				-500,000
Transfer to ACF – Head Start				-100,000
Transfer to OIG				-5,000
Transfer to OGA				-250
Sequester				-38,343
FY 2014				
Appropriation	1,289,531		1,304,400	1,243,430
FY 2015				
Estimate	1,422,936			

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Summary of Request

Budget Summary
(Dollars in Thousands)

Office of the Assistant Secretary for Preparedness and Response (ASPR)	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Program Level	897,104	1,165,375	1,372,085	+206,710
Budget Authority (non-add)	*482,104*	*1,165,375*	*1,357,208*	*+191,833*
Other Sources (non-add)	*415,000*	-	*14,877*	*+14,877*
FTE	569	601	601	-

Note: Totals include ASPR's portion of Pandemic Influenza funding.

Summary of Request

The mission of the Office of the Assistant Secretary for Preparedness and Response (ASPR) is to lead the Nation in preventing, preparing for, responding to, and recovering from the adverse health effects of public health emergencies and disasters. These events include naturally-occurring threats such as hurricanes and influenza pandemics, along with manmade threats from the use of chemical, biological, radiological, and nuclear (CBRN) agents. ASPR promotes community preparedness and prevention; builds partnerships with other Federal departments and agencies, academic institutions, and private sector partners; coordinates Federal public health and medical response capabilities; and develops and procures medical products that fight pandemic diseases and CBRN threats to health.

The FY 2015 Request for ASPR is $1,372,085,000. It includes $1,357,208,000 in budget authority and $14,877,000 from amounts made available under section 241 of the *PHS Act*. The request is an increase of +$191,833,000 above the FY 2014 Enacted level of budget authority. This funding level is necessary to maintain national security by ensuring that communities are prepared to respond to natural disasters and public health threats and that they can limit adverse health effects, and foster resilience and rapid recovery. The request also supports the Administration's multi-year commitment to procure novel medical countermeasures (MCMs) against CBRN threats and pandemic diseases.

Programmatic Increases:

- Project BioShield (+$160.0 million above the FY 2014 Enacted level: $415.0 million total)
  The Budget provides $415,000,000 through Project BioShield for ASPR to procure new MCMs against CBRN threats. Over the last decade, the United States has procured 12 new MCMs through Project BioShield. This request builds upon that progress and contributes to the goal of procuring 12 more CBRN MCMs by 2018. The request will support new procurements of artificial skin for thermal burn victims; antidotes for chemical threats; biodosimetry devices to determine the level of exposure to ionizing radiation; smallpox vaccine for use in at-risk individuals; additional doses of anthrax antitoxins to maintain current levels through this decade; and maintenance costs for a vendor-managed inventory of anti-neutropenia cytokines at the current preparedness level.

- Pandemic Influenza (+$55.0 million above the FY 2014 Enacted level: $166.0 million total)
  The budget provides $166,000,000 for ASPR to fund research on and development of MCMs to fight pandemic influenza and other emerging infectious diseases. The request includes $140 million for

ASPR's Biomedical Advanced Research and Development Authority (BARDA) that is available until expended and another $26 million in annual funding for BARDA ($23 million) and ASPR's Office of Policy and Planning ($3 million). The request builds on U.S. progress in new vaccine technologies. It includes funding for BARDA's advanced development of candidates for universal influenza vaccines. The budget also includes funding to continue preparing for and responding to pandemic disease threats posed by viruses such as H7N9, an avian influenza strain identified in Asia. Other activities supported by this funding include the advanced development of next-generation antiviral drugs and annual sustainment costs for vaccine stockpiling and the fill and finish network. (In addition to this funding for ASPR, the FY 2015 Budget requests $4 million for the Office of Global Affairs to continue to support global health diplomacy activities for international pandemic preparedness and response. See also the Pandemic Influenza section of the justification.)

- Antimicrobial Resistance ($79.0 million of the Advanced Research and Development (ARD) request)
  As part of the President's new initiative to combat antimicrobial drug resistance, ASPR's BARDA will spend $79 million of its FY 2015 ARD funding (which totals $415 million) to develop new classes of antimicrobial drugs for treating and diagnosing biothreats and community- and hospital-acquired antimicrobial drug resistant pathogens.

Programmatic Decreases:

- Preparedness and Emergency Operations (-$3.3 million below the FY 2014 Enacted level: $24.8 million total)
  The request provides $24,789,000 for ASPR's Preparedness and Emergency Operations. This funding level is -$3.3 million below the FY 2014 Enacted level. The request supports the Office of Emergency Management's (OEM) ability to respond rapidly to a disaster or other public health or medical incident. The budget also supports OEM's coordination with the ten emergency response regions and state and local responders throughout the nation. The request includes $5 million in no-year funding to prepare for and respond to National Special Security Events like the President's annual State of the Union address, and other planned and unplanned events that are not eligible for assistance from the Federal Emergency Management Agency under the *Stafford Act*.

- Medical Countermeasure Dispensing (-$5.0 million below the FY 2014 Enacted level: $0)
  For FY 2015, consistent with its core functions and ongoing mission, ASPR will continue to provide subject matter expertise to state and local governments specific to all-hazards emergencies impacting health and medical issues. If local or state jurisdictions decide to allocate resources to design or develop additional MCM distribution models, ASPR and the Department remain committed to offer support, share best practices, and assist the planning activities.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Overview of Performance

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

Lead the country in preparing for, responding to, and recovering from adverse 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.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will achieve its mission through implementation of our strategic plan, consisting of six core ASPR goals, which serves 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.

ASPR's Budget Justification Performance Data

ASPR believes that the development and implementation of capability-based performance measures 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 highlight ASPR's commitment to refining and developing the best measures that align to ASPR's new strategic plan and illustrate progress towards the core ASPR goals. Additionally, the work performed by ASPR helps meet the Department's strategic goal 3F: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies.

ASPR's Performance Management Process

During the past year, ASPR did a mid-point assessment of the plan and decided that it needed to be updated to reflect progress to date and, more importantly, where the agency wants to be at the end of this strategic plan in FY 2015. ASPR has added new and challenging action steps to achieve each of the six core goals over the next two years.

For regular performance tracking, ASPR has assigned goal chairs to provide updates to senior leadership regarding the progress of meeting these respective goals. Goal chairs will lead the refinement of goals as needed, establish priority action items for implementation tracking and reporting, and ensure that ASPR is on track to achieve the desired outcomes for that goal. Goal chairs will be responsible for coordination and collaboration across ASPR program offices and will facilitate regular discussions with ASPR senior leadership on accomplishments, progress, and challenges related to the goal.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Preparedness and Emergency Operations

Budget Summary
(Dollars in Thousands)

ASPR Preparedness and Emergency Operations	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	27,984	28,079	24,789	-3,290
NSSE/Public Health Emergencies/1 (non-add)	*9,376*	*5,000*	*5,000*	-
FTE	93	111	111	-

1/ "NSSE" stands for "National Special Security Event."

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method……Direct Federal/Intramural, Contracts

Program Description and Accomplishments

The Preparedness and Emergency Operations funds support ASPR's Office of Emergency Management (OEM) (formerly the Office of Preparedness and Emergency Operations). OEM brings together assets and expertise to save and sustain lives by supporting communities as they prepare, respond to, and recover from the public health and medical impacts of emergencies and disasters. OEM strives to define and prioritize medical and response challenges for preparedness, response, and recovery activities while delivering service excellence and innovative products in a rapidly changing world.

More specifically, OEM supports: (1) the integration of capabilities, programs, and assets to support response and recovery efforts; (2) a nimble, effective, and coordinated response to public health and medical incidents; (3) maintenance of adaptable and resilient planning guidance; and (4) alignment of grant programs to support strategic priorities to enhance community resilience. In addition, to mitigate the lasting impacts of disasters, after each response OEM identifies challenges and implements corrective actions to ensure the organization provides a thorough and effective response to future emergencies.

OEM consists of ten divisions that work together to partner with other HHS divisions, Federal agencies, and every U.S. state and territory to make sure that American communities stand ready to withstand, and recover rapidly and fully, from disasters and emergencies. Within HHS, OEM manages the Secretary's Operations Center, which provides monitoring and analysis of actual and potential public health emergencies and disasters.

Responding to Public Health and Medical Incidents

Under the National Response Framework, HHS serves as the primary agency for Emergency Support Function-8 (ESF-8). HHS has primary responsibility for ensuring the Nation's preparedness and response to the public health and medical consequences of disasters, including terrorist incidents involving weapons of mass destruction. Within HHS, ASPR is the lead for all activations of ESF-8, and within ASPR, OEM is the lead. ESF-8 activations include those under Sections 311 and 319 of the *Public Health Service Act*, Federal-state cooperation, temporary assistance to states, National Special Security Events, and public health emergencies. Additionally, HHS provides public health and medical resources for international events in support of the Department of State (DOS), the U.S. Agency for International

Development (USAID), and the Department of Defense (DOD).

Response Operations
OEM's Division of Operations leads deployments and exercises, and provides informed situational awareness of all emergency events, both domestic and international. OEM provides sophisticated analysis and consolidated reporting to senior leadership to support situational awareness and decision-making before, during, and after response operations.

Following are recent examples of major HHS/ASPR/OEM response deployments:

- **Hurricane Sandy: October and November 2012**
  OEM deployed personnel and medical assets to support health and medical response efforts in New York and New Jersey. Approximately 2,300 National Disaster Medical System (NDMS) personnel were deployed to assist state and local authorities to deal with the medical effects. NDMS personnel included 26 deployed Disaster Medical Assistance Teams (DMATs) comprised of doctors, nurses, paramedics and other clinical and command staff. The DMATs were sent to supplement, or in some cases temporarily replace, local medical care. Improvements in planning and decision-making processes enabled NDMS team members to begin caring for survivors within 4.5 hours of a request for assistance from state or local governments, far exceeding a prior goal of 48 hours. These teams mitigated a substantial surge in emergency departments, preventing many from life-threatening exacerbations of their chronic illnesses, and allowing these facilities to place priority on treating critically-ill patients affected by the storm.

  OEM's response to Hurricane Sandy incorporated lessons learned from past response operations, including Hurricane Isaac, a major storm that affected the Gulf Coast in August 2012. Specifically, OEM forward-deployed response teams ahead of the storm to support an immediate and comprehensive response. This modification supported a more nimble and flexible organization and decreased the lead time required to move assets. In addition, OEM actively communicated with local responders to better determine specific requirements and was able to tailor the response based on exact need. OEM also reconfigured caches and supplies, enabling DMATs to be more agile and modular throughout the responses. OEM also deployed Behavioral Health Specialists with DMATs to support patients and deployed responders. This aspect of deployment is new for our teams. NDMS also has added capabilities by training team employees on geriatrics and pediatrics. All of these modifications enhanced overall response to Hurricane Sandy.

  After Hurricane Sandy, NDMS assets on the ground provided a wide range of medical support. They had major missions that supported the Federal Emergency Management Agency (FEMA), emergency room decompression, door-to-door wellness checks, veterinary support, and general and special medical needs shelters across New York City and in New Jersey. A tent-based field hospital established by NDMS met the medical needs of one community by receiving ambulances and providing emergency and routine care able to issue hundreds of prescriptions for critical medications including: inhalers for asthma sufferers, blood pressure medication, and insulin refills and glucose testing strips for people with diabetes.

- **Connecticut School Shooting: December 2012**
  HHS assisted with the response to the shooting at Sandy Hook Elementary School in Connecticut, deploying a Mental Health Team to support state, local, and other Federal efforts. They recorded over 3,000 mental health encounters.

- **Boston Marathon Bombings: April 2013**
  HHS responded to the Boston Marathon bombings by rapidly deploying a group of combined NDMS and Public Health Service (PHS) mental health specialists to provide support for a variety of missions including hospitals and marathon organizers. ASPR, HHS partners, and other organizations recorded more than 1,000 encounters relating to mental health.

- **Oklahoma Tornado: May 2013**
  HHS rapidly deployed two DMATs, one NDMS Disaster Mortuary Assistance Team, and two DMAT caches to support state, local, and other Federal efforts in and around Oklahoma City.

Response deployments are supported by several OEM offices:

Division of Fusion

OEM's Division of Fusion captures, analyzes, and interprets information before, during, and after an emergency to ensure decision-makers receive timely and updated situational analysis and information. The Division of Fusion uses a visualization platform – Fusion Analytics – that incorporates data from a variety of ASPR programs and sources, such as the Resource Management System (RMS) and electronic medical records. This information is coupled with an innovative and comprehensive Disaster Medical Information Suite that captures real-time medical information on all patient encounters during a response.

The resulting product, MedMap, is a tool used by leadership to inform and guide the deployment of personnel and resources to support a dynamic ESF-8 response. MedMap currently has more than 800 users representing 30 agencies within the Federal government and 28 states. MedMap is continuing to be developed and refined for needs as they emerge. The Division of Fusion continues to update data sets that allow use of MedMap as a demographics tool, enabling the identification of the neediest and most vulnerable communities and making it easier to target scarce resources to them. MedMap is also leading the way in Federal and state collaboration by allowing states to access the data within MedMap, which allows state-run applications to receive and use the data in their own applications and increase their situational awareness.

The Division of Fusion is developing additional analytic tools that promote the use of technologies to maximize response and aid responders, leaders, and decision-makers during emergencies. One such system – National Hospital Available Beds for Emergencies and Disasters (HAvBED) – provides decision-makers with information on bed capacity as reported by the states and territories in support of potential catastrophic events for movement of patients. In planning for events such as a Presidential Inauguration or State of the Union address, OEM is able to determine in real-time the capacity within states or regions to assist in patient movement based on actual or potential threats.

In 2012, OEM's Division of Fusion developed a challenge competition to find a better way to analyze and make useful the data available on microblog and social media sites such as Twitter. The purpose of the "Now Trending Challenge" was to create a web application that identifies the Top 5 diseases or conditions trending on Twitter in a local community. This information can then be available for use in indications or warnings of emerging issues, to validate traditional sources, or to develop a baseline of issues the public is concerned about to inform messaging.

The winning tool, MappyHealth (www.mappyhealth.com) allows users to easily view Twitter data trends

by geographic location or by illness type. These benefits made it an important situational awareness technology for OEM's tool kit during both Hurricanes Isaac and Sandy and during the 2013 influenza season. OEM used MappyHealth in conjunction with traditional surveillance data and open source and social media searching strategies to gain a more complete and timely picture of the situation on the ground in disasters.

In addition, the Division of Fusion is working to incorporate information from open source news media for early warning of potential public health and medical issues. During the 2013 northeast winter storms and Oklahoma tornadoes, the customized feeds were analyzed for early indications of potential medical concerns. These news feeds provided early warning information for leadership on several topics including hospital and nursing home status, fatalities, and public health issues related to these natural disasters.

The Secretary's Operations Center (SOC)

OEM operates the Secretary's Operations Center (SOC). The SOC is the focal point for collecting and distributing critical public health and medical information on behalf of the U.S. Government. The SOC provides real-time situational awareness, analysis, and monitoring of the public health, medical, and human services environment. The SOC continually monitors potential or developing incidents or public health emergencies, and supports and tracks field operations during incidents. Regular surveillance and monitoring of multiple information sources is conducted to maintain situational awareness and identify any emerging threats.

During emergencies, the SOC supports incident management system responses for HHS, serving as a conduit for information from HHS organizations, field teams, and partners. The SOC conducts required notifications of Headquarters staff, and collects, integrates, conducts initial analysis of, and disseminates incident information. The SOC serves as a liaison to the Department of Homeland Security (DHS), its National Operations Center, and other organizations on public health issues, and establishes and maintains communications and coordination with other federal Emergency Operations Centers. In addition, the SOC is the U.S. central reporting point for incidents related to International Health Regulations.

To support enhanced communication and information management capabilities, OEM continues to make investments in the SOC. Since it became operational in 2002, the SOC has undergone several phased information technology (IT) and other upgrades. A major SOC renovation was completed in 2012 to support implementation of leading edge technologies. OEM will continue to support smaller annual investments to provide sustained enhancements to individual mission essential areas and systems. This strategy provides greater operating efficiency and improved managed lifecycle of technologies.

In addition to enhanced IT capabilities, the SOC is strengthening its relationships with other programs, offices, and private-sector partners by including partners as soon as the emergency occurs and supporting an open communication exchange to maintain situational awareness before, during, and after incidents. These partners include: OEM's Critical Infrastructure Protection (CIP); HHS' Office of Security and Strategic Information (OSSI), the Food and Drug Administration, and Centers for Disease Control and Prevention (CDC); DOD; the World Health Organization (WHO), the Pan American Health Organization; the American Red Cross; the National Association of County and City Health Officials; the Association of State and Territorial Health Officials; state and local governments; and other partners involved in response and recovery activities. Open and ongoing information exchanges and communication with these partners throughout the continuum of preparedness, response, and recovery

will help maintain a comprehensive common operating picture platform and decision support system for the Secretary and the Assistant Secretary.

National Special Security Events and Emergency Support Teams

OEM also supports National Special Security Events (NSSEs). These events include the President's State of the Union address; Independence Day celebrations in Washington, D.C.; NATO summits; the quadrennial Democratic and Republican National Conventions; the National Football League's Super Bowl; and other public events such as State Funerals. Deployment to NSSEs serves a dual purpose. First, it supports collaboration among several Departments and organizations including OEM responders, the PHS Office of Force Readiness and Deployment, and other partners. Second, it prepares teams for future public health and medical incidents.

OEM also supports the Domestic and Foreign Emergency Support Teams (DEST/FEST). OEM provides subject matter expertise in public health and medical threat assessments, consequence management, technical reach-back, food and water safety, medical management planning, and health surveillance. These teams are comprised of interagency partners, including HHS, DOS, DOD, the Federal Bureau of Investigation (FBI), FEMA, the Department of Energy (DOE), and the Environmental Protection Agency (EPA). These teams include subject matter experts in consequence management and technical operations, supporting domestic and international man-made disasters or when the use of a weapon of mass destruction is thought to be imminent.

Accomplishments in FY 2013 include a successful DEST notification and the recall and deployment of HHS personnel to support a joint FEMA/FBI two-day exercise conducted in Atlanta, Georgia. While in Atlanta, HHS played a principal role in the exercise as the primary resource for patient movement, casualty management, and public health and safety concerns.

Planning and Preparing for Public Health and Medical Incidents

Division of Planning

One of the most important parts of effective public health response is the planning that occurs before the disaster or other public health emergency. OEM's Division of Planning, in coordination with Federal partners, coordinates response and recovery planning among all levels of government. The goal is planning and responses that are nimble, flexible, and adaptable to all public health and medical incidents.

Following are examples of some recent OEM planning initiatives and accomplishments:

- OEM coordinated with DHS/FEMA a plan for regional MCM distribution. The proposed Federal MCM Regional Planning Strategy will support the distribution of MCMs to mitigate against possible anthrax attacks. This plan includes local emergency responders, emergency medical services, hospitals, public health agencies, law enforcement, and other partners.

- OEM coordinated with FEMA to plan for a Cascadia Subduction zone earthquake. This zone runs along the Pacific coast of Washington, Oregon, and northern California. The group is developing a plan to allocate resources among entities involved in recovery. This framework will build on the lessons learned from the national level exercise for the New Madrid Seismic Zone – which is in the area where Arkansas, Kentucky, Missouri, and Tennessee meet.

- OEM worked with the Institute of Medicine of the National Academies to develop a framework for the allocation of scarce resources during a catastrophe. OEM also worked with the U.S. National Library of Medicine to develop a web-based All-Hazard Plan that will include event-specific tabs; information on core capabilities from the Federal interagency response plan; and information on regional, state, and local planning support.

- OEM supported DHS in developing a maritime mass-migration plan for a potential influx of Cuban or Haitian migrants. OEM also provided planning support for a potential influx of repatriated citizens and foreign nationals resulting from a North Korean nuclear strike.

- OEM partnered with ASPR's Office of Policy and Planning and Biomedical Advanced Research and Development Authority in collaborating with international partners to plan for how to strengthen MCMs and respond to global health threats like pandemic diseases, including such threats as H7N9 influenza. One such meeting was with the Republic of Korea's health and food and drug safety attaches.

Division of Tactical Programs

Another critical component of preparing for responses is the knowledge gained from methodical analysis, training, and documentation of lessons learned. OEM's Division of Tactical Programs specializes in these tasks. The division consists of three branches: (1) the Training, Exercises and Lessons Learned branch; (2) the Chemical, Biological, Radiologic, Nuclear and Explosives branch; and (3) the Center for Tactical Medicine.

The Training, Exercises and Lessons Learned branch (TELL) provides a realistic environment for HHS to learn, test, and evaluate its capability to manage and coordinate its emergency preparedness, response, and recovery missions. TELL uses exercises and training to help ensure that HHS responders are able to perform the missions, provide the support required, and execute HHS' core capabilities and responsibilities during public health and medical incidents. These capabilities include: effective all-hazards training; exercising within a robust and realistic domain; identifying lessons learned from training, events, exercises, and real-world contingencies; and implementing corrective action plans that inform future plans and enhance overall preparedness. Finally, TELL coordinates evaluation of training and exercises to address gaps and strengths using a database of corrective actions and lessons learned.

Following are some examples of recent initiatives and accomplishments of TELL:

- ***International Personnel Response Framework*:** In coordination with DOS, DOD, and USAID, TELL developed ASPR's International Personnel Response Framework guidance and metrics (including the health services response annex). OEM trains more than 50 HHS personnel annually. This training involves collaboration with interagency, academic, and private-sector partners to develop culturally appropriate criteria for at-risk regions and countries with failing infrastructure indicators.

- ***HHS Noble Lifesaver 2013:*** TELL coordinated this annual, full-scale, HHS-sponsored interagency exercise designed to test and validate the coordination processes and capability to conduct patient movement of medical evacuees using aero-medical evacuation.

- ***Smallpox Vaccine Response Strategy:*** TELL led this exercise – the first in a series – focused on examining the application of improved smallpox vaccine capability and the effect on current smallpox response strategies. The exercise included the scientific and response communities from

the Federal, state, and local levels to examine existing plans, resources, and capabilities to respond to a smallpox outbreak.

- ***After Action Reviews*:** TELL conducted seven After Action Reviews that led to improvement plans designed to fill identified gaps and weaknesses and enhance preparedness overall in the Department.

Following are some of the exercises that TELL is planning and coordinating for FY 2014:

- ***National Exercise Program Capstone Exercise***: A preparedness exercise to evaluate the whole of community's ability to prevent, protect, respond, recover, and mitigate acts of terrorism and catastrophic incidents.

- ***HHS Nobel Lifesaver 2014***: An annual, full-scale, HHS-sponsored interagency exercise designed to test and validate the coordination process and capability to conduct patient movement evacuees using aero-medical evacuation.

- ***Able Response 2014*:** An annual U.S./Republic of Korea exercise series designed to improve the partners' ability to prepare for and respond to a naturally-occurring or intentional biological incident by employing a "whole-of-government" approach through bilateral cooperative engagements and existing policies and plans.

- ***The Secretary's Operations Center Thunderbolt:*** The SOC's "Thunderbolt Exercise" series is an eight hour, no-notice exercise that focuses on the HHS Emergency Management Group's immediate response actions. This is an annual exercise series.

- ***ASPR IT Contingency Plans Table Top Exercise Series*:** ASPR's IT systems are required to successfully test their contingency plans each year. Working with the Chief Information System Security Office, TELL has developed, designed, and implemented this annual Table Top Exercise validation series.

- ***Principal Level Exercise***: Exercise to provide the Homeland Security Council (HSC) Principals an opportunity to review and evaluate the federal government's preparedness to mount an effective response at the height of a worldwide pandemic.

- ***Senior Level and Principal Level Exercise***: Coordinate HHS involvement and equities during NSS exercise designed to provide the Domestic Resilience Group and the HSC Principals an opportunity to review and evaluate the federal government's preparedness.

The Chemical, Biological, Radiologic, Nuclear and Explosives (CBRNE) branch coordinates and provides medical and health-related subject and operational expertise. During preparedness and in response to an accidental or intentional incident domestically or internationally, CBRNE branch coordinates and provides strategic, technical and operational leadership, as well as advice and guidance regarding medical and public health impacts and interventions.

Here are some examples of recent CBRNE branch initiatives and accomplishments:

- ***Online Resources on Chemical Threat:*** CBRNE branch continued to manage the Chemical Emergency Medical Management (CHEMM) website, an important field resource that provides responders, individuals, and various professionals with ready information. The integrated WISER/CHEMM mobile applications were released in FY 2013.

- ***Nuclear Preparedness Principles:*** CBRNE branch developed 10 manuscripts about nuclear preparedness in a supplement issue of the American Medical Association's Journal of Disaster Medicine and Public Health Preparedness, as well as companion manuscripts and manuals on evidence-based principles.

- ***Online Resources on Radiation:*** CBRNE branch initiated Radiation Emergency Medical Management (REMM), a web-based resource developed in collaboration with experts from the National Cancer Institute and the National Library of Medicine. Following the 2011 earthquake in Japan, the Fukushima Daiichi nuclear power plant was damaged and radioactive material was released. REMM and its Mobile REMM app became a highly-utilized, vital source of information worldwide about the consequences of this radiological incident. REMM and the mobile applications were updated and enhanced in FY 2013.

The Center for Tactical Medicine (CTM) focuses on the establishment of HHS as a provider of choice for tactical medicine in the Federal government. Through its Counter-Narcotics and Terrorism Operational Medical Support Program, CTM promotes creation of a Federal standard for excellence in providing high-quality training in tactical emergency medicine for Federal, state, local, tribal, and territorial responders. Through support of partner Federal law enforcement agencies, CTM helps to "protect the protectors." Through medical oversight, CTM assists other Federal agencies in developing emergency medical support programs.

Following are some examples of recent CTM initiatives and accomplishments:

- ***Medical Training*****:** Through its Counter-Narcotics and Terrorism Operational Medical Support Program, CTM provided high-quality medical training courses for Federal, state, local, tribal, and territorial responders.

- ***Personnel Protection*****:** CTM continued coordinating the ESF-8 Early Force Protection Program to provide a safe and secure environment for personnel on deployment during a disaster or terrorist incidents.

- ***Support for Federal Partners*****:** CTM provided operational support and medical oversight for medical providers of partner Federal law enforcement agencies on numerous missions, including special operations, NSSEs and other high impact public events.

Maintaining Continuity of Operations (COOP)

Another responsibility of OEM is to ensure that ASPR, the Office of the Secretary (OS), and other parts of HHS can continue to perform essential functions and responsibilities at all times – even when a disaster or public health emergency strikes. The Division of Resilience and Infrastructure Coordination's COOP staff ensures the continuation of HHS' essential functions during all hazards in accordance with Federal and Presidential directives. COOP staff also maintains the day-to-day operations and implementation of the OS Continuity Program and the OS Emergency Relocation Facility.

In recent years, HHS has achieved a significant increase in its continuity communications capabilities, with testing and compliance metrics now consistently among the highest in the Federal government. The COOP staff has also increased HHS' emergency communications capabilities, including the implementation of Wireless Priority Service (WPS) for continuity personnel, procurement, and installation of high-frequency radio equipment, back-up satellite phones at headquarters and alternate

locations, and in-transit communications for senior leadership. Additionally, the COOP staff has facilitated a nearly-tenfold increase in bandwidth capacity at the OS COOP site, which is located away from the Washington, DC headquarters. These capabilities allow HHS to develop and maintain a strong, redundant, and resilient communications capability while reducing costs.

In FY 2013, the COOP staff:

- Hosted a Devolution Planning Workshop for HHS divisions, a senior leadership COOP workshop focused on IT challenges and interdependencies, and a reconstitution workshop;
- Participated in the White House-led annual continuity exercise, achieving all 10's in the FEMA-evaluated exercise in COOP program implementation and execution; and
- Continued to implement the unified HHS COOP program, which has allowed HHS to coordinate a comprehensive Department-wide continuity program while eliminating redundancies and addressing gaps in a cost-effective manner.

For FYs 2014 and 2015, COOP will continue to conduct a robust training and exercise series that is expected to include an IT Interdependency Workshop, and additional senior leaders COOP workshops. The COOP staff will provide additional assistance to the regions, distributing and facilitating regional continuity exercises and exercise materials.

Funding History

Fiscal Year	Amount
FY 2011	$29,587,000
FY 2012	$29,583,000
FY 2013	$27,984,000
FY 2014	$28,079,000
FY 2015 PB	$24,789,000

Budget Request

The FY 2015 Request for Preparedness and Emergency Operations is $24,789,000. The request is -$3,290,000 below the FY 2014 Enacted level. The request supports OEM's ability to immediately respond to a public health or medical incident and its capacity to maintain a strong presence in the ten public health emergency response regions.

The request includes $5 million in no-year funding to prepare for and respond to NSSEs and other planned and unplanned events that are not eligible for Stafford Act assistance from FEMA. As noted earlier, NSSE funding supports the activation of response teams for planned events such as the President's State of the Union address and quadrennial national political conventions. HHS also may use NSSE funding to support other events that may not be anticipated or that are not authorized under the Stafford Act for reimbursement from FEMA. For example, in December 2012, ASPR used NSSE funding to rapidly deploy mental health support to Connecticut after the Sandy Hook Elementary School shootings. Looking to the future for anticipated funding needs, HHS may support a Papal visit to the United States, which is expected in 2014 or 2015, and a global summit or State Funeral within the next several years is possible.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

National Disaster Medical System

Budget Summary
(Dollars in Thousands)

ASPR National Disaster Medical System	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	49,708	50,054	50,054	-
FTE /1	85	103	103	-

1/ The FTE level for FY 2014 is higher than for FY 2013 because several positions were converted from contract-supported to Federal employee positions.

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method……Direct Federal/Intramural, Contracts

Program Description and Accomplishments

The Office of Emergency Management's (OEM) National Disaster Medical System (NDMS) is a federally coordinated system that augments the Nation's medical response capability during public health emergencies that states and local communities cannot handle on their own. Since 1984, NDMS has responded to nearly 300 requests for assistance from states or Federal agencies. NDMS is a cooperative, asset-sharing partnership among HHS, the Department of Defense (DOD), the Department of Homeland Security, and the Department of Veterans Affairs. NDMS leverages Federal and non-federal resources to support two general missions. The first mission is to support requests for medical assistance from states or other Federal agencies. The second mission is to assist the DOD medical system in the event of a large-scale wartime conflict. NDMS consists of three key areas: (1) medical, veterinary, and mortuary response; (2) patient movement; and (3) definitive medical care.

Medical, Veterinary, and Mortuary Response

More than 7,000 intermittent Federal employees support nearly 90 response teams that comprise NDMS. The national system is supported by a full-time NDMS headquarters staff. The teams consist of clinical professionals and include experienced command and support staff. Most NDMS medical providers are clinically active in their communities, and all are credentialed by NDMS to validate their medical credentials. NDMS consists of a few types of response teams:

- Disaster Medical Assistance Teams (DMATs) provide a range of medical capabilities, including stabilizing emergency care, to communities affected by disaster.
- International Medical Surgical Teams provide stabilizing surgical care and can be deployed domestically or internationally.
- Disaster Mortuary Assistance Teams (DMORTs) support a community that has experienced a mass fatality event.
- National Veterinary Response Teams (NVRTs) deliver disaster medical care for large and small animals upon request.

- The Joint Patient Tracking System (JPATs) assists with patient accountability during mass events.

- There are also specialty teams within NDMS, including the innovative Mobile Acute Care Strike Teams that provide stabilizing critical care services to support hospital patients who are being held at an airport for medical evacuation during a disaster.

Patient Movement
Through the cooperative partnership with DOD, NDMS assists states with medical patient evacuation. The patient movement process includes coordination and tracking with Federal, state, and local authorities, private-sector healthcare, transportation assets, and medical care resources during evacuation. Patients transported by Federal resources are delivered to a network of Federal Coordinating Centers that receive and distribute patients to NDMS' network health care facilities (see "Definitive Medical Care" below). The program also supports the return of those patients home after their medical care is complete. NDMS has specific teams dedicated to patient tracking using the Disaster Medical Information Suite (DMIS) and JPATS. These teams were deployed to support NDMS missions in 2008 for Hurricanes Gustav and Ike and in 2010 after the earthquake in Haiti.

Definitive Medical Care
Definitive medical care consists of medical treatment or services delivered to an NDMS patient through one of nearly 2,000 non-federal health care facilities that have signed a memorandum of understanding with NDMS. This program works in conjunction with the Federal Coordinating Centers to ensure that patients are allocated to a site that can provide them appropriate care. NDMS reimburses these facilities for the patient's care if there is no other mechanism that exists to do so, such as private insurance.

Funding History

Fiscal Year	Amount
FY 2011	$52,404,000
FY 2012	$52,735,000
FY 2013	$49,708,000
FY 2014	$50,054,000
FY 2015 PB	$50,054,000

Budget Request
The FY 2015 Request for NDMS is $50,054,000, which is equal to the FY 2014 Enacted level. The request supports central headquarters operations, regional emergency coordination, and medical response assets – including teams, supplies, and equipment. The Request funds logistics support for cache maintenance, including medical and pharmaceutical supplies, IT, and communications capabilities. The Request will help to ensure that all equipment caches will sustain deployed medical personnel throughout the full range of emergent care in the field. The Request also will support the innovative DMIS emergency medical records and patient tracking system that was custom designed for field disaster medical use.

NDMS' structure continues to evolve to ensure that the right assets are being deployed to the right mission in a fiscally responsible and safe manner. OEM is exploring changes to facilitate the deployment of smaller and highly functional modules that are targeted to deliver a specific type of care. The quality

of care is an important focus. Clinical providers undergo clinical credentialing for NDMS just as they would for employment at any other medical facility.

FY 2015 activities will include further development of policies and procedures related to training standards, objectives, and cycles. NDMS will emphasize regional training and exercises for more than 86 NDMS Response Teams. Training and exercises will include DMATs, DMORTs, NVRTs, and other NDMS specialty teams across the country. An effective multiyear training and exercise program to ensure that the employees are ready to respond is a significant and critical investment to ensure that the care delivered by NDMS is of consistent high quality, and to mitigate the risk that is inherent in the direct medical care mission of this program.

The request also supports 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.

FY 2015 funding also will 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 Emergency Support Function-8. Finally, OEM will use some FY 2015 funding for NDMS to improve planning and preparedness activities associated with the development of an integrated national strategy for fatality management.

ASPR National Disaster Medical System - Outputs and Outcomes Table

Long-term objective: ASPR Goal #2: Strengthen Federal public health and medical preparedness, response, and recovery leadership and capabilities. Strategy 2.8: Identify and promote best practices for behavioral health disaster response and recovery by developing and implementing Concepts of Operations for behavioral response and recovery, monitoring their use, and incorporating into the after action process.

Program/Measure	Most Recent Result	FY 2014 Enacted	FY 2015 Target	FY 2015 +/- FY 2014
1.1 Percent of new NDMS intermittent staff that complete psychological first aid training	N/A	N/A	100%	+100%

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Hospital Preparedness Program

Budget Summary
(Dollars in Thousands)

ASPR Hospital Preparedness	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority: HPP	358,231	255,060	255,060	-
ESAR-VHP (non-add)/1	*0.500*	*0.505*	*0.500*	-
FTE	41	47	47	-

/1 ESAR-VHP stands for Emergency System for Advance Registration of Volunteer Health Professionals

Authorizing Legislation:
FY 2014 Authorization……..……PAPHRA
Allocation Method……..Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments

The ASPR Office of Emergency Management's (OEM) Hospital Preparedness Program (HPP) is one of the most important mechanisms for improving the preparedness and resilience of the nation's healthcare system in the face of public health emergencies. HPP has become a critical component of community resilience and population health by building foundational healthcare coalitions that prepare and respond to disasters and mass causality events. The program provides leadership, guidance, and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve the resilience and surge capacity of the healthcare system, thereby enhancing community preparedness for public health emergencies. Awardees have used the National Healthcare Preparedness Capabilities developed by HPP to identify gaps and better target investments. Ultimately, HPP funding is used to encourage the competitive national healthcare system to respond collaboratively in disasters.

HPP's activities support the ASPR Strategic Plan by helping local providers develop key capabilities, build community healthcare coalitions, and enhance the resilience of the healthcare system so that they can deliver coordinated and effective care during public health emergencies and mass casualty events.

HPP will continue to support communities' efforts to build healthcare capabilities. These capabilities are promoted in the ASPR publication Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness. Grant awards will continue to help state and local governments, community healthcare coalitions, and ESF-8 planners, by identifying gaps in preparedness, determining specific priorities, and developing plans for building and sustaining eight national stakeholder-created evidence-informed healthcare capabilities.

Building Eight Key Preparedness Capabilities

During FY 2013, ASPR continued to help state and local governments, community healthcare coalitions, and Emergency Support Function-8 (ESF-8) planners identify gaps in preparedness, determine priorities, and develop plans for building and sustaining essential capabilities. HPP is using a relatively new approach to support community preparedness and a resilient healthcare system. HPP stakeholders identified eight key capabilities (see figure). This capabilities-based planning answers the question, "Do I

have the right mix of training, organizations, plans, people, leadership and management, equipment, and facilities to perform a required emergency function?"

ASPR's recent publication Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness details these capabilities, which are summarized below:

1. **Healthcare System Preparedness:** The required steps for planning, equipping, training, exercising, and evaluating activities are defined by the objectives and supporting resources that are needed for a system to be prepared. It is a continuous cycle to ensure effective coordination during incident response.

2. **Healthcare System Recovery:** Recovery planning builds stakeholder partnerships that lead to community restoration and future sustainability and resiliency. This capability encompasses both short-term and long-term efforts for rebuilding and revitalizing affected communities.

3. **Emergency Operations Coordination:** Response planning provides rapid and disciplined incident assessment to ensure a quickly scalable, adaptable, and flexible response. This process reduces the physical, psychological, social, and economic effects of an incident.

4. **Fatality Management:** Fatality management must be incorporated in a community's surveillance and intelligence-sharing networks to identify sentinel cases of bioterrorism and other public health threats.

5. **Information Sharing:** Communities need to ensure durable, reliable, and effective information exchanges between those people who are responsible for gathering information and the analysts and consumers of threat-related information.

6. **Medical Surge:** This capability reflects a community's preparedness to rapidly expand the capacity of existing healthcare systems to provide triage and subsequent medical care.

7. **Responder Safety and Health:** Communities need to identify critical resources needed to ensure that healthcare workers are protected from all hazards.

8. **Volunteer Management:** The goal is to use volunteers to augment incident operations. Achieving this goal requires a community to build its capability to effectively coordinate the use of volunteers in support of domestic incident management.

Recent Examples of Community Healthcare Preparedness and Resilience

HPP is seeing this shift in focus to coalition preparedness play out in response efforts locally.

- **Boston Marathon Bombings: April 2013**: The recent shift in HPP's focus to coalitions and encouraging community preparedness proved instrumental in the local and state response to the Boston Marathon Bombings. The Boston Healthcare Preparedness Coalition meets bi-monthly to review upcoming events, discuss potential hazards, and fine-tune response protocols. Hospitals in the system had just 10 minutes to activate command centers and assemble trauma teams. Boston Children's Hospital stated that there was no delay—planning prepared them to act quickly to save

lives. Many preparedness leaders involved in this incident have credited HPP with its important contributions to the planning that enabled this lifesaving response.

- **West, Texas Explosion: April 2013:** Throughout the night of the explosion and until demobilization days later, the Texas Department of State Health Services deployed and staged response resources funded by HPP (also in partnership with CDC's Public Health Emergency Preparedness program):
  - Two Medical Incident Support Team members – The team deployed to assist in the coordination of medical transportation with hospitals and nursing home patients.
  - Three multi-patient vehicles (commonly known as "ambuses") – By coordinating its crosscutting preparedness grants, Texas has purchased 13 ambuses over the past few years. In a worst case scenario, these 13 ambuses could transport up to 260 patients simultaneously and then return to the emergency site for more patients.
  - One Type 2 Mobile Medical Unit and staff – The unit treated victims who had not gone to hospitals and some responders until demobilization two days later.
  - Two mortuary trailers and a mortuary team – The team used the trailers to store and transport deceased individuals to Dallas for identification.

The response to the fertilizer plant explosion is a good example of how HPP resources are making a difference through the capability framework. Prior to the explosion, HPP supported training to hospital decontamination teams, Hospital Incident Command Systems (HICS) training, a hospital decontamination training refresher and competency courses, and regional Simple Triage and Rapid Treatment triage training for hospitals, emergency medical services and first responders. HPP also supported regional exercises including a radiation exercise and a functional alternative care site exercise. These training and exercise programs aided response to the 2013 explosion. Specifically, responders were able to communicate better with one another, understanding how systems support one another during response. Emergency operations coordination was executed successfully from the local hospitals and health department, through the Regional Medical Operations Center, and extending to the State Medical Operations Center. Medical surge was effectively synchronized to meet the need. Responder Safety and Health was successfully coordinated to protect responders from the physical and chemical hazards posed by the explosion site. Fatality management was also an essential part of the response.

- **Hurricane Sandy: October 2012:** When Hurricane Sandy hit the Atlantic Coast on October 29, 2012, it placed a severe strain on hospitals and healthcare systems, particularly in New York and New Jersey. Five hospitals in New York City evacuated 1,300 patients, 17 nursing homes evacuated 2,507 patients, and 14 adult care facilities evacuated 1,999 residents. In New Jersey, 1,746 healthcare residents and patients were evacuated from two acute care hospitals and 11 long-term care facilities. Thirty-nine acute care hospitals and 74 long-term care or assisted living facilities lost their primary electric power source.

  Despite the challenges, these states and local communities' demonstrated preparedness and resilience due, in part, to HPP's focus on strengthening healthcare coalitions throughout the community. Following are some examples:

- New York City used HPP funding to develop and practice emergency and evacuation plans that contributed to the successful evacuation of over 5,800 patients. Evacuation Sleds purchased with HPP funds were used to evacuate 20 infants and other patients at New York University. In addition, New York City used HPP funding to purchase radios used during patient evacuation, blankets used to keep patients warm, and headlights to illuminate evacuation routes.
- The State of New Jersey used two Mobile Satellite Emergency Department Units funded by HPP to relieve surge issues by using them as triage and treatment facilities. At one point, these units replaced a level 2 trauma center's emergency department after it was made inoperable by flooding. In addition, the establishment and staffing of specific Medical Needs Shelters alleviated some stress on hospital emergency departments.
- Hospitals in the surge and wind zones in Rhode Island, Connecticut and Massachusetts activated their Emergency Operations Centers using the HICS and monitored events with other partners in their coalition's tracking facility. State health departments monitored hospital beds via various centralized bed tracking systems that helped them divert patients when particular hospitals surged. As shelters opened in Rhode Island, Connecticut, and Massachusetts, coalitions provided healthcare staffing using the Medical Reserve Corps (MRC; see also the separate section of this request for MRC) and the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) to identify appropriate and available staff.
- In Pennsylvania, Delaware, Maryland, Virginia, and West Virginia, the impact of the HPP grants was clearly evident. All regional health and medical needs were effectively managed at the local level, which negated the need to deploy Federal responders. The total cost of ESF-8 assistance for Hurricane Sandy was less than $50,000 in these states.
- In Southeastern Pennsylvania, the Surge Medical Assistance Response Team (SMART) has increased the region's resiliency. In addition to doctors, nurses, and emergency medical technicians, the SMART has the ability to provide mobile back-up power, medical gases, telemetry, and portable heat and air conditioning systems. They paid for this capability using a combination of funds from HPP and the Federal Emergency Management Agency's (FEMA) Urban Areas Security Initiative. It is staffed by MRC volunteers. The Commonwealth of Pennsylvania has built two more SMARTs based on this model.

- On a smaller scale, there have been some extreme weather events that were not categorized as a national disaster but proved HPP is a valuable tool in supporting resilient communities. During one such event, a line of thunderstorms that crossed Ohio's Miami Valley in 2012 downed several hundred trees and power lines and left thousands without power. To treat the resulting injures, patients were transported to hospitals. The hospitals throughout the region were prepared and were able to continue business as usual as a result of generators purchased with HPP funds. In addition, emergency shelters were opened to protect the frail and elderly from extreme heat and humidity.

- **Other Accomplishments:**
  - HPP continued working with state partners to implement standard operating procedures for community healthcare coalitions and to emphasize and strengthen several core capabilities (see below). HPP also expanded its outreach, training, and technical assistance to states to improve training and increase states' accountability for the program's results. To better manage grants and ensure that HPP maximizes efficiencies and cost-effectiveness, while also reducing awardee burden, the program improved its financial monitoring and communication with the Centers for

Disease Control and Prevention (CDC) and state partners, who play large roles in the success of HPP.

- Working with Booz Allen Hamilton, HPP and CDC developed a Program Assessment Reporting Tool. Pilot testing began in FY 2014. Once fully implemented, it will provide a more robust mechanism for reviewing and validating awardee reported data and enable more effective programmatic oversight.
- Working with the Rand Corporation, HPP expanded the Hospital and Healthcare Coalition (HCC) Surge Stress Test. The initial surge stress testing was conducted in 2012 and focused on healthcare facilities, primarily hospitals. The next generation surge stress tests are designed to emphasize the collaborative nature of healthcare system preparedness and focus more on healthcare coalitions. This work will help HPP identify both strengths and weaknesses in designated HCCs and provide the program with a means to develop corrective action plans for specific coalitions.
- HPP sponsored national and regional healthcare preparedness, response, and recovery-related calls. HPP presented special topic calls to raise awareness of the HPP capabilities and address preparedness concerns such as immediate bed availability, pediatrics and special needs, preparedness impacts of healthcare reform, and rural coalition development.

Aligning Federal Preparedness Grants

In FY 2013, HPP and CDC's Public Health Emergency Preparedness (PHEP) program again awarded funds jointly in accordance with a multi-year grant project period. This approach enables continued cooperation between the nation's healthcare and public health systems. This change follows a multiyear effort by ASPR and CDC to align the two Federal preparedness programs. These programs represent critical and complementary sources of funding and support for public health and healthcare preparedness systems.

Improved coordination among Federal emergency preparedness programs is a high priority of not only HHS and other Federal agencies, but also HPP and PHEP grant recipients. With aligned HPP and PHEP cooperative agreement programs, states and communities can more easily, efficiently, and effectively conduct joint planning, exercising, and program operations. HPP and PHEP worked together to define the capabilities awardees need. In total, there are 15 specific capabilities that awardees should work to achieve, eight of which are aligned to *Healthcare Preparedness Capabilities*, as described above. These activities are vital in preparing communities to respond to and recover from emergencies and helping them manage health care and public health on a daily basis.

ASPR and CDC aligned HPP and PHEP cooperative agreements to advance all-hazards preparedness and national health security, promote responsible stewardship of Federal funds, and reduce the administrative burden for grant recipients. The programs support complementary preparedness capabilities and performance measures. They use the same processes for grants administration, technical assistance and data management, use common reporting requirements, and have compatible IT systems

Although they are closely aligned in many aspects, HPP and PHEP continue to remain individual programs, in accordance with authorizing legislation and the distinct capabilities required by the healthcare system. HPP and PHEP budgets also will remain separate to ensure accountability for the statutory requirements.

Additionally, ASPR, CDC, the Health Resources and Services Administration, FEMA, and the National Highway Transportation Safety Administration signed a memorandum of understanding to create an interagency group that will meet regularly to identify and discuss grant coordination opportunities. Ultimately, the hope is to optimize the Nation's investments in public health and healthcare emergency preparedness to help ensure consistency with national strategies and priorities, and improve preparedness outcomes. The grant programs involved in this work include HPP, ESAR-VHP (see below) and Medical Countermeasure Dispensing (see also the separate section of ASPR's request) programs; and FEMA's Homeland Security Grant Program (i.e., the State Homeland Security Program, the Citizen Corps Program, the Metropolitan Medical Response System Program, and the Urban Areas Security Initiative).

These efforts support the ASPR Strategic Plan by aligning strategic priorities among Federal entities that fund preparedness grants by spearheading a grant alignment process.

Other Work to Improve Healthcare Preparedness

HPP resources not only support grants to states, local, and territorial health departments, but also other important work to improve public health preparedness nationwide:

The Emergency Care Coordination Center (ECCC)

In June of 2006, the Institute of Medicine published a series of reports on the future of emergency care in the US. These eye-opening reports characterized the US emergency care system as being in a state of crisis and focused specifically on issues such as emergency department crowding, specialist shortages, and a lack of cohesion and system-wide communication.

In response, Homeland Security Presidential Directive #21 was issued. It specifically directed the creation of an office for emergency care within the HHS to "lead an enterprise to promote and fund research in emergency medicine and trauma health care; promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution, and care of routine community patients; promote local, regional, and State emergency medical systems' preparedness for and response to public health events." The office was also tasked with advancing regional partnerships and promoting local, regional and State emergency systems' preparedness for and response to public health events. The Emergency Care Coordination Center (ECCC) is ASPR's lead for implementing the Directive.

ECCC's efforts over the past two years include working to address barriers to emergency care research by hosting a national Institutional Review Board in Emergency Care symposium. This symposium developed recommendations for emergency care research processes. ECCC also continues to develop research on the underlying causes of boarding patients in emergency departments, which potentially inhibits the emergency care system from surging during large medical events. ECCC has also partnered with ASPR's Biomedical Advanced Research and Development Authority (BARDA) and CDC to conduct focus groups to obtain first responder input on the administration and distribution of essential medications following a nuclear incident and utilization of anti-toxins for an anthrax release.

These engagements support the connectivity between the medical countermeasure enterprise and the first responders. In collaboration with BARDA, ECCC is providing support for a project to improve the science of decontaminating patients exposed to chemical agents. ECCC is also working with stakeholders across the Nation to support a "national burn surge framework" that outlines the local, state, regional and Federal guidelines that will enable the Nation to respond to a large burn event.

Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP): ESAR-VHP is a national network of health professionals who are able to provide assistance during an emergency. All 50 states have established a system to verify the credentials, certifications, licenses, and hospital privileges of health professionals in advance of an emergency. A standardized system is important because it allows the quick and easy exchange of health professionals among states to serve a larger population during a disaster or public health emergency. ESAR-VHP funding supports the ASPR Strategic Plan strategy to develop a consistent national framework on regional coordination of preparedness, response, and recovery activities. There are now more than 205,000 volunteers registered under ESAR-VHP.

Science Healthcare Preparedness Evaluation and Research (SHARPER): The Science Healthcare Preparedness Evaluation and Research branch (SHARPER branch, formerly known as the "Healthcare Systems Evaluation Branch") provides evaluation services to HPP and will be expanding its evaluative scope to include components of ASPR's National Disaster Medical System and Healthcare Systems Policy. Many of its activities respond to the requirements of the Pandemic and All-Hazards Preparedness Reauthorization Act, such as implementing an accountability system and monitoring awardees' performance in HPP. SHARPER designs evaluations to monitor awardees' performance, improve data collection and measurement, and inform technical assistance activities to support and enhance healthcare preparedness, response, and recovery. Moreover, whenever possible, SHARPER identifies business processes to reduce unnecessary awardee burden.

In July 2012, SHARPER developed new provisional program measures that align with the 2012 Healthcare Preparedness Capabilities and the new strategic direction to build community healthcare coalitions. The new program measures were included in the FY 2012 Funding Opportunity Announcement so that awardees would be aware of the program measures when writing their applications. SHARPER provided a continuum of training opportunities and technical assistance for awardees and Field Project Officers on the FY 2012 program measures and published implementation guidance to improve the quality of the data collected.

A refined set of program measures was developed for 2013 and 2014 to begin establishing a meaningful baseline and stable set of indicators. The FY 2013 program measures will remain consistent and comparable through FY 2017 to ensure that incremental awardee progress can be monitored over the course of the project period. These measures continue to be aligned with the Healthcare Preparedness Capabilities, but are also integrated with the National Health Security Strategy and disaster cycle which refers to the continuum of prevention/mitigation, preparedness, response, and recovery. HPP measures and the companion indicators focus on the continued development and functionality of community healthcare coalitions. This process will inform how SHARPER may further re-calibrate the future assessment of healthcare preparedness, response, and recovery.

Once the 2013-2015 program measures and incremental targets and milestones are established and stabilized, SHARPER will work with awardees to develop appropriate trainings, technical assistance, and sharing and learning opportunities. In FYs 2014 and 2015, SHARPER will develop incremental milestones tied to program measures and quantify objective performance targets informed by emerging data, evidence, and science related to the achievement of the eight key capabilities.

Critical Infrastructure Protection (CIP): CIP is a public -private-sector partnership dedicated to managing risks to the healthcare and public health sector from all hazards. The program fulfills HHS's

responsibilities under Presidential Policy Directive 21 (PPD-21), Critical Infrastructure Security and Resilience, and Executive Order 13636 (EO 13636), Enhancing Critical Infrastructure Cybersecurity. In FY 2013, CIP staff served on the Interagency Policy Committee and Integrated Task Force for PPD-21 and EO 13636 Implementation. Through this effort, CIP staff contributed to such deliverables as the revised National Infrastructure Protection Plan and the Cybersecurity Framework. These documents and other deliverables of the past year will serve as guides for much of CIP's work in FY 2014 and beyond.

Also in FY 2013, the CIP program continued to implement core elements of its program to enhance security and resilience of the healthcare and public health sector. CIP staff worked closely with private-sector partners to develop an Infrastructure of Concern (IOC) list for the healthcare and public health sector. The IOC list combines a list of nationally critical infrastructure from FY 2012 with a new list of infrastructure assets that are critical at the regional level. As directed by EO 13636, CIP staff performed a similar analysis for cyber-dependent critical infrastructure, which was added to the IOC list. The CIP program also enhanced its information sharing initiative by migrating its information sharing portal to the new version of the Homeland Security Information Network, encouraging State Health Officials to apply for security clearances through HHS, and deploying secure telecommunications devices to four state health departments.

In FY 2014, CIP staff are developing a high level risk assessment of critical infrastructure based on the IOC list and using that assessment to focus its information sharing and other risk mitigation activities. These initiatives include sharing information on threats and vulnerabilities, developing educational materials, hosting information webinars, assessing physical and cyber security (in collaboration with the Department of Homeland Security), conducting research and development activities, and developing infrastructure priority lists for incident response. CIP staff are also working with the sector to build and maintain a robust information-sharing partnership for emergency preparedness and response.

In FY 2015, CIP staff will continue to focus on the implementation of the policy direction established in FY 2013 and FY 2014. This will involve working with private sector and governmental partners to produce additional toolkits, informational materials, and other documents to enhance the security and resilience of healthcare and public health sector critical infrastructure using national standards and guidelines. It will also involve continued assessment of risk to the health and public health sector critical infrastructure identified in FY 2013 and FY 2014 and tailoring of technical assistance and informational products to mitigate the highest priority risks to the Sector.

Division of Recovery: OEM's Division of Recovery leads the coordination of Federal health and social services efforts to support communities' recovery from emergencies and disasters. The division also promotes pre-disaster health and social services recovery planning, and systematic improvements in public health emergency and disaster recovery planning. It works with the ASPR Regional Emergency Coordinators; other HHS divisions; Federal interagency partners; state, local, territorial, and tribal governments; and private-sector and non-profit entities to advance the Nation's ability to recover from the health and social services effects of emergencies and disasters.

Under the National Disaster Recovery Framework (NDRF), HHS is the coordinating agency for the Health and Social Services Recovery Support Function (RSF). The Division of Recovery is responsible for these coordination efforts. Having the division located within OEM provides opportunities to ensure that preparedness planning and response include recovery planning.

In 2012, HHS was activated under NDRF for three disasters: (1) Hurricane Isaac in Louisiana, (2) the drought across the United States, and (3) Hurricane Sandy in both New Jersey and New York. For Hurricane Isaac, a Recovery field coordinator has provided intermittent onsite support at the Joint Field Office in Baton Rouge. The role of a field coordinator is to work with appropriate primary and supporting agencies and organizations and other Federal, state, tribal, and local partners to conduct joint assessments of disaster-related recovery needs and priorities, develop a recovery support strategy, and coordinate Federal health and social services recovery efforts. For the drought, the Division of Recovery and HHS regional partners participated in a series of regional meetings hosted by state and local partners aimed at identifying concerns and issues. The division established a drought behavioral health task force with HHS, the Department of Agriculture, and other partners to identify resources and address concerns around stress. In response to Hurricane Sandy, the division deployed two field coordinators, one to New Jersey and one to New York, both within two and one-half weeks of the storm's landfall and who were deployed for several months.

The Division of Recovery also works with partners in pre-disaster planning. Staff are actively engaged in the review of HPP grant applications and in providing technical assistance to awardees on the healthcare recovery capability. The division also routinely engages with HHS and other Federal regional staff and state, local, tribal, territorial and non-governmental partners in planning and training. Recent examples include working with FEMA on their all-hazards planning in Regions 4, 6, and 9; conducting a webinar training on the RSF; and working with RAND Corporation on developing tools for stakeholders.

Funding History

Fiscal Year	Amount
FY 2011	$381,171,000
FY 2012	$379,639,000
FY 2013	$358,231,000
FY 2014	$255,060,000
FY 2015 PB	$255,060,000

Budget Request

The FY 2015 Request for HPP is $255,060,000, which is equal to the FY 2014 Enacted level. Of the Request, $254,555,000 will support grants to states for community healthcare coalitions, program management and administration, and other activities including evaluation, CIP, and recovery. These funds will support grants to states to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Grantees and their community healthcare coalitions will further their work, begun in FY 2012, to implement and become fully prepared in all eight capabilities outlined in Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness. This amount also includes $15,000,000 for competitive grants to test innovative processes that lead to a better prepared community or state. Finally, the request includes $500,000 for ESAR-VHP.

States receiving HPP funding will continue to strengthen the capabilities identified in the national guidance through their community healthcare coalitions. The guidance assists awardees in prioritizing activities critical to accomplishing all eight capabilities over time. The funding will be used to improve national preparedness not only in times of emergency, but every day.

ASPR Hospital Preparedness Program - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
2.4.2 G% of States with heightened healthcare coalition engagement in statewide/regional exercises. (Outcome)	N/A	N/A	30 %	N/A
2.4.2.H % of States with established operational healthcare coalitions. (Outcome)	N/A	N/A	50 %	N/A

ASPR Hospital Preparedness Program: Summary of Grant Awards

(Amount in Dollars)

Grants	FY 2013 Final	FY 2014 Enacted (estimate)	FY 2015 President's Budget (estimate)
Number of Awards	62	62	62
Average Award	$5,350,966	$3,685,484	$3,540,323
Range of Awards	$270,175-$27,009,882	$263,288-$17,960,899	$262,688-$17,172,200

ASPR Hospital Preparedness Program Grant Awards by State

(Amount in Dollars)

Grants	FY 2013 Final	FY 2014 Enacted (estimate)	FY 2015 President's Budget (estimate)	Difference +/- FY 2014
Alabama	5,118,503	3,542,006	3,404,600	-137,406
Alaska	1,186,273	952,018	931,601	-20,417
Arizona	6,676,397	4,568,122	4,384,368	-183,754
Arkansas	3,317,556	2,355,801	2,271,975	-83,826
California	27,009,882	17,960,899	17,172,200	-788,699
City of Chicago	*3,104,668*	*2,215,581*	*2,138,089*	*-77,492*
Colorado	5,359,548	3,700,771	3,556,194	-144,577
Connecticut	3,953,533	2,774,691	2,671,945	-102,746
Delaware	1,367,644	1,071,479	1,045,666	-25,813
District of Columbia	1,081,425	882,959	865,661	-17,298
Florida	18,667,091	12,465,867	11,925,376	-540,491
Georgia	9,860,862	6,665,590	6,387,094	-278,496
Hawaii	1,814,414	1,365,747	1,326,642	-39,105
Idaho	2,014,703	1,497,669	1,452,605	-45,064
Illinois	10,293,152	6,950,320	6,658,963	-291,357
Indiana	6,765,086	4,626,538	4,440,144	-186,394
Iowa	3,443,593	2,438,816	2,351,241	-87,575
Kansas	3,256,875	2,315,833	2,233,813	-82,020
Kentucky	4,692,988	3,261,738	3,136,992	-124,746
LA County	*9,987,397*	*6,748,933*	*6,466,672*	*-28,261*
Louisiana	4,880,449	3,385,210	3,254,887	-130,323
Maine	1,783,552	1,345,419	1,307,232	-38,187
Maryland	6,078,794	4,174,508	4,008,532	-165,976
Massachusetts	6,826,760	4,667,160	4,478,932	-188,228
Michigan	10,050,238	6,790,324	6,506,194	-284,130
Minnesota	5,625,009	3,875,619	3,723,145	-152,474
Mississippi	3,367,202	2,388,500	2,303,198	-85,302
Missouri	6,286,904	4,311,580	4,139,414	-172,166
Montana	1,456,039	1,129,701	1,101,258	-28,443
Nebraska	2,264,734	1,662,353	1,609,850	-52,503
Nevada	3,109,454	2,218,733	2,141,099	-77,634
New Hampshire	1,772,062	1,337,851	1,300,006	-37,845
New Jersey	8,995,320	6,095,495	5,842,750	-252,745
New Mexico	2,489,717	1,810,540	1,751,343	-59,197
New York	11,325,062	7,629,995	7,307,937	-322,058
New York City	*8,399,364*	*5,702,965*	*5,467,950*	*-235,015*
North Carolina	9,713,825	6,568,743	6,294,622	-274,121
North Dakota	1,149,903	928,062	908,727	-19,335

Grants	FY 2013 Final	FY 2014 Enacted (estimate)	FY 2015 President's Budget (estimate)	Difference +/- FY 2014
Ohio	11,647,346	7,842,269	7,510,623	-331,646
Oklahoma	4,124,808	2,887,502	2,779,660	-107,842
Oregon	4,201,841	2,938,241	2,828,107	-110,134
Pennsylvania	12,773,893	8,584,276	8,219,114	-365,162
Rhode Island	1,517,061	1,169,894	1,139,635	-30,259
South Carolina	4,969,338	3,443,757	3,310,789	-132,968
South Dakota	1,286,715	1,018,175	994,769	-23,406
Tennessee	6,632,034	4,538,902	4,356,467	-182,435
Texas	24,797,333	16,503,589	15,780,717	-722,872
Utah	3,170,652	2,259,041	2,179,586	-79,455
Vermont	1,104,633	898,245	880,257	-17,988
Virginia	8,231,128	5,592,155	5,362,146	-230,009
Washington	6,997,703	4,779,752	4,586,439	-193,313
West Virginia	2,290,487	1,679,316	1,626,047	-53,269
Wisconsin	5,995,149	4,119,414	3,955,927	-163,487
Wyoming	1,044,613	858,713	842,510	-16,203
States Subtotal	**325,330,712**	**223,497,377**	**214,621,710**	**-8,875,667**
Indian Tribes				
Migrant Program				
American Samoa	314,192	292,280	290,371	-1,909
Guam	424,764	365,109	359,911	-5,198
Marshall Islands	313,637	291,915	290,022	-1,893
Micronesia	353,539	318,197	315,116	-3,081
Northern Mariana Islands	296,687	280,751	279,362	-1,389
Palau	270,175	263,288	262,688	-600
Puerto Rico	4,100,108	2,871,234	2,764,126	-107,108
Virgin Islands	356,048	319,849	316,694	-3,155
Territories Subtotal	6,429,150	5,002,623	4,878,290	-124,333
Total States/Territories	**331,759,862**	**228,500,000**	**219,500,000**	**-248,666**
Technical Assistance				
States Penalties				
Contingency Fund				
Competitive Grant	-	-	15,000,000	+15,000,000
Subtotal Adjustments	**-**	**-**	**15,000,000**	**+15,000,000**
TOTAL RESOURCES	**331,759,862**	**228,500,000**	**234,500,000**	**+6,000,000**

Note: The FY 2014 levels are only estimates. They were calculated using population data that will be updated before the grant announcement is released. The total amount for grants will remain the same, but the distribution among states may change.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Medical Countermeasure Dispensing

Budget Summary
(Dollars in Thousands)

ASPR Medical Countermeasure Dispensing	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	-	5,000	-	-5,000
FTE	-	-	-	-

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method…….Competitive grant/cooperative agreement; direct federal/intramural, contracts

Program Description and Accomplishments

In 2004, HHS established the Cities Readiness Initiative 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 the decision. The initial effort was established through a February 2004 Memorandum of Agreement signed by the Secretaries of HHS and Homeland Security 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). This 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.

On December 30, 2009, the President issued Executive Order 13527. This order makes it the policy of the Federal government to plan and prepare for the timely provision of medical countermeasures (MCMs) 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 capacity to distribute MCMs. Section 2 of the order 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 MCMs for a biological attack. As a result of the approval of the National Postal Model, HHS became responsible for providing the health safety support to USPS participants. HHS' role relieved the local public health departments of the obligation to perform a task that was deemed by the Minneapolis pilot to be expensive and labor-intensive.

ASPR subsequently 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 with their strategic security plans. In 2011, HHS released funds through a cooperative agreement to five cities – Boston, Philadelphia, Louisville, San Diego, and Minneapolis-St. Paul. The Cooperative Agreement provided funds to support planning and resource acquisition for implementation of the National Postal Model. Since this time, the JPE has worked closely with the five cities to further develop and test the operational capability in these municipalities. As of July 31, 2013, there are approximately 1,600 U.S. postal workers who could be called upon to deliver

antibiotics in the event of an anthrax attack to 125 zip codes (approximately 2 million households) in the five jurisdictions.

To assure the readiness of USPS to respond, the Food and Drug Administration (FDA) authorized an Emergency Use Authorization (EUA) for the pre-placement of doxycycline hyclate kits (also known as MedKits) for USPS participants and their household members to keep at work and in their homes. Prior to 2011, these home MedKits had to be replaced every year, and the USPS participants and their families had to be screened again by medical providers if there had been changes to their health status or additions to their households. Currently, the MedKits need to be replaced (or refreshed) as the medication expires approximately every two years. Reports concerning the condition of the kits are issued to FDA every six months.

Approximately 8,000 MedKits have been deployed to Louisville, Minneapolis, San Diego, Philadelphia, and Boston. In accordance with the EUA, the JPE filed status reports for Minneapolis-St. Paul and Louisville with FDA in December 2012, San Diego in January 2013, and Philadelphia and Boston in April and May 2013, respectively. MedKits have been replaced for more than 300 participants in Minneapolis-St. Paul. Kits for small numbers of USPS participants in San Diego and Louisville were replaced in FY 2013. Kits for all five jurisdictions will be replaced in 2014.

The JPE conducted tabletop exercises in Minneapolis-St. Paul in January 2011, Louisville in April 2012, San Diego in June 2012, Philadelphia in July 2012, and Boston in August 2012. A full scale, two-day exercise was successfully conducted in May 2012 in Minneapolis-St. Paul. The JPE completed after-action reports for all cities to assist in the development of their improvement planning. In March 2013, Philadelphia conducted a follow-on exercise to ensure previously recommended changes to the plan are operationally feasible. USPS conducted command post exercises in each of the five jurisdictions between May and September, 2013. Conducting robust exercises ensures that postal workers and their law enforcement escorts will be able to perform this operational capability if needed.

Funding History

Fiscal Year	Amount
FY 2011	$0
FY 2012	$0
FY 2013	$0
FY 2014	$5,000,000
FY 2015 PB	$0

Budget Request

ASPR requests no funding for Medical Countermeasure Dispensing for FY 2015, which is -$5,000,000 below the FY 2014 Enacted level. In the FY 2014 appropriation, $5 million in multiyear funding was included to support this program. Because of the limited ongoing costs, this multiyear funding will be sufficient to support FY 2015 activities. For FY 2015, consistent with its core functions and ongoing mission, ASPR will continue to provide subject matter expertise to state and local governments specific to all-hazards emergencies impacting health and medical issues across the nation. If local or state jurisdictions decide to allocate resources to design or develop additional medical countermeasure distribution models, HHS remains committed to offer support, share best practices, and assist the planning activities.

ASPR Medical Countermeasure Dispensing - Outputs and Outcomes Table

Long-Term Objective: Expansion of the Cities Readiness Initiative USPS Strike Teams in up to 15 cities (Outcome)

Program/ Measure	Most Recent Result	FY 2014 Enacted	FY 2015 Target	FY 2015 +/- FY 2014
Target	Expand to 2 additional cities	No additional cities. Sustain the capabilities of the 5 participating cities, and remain available to assist other jurisdictions that allocate their own resources to this kind of planning.	No additional cities. Remain available to assist jurisdictions that allocate their own resources to this kind of planning.	-
Result	The original pilot city and 4 awardees possessed this capability, and no expansions occurred.	In progress	In progress	

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Biomedical Advanced Research and Development Authority

Budget Summary
(Dollars in Thousands)

ASPR Biomedical Advanced Research and Development Authority	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	415,000	415,000	415,000	-
Advanced Research and Development (non-add)	*350,000*	*355,000*	*335,000*	*-20,000*
Strategic Investor (non-add)	-	-	*20,000*	*+20,000*
Operations (non-add)	*65,000*	*60,000*	*60,000*	-
FTE	155	155	155	-

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method……Direct Federal/Intramural, Contracts, Grants

Program Description and Accomplishments

Many serious health threats facing our nation come from naturally-occurring events like pandemic influenza and emerging infectious diseases. Other threats are from the human use of chemical, biological, radiological, or nuclear (CBRN) materials. Using the latest scientific research and innovations, HHS has supported the development of medical countermeasures (MCMs) against these threats, including vaccines, therapeutic products, diagnostics, medical devices, and non-pharmaceutical agents. These MCMs enable the country to prepare appropriately for and respond effectively to these threats.

The Department's MCM enterprise has grown significantly in the last decade, acquiring new capabilities and employing new business approaches leading to unprecedented success in the development and acquisition of MCMs. Following the anthrax attacks of 2001, Congress recognized that the nation needed to acquire and stockpile MCMs that were vital to mitigating or preventing the effects of CBRN threats, and it took action by authorizing Project BioShield (BioShield). BioShield is a program that supports development and purchase available MCMs and serves as an incentive to pharmaceutical and biotechnology companies to develop new MCMs.

The mission of ASPR's Biomedical Advanced Research and Development Authority (BARDA) is to support development of and make available MCMs to protect the nation from man-made and natural public health emergencies through product development and innovation, manufacturing infrastructure building, core service assistance, and product acquisition for stockpiles. Because these products require significant development over time, investments made now will greatly impact the nation's preparedness a decade from now.

Developing a Flexible, Nimble Medical Countermeasures Enterprise

The MCM enterprise has evolved substantially since the creation of BioShield. The first phase of this evolution was spurred by the recognition that advanced development was necessary to create a pipeline for MCMs that could be purchased and stockpiled. With the passage of the *Pandemic and All-Hazards Preparedness Act* (PAHPA) in 2006, Congress created BARDA and concurrently expanded certain portions of the authorities under BioShield.

Recognizing the long development times and significant upfront costs associated with MCM development, and realizing that the nation's MCM pipeline contained few off-the-shelf products, Congress created BARDA with the mission to guide promising technologies from early-stage development through regulatory approval. BARDA's mandate is to support development across the so-called "valley of death", through scale-up manufacturing, until the developed technologies and products are licensed and able to be procured and stored in the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile (SNS). Prior to BARDA's authorization, few MCMs commercial markets existed, which required manufacturers to rely solely on government contracts for their revenues.

Following the 2009 H1N1 influenza pandemic, Secretary Sebelius called for a review of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). That review recommended that the nation should transition from a 'one bug, one drug' approach of MCM development to a flexible, nimble development strategy that emphasizes platform technologies and broad spectrum, multiple application products. In addition, the review found that the nation lacked the domestic vaccine manufacturing capacity to respond to a pandemic, and that MCM development and manufacturing would benefit greatly from enhancing its structure and governance. Once the proposed Strategic Investor (SI) – an independent venture capital entity – is authorized, each of the *2010 PHEMCE Review's* recommendations will have been implemented.

BARDA has created a robust and formidable product development pipeline comprised of more than 85 MCM candidates for CBRN threats. BARDA used this pipeline to furnish the SNS with 12 new MCMs since 2004 under BioShield. Two of these MCMs - Raxibacumab® anthrax antitoxin and HBAT® botulinum antitoxin – were approved by the Food and Drug Administration (FDA) in FY 2013 under the Animal Efficacy Rule – the first novel products approved under this authorization and program. ASPR/BARDA expects 12 more MCM candidates to mature sufficiently by FY 2018 for acquisition under BioShield and three to four FDA approvals of these MCMs.

BARDA has stimulated dormant industry sectors, built proven relationships, and supported the development of innovative products. For example, with BARDA's support, a new next generation ventilator that is lighter, easier to use, and less expensive was developed and FDA approved. In the area of broad spectrum antimicrobials, the first new classes of antibiotics to treat multi-drug resistant pathogens such as Carbapenem resistant enterobacteriaceae (known as CRE) and Methicillin-resistant Staphylococcus aureus (known as MRSA) are being developed through partnerships with small and large pharmaceutical companies. BARDA's partnership with six companies for antibiotic development has led to a re-emergence of this pharmaceutical industry sector and contributes to the President's initiative to combat the national crisis on antimicrobial drug resistance.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) requires the Department to develop annually a coordinated five-year budget plan of MCM priorities. In the spring of 2014, the Department will be providing the first formal submission of this annual report to Congress, covering FYs 2014-2018. This report will specifically provide: projections of the research, development, procurement, and stockpiling costs across the Department; and details of coordinated efforts between PHEMCE members as MCMs progress through various stages of development.

Enhancing Public-Private Partnerships to Face Health Threats

Commensurate with other changes in the PHEMCE, BARDA has been improving how it does business with its private-sector partners. For instance, the Department and ASPR have taken multiple steps and enhanced business practices to shorten the time cycle for awarding contracts. In addition, MCM products increasingly are being stored through the use of vendor-managed inventory (VMI), addressing

unsustainable life cycle management issues for stockpiled MCMs. This change was highlighted in September 2013 when BARDA awarded contracts to Amgen and sanofi-aventis for late stage development and procurement of their cytokine products to treat neutropenia resulting from ionizing radiation exposure after a nuclear explosion. Neupogen® and Leukine® will be maintained by the manufacturers and rotated through the commercial marketplace with the government having immediate access to the acquired doses if necessary. Maintaining products under VMI ensures they will not expire due to stockpiling and significantly reduces the overall life-cycle management cost for these products.

Additionally, in June 2012 the Department made multiple awards establishing public-private partnerships for the creation of three Centers for Innovation in Advanced Development and Manufacturing (CIADM). The CIADM will assist biotechnology companies in transforming their technology into proven products while also providing next generation pandemic influenza vaccine manufacturing capacity during an emergency.

Other improvements are on the horizon, including the creation of the proposed SI, as recommended by the *2010 PHEMCE Review.* ASPR is proposing SI in response to the biodefense sector's need for an independent, government-sponsored investment firm. In exchange for a capital investment, the SI will provide scientific, regulatory, and strategic management expertise to nascent biotechnology companies with promising technologies applicable to MCM development. The SI also will lower the risk to the Department of contracting with these firms by lowering the financial and management risk and allowing the technology to succeed based solely on the science.

Advanced Research and Development

Since its inception, BARDA has prioritized the development and procurement of MCMs for the highest risk threats, including pandemic influenza and the malicious use of CBRN materials. BARDA's CBRN programs have focused on developing MCMs to meet the requirements determined to be necessary to address the 12 material threats identified by the Department of Homeland Security (DHS) in accordance with BioShield.

The *2010 PHEMCE Review* articulated a new vision stating that the "Nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown." To that end, BARDA's Advanced Research and Development (ARD) program has made unprecedented progress in filling the developmental pipeline in the last five years. Prior to the ARD program, there were relatively few MCMs available for procurement.

In 2009, BARDA issued its first Broad Agency Announcement (BAA) as a means to expand its partnership with industry and solicit a broader range of potential products and candidates for advanced research and development. Since then, BARDA has issued special instructions to prioritize a range of product areas including anthrax vaccines and antitoxins; therapeutic countermeasures for skin and lung injury associated with acute radiation syndrome; and broad spectrum antimicrobial drugs with efficacy against biothreats and public health infections, including antibiotic-resistant strains of community- and hospital-acquired bacteria pathogens. In the July 2013, BAA released the priorities for the development of CBRN MCMs, which have been aligned with the *2012 HHS PHEMCE Strategy and Implementation Plan*. The new BAA will remain open for two years and has already proven to be the catalyst for building a robust pipeline of candidate products under advanced research and development. In FY 2014, BARDA will emphasize addressing remaining gaps in preparedness such as viral hemorrhagic fever viruses, biodiagnostics, chemical threats, thermal burn, and blood products as well as antimicrobial products.

The BAA can be amended at any time during the two years to make sure the priorities align with any alterations in the larger PHEMCE strategy. Progress on specific portfolios is described below.

Anthrax

In the anthrax MCM portfolio, BARDA has invested in the development and acquisition of three major MCM types: vaccines, antitoxins, and antibiotics. There are currently four anthrax vaccine adsorbed (AVA) anthrax vaccine projects and four next-generation recombinant protective antigen (rPA) anthrax vaccine projects in development. There also is one vaccine manufacturing project.

In FY 2011, BARDA awarded a contract for a new anthrax rPA vaccine candidate that utilizes a novel platform technology that may have application to other vaccine needs. In FY 2012, a consortium of HHS agencies – including BARDA, CDC, FDA, and the National Institutes of Health (NIH) – initiated studies to determine whether antigen- and dose-sparing strategies with licensed anthrax AVA are feasible. The clinical trial has been completed, and the resulting data was analyzed and presented at the ASPR-led anthrax MCM portfolio review in January 2014. The data will provide policy makers with important information if an anthrax vaccine shortage is realized after an incident. The data could expand the current stockpile of vaccine by allowing antigen or dose sparing. Information will only be used to inform decisions during or after an incident when the product is used under Emergency Use Authorization (EUA); it will not affect licensure. Together, the anthrax vaccine program addresses immediate and long-term needs and mitigates inherent risks associated with pharmaceutical product development in general and those specifically associated with anthrax vaccines, such as poor vaccine stability.

The BARDA anthrax antitoxin program now has three antitoxin candidates (two monoclonal antibodies and one polyclonal antibody product). In FY 2012, BARDA continued support for one anthrax monoclonal antibody product that may have greater efficacy (i.e., faster effect), easier storage (i.e., freeze-dried product at room temperature), and better administration (i.e., intramuscular). Two of the existing antitoxin products have been procured with BioShield funds and delivered to the SNS for utilization under an EUA while their developers seek licensure. In FY 2013, FDA approved one of the monoclonal products: Human Genome Sciences/GlaxoSmithKline's (GSK) Raxibacumab®. The approval applies to treatment of individuals who are symptomatic with anthrax or for post-exposure prophylaxis. In addition, FDA approved pediatric dosing for this product. Raxibacumab® is the first novel product approved under the FDA Animal Rule[1] and the first approved product procured and developed with BioShield funding. This achievement is a significant milestone for both BioShield and the PHEMCE. FDA approval of the anthrax polyclonal antibody product is expected during 2014.

In September 2013, BARDA made awards under BioShield to maintain the current level of anthrax antitoxins in the SNS formulary and to procure cell banks used by developers of monoclonal anthrax antitoxins that have been supported by the PHEMCE as a risk mitigation strategy. Under the awards, BARDA will procure an additional 60,000 treatment courses of Raxibacumab® from GlaxoSmithKline (GSK) and maintain preparedness levels until 2017. In addition, BARDA will support Cangene to reinitiate the Stimulate Immunity program (known as the STIM program) to collect plasma from individuals vaccinated with the anthrax vaccine and store the plasma (10,000 treatment course equivalents) to be later manufactured into anthrax immune globulin (AIG) as the current product in the SNS begins to expire. This procurement will maintain preparedness to 2018, and the manufacturing of AIG will maintain preparedness to 2023. BARDA also purchased the cell banks used to generate three

[1] See 21 CFR Parts 314 and 601 at http://www.gpo.gov/fdsys/pkg/FR-2002-05-31/pdf/02-13583.pdf

different monoclonal anthrax antitoxins as a risk mitigation strategy. The cell banks will be transferred to the CIADM for long-term storage.

Also in FY 2012, BARDA continued to lead an HHS effort to determine the feasibility of expanded usage of antibiotics in the form of MedKits, including with the first responder community, through palatability and label comprehension studies.

Smallpox

Since 2006, BARDA has invested in the development and acquisition of smallpox vaccine candidates and antiviral candidate products. Currently, the SNS holds, and is taking further deliveries of, a BARDA-supported smallpox modified Vaccinia Ankara (MVA) vaccine for immunocompromised individuals. In November 2013, Bavarian Nordic completed delivery of the 20 million doses of vaccine under the original contract. In addition, they initiated delivery of four million doses under an option executed in March 2013 for $110 million. These deliveries will maintain the levels laid out in the *2010 PHEMCE Review* as vaccine expires.

A second option could be executed in FY 2014 to maintain preparedness to 2015 and allow the PHEMCE to transition to the freeze-dried product in 2016. A freeze-dried formulation of this product that could potentially reduce stockpile costs by increasing product shelf life is under development. It was supported under an ARD project. The MVA vaccine is available for use under an EUA during a declared emergency. In FY 2012, the emergency use protocol for this vaccine was expanded to include not only HIV-positive individuals but also those with atopic dermatitis, consistent with BARDA's directive to develop MCMs for special populations. Additionally, this protocol allows usage of this vaccine in individuals of all ages and in pregnant and nursing mothers who are afflicted with either condition. In 2013, Bavarian Nordic completed a large Phase 3 study to evaluate lot-to-lot consistency and safety; vaccinating 3,000 individuals. The pivotal clinical study to determine non-inferiority to ACAM2000 will commence in mid-2014. Both studies are necessary to support licensure of the product. Finally, in 2013, Bavarian Nordic received regulatory approval for its smallpox vaccine in the European Union and Canada based on studies supported by HHS.

The PHEMCE has a goal of developing and acquiring two smallpox antivirals to mitigate the emergence of drug resistance during an outbreak. In FY 2011, BARDA supported advanced development of two smallpox antiviral drugs. One of these products has demonstrated broad spectrum antiviral activity (i.e., efficacy against other viruses), which may provide a commercial market to enhance product and company sustainability. The other smallpox antiviral drug product, which transitioned in development from NIH in 2008, was awarded a BioShield contract in FY 2011. The first delivery of the product to the SNS occurred in March 2013. Although this product is not yet FDA-approved, it may be used under an EUA in the event of a declared emergency to treat individuals symptomatic with smallpox disease. In FY 2014, BARDA will continue to support the development of both products. BARDA is working with both manufacturers and FDA to develop rabbitpox and ectromelia animal models to support approval of both products. This collaborative effort is a testament to the collegial environment within the PHEMCE and with our partners; understanding that we can accomplish more when we work together.

Broad Spectrum Antimicrobials

BARDA also has begun to address the threat of antimicrobial resistance, emerging infectious diseases, and other novel threats by initiating programs supporting the development of broad-spectrum antimicrobials and technologies and platforms with multi-use potential. This effort is critical because antimicrobial resistance complicates the treatment of severe diseases from bioterror agents, burns, and

blast wounds. This portfolio also responds to other biologic threats such as plague, tularemia, typhus, glanders, and viral hemorrhagic fever.

In FY 2010, BARDA awarded its first contract for the advanced development of a new broad spectrum antibiotic, a cephalosporin against plague and tularemia. The product will also be evaluated as a potential treatment against hospital-acquired pneumonia and urinary tract infections. In addition, this product marks the first CBRN MCM supported by BARDA that has direct multi-purpose potential for biothreat preparedness and routine public healthcare. In 2012, another program was added to the portfolio of candidate products with the potential to address multiple biodefense pathogens and the emergence of antibacterial resistance, addressing an immediate public health concern.

In FY 2013, BARDA further expanded the portfolio to include a public-private partnership with GSK, and two biotechnology companies, one of which is addressing the threats of glanders and melioidosis. Currently, there are no antibiotics in the SNS formulary for this threat. In FY 2013, BARDA continued to support the candidates under development. One project received approximately $60 million to initiate a global clinical study to address antimicrobial resistance. In February 2014, BARDA awarded another contract to support development of an antimicrobial to address Burkholderia bacteria that cause glanders and melioidosis. This award brings the number of projects in the portfolio to six. BARDA will continue to support the projects in FY 2014 and look for promising candidates to add to the portfolio based on availability of funds in FY 2015. BARDA is supporting both the biothreat indication as well as the commercial indications being addressed by the various sponsors. In doing so, the products will be commercially available and decrease or eliminate the need for the Federal government to stockpile the antimicrobials.

Radiological and Nuclear Threats

The treatment of acute radiation syndrome (ARS) remains one of the most difficult medical challenges due to the effects of radiation on the entire body of the person exposed. Effective treatment requires MCMs targeted to several organ systems (blood, gastrointestinal, skin, lung, and neural) and the ability to accurately quantify a person's exposure in the field.

To support the early development of a wide variety of therapeutic MCMs for neutropenia (lack of neutrophils results in serious opportunistic infections) associated with ARS, BARDA began support of ten new product candidates in FY 2010 and four new product candidates in FY 2011 for therapeutic products to treat skin, lung, and gastrointestinal injury. In FY 2012, this portfolio continued supporting development of several new and existing product candidates, including treatments for skin and lung injury and enhancements to existing blood products.

In FY 2013, BARDA continued to fund multiple projects to address the sub-syndromes of ARS resulting from exposure to ionizing radiation. Products under development have the potential to address hematopoietic, skin, lung and gastrointestinal injury. BARDA will continue to support these projects based on their achieving scientific milestones of safety and efficacy. Also in FY 2013, BARDA expanded the portfolio of products to include those for thermal and radiation burns and blood products. For the treatment of children, BARDA is supporting the development of a pediatric-friendly formulation of Prussian Blue (a drug needed to remove ingested radioactive contaminants), thereby addressing a mandate of the *Pandemic and All-Hazards Preparedness Reauthorization Act* of 2013 (PAHPRA) to develop MCMs for at-risk individuals.

In September 2013, BARDA awarded two contracts under BioShield for late stage development and procurement of Neupogen (Amgen) and Leukine (sanofi-aventis). These cytokine products are approved to treat neutropenia resulting from chemotherapeutic treatment of cancer patients. They can be used under an EUA to treat neutropenia resulting from ionizing radiation exposure after a nuclear explosion. Neupogen and Leukine will be maintained by the manufacturers and rotated through the commercial marketplace with the government having immediate access to the acquired doses when necessary (highlighted above under VMI).

The amount of radiation an individual has been exposed to greatly affects the recommended course of treatment. Therefore, BARDA has aggressively supported the development of its biodosimetry portfolio. This portfolio supports the development of biomarker assays and detection devices to measure the amount of radiation that a person has received. Initially, 10 biodosimetry device candidates were awarded contracts for the development of biomarkers, assays, and point-of-care and high-throughput diagnostics. Several of these potential devices have shown progress, and in FY 2012 BARDA provided additional support for many of these candidates. Three of these programs were able to show biomarker feasibility – a significant milestone. In FY 2013, funding supported the transition of promising biodosimetry devices to an advanced stage of development. BARDA awarded two contracts in FY 2013 to support a biodiagnostic platform technology to detect exposure to biothreat pathogens and a deep view thermal imaging device to assist in the debridement of thermal burns.

In FY 2014, these programs continue to progress into the product development stage with the production of prototype devices. Moving forward, BARDA will emphasize expanding the number of projects under biodiagnostic devices to address other threats under the umbrella of CBRN.

Chemical Threats

The lack of antidotes for exposure to chemical threats remains a major gap in MCM preparedness. A recent clinical trial funded in part by BARDA compared the effectiveness of intramuscular injections of midazolam with that of intravenous lorazepam for the treatment of status epilepticus. The results of the study, called the "Rapid Anticonvulsant Medications Prior to Arrival Trial (RAMPART)"[2], were reported in *The New England Journal of Medicine*. The results indicated evidence to support the usage of midazolam to treat seizures associated with exposure to chemical agents. Approximately 13 percent of the RAMPART study participants were children. In September 2013, BARDA awarded a contract for late stage development and procurement of midazolam to Meridian Medical Technologies (owned by Pfizer). Under this project, funding will support clinical indications for status epilepticus and seizures resulting from exposure to chemical nerve agents in both adults and pediatrics. Midazolam will replace the diazepam currently in the SNS CHEMPACKs as it expires.

Finally, the PHEMCE agreed to include "decontamination" as an MCM category in FY 2012. In response, BARDA has supported a program to determine the most efficient way to remove chemical agents from the skin of exposed individuals. In February 2013, ASPR staff participated with the University of Hertfordshire in two demonstrations at sites in Los Angeles and Boston. In March 2014, BARDA will participate in an exercise in the United Kingdom. Data collected at these demonstrations is being used to inform experiments and studies to inform the ultimate deliverable of the project: a scientifically supported guidance document for best practices in mass-casualty decontamination. Removal of chemical agents is the most effective way to mitigate the short and long term effects of exposure to

[2] "Intramuscular versus Intravenous Therapy for Prehospital Status Epilepticus", *The New England Journal of Medicine*, Vol. 366, No. 7, February 16, 2012, http://www.nejm.org/doi/pdf/10.1056/NEJMoa1107494.

these agents. BARDA will emphasize supporting new candidate products under ARD to address the threat of chemical agents in FY 2014.

Product Innovation

Consistent with several of the *BARDA Strategic Plan 2011-2016* goals, the focus of the BARDA Innovations Program is to create a more diversified and adaptable MCM enterprise by nurturing products that have greater utility, such as broad-spectrum indications. The program also invests in technologies that make the development and manufacturing pipeline faster, more efficient, and less expensive using standardized platforms and templates. Beginning in FY 2010, the program supported eight projects including: development of new product sterility assays for vaccines; optimization of high-production vaccine virus seed strains for influenza; and establishment of a system for *in vitro* immunity testing. These initiatives addressed specific technological gaps that were noted in both the *2010 PHEMCE Review* and the President's Council of Advisors on Science and Technology report[3] on pandemic influenza vaccine production.

The Innovations Program seeks 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. In FY 2012, one of the platform technology projects for vaccine manufacturing progressed from an innovation to an actual vaccine product candidate for anthrax. In FYs 2012 and 2013, three new projects have been added to the portfolio as other projects are completed. BARDA is prioritizing efforts to address specific technological needs and opportunities that may contribute to the success of BARDA's mission. These efforts include testing 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.

Animal Studies

To secure regulatory approval under the FDA Animal Rule, BARDA has supported the development of animal models for safe and effective testing of MCMs. These studies are coordinated with programs at NIH and the Department of Defense, in consultation with FDA and CDC. In FY 2011, BARDA awarded 12 contracts to establish a network of contractors who can perform animal studies. These studies refine current animal models and create new models to better understand the pathogenesis of disease caused by various threat agents and then assess product efficacy.

Support in FY 2012 through FY 2014 has entailed numerous studies to evaluate potential and existing product candidates in animal challenge studies. Many of these studies will be pivotal in supporting eventual FDA approval. BARDA has supported 22 programs under this effort, and the work will continue through FY 2014. Through this network, BARDA continues to support the development of animal models, assays, reagents, and studies for such threats as anthrax, smallpox, plague, glanders, and ARS. BARDA is using the network as core service assistance to test manufacturers' product candidates, provide the results to manufacturers, and inform decisions about whether to support the development of new MCMs. BARDA also is using this network to evaluate the potential repurposing of already licensed products. BARDA has the ability to test these products in animal models being established under the network and evaluate their efficacy for radiological, nuclear, and chemical exposure. In

[3] *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza*, Executive Office of the President; President's Council of Advisors on Science and Technology, August 2010, http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf.

FY 2013, BARDA supported studies to evaluate repurposing of two products. In FY 2014, BARDA will continue to evaluate repurposing of products.

Core Service Assistance Programs

BARDA has established core service assistance programs to help inexperienced MCM developers evaluate product candidates prior to significant investment, perform studies or produce products on behalf of BARDA for national security and public health reasons, and provide BARDA with response capabilities to develop, test, and manufacture MCMs in an emergency. In 2010, BARDA established an Animal Studies Network comprised of 17 laboratories across the United States and in the United Kingdom. The network helps to evaluate MCM candidates in well-characterized animal models for CBRN threats. To date, more than 20 MCMs have benefitted.

In 2013, BARDA established a Fill Finish Manufacturing Network comprised of four domestic aseptic product manufacturers. This network supplements our national pandemic influenza vaccine manufacturing surge capacity, assists the CIADM with fill finish manufacturing of clinical investigational lots and stockpiled products, and helps address public health drug shortages.

In FY 2014, BARDA will establish a Clinical Studies Network comprised of multiple Contract Research Organizations. This network will conduct clinical studies for BARDA MCM developers and BARDA during emergency responses.

Centers for Innovation in Advanced Development & Manufacturing (CIADM)

Another key core service assistance program and a goal in the BARDA Strategic Plan is to provide core services to MCM innovators. In June 2012, BARDA made three awards to public-private partnerships to build, maintain, and operate U.S.-based flexible MCM manufacturing facilities. These facilities will assist in product development and manufacturing, ensure domestic pandemic influenza vaccine manufacturing surge capacity using modern technologies, and provide workforce development training programs. Once the new CIADM are functional, smaller manufacturers will have an opportunity to partner with a larger manufacturer to successfully scale-up manufacturing for clinical lots or to achieve regulatory approval of a product. Moreover, these facilities will help train the next generation of MCM scientists to ensure the nation has the talent available to manufacture the products necessary for its security.

The construction and renovation of these CIADM were supported by supplemental appropriations for pandemic influenza. Moving forward, appropriations for ARD will support the annual operating costs. The CIADM will become operational beginning in FY 2014.

Strategic Investor (SI)

As part of its goal to develop a pipeline replete with MCMs and platforms to address public health needs, ASPR/BARDA requests authorization and funding to implement the final recommendation of the *2010 PHEMCE Review*: the SI. As proposed in the FY 2015 Request, SI will serve as an independent, government-sponsored program to provide both financial support and business expertise to newly emerging businesses in the biodefense sector. Using an approach similar to other venture capital endeavors of the Federal government, SI will seek companies that have technologies with the potential to be successful commercially and be applied to specific CBRN MCMs.

Funding History

Fiscal Year	Amount
FY 2011	$387,426,000
FY 2012	$415,000,000
FY 2013	$415,000,000
FY 2014	$415,000,000
FY 2015 PB	$415,000,000

Budget Request

The FY 2015 Request for BARDA is $415,000,000, which is equal to the FY 2014 Enacted level. The request includes $20,000,000 to finance SI. The request also includes $16,000,000 to support operating costs for the three CIADM, which will become operational on a rolling basis beginning in FY 2014. The request will allow BARDA to maintain the robust portfolio of candidate MCMs and allow for new starts if current programs are down-selected due to the sponsors' inability to show safety or efficacy.
The request will support the advanced development of the highest priority MCMs against the 12 material threats identified by DHS and prioritized in the 2012 HHS *Strategy and Implementation Plan*. Specifically, ASPR requests funding for BARDA to continue support for existing advanced development of candidate products in the following portfolios: anthrax vaccines and antitoxins; smallpox vaccines and antiviral drugs; broad spectrum antimicrobial drugs; therapeutics and biodosimetry products for use in response to radiological and nuclear threats; and MCMs against chemical threats.

In addition, the request will support new contracts in the following threat areas: redirection of existing candidates in the anthrax vaccine portfolio towards the CIADM; platform biodiagnostics devices to quantify the level of exposure to biological agents; new broad spectrum antimicrobial drugs, especially antivirals against filoviruses; new candidate products for addressing the six illnesses resulting from injuries from radiological or nuclear events, including thermal burns; and new antidotes for treatment of chemical agents. BARDA does not anticipate expanding the programs supporting development of rPA-based anthrax vaccines, additional anthrax or botulism antitoxins, or smallpox vaccines and antivirals beyond the current portfolio. These programs are mature and/or replete with promising candidates. The near-term objective is to support the licensure of anthrax vaccine adsorbed for post-exposure prophylaxis. However, as mentioned previously, new starts may only occur if existing programs fail to meet milestones associated with safety or efficacy. New starts also may be limited at the requested level because, as successful programs move through the development pipeline, there is an increased cost associated with phase II clinical studies, non-clinical studies beyond proof of concept, and scale-up of manufacturing moving toward potential procurement under BioShield in FYs 2014-2018.

Finally, the FY 2015 Request includes $20,000,000 for SI, which will provide both financial and business support to companies who are pursuing the development of products that directly address the Federal government's needs for MCMs. FY 2015 funding is necessary to move the SI program into operation and invest in new technologies that can serve as MCMs. In the absence of authorization and funding to establish SI, BARDA will use these funds to increase support for existing or new candidate products primarily in the areas of biodiagnostics, broad spectrum antimicrobials, and thermal burn and blood products.

BARDA also will use FY 2015 funds to continue the development of animal models that are essential to support licensure or approval of these critical MCMs. Further work is critical in ARS, skin, and chemical MCM testing. It is also anticipated that viral hemorrhagic fever models will need to be qualified as

products come into BARDA's pipeline.

ASPR Biomedical Advanced Research and Development Authority - Outputs and Outcomes Table

2.4.13: Increase the number of new Chemical, Biological, Radiologic, and Nuclear (CBRN) and emerging infectious disease (EID) medical countermeasure under Emergency Use Authority (EUA) or licensed

	Most Recent Result	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
Target	CBRN Licensed= +0; EUA= +3; Pan Flu/EID Licensed= +3; EUA= +0	CBRN Licensed = +2 EUA= +2 Pan flu/EID Licensed +2	CBRN: Licensed= +4; EUA= +2. Pan Flu/EID: Licensed= +5; EUA= +3	CBRN Licensed = +2 EUA=+0 Pan Flu/EID Licensed = +3 EUA = +3
Result	**CBRN EUA= 2;** ST-246 antiviral for smallpox approved by FDA for EUA and Neupogen an anti-neutropenia cytokine for radiation treatment. 2 other packages were submitted but not acted on during the performance period. **Pan Flu licensed=3**; Licensed by FDA are: 1) Flucelvax, the first cell0based seasonal influenza vaccine, 2) Flublok, the first recombinant-based seasonal influenza vaccine, and 3) Aura, a next generation portable ventilator for adults. While not part of the goal, BARDA saw the first anthrax antitoxin and the first botulinum antitoxin licensed by FDA. Both projects were supported by Project BioShield and approved under the FDA's Animal Efficacy Rule.	In Progress	In Progress	
Status	**Target Not Met but Improved**	**In Progress**	**In Progress**	

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Project BioShield

Budget Summary
(Dollars in Thousands)

ASPR Project BioShield	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	-	255,000	415,000	+160,000
FTE	-	-	-	-

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method…… Direct Federal/intramural; contracts; grants

Program Description and Accomplishments

The medical countermeasure (MCM) pipeline has never held more promise than it does today. Innovation, enhanced partnerships and collaboration, as well as sustained investments throughout the last decade have resulted in the addition of 12 new MCMs to the Strategic National Stockpile (SNS). Each having been supported by Project BioShield (BioShield), these MCMs are able to treat the effects of anthrax, botulism, smallpox, and radiological and nuclear agents.

The *Project BioShield Act of 2004* (Public Law 108-276) was designed to provide additional authorities and funding to financially support the development and procurement of MCMs against chemical, biological, radiological, and nuclear (CBRN) threat agents. It was also designed to provide the Federal government with the authority to quickly authorize the use of these MCMs during public health emergencies. BioShield authorities were further delineated, clarified, and extended by the *Pandemic and All-Hazards Preparedness Act of 2006* and the *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013* (PAHPRA). Project BioShield was initially funded with a $5.6 billion appropriation available over 10 years (FYs 2004-2013).

BARDA has procured a total of 12 new MCMs through BioShield and the Special Reserve Fund (SRF) that supports it. Two products were approved by the Food and Drug Administration (FDA) in FY 2013. Raxibacumab®, an anthrax antitoxin, was approved by FDA in December 2012 for the treatment of individuals symptomatic with inhalational anthrax and post-exposure prophylaxis for individuals potentially exposed to anthrax. The approval included dosing for pediatric populations. In March 2013, FDA approved Heptavalent botulinum antitoxin (HBAT®) for the treatment of individuals with confirmed or suspected botulism intoxication. FDA approval included dosing for pediatrics as well. Both of these antitoxins were the first novel MCMs approved by FDA. BARDA added three new MCMs under BioShield – Neupogen, Leukine, and Midazolam – for treatment of hematopoiesis associated with Acute Radiation Syndrome (ARS) and convulsions resulting from chemical agent exposure.

Of the original $5.6 billion that Congress appropriated to the SRF for BioShield a decade ago, BARDA expended $3.4 billion to deliver the 12 new MCMs and $2.2 billion to establish a robust CBRN MCM development pipeline comprised of more than 85 product candidates. Because of these substantial investments, the nation's level of preparedness against CBRN threats is greatly enhanced as compared to 2004, when BioShield commenced.

With the continued support requested for BioShield for FY 2015, and additional investments in the coming years, BARDA anticipates maintaining current capabilities, capacities and preparedness, and procuring 12 new MCMs during FYs 2014-2018. These procurements will make strides to greatly enhance our nation's preparedness. BARDA also has more than 85 products undergoing advanced research and development as MCM candidates for future BioShield procurements. New MCMs emerging from this development pipeline that mature enough for BioShield procurement and qualify for utilization in an event under Emergency Use Authorization (EUA) from FYs 2014-2018 include the following products:

- Next generation artificial skin replacement therapy for definitive care treatment of thermal and radiation burns;
- Antimicrobial drug-impregnated mesh dressings for point-of-care treatment of thermal and radiation burns;
- Gene expression- and other technology-based biodosimetry devices for quantitative measurement of ionizing radiation exposure in affected persons following a nuclear event;
- Multiple chemical antidotes for cyanide poisoning and highly-volatile nerve agents;
- Multiple therapies using cell-based, recombinant protein, and small molecule technologies for treatment of hematopoietic, skin/lung, and gastrointestinal illnesses associated with acute radiation syndrome (ARS);
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biothreats; and
- Next-generation anthrax vaccine

Funding History

Fiscal Year	Amount
FY 2011	$0
FY 2012	$0
FY 2013	$0
FY 2014	$255,000,000
FY 2015 PB	$415,000,000

Budget Request
The FY 2015 Request for Project BioShield is $415,000,000, which is +$160,000,000 above the FY 2014 Enacted level. ASPR requests this funding to continue support of the Administration's multi-year commitment to protecting the nation against CBRN threats, consistent with PAHPRA.

At the requested level, BARDA will make the following six acquisitions in FY 2015:

1. New artificial skin replacement therapy for definitive care treatment of thermal and radiation burns experienced in persons exposed to a nuclear or other fire event;

2. Replenishment of the expiring stockpile of smallpox vaccine for immunocompromised persons;

3. Maintenance costs for a vendor-managed inventory of anti-neutropenia cytokines used to treat persons exposed to high amounts of ionizing irradiation and experiencing ARS illnesses;

4. New biodosimetry devices capable of determining an individual's level of exposure to ionizing radiation;

5. Replenishment of expiring anthrax antitoxins to maintain the current state of preparedness and maintain the manufacturing capacity previously established; and

6. New chemical antidotes to mitigate the potential longer term effects of exposure to highly volatile nerve agent(s).

Beyond FY 2015, BARDA will seek support for purchase of new MCMs, including biodosimetry and biothreat diagnostic devices, chemical antidotes for cyanide poisoning and highly-volatile nerve agents, next-generation anthrax vaccines, and broad spectrum antibiotics for plague, tularemia, and other biothreats. These MCMs, which the Advanced Research and Development program has supported since 2008, are expected to mature sufficiently for procurement and stockpiling and be accessible under an EUA in a CBRN event. BARDA also will request funding in future years to replenish existing anthrax antitoxins and enhanced smallpox vaccines.

In addition, there are projects underway that address the long-standing critical portfolios of anthrax and smallpox. BARDA plans BioShield procurements to move closer to meeting the full requirement for anthrax antitoxins, which has only been met partially because of funding, product availability, manufacturing capacity, and other priorities. Further, the acquisition of next-generation anthrax vaccines under BioShield may occur sooner than originally anticipated, depending on the present development of candidates. BARDA also anticipates that the lyophilized formulation of the smallpox modified Vaccinia Ankara vaccine (AVA) for at-risk individuals (including children, and pregnant and nursing mothers) will be ready for procurement in FY 2016. This formulation will provide significant cost savings because the product can be stored at warmer temperatures and has a shelf life that is greater than three times the shelf life of the current product.

A key BARDA goal is decreasing life-cycle costs associated with stockpiling critical MCMs. For threat areas using commercially available products such as radiation therapies and antimicrobials, the approach used for anti-neutropenia cytokines – creation of a stockpile at the company that is vendor-managed – may decrease and control life-cycle management costs over the long-term to create a sustainable armamentarium. The products could be used to treat individuals undergoing radiation therapy for cancer and to address the broader public health concern of antimicrobial resistance.

Commercial markets offer the government a unique opportunity to leverage the commercial use and need for these products and purchase a "bubble" that would continue to rotate through the commercial market without the necessity to stockpile the product. Under a vendor managed inventory (VMI), as was done with cytokines purchased in FY 2013, the product does not expire yet the government has immediate access to the product if it is needed for an emergency. Most threats that BARDA is addressing do not provide the opportunity for VMI. However, where possible, BARDA will leverage commercial markets for products with a dual purpose to decrease the overall life-cycle management costs and increase sustainability.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Office of Policy and Planning

Budget Summary
(Dollars in Thousands)

ASPR Office of Policy and Planning	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Program Level	14,877	14,877	14,877	-
Budget Authority (non-add)	*14,877*	*14,877*	-	*-14,877*
Funding from Section 241 of PHS Act (non-add)	-	-	*14,877*	*+14,877*
FTE	43	53	53	0

Authorizing Legislation:
FY 2014 Authorization……..……PAPHRA
Allocation Method……..Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments

The ASPR Office of Policy and Planning's (OPP) mission is twofold: (1) OPP advises the Assistant Secretary on policy options and approaches to support, strengthen, and sustain the Nation's domestic and international public health and healthcare emergency preparedness and response capabilities; and (2) OPP facilitates the development of organizational, Federal, and national strategic plans related to domestic and international public health emergency preparedness and response. Some OPP staff with science-policy expertise write medical countermeasure (MCM) requirements and related policy papers for a wide range of chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases such as pandemic influenza. Their analysis requires 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.

Supporting the National Health Security Strategies

OPP also provides 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 work includes the coordination, analysis, and implementation of relevant laws and regulations, proposed policies, HHS and national strategies, presidential directives, executive orders, and the development of requirements and strategies for MCM research, development, acquisitions, and utilization.

In December 2009, HHS issued its first NHSS as directed by the *Pandemic and All-Hazards Preparedness Act of 2006* (PAHPA). The NHSS is HHS' first comprehensive strategy focusing specifically on the Nation's goal of protecting the public's health in the case of an emergency by building community resilience and strengthening and sustaining health and emergency response systems. 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 Americans are prepared for, protected from, able to effectively respond to and recover from public health emergencies. OPP is responsible for

developing the strategy, and using it as the primary guide for public health emergency preparedness and response policy development.

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 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 supports implementation of the White House National Security Council'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. efforts to strengthen pathogen security through enhancing domestic and international laboratory biosafety, biocontainment and biosecurity oversight and outreach. OPP coordinates the participation and collaboration of HHS across the Federal government under the Biological and Toxin Weapons Convention, on the foundation built by the *National Strategy for Countering Biological Threats* and the President's Open Government Directive.

Providing Global Leadership on Health Security

OPP also provides leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response, in order to protect and enhance U.S. national health security. Specifically, OPP develops critical policy and assistance frameworks to guide the HHS' provision and acceptance of international assistance during public health and medical emergencies, including the sharing of public health and medical personnel and MCMs. In addition, OPP provides leadership and oversight for the Federal government's compliance with the United States' obligations under the legally-binding health security framework of the International Health Regulations. These efforts include managing the risk assessment and notification process to alert the international community of all domestic events that may constitute potential Public Health Emergencies of International Concern and providing policy advice and support to partner countries and the National Security Council.

Other OPP Leadership

On behalf of the Secretary and Assistant Secretary, OPP also 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, community resilience, and disaster human services coordination across the department.

OPP also provides policy and strategic direction for the NHSS objective of promoting an effective MCM enterprise, through leading the coordination of the end-to-end Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This direction includes leading the development of civilian requirements for medical countermeasures to ensure alignment of early research (National Institutes of Health), advanced development (Biomedical Advanced Research and Development Authority, BARDA) and acquisition activities (BARDA and the Centers for Disease Control and Prevention, CDC), and effective distribution, deployment, dispensing, and administration (ASPR, CDC) of Federal MCM

assets. This leadership also includes implementing recommendations in the Secretary's *2010 PHEMCE Review*, as well as providing coordination, management and operational services for the PHEMCE). Through the PHEMCE, OPP leads the establishment of requirements for MCM research, development and acquisition, as well as related policies for their effective distribution, dispensing, and administration. Also, in collaboration with other ASPR offices, OPP leads maintenance and tracking of the *2012 HHS PHEMCE Strategy* and *Implementation Plan,* which provides the blueprints the PHEMCE will follow in the near-, mid-, and long-term to make the best use of available resources to enhance national health security. OPP, on behalf of ASPR, also co-leads, with CDC's Division of the Strategic National Stockpile (SNS), the PHEMCE SNS Annual Review mandated by PAHPA and Homeland Security Presidential Directive-21.

Additionally, OPP works to establish policies that support integrated and scalable health systems in support of a NHSS Strategic Objective. To that end, OPP engages in activities that encourage the widespread use of interoperable electronic health records, improve access to emergency care, and align incentives. OPP works closely with ASPR's Hospital Preparedness Program and other partners within and outside ASPR, including HHS' Centers for Medicare & Medicaid Services and the Office of the National Coordinator, to promote strong public health, healthcare, and emergency response systems.

OPP's Accomplishments

OPP has begun a quadrennial review of the NHSS, and has initially drafted an Evaluation of Progress to meet the statutory requirement to submit an updated NHSS to Congress by December of 2014. OPP has also led and coordinated HHS' input and involvement in all aspects of Presidential Policy Directive 8: *National Preparedness*, and published the *2009 H1N1 Influenza Improvement Plan*, which shares the Secretary's priorities for pandemic influenza preparedness post-H1N1. OPP also published the *2012 HHS PHEMCE Strategy and Implementation Plan*, which articulates the strategic direction and guides policies and decisions for the end-to-end mission of the PHEMCE by describing the activities and programs that HHS, in collaboration with its interagency partners, is undertaking over the next five years to increase MCM preparedness for national health security threats.

In coordination with DHS, OPP developed the *Strategic Implementation Plan to Conduct Material Threat Assessments*, which describes the processes and procedures to be used by DHS and HHS when collaborating on the development of Material Threat Assessments. These assessments provide in-depth analyses of the potential for specific chemical, biological, radiological, and nuclear agents that cause high consequence scenarios. Similarly, OPP led the development of MCM requirements for botulinum toxin, improvised nuclear devices, cyanide, vesicants, and nerve agents.

OPP's international policy work continues to alert international communities of 52 domestic potential Public Health Emergencies of International Concern and provide policy advice and support to Federal partners on the International Health Regulations. OPP has developed new policy frameworks to guide HHS' response to international requests for both public health emergency MCMs and public health and medical personnel. OPP also led U.S. participation in the trilateral Health Security Working Group and overseeing the implementation of the North American Plan for Animal and Pandemic Influenza, and served as a liaison to the State Department for Biological Weapons Convention and United Nations Security Council Resolution 1540 implementation.

OPP co-chairs the Children's HHS Interagency Leadership on Disasters Working Group which makes recommendations to HHS leadership to better address the disaster-related needs of children, and is

leading the creation of a new Federal Advisory Committee to address the needs of children in disasters as required by PAHPRA.

OPP's Division of Health Systems Policy (DHSP) will continue the development of "no-notice" drill for hospitals and coalitions to assess the ability to meet the Immediate Bed Availability goals for medical surge through the Emergency Care Coordination Center (ECCC). ECCC will engage stakeholders to define units of measure for quality metrics in the emergency care system and categorize the acute care capabilities of hospitals. DHSP also will continue work using administrative data to support preparedness, response, and recovery, and build infrastructure to support science preparedness and disaster research.

Funding History

Fiscal Year	Amount
FY 2011	$18,327,000
FY 2012	$15,674,000
FY 2013	$14,877,000
FY 2014	$14,877,000
FY 2015 PB	$14,877,000

Budget Request

The FY 2015 Request for OPP is $14,877,000, which is equal to the FY 2014 Enacted level. For FY 2015, OPP will be funded from amounts available under section 241 of the *PHS Act*. Funds requested for OPP support activities aligned with all six goals in *ASPR's Strategic Plan.*

In FY 2015, OPP will release the second NHSS and Implementation Plan, continuing the process of refining measures, monitoring implementation, and evaluating progress toward achieving national health security.OPP will provide coordination, management, and operational services for the NBSB. OPP also will lead national health security policy development, analysis, and coordination efforts on behalf of ASPR, to include Presidential policy directives, executive orders, relevant laws and regulations, and HHS and national strategies.

ASPR will prioritize some of the requirements detailed in the NHSS Implementation Plan, including efforts to integrate healthcare organizations into coalitions; enhance state and local coordination; promote the integration of disaster behavioral health as outlined in the *HHS Disaster Behavioral Health Concept of Operations* (DBH CONOPS); implement dissemination strategies for best practices on community resilience, including planning tools that address the functional needs of at-risk individuals and children; build initiatives to exercise, measure, and report the ability to surge during a public health emergency or disaster; and promote solutions to barriers to forming healthcare coalitions.

OPP also will advance U.S. domestic health security by leading the development and implementation of policies, initiatives, and plans with domestic and international partners. OPP will complete the development of policy frameworks to guide the Federal government's provision and receipt of international assistance during public health and medical emergencies and will continue to work with domestic and international stakeholders to identify and address legal, regulatory, and logistical barriers to international assistance. OPP will oversee the implementation of the trilateral and multi-sectoral North American Plan for Animal & Pandemic Influenza with Canada and Mexico and will coordinate international preparedness efforts to address CBRN and pandemic influenza threats through the Global

Health Security Initiative. OPP will collaborate closely to implement the health security area of the Beyond the Border Initiative with Canada. OPP will continue to provide leadership and oversight for the Federal government's compliance with U.S. obligations under the legally-binding health security framework of the International Health Regulations (IHR), and will also support IHR core capacity development under the USG Global Health Security Agenda.

OPP continues to serve as the focal point within ASPR for activities related to biosafety, biocontainment, and biosecurity (or, "biorisk management"). Working groups across the Department 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 was formed by Executive Order in 2010, and continues its work to enhance the security of biological select agents and toxins; to support trans-Federal efforts to address dual use research issues, including the development of U.S. policy related to dual use research of concern; and to support a range of efforts on international bioengagement.

OPP also will continue to work with partners in the PHEMCE. OPP will work with other ASPR offices, NIH, FDA, and CDC – as well as partners at state, local, tribal and territorial levels – to define civilian MCM requirements that meet the Nation's needs. OPP will work with BARDA Analytic Decision Support to reduce the unmitigated risk inherent in the advanced development of MCMs. In coordination with the CDC, OPP will continue to work to develop clinical guidance and utilization policies for these MCMs. OPP also will help determine the best methods for distribution and dispensing of MCMs to the public.

Office of Policy and Planning - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2013 Target	FY 2015 Target	FY 2015 +/- FY 2013
2.4.9: Establish and coordinate implementation of national strategies for public health and medical preparedness and response.	FY 2012: OPP has published and is now implementing a number of strategy documents, including: The NHSS Implementation Plan and the 2009 H1N1 Influenza Improvement Plan. Also, OPP has coordinated HHS-wide PPD-8 input, resulting in the publication of numerous policy documents including the *National Preparedness Goal*.	Move toward goal of publishing the second *National Health Security Strategy*.	Publish the NHSS.	N/A

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Operations

Budget Summary
(Dollars in Thousands)

ASPR Operations	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	31,304	31,305	31,305	-
FTE	163	171	171	-

Authorizing Legislation:
FY 2014 Authorization……PAPHRA
Allocation Method……Formula Direct
Federal/intramural; contracts

Program Description and Accomplishments
The Operations activity supports funding for the Assistant Secretary's Immediate Office; the Office of the Chief Operating Officer; the Office of Acquisitions Management, Contracts, and Grants; and the Office of Financial Planning and Analysis.

The Immediate Office of the Assistant Secretary (IO): The IO supports the Assistant Secretary's role as principal advisor to the Secretary on all matters related to public health and medical emergency preparedness and response. In addition, the IO provides overall leadership and strategic management of ASPR, ensuring a collaborative and comprehensive approach to implementing ASPR's goals and strategies, and leading regular senior-level evaluation of the organization's progress in meeting preparedness priorities, including the science of preparedness and medical countermeasures.

The Office of the Chief Operating Officer (COO): 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; legislative coordination; and the Executive Secretariat. In FY 2014, COO is continuing to implement initiatives to improve business operations, strengthen ASPR's human capital and communications practices, and create a more nimble and flexible organization able to adapt to threats impacting public health. In addition, COO has completed a long-term strategy to co-locate 90 percent of ASPR staff in one building: the Thomas P. "Tip" O'Neill Federal Office Building. This consolidation has proved to strengthen communication and coordination among organizational divisions. Also in FY 2014, consistent with Executive Order 13589: Promoting Efficient Spending, COO is instituting a number of strategic efforts to monitor and contain costs for services it administers. These efforts include the incorporation of Quality Improvement systems for business management.

In 2015, COO will strengthen initiatives to promote a leadership and mentoring culture capable of addressing evolving threats and emerging challenges to public health as well as able to implement innovative solutions in the face of future disasters. COO will continue to build the culture of quality improvement throughout ASPR and will implement strategies to mitigate risk and improve program quality. Lastly, COO will leverage innovative communication tools and technologies – including social networking – to enhance community connectedness and to empower individuals to take action during public health and medical emergencies.

The Office of Acquisition Management, Contracts, & Grants (AMCG): AMCG provides acquisitions and grants management oversight and support to each office within ASPR. AMCG is ASPR's focal point for management and leadership of the awarding of contracts, acquisition policy, and administration of grants, cooperative agreements, and Other Transaction Authority agreements. Although there is a particular focus on providing major acquisition support to BARDA and contractual support to OEM, AMCG also provides functional support activities to ASPR, including but not limited to requirements analysis, operations development, support acquisition strategy development, and tracking of milestones.

Funding for AMCG is aligned with *ASPR's Strategic Plan 2011-2015* and supports the goal to promote an effective medical countermeasures enterprise. AMCG promotes the development and acquisition of medical countermeasures with an emphasis on innovation, flexibility, and broad-spectrum application.

AMCG supports the goal to strengthen Federal public health and medical preparedness, response, and recovery leadership and capabilities though the solicitation, award and administration of contracts and grants. ASPR has established a contract architecture that enables responders to obtain the supplies and services needed to effectively lead the public health and medical response to emergencies under Emergency Support Function-8 (ESF-8). The Division of Acquisition Program Support (APS) within AMCG provides a wide range of program management support to the ASPR and direct program support to BARDA and OEM. This support includes the ASPR Acquisition Management System with procurement oversight and control tools such as Decision Gate, event-driven In-Process Reviews, and Milestone Decision Reviews of applicable contracts. Other support is provided through Earned Value Management, auditing, cost and price analysis, and the development and execution of various acquisition-related training programs, such as the ASPR Medical Acquisition Course. Additionally, functional support activities of APS include requirements analysis for statements of work, statements of objectives, and performance-based statements of work, along with acquisition strategy development, acquisition planning, and tracking contractual milestone dates with measurable success criteria.

The Office of Financial Planning and Analysis (OFPA): OFPA helps to ensure that ASPR's financial resources are aligned to its strategic priorities and conducts regular annual planning under a multi-year strategy to align resources to priorities, measuring performance and correcting course when necessary. OFPA carries out its responsibilities by formulating, monitoring, and evaluating ASPR budgets and financial plans that support program activities and ensuring the efficient execution of ASPR's financial resources. In coordination with BARDA and other partners in the Public Health Emergency Medical Countermeasures Enterprise, OFPA has developed multi-year budget projections that help inform resource allocation for medical countermeasures. OFPA also oversees emergency administration and finance operations that provide *Stafford Act* expertise, financial tracking, and emergency administrative functions that directly support HHS responders and stakeholders. When the HHS Emergency Management Group is activated as ESF-8 under the National Response Framework, OFPA integrates with the EMG under the structure of the Incident Command System. OFPA works closely with 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 serves as the primary point of contact with HHS' Office of the Assistant Secretary for Financial Resources, the Office of Management and Budget (OMB) and Congressional Appropriations Committees. OFPA ensures accountability and effectiveness of ASPR's financial programs and operations by establishing, assessing, correcting, and reporting on internal controls, as required by OMB

Circular A-123. OFPA also coordinates efforts to achieve ASPR's goals supporting the Secretary's Program Integrity initiative. Further, OFPA coordinates cross disciplinary reviews of high-impact, high-visibility programs to identify risks to mission completion and develop strategies to ensure effective and efficient operations.

Funding History

Fiscal Year	Amount
FY 2011	$36,651,000
FY 2012	$32,981,000
FY 2013	$31,304,000
FY 2014	$31,305,000
FY 2015 PB	$31,305,000

Budget Request

The FY 2015 Request for ASPR's Operations is $31,305,000, which is equal to the FY 2014 Enacted level. These funds are integral to achieving all of the *ASPR Strategic Plan 2011-2015* goals and to the success of all of ASPR's activities. The request supports staff salaries for IO, COO, AMCG, and OFPA; rent and service changes; equipment costs; travel; telecommunications; training; and continued implementation of internal controls. Funds also will support the continued development of ASPR's performance measurement, quality improvement, and strategic human capital management initiatives. The request also funds the development of short- and long-term policy and strategic objectives, including implementation of mandates included in PAHPRA and other relevant legislation. Lastly, the request supports ASPR's strategic communication efforts, including programming support for the HHS TV studio, which provides 24-hour emergency health preparedness information to the public.

ASPR Operations - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2013 Target	FY 2015 Target	FY 2015 +/- FY 2013
2.4.8: Improve strategic communications effectiveness.	FY 2013: Implementation of Quality Improvement initiatives. (Target met) Continued improvement in ASPR's central infrastructure for public web communications to support interagency collaboration. (Target met). Innovative use of new technologies – social networks – to enhance community connectedness and to empower individuals to take action. (Target met)	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.	Continue efforts toward effective and strategic communications, including expanding message content to ensure information is available in multiple formats, and communications are clear, concise, and timely before, during, and after public health and medical emergencies.	N/A

Program/Measure	Most Recent Result	FY 2013 Target	FY 2015 Target	FY 2015 +/- FY 2013
2.4.9: Attract high quality staff [“high quality” defined as subject matter experts with medical countermeasure, response, or other ASPR specific expertise]	N/A	N/A	Increase recruitment presence at industry specific events (attend five industry specific events).	

ASSISTANT SECRETARY FOR ADMINISTRATION
Cybersecurity

Budget Summary
(Dollars in Thousands)

Cybersecurity	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	37,884	41,125	45,270	+4,145
FTE	34	88	112	+24

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method……Direct Federal

Program Description and Accomplishments

The Department of Health and Human Service (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 requirements of Federal laws and compliance with Office of Management and Budget (OMB) and National Institute for Standards and Technology (NIST) guidance related to IT security and privacy. 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 Department of Homeland Security (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 2014 and FY 2015 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) act as the hub for the collection, analysis, coordination and dissemination of Cybersecurity information for the Department. The SOCs now operating within HHS were established or upgraded at the operating divisions (OpDivs) and now enable the Department and the OpDivs to quickly share security incident information and better coordinate our responses to attacks.

The Budget invests in engineering and implementation work necessary to implement the 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 three TIC locations (Washington DC, Atlanta, Georgia and Albuquerque, New Mexico) became operational in FY 2013, while adding the special monitoring technologies provided by DHS (Einstein). As of February, 2014 TIC has migrated 61% of all HHS internet traffic. During the remainder of FY 2014, the migration of restricted internet traffic will be completed across all of the OpDivs within HHS and the TIC Virtual Private Network (VPN) migration and integration of Cloud Services will begin and continue into FY 2015.

The HHS Cybersecurity Program also manages the procurement of enterprise licenses for a wide variety of security tools including tools for the encryption of sensitive information, tools that provide for continuous security monitoring, vulnerability scanning, asset inventory, and IT systems and application software security configuration compliance.

The HHS Cybersecurity Program continues efforts to re-validate and update its inventory of information systems on a quarterly and annual basis. The Department's annual Federal Information Security Management Act (FISMA) report was submitted ahead of schedule on November 27, 2013. With the issuance of updated guidance from NIST – specifically, National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-53 Revision 4, *Security and Privacy Controls for Federal Information Systems and Organizations* - which updated and expanded set of security controls for Federal systems and major revisions to system security authorization processes, the Department initiated an update of its Department-wide IT security policies, standards and processes to conform to the latest Federal guidance. The Department issued guidance in November 2013, to address security for cloud computing, relaying Office of Management and Budget (OMB) guidance for cloud computing known as FedRAMP (Federal Risk and Authorization Management Program). Additionally, the Department sponsored IT security authorizations for multiple cloud service providers (CSPs) consistent with FedRAMP process. These cloud service providers currently include Amazon Web Services (AWS), Salesforce, Adobe and Verizon Terremark.

The Department of Homeland Security (DHS) Continuous Diagnostics Management (CDM) initiative is driving HHS to adopt an automated, continuous monitoring capability. As part of this initiative, DHS is planning to provide cost-effective and dedicated tools and implementation resources to the Department to support the development of a consistent and mature continuous monitoring capability. To take full advantage of the DHS CDM initiative, HHS undertook a process to obtain a detailed understanding of its continuous monitoring needs and priorities. The resulting *HHS Continuous Monitoring Architecture Roadmap (CMAR)* – specifically an assessment of the "As-Is" state of Department-wide continuous monitoring capabilities, creation of an enterprise-wide continuous monitoring "To-Be" state, and identification of recommended steps to achieve that state - lays the foundation for the Department to

take full advantage of the DHS CDM initiative. With the release of the OMB Memorandum (M) 14-03, *Enhancing the Security of Federal Information and Information Systems,* the Department began undertaking multiple initiatives including the development of a forward looking continuous monitoring strategy, an assessment of tools, and a workforce-focused skill set analysis. HHS will continue on standardizing continuous monitoring fundamentals across HHS so that senior management and IT staff can make risk based decisions based off of data obtained from the implemented CM tools sets across HHS. 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

Fiscal Year	Amount
FY 2011	$56,680,000
FY 2012	$39,924,000
FY 2013	$37,884,000
FY 2014	$41,125,000
FY 2015 PB	$45,270,000

Budget Request

The FY 2015 request for the HHS Cyber Security Program is $45,270,000, an increase of $4,145,000 above FY 2014 Enacted. Also included in the request is the ongoing reduction in the reliance and dependency on contractor staff. In order to enable the HHS Cybersecurity Program to be as efficient and cost effective as possible, the Cybersecurity Organization is actively executing contractor conversions which result in a budget neutral impact.

The FY 2015 request will enable the HHS Cybersecurity Program to continue to provide management and oversight of the Department's IT Security Program and to ensure compliance with the requirements of FISMA. This request will also help to sustain prior year security investments, which were instrumental in enabling the completion of the security engineering and design work for the Trusted Internet Connections (TIC) initiative, and directly contributed to the project being able to begin the procurement and implementation efforts at the TIC locations and their ongoing maintenance and operations, support security engineering, 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.

FY 2015 Budget Request by Major Category Description
(Dollars in Millions)

Activity	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget
FISMA Program Management	14.220	13.718	13.718
Computer Security Incident Response Center (CSIRC) and Security Incident Response & Situational Awareness	14.103	14.389	14.390
Trusted Internet Connection (TIC)	5.998	8.718	12.862
Endpoint Protection Security Tools	3.563	4.300	4.300
Total	**37.884**	**41.125**	**45.270**

FISMA Program Management ($13.718 M): The request is at the same level as the FY 2014 Enacted and allows 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 ($14.390 M): The request is at the same level as the FY 2014 Enacted and allows for the CSIRC systems engineering and integration efforts associated with monitoring and securing these technologies to continue and be closely aligned with the TIC initiative and other Department of Homeland Security efforts to improve the Federal government's ability to counter attacks. Since establishing the CSIRC, the Department has been able to provide Cybersecurity situational awareness across the entire enterprise. It has also been possible to address several threat vectors simultaneously by having a central view into all of the OpDiv networks. Numerous attacks have been minimized due to the fact that mitigations were developed for the initial attack and then promulgated to all of the OpDivs, in many cases before the attacks occurred within those networks. The FY 2015 budget will allow for the ongoing operations and maintenance of CSIRC and will enable the Department to sustain a very robust capability to defend against computer attacks, and also better detect and respond to any attacks. OSSI's Cyber Threat Intelligence effort will establish and maintain capabilities to provide intelligence support and counterintelligence analysis for the HHS cybersecurity efforts. In addition, OSSI will establish a program to provide oversight of the Department's cyber incident prevention, warning, detection, forensics, response, and remediation, in coordination with ASA/OCIO and the CSIRC.

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) ($12.862 M): The implementation of three TIC sites in FY 2013 and FY 2014 allowed the Department to align with DHS initiatives for providing greater security in the government's internet connections and facilitate the necessary infrastructure to implement Einstein for the entire Department. Additionally, the three TIC sites have a security solution suite which allows the

Department to provide real time redundancy and failover capability in the event of a security infrastructure failure at any OpDiv – this includes firewalls, Intrusion Detection Systems (IDS), netflow analysis, and Security Information and Event Management (SIEM). Finally, the TIC provides core capabilities for the Department's continuous monitoring plan. In FY 2014, the Department will complete the cutover to TIC of any remaining complex circuits that were not cutover in FY 2013.

Migration status as of February, 2014:

- **Completed TIC migration** – TIC has migrated a total of 61% of all HHS- Internet traffic. The National Institutes of Health, Food and Drug Administration (FDA; Phase 1/2), ITIO customers (including the Office of the Secretary and smaller Operational Divisions), Indian Health Services- East Coast (IHS), and the Health Resources and Services Administration.

- **Planned migration, March 2014** – The Centers for Disease Control and Prevention - (CDC; Phase 1), FDA (Phase 4a & 4b)

- **Planned migration, April 2014** – CDC (Phase 2)

- **Planned migration, May 2014** – Centers for Medicare and Medicaid Services (CMS; Phase 1), FDA (Phase 3 & 4c), Office of the Inspector General (OIG; Phase 1/2)

- **Planned migration, June 2014** – OIG (Phase 3) – Pending circuit & hardware procurement, CDC (Phase 3), CMS (Phase 2)

- **Planned migration, July 2014** – CMS (Phase 3)

- **Planned migration, TBD** – Indian Health Services (IHS - West) – TBD - pending protest resolution and new RFP

In FY 2014, TIC will also begin the VPN migration and integration of Cloud Services. In FY 2015, the additional $4.1M in funding will support the annualized costs of operating and maintaining the three TIC sites as well as continuing with the VPN migration efforts and the integration of Cloud Services activities.

Endpoint Protection Security Tools ($4.300 M): The request is at the same level as the FY 2014 Enacted and as threats continue to evolve from new variations of malicious software used by attackers, HHS will continue to enhance the IT security at the OpDivs 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. The implementation of Network Access Control (NAC) was successful and is now providing security and endpoint protection to better secure 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 FY 2015 Budget provides funding 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.

Cybersecurity - Outputs and Outcomes Table

Measure	Year and Most Recent Result/Target for Recent Result (Summary of Result)	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
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 tools).	FY 2013: 89% Target: 90%	95%	95%	0%
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 2013: 45% Target: 90%	95%	95%	0%
Vulnerability management: Percentage of IT assets covered by automated vulnerability management, using security continuous monitoring automated tools.	FY 2013: 58% Target: 90%	95%	95%	0%
Boundary protection: Percentage of HHS network connections to the Internet in compliance with TIC implementation requirements.	FY 2013: 0% Target: 75%	100%	100%	0%
FISMA System Inventory Compliance: Percentage of systems with current Security Authorization to Operate (ATO)	FY 2013: 89% Target: 95%	95%	95%	0%

ASSISTANT SECRETARY FOR ADMINISTRATION
Office of Security and Strategic Information

Budget Summary
(Dollars in Thousands)

Office of Security and Strategic Information	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	6,118	6,118	7,470	+1,352
FTE	33	33	33	-

Authorizing Legislation:
Allocation Method……..Direct Federal

Program Description and Accomplishments
The Office of Security and Strategic Information (OSSI) manages department-wide security programs to protect HHS personnel, facilities, assets, and sensitive information from internal or external threats, and integrates strategic information into policy and operational decisions to safeguard the nation's health and well-being. Funding directly supports the Directorate for Intelligence and Counterintelligence, which includes the HHS Defensive Counterintelligence (CI) and Insider Threat Program and ensures coordination across the operating divisions for the integration of mission impacting information and safeguards.

The Secretary of Health and Human Services (HHS) designated OSSI as a Federal Intelligence Coordinating Office (FICO). In this capacity, OSSI manages the sharing and safeguarding of classified national security information across HHS and with the Office of the Director of National Intelligence (ODNI) and its component agencies within the Intelligence Community. OSSI integrates and synthesizes information on terrorism, weapons of mass destruction, global health threats, and homeland security to support HHS missions, enhance national security, and help keep Americans safe. This operational responsibility is in support of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Executive Order 13587, *Structural Reforms to Improve the Security of Classified Networks and the Responsible Sharing and Safeguarding of Classified Information*, and other orders, directives and policy guidance.

Beginning with the 2011 Strategic Risk Assessment conducted in collaboration with the ODNI, Office of the National Counterintelligence Executive (ONCIX), OSSI has continued to identify the risks and vulnerabilities posing a threat to HHS operational missions. OSSI findings, which are based upon extensive reviews and interviews of the major operating divisions across HHS, continue to reveal that the Department is a soft target and viable venue ripe for exploitation by hostile elements, including foreign intelligence services (FIS), insider threats, criminal activities and other threats to our national security. These findings were again recently emphasized by the Executive Director of ONCIX in the annual review of the HHS Counterintelligence Program Summary of Findings dated, 07 February 2013, #NCIX-051-13:

> *"… although much of the work undertaken by HHS is unclassified, I believe that our adversaries, including FIS, are using sophisticated intelligence tradecraft to target HHS plans, research, and other sensitive information in your operating divisions. A proactive and well-resourced CI*

program, working in tandem with an equally effective security program, is essential to counter these efforts and protect both the vital classified and unclassified programs in HHS."

In order to fulfill these critical national security mandates and facilitate mitigation strategies, HHS senior leadership continues to take the necessary steps to address the ODNI concerns and reorganize its departmental security components to achieve operational efficiencies and ensure protocols are being implemented to guard against these risks and vulnerabilities and future threats. As a critical component to the security reorganization, the Secretary established a Deputy Assistant Secretary for Security (DAS Security) who leads OSSI and also serves as the Secretary's Senior Intelligence Official. The DAS Security serves as the principal advisor to and representative of the Secretary and Deputy Secretary on national security matters, physical and personnel security policy, security awareness, classified information security, and related medical, public health, and biomedical strategic information matters. OSSI has Department wide programmatic responsibility impacting over 83,500 federal employees for all aspects of security and intelligence programs and policies in addition to ensuring coordination across the operating divisions for the integration of mission impacting information and safeguards.

In FY 2013, OSSI has streamlined processes, defined program functions, and hired critical personnel to implement the necessary changes to fulfill these national security requirements and Department wide policies have been drafted and implemented. The reorganization has generated operational efficiencies for the intelligence and counterintelligence programs in the near term. However, in order to advance these critical programs to the next operational level for further integration and implementation across HHS, specific elements of these programs require funding to enhance capabilities, acquire IT solutions for augmenting analytical capabilities, and supplementing personnel resources to manage the multiple facets of the programs. The complexity and sensitivity of these programs require personnel with specific skill sets, including intelligence, counterintelligence and cyber threat analysis, to ensure its successful implementation. OSSI is the Department's central conduit for the establishment and implementation of an integrated defensive counterintelligence and insider threat program across the operating divisions which do not have resident programs or have nascent capabilities. OSSI is comprised of the Security Directorate and the Intelligence and Counterintelligence Directorate:

- **OSSI Security Directorate**: OSSI coordinates personnel security, security access management, and physical security programs across the Department. OSSI provides policy oversight, manages the accreditation program for implementation of HSPD-12, and directs the HHS critical infrastructure program. Based on the various duties, these security programs are resourced either by General Departmental Management (GDM) or the Service and Supply Fund (SSF), all non-PHSSEF funds.

- **OSSI Intelligence & Counterintelligence Directorate:** OSSI serves as a Federal Intelligence Coordinating Office and manages all intelligence and defensive counterintelligence activities for the Department. These programs are resourced with PHSSEF funds.

Operational Environment

HHS is a primary target for cyber-attacks, theft of intellectual property, technical data or sensitive information. HHS is the leader in the U.S. for medical research, medical product and pharmaceutical regulation. In addition, HHS administers billions of program dollars supporting health and human services programs domestically and internationally, and is the principal repository for personal medical and health related data. HHS personnel conduct health investigations and emergency response operations, speak at conferences and planning meetings, provide oversight of foreign food processing

and pharmaceutical facilities, and perform many other critical missions. To foster sound, sustained advances in medicine, public health, and social services, HHS personnel work side-by-side in laboratory and research facilities with lead scientists and student trainees from other nations. Increasingly, the Department exchanges a wealth of valuable health information via an open government IT systems environment.

Recent press reporting indicates the United States continues to experience computer intrusions resulting in loss of sensitive information and potentially compromising the integrity of data. Cyber insecurity is a major part of the problem, but HHS is also vulnerable to a wide range of national security threats, from insider theft of sensitive information to foreign intelligence elicitation of our personnel. Breaches in the Department's ability to defend our critical assets pose a risk to HHS missions, and also represent a significant hazard for the nation. Loss of economic advantage could result from the inadvertent or intentional release of HHS proprietary information or sensitive data on new biotechnologies or other health-related research. Sensitive information on stockpiles of medical countermeasures or actual samples of select biological agents, if stolen, could be used by our adversaries in efforts to conduct a terrorist or a homegrown violent extremist attack. These and other critical assets represent key HHS mission areas requiring vigilant security management.

OSSI synthesizes information, shares ideas, and works collaboratively with multiple partners and stakeholders both domestically and internationally to enhance the health and well-being of Americans in support of HHS global missions. Enabling the Department's national and global missions necessitates OSSI work with the operating and staff divisions to ensure the security of our personnel, IT systems, and critical infrastructure. The OSSI Intelligence & Counterintelligence Directorate includes a cadre of intelligence analysts, counterintelligence officers, scientific technical experts in various chemical, biological, radiological, or nuclear areas who facilitate the cultivation, exploitation, analysis and dissemination of information and intelligence to senior leadership and the operating divisions to integrate into their decision making processes.

The OSSI Intelligence and Counterintelligence Directorate provides policy guidance and manages the Department's programs for intelligence and counterintelligence, which encompasses the analysis and integration of classified and unclassified information on the numerous programmatic areas addressed by the operating divisions across HHS. These include identification and analysis of national security threats from terrorism, weapons of mass destruction or naturally occurring health threats, management of classified and secure facilities, coordination with federal agencies and partners via the Information Sharing Environment, and defensive counterintelligence initiatives. The HHS defensive CI program integrates key elements to identify and stem potential vulnerabilities to our operating environment: monitors foreign visitors and foreign travel, conducts inquiries and assessments, and analyzes supply chain risk, and implements mitigation strategies and actions to defend against insider or external threats.

Where appropriate, OSSI provides scientific assessments to the intelligence and federal law enforcement communities. OSSI, to the extent possible, incorporates information and representatives from stakeholder organizations into its work. In addition, OSSI represents HHS on the National Security Council committees responsible for interagency coordination on security threats and intelligence issues, including the sharing and safeguarding of national security information. OSSI also 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 training for the workforce, classified information management, and related medical, public health, and biomedical information matters. OSSI has Department-wide responsibility for coordination,

convergence, and oversight of all aspects of integration of national security information, including classified and unclassified intelligence, into HHS policy decisions. As a member of the White House Information Sharing and Access, Interagency Policy Committee, OSSI ensures full Department compliance with information sharing policies, procedures, guidelines, rules, and standards. Through a delegation of authority from the Secretary, OSSI has original classification authority for national security information and material produced by any HHS component.

Funding History

Fiscal Year	Amount
FY 2011	$7,428,000
FY 2012	$6,448,000
FY 2013	$6,118,000
FY 2014	$6,118,000
FY 2015 PB	$7,470,000

Budget Request

The FY 2015 request for OSSI is $7,470,000, which is an increase of $1,352,000 above the FY 2014 enacted appropriation.

This budget request will provide the necessary support to the HHS Defensive Counterintelligence Program initiatives commenced in FY 2012 and FY 2013, including the HHS Foreign Visitor Program, the HHS Foreign Travel Program, and the new initiatives which have been integrated as a direct result of counterintelligence cases, the Cyber Threat Analysis Unit, the Supply Chain Program, and the Suspicious Activity Reporting Program. This increase also accounts for the additional need to meet budgetary demands to support growth in secured IT system expenses, and needed program expansions, with increased users' the increase is direct reflection for additional operations and maintenance funding, along with added maintenance of newly acquired case management system, program continues to see a continued jump in cost of over 70% from FY2013 through FY 2014. OSSI must rely on across Department maintenance and support for secured networks and costs to continue use of these secured networks systems.

OSSI has taken significant strides over the past two fiscal years to ensure that a security awareness and culture is instilled across HHS. The improvements are a result of OSSI recognizing its mission goals in fulfilling the numerous presidential directives, and national security directives and requirements and will result in affecting the scientific and Public Health and Secretarial objectives/goals. At this level, higher priority is directed toward counterintelligence initiatives such as suspicious activity reporting and CI inquiries will be funded. The Department's operating and staff divisions rely on OSSI to provide counterintelligence expertise; for those divisions that do not have the funding for an internal CI program, OSSI will perform those activities required to ensure risks are mitigated and HHS equities are safeguarded.

The security, intelligence, and counterintelligence programs managed by the OSSI enable a nation-wide Departmental response capability that also provides senior leadership with science-based, intelligence-informed, threat reporting. This effort works to prevent security breaches from HHS that could raise major concerns for the Secretary and create questions about the Department's ability to safeguard its personnel and information, and its ability to protect our National Security interests. In

addition, vulnerabilities the Department fails to characterize and address can create vulnerabilities in other Departments or Agencies.

OSSI is also working with the HHS operating and staff divisions to conduct counterintelligence inquiries and assessments to resolve allegations or suspicions actions by, or on behalf of, foreign entities. OSSI is developing protocols for suspicious activity reporting and guidelines for case management to preserve the potential for follow-on FBI or the Office of the Inspector General (OIG) actions, as appropriate. In addition, OSSI CI inquiries and assessments seek to identify insider (lone wolf) threats to HHS personnel, critical infrastructure and IT systems. CI inquiries and assessments discover the facts and convey them to decision makers and maintain a full range of Departmental response options, including support of the OIG during investigations.

Operational Activities Supported by OSSI:

1. **Defensive Counterintelligence Program**
   Results of OSSI CI inquiries and assessments 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.

   - **OSSI Support to Operating Divisions at Headquarters & Regions:** OSSI provides centralized and direct support to all operating elements under HHS for the defensive Counterintelligence Program. The Department's operating divisions rely on OSSI to provide counterintelligence expertise, fact-finding, analytical support and training. OSSI serves as the central point for managing and providing the critical oversight necessary for the integration of a defensive counterintelligence program.

     - The HHS defensive Counterintelligence Program is centrally managed to ensure the proper technical expertise is applied, the highest level accountability is implemented, and most importantly information sharing occurs across senior leadership and the operating divisions in a consistent and timely manner. Key stakeholders in the regional sites supported by OSSI include ASPR, FDA, CDC, and CMS. All of these operating divisions have and will continue to require the critical support provided by the OSSI Counterintelligence Program in order to fulfill their operational mandates which range from preparedness and response missions, to the safeguarding of our sensitive research laboratories and pharmaceutical studies, to the protection of the review and payments of Medicare and Medicaid benefits.

     - OSSI aggregates and analyzes the information and intelligence to support the assessments and inquiries being conducted by the operating divisions. For those operating divisions that do not have the funding for an internal CI program, OSSI will perform those activities required to ensure risks are mitigated and HHS equities are safeguarded. Once again, if the operating division does not have an internal capacity to support defensive counterintelligence activities, OSSI has been and will continue to be the primary instrument to perform those duties from inception to the ultimate closing of the assessment. These activities are resource intensive and require not only personnel support, but also the analytical tools, liaisons and databases to effectively generate the desired results.

- **Counterintelligence Inquiries and Assessments File Management:** OSSI is responsible for counterintelligence file management for the Immediate Office of the Secretary, the HHS staff divisions, and any HHS operating divisions that do not have an OSSI reviewed and designated defensive CI Program. The OSSI, Division of Intelligence and Counterintelligence, Associate Director for the Counterintelligence Division, is responsible for the oversight and overall file management of CI assessments to include the opening and closing of assessments and cases. In an operating or staff division that does not have a fully established CI program; OSSI will assist the division and facilitate the coordination of resources to complete the investigation in the most expeditious manner. The OSSI Director of Intelligence and Counterintelligence reviews the memorandums that requests an assessment be opened to ensure cases are aligned with the intent of the Department's Counterintelligence Program. This level of review and accountability ensures that OSSI is capturing threats and areas of concern posing risks to the HHS operational mission, while ensuring cases are being opened in a manner consistent with departmental policy. The Counterintelligence Program is labor intensive and as has already been demonstrated during FY13 to date. For example, as employees become aware of insider threats through OSSI outreach visits and training, there has been an increase in the number of assessments that opened and reviewed to ensure that risks are being addressed and mitigated in a timely manner.

2. Insider Threat Program

- **HHS Foreign Travel Briefs**: OSSI funding will support the continued development and maintenance of the HHS foreign travel briefings and monitoring. The CI program is using existing GovTrip or equivalent software to identify personnel requiring foreign travel briefings, as well as advance reporting by the operating and staff divisions through daily coordination efforts. The program is labor intensive because it requires both pre- and post-travel briefings, analytical assessments, and trend reporting. The 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. Foreign travel briefing program requires that:

    - HHS policy provides a mechanism to address the more than 10,000 trips per year undertaken by HHS employees.
    - Foreign travel briefs are conducted with applicable personnel on a regular and recurring basis and information of value should be disseminated in a timely manner.
    - Pre and post travel contact procedures are clearly delineated to facilitate information exchanges between official HHS travelers and communities of interest.
    - Post travel instruction and expectation sheets are provided to the traveler and then the information is analyzed for anomalies or other indicators of concern.
    - Post travel interviews are scheduled with a minimum of 90 minute time slots to allow for the greatest flexibility in discussions and to facilitate the maximum amount of information gathering about the activities of interest without requiring a second round of interviews which may inconvenience the busy traveler.
    - Contract staff will be responsible for 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.

- OSSI continue to provide formalized scheduling and contact procedures.

- **Foreign Visitor Tracking System**: OSSI funding supports CI initiatives related to tracking foreign visitors to HHS facilities and monitoring trends. This information will be used to build CI training modules for HHS personnel in order to raise awareness on potential threats and vulnerabilities to HHS personnel, IT systems, and critical infrastructure. Expansion of these modules will be necessary to ensure that Department wide information can be fed into the centralized system so as to be able to capture and share trends and patterns across the operating divisions. The Foreign Visitor Tracking System meets all accreditations and FISMA requirements and has been in existence since 2005. Current Federal customers include US Army at Redstone Arsenal, USAF at Eglin AFB, NASA, and most recently, National Institutes of Health (NIH). Currently the system tracks credentials, personnel, and individual visitors as well as maintains a log of their visits to multiple locations. It also allows for the screening of all known organizations and subordinate organizations affiliated with criminal and terrorist organizations. The Foreign Visitor Tracking System screens:

  - All terrorist watch group lists (DHS, TSA, CIS), FBI terrorist watch lists, Department of the Treasury - Office of Foreign Assets Control (OFAC) lists, INTERPOL lists, etc.
  - The State Department's list of countries listed as Sponsors of State Terrorism and allows HHS to modify the list according to the threats that have been detected and corroborated.

- **Risk Assessments:** In integral factor within an Insider Threat Program is the integration of the information or intelligence gleaned from risk assessments. Risk assessments are dual-faceted under an Insider Threat Program and they focus on two key areas: 1) risk assessments which evaluate the quality and effectiveness of physical security in and around HHS buildings and facilities that are either government-owned, leased or managed; and 2) counterintelligence risk assessments which examine threat information and identify organizational vulnerabilities to make informed determinations about the likelihood and consequence of the loss or compromise of critical assets. Critical assets are defined as any resource, whether a person, group, relationship, instrument, installation, process, or supply, at the disposition of an organization for use in supporting its operational mission. The Insider Threat Program needs to integrate the risk assessment function into the overall framework which identifies and feeds tactical and operational level information posing risks to the mission of HHS. Presently the program is lacking this function which is critical to ensuring the direct information gathering and flow of potential threats across the Department.

3. Cyber Threat Analysis & Forensics Unit

OSSI is establishing capabilities to analyze cyber threat intelligence and is working with HHS Office of the Chief Information Officer (OCIO), Computer Security Incident Response Center (CSIRC), and the HHS operating divisions to conduct classified analysis and forensics for foreign attempts to perform cyber-attacks, intrusions, or exfiltrate and/or alter HHS data. OSSI has established an integrated program that will afford and maintain capabilities to provide intelligence support, counterintelligence analysis, and cyber forensic technical skill sets for the HHS Cybersecurity efforts. The OSSI Cyber Forensics Team will be providing oversight of the Department's cyber incident prevention, warning, detection, forensics, response, and remediation, in direct coordination and collaboration with the OCIO and the CSIRC.

- **Cyber Forensic Software, Equipment & Tools:** OSSI's expanding requirements to support classified cyber threat analysis and forensics requires updates and operations/maintenance

funds to support HHS access to secure IT systems, including the Joint Worldwide Intelligence Communications System (JWICS), Secure Internet Protocol Router Network (SIPRNET) and the Homeland Security Data Network (HSDN), which are used to monitor intelligence on all threat reporting, including 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.

- **Secure Facilities for Integration of Cyber Capabilities**: OSSI analysis and classified information sharing across the Department requires access to secure compartmented information facilities (SCIF) and secure video teleconference capabilities. OSSI is enhancing work facilities share space with the OCIO to conduct real time classified cyber threat intelligence analysis and forensics on foreign attempts to exfiltrate and/or alter HHS data or systems. The addition of the SCIF will require the allocation of an additional full time personnel resource (GS-132-9/11), to serve as an SSO to monitor and safeguard the integrity of the secure facility. The primary responsibility rests with OSSI who will rotate the on-site monitoring and physical safeguarding responsibility of the SCIF among existing OSSI personnel with ad hoc assistance from the OCIO. This will detract and drain resources from performing their day to day analytical duties and operational support to the operating divisions.

4. Supply Chain and Acquisition Risk

This counterintelligence initiative focuses on procurements and acquisitions in advance to identify concerns related to foreign ownership control and influence and attempts to reduce the risk of adversarial exploitation of our supply chain. There is a heightened threat and potential compromise to the supply chain due to the growing speed, scale, and complexity of the distributed global supply chain. To achieve cost efficiencies and innovations, HHS as do most government agencies, rely on commercial information technology, communication, and other aspects of private industry for components, supplies, and services that support mission-critical networks, systems, and innovative research. HHS critical assets and infrastructure include sensitive technologies, key resources, medical and scientific data, networks, and intellectual property, all of which are vulnerable during their entire lifecycle – from the research and development stages, through acquisition, and into the manufacturing and deployment phases. HHS operating divisions fund sensitive and proprietary innovative research and development and the results could be compromised, transferred overseas, and incorporated into foreign products for sale to the U.S. markets impacting the national security and economic interests.

- **Support to Operating Divisions:** OSSI supports the operational divisions supply chain concerns and initiatives by cultivating information to reduce the acquisition of products and services including:

  - The Office of the Chief Information Officer (OCIO) areas of concern focus on IT related products presenting cyber threats in the form of malicious software or untrustworthy computer media or equipment.

  - The Food and Drug Administration (FDA) integrity program focuses on the pharmaceutical supply chain and manufacturing threats which can include counterfeit materials and substandard manufacturing processes.

- The Center for Medicare and Medicaid Services (CMS) areas of concern involve the procurement and contracting of services for the first level qualified independent contractors (QICs) reviewing benefits claims, as well as the second level procurement for qualified independent contractors.

- Procurement and Acquisitions management areas of concern are directly related to the reviewing of sensitive acquisitions in advance for possible Foreign Ownership Control and Influence (FOCI) and the risk of potential adversarial exploitation of our supply chain across HHS.

- **Analytical Software, Research Tools and Databases:** OSSI directly or indirectly supports the operational divisions supply chain concerns and initiatives. In order to properly aggregate and compile all source information and intelligence, OSSI needs to have the in-house resident capability and access to several private and commercial databases and data sources which can provide the critical domestic and international business data for the analysis of potential FOCI and suspect links in the supply chain impacting HHS equities.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Division of the Civilian Volunteer Medical Reserve Corps

Budget Summary

(Dollars in Thousands)

Division of the Civilian Volunteer Medical Reserve Corps	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	10,672	10,672	8,979	-1,648
FTE	7	7	7	-

Authorizing Legislation: Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
FY 2014 Authorization……Indefinite
Allocation Method……Direct Federal; Contract; and Cooperative Agreement

Program Description and Accomplishments

The Medical Reserve Corps (MRC) was established by the Office of the Surgeon General (OSG) within the HHS Office of the Assistant Secretary for Health (OASH) as a demonstration project in March 2002. The MRC was initially authorized by Congress in the 2006 Pandemic and All-Hazards Preparedness Act and reauthorized in the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA). The PAHPRA legislation assigned authority over and responsibility for the MRC to the Assistant Secretary for Preparedness and Response (ASPR). A Memorandum of Understanding was developed between ASPR and OASH in 2013 to establish a unified, strategic approach for MRC operations and outline the roles and responsibilities of OASH, OSG and ASPR to support and coordinate program operations and policies.

The MRC is a national network of volunteers, organized in local community-based groups and committed to strengthening public health, reducing vulnerabilities, improving local preparedness, response and recovery capabilities, and building community resilience. MRC volunteers include medical and public health professionals, and non-medical volunteers. MRC units have mechanisms in place to identify, screen, train, and organize the volunteers to support routine local public health activities and augment emergency preparedness and response efforts. In addition, MRC units help locally to support HHS public health initiatives such as the Million Hearts campaign and "Let's Move!" In FY 2013, over 980 MRC units with more than 200,000 volunteers in all 50 states, the District of Columbia, and most territories participated in and reported almost 16,000 activities, including 4,544 training; 2,620 public health; 2,489 community preparedness and 1,499 emergency response activities.

Within the OSG, the Division of the Civilian Volunteer Medical Reserve Corps (DCVMRC) coordinates support for the MRC network, and functions as a clearinghouse for information and guidance to help communities establish, implement, and sustain local MRC units nationwide. Additionally, DCVMRC manages strategic planning, intra- and interagency coordination, communications, policy development, program operations, grants management, contract oversight, technical assistance, training and response operations for the MRC program. The PAHPRA legislation gave "authority over and responsibility for" the MRC to the Assistant Secretary for Preparedness and Response (ASPR). A Memorandum of Understanding was developed in 2013 to establish a unified, strategic approach for MRC's operations and outline the roles and responsibilities of OASH, OSG and ASPR to support and coordinate program operations and policies.

DCVMRC works with a wide range of organizations to achieve its mission, including:

- National Association of County and City Health Officials (NACCHO) – a cooperative agreement assists with capacity building for local MRC units, and increase awareness and understanding of the MRC through their communications, outreach and marketing efforts.
- ICF – a program support and technical assistance contract provides support for the MRC network at the national, regional, state and local levels, and includes regional coordination, operations, communications, IT, technical assistance and outreach support.
- Centers for Disease Control and Prevention (CDC) – an Interagency Agreement with CDC funds the Public Health Foundation to support MRC-Train (a learning management resource offered to all MRC units).

The MRC program has seen significant growth since 2002, both in the number of units and in the number of volunteers. In recent years, the rate of growth has leveled off as the network is nearing coverage of approximately 90% of the US population.

	New MRC Units	Total Number of MRC Units	Total Number of Volunteers
FY 2008	103	787	168,996
FY 2009	90	856	189,245
FY 2010	101	940	210,114
FY 2011	45	967	202,801
FY 2012	43	980	206,930
FY 2013	**36**	**978**	**205,920**

The following table provides a summary of the type and number of activities reported by MRC units:

Activity Focus	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Unit Development	921	1,054	1,866	3,535	4,820
Preparedness	1,576	1,496	1,695	2,124	2,489
Public Health	1,121	2,819	1,845	2,200	2,620
Response	774	1,834	997	1,173	1,499
Training	2,076	2,241	2,951	3,775	4,544
Total	**6,468**	**9,444**	**9,354**	**12,807**	**15,972**

Accomplishments in FY 2013 include:

- Launch of *MRC Factors for Success*, a comprehensive set of expectations and performance measures that MRC unit leaders can follow to develop their MRC units. Resources, including guidance, templates and links, are included to assist unit leaders achieve their goals and improve the sustainability of the unit.
- Support for the Secretary's priority to "Protect Americans' Health and Safety during Emergencies, and Foster Resilience in Response to Emergencies," through:
    - Over 150 MRC units and more than 3,300 MRC volunteers contributing to local preparedness, response and recovery efforts related to Hurricane Sandy. These volunteers supported sheltering operations, provided health education and emergency communications support, and augmented staffing to local hospitals, emergency management agencies, and public health departments.

- Fourteen MRC units supplied over 250 volunteers (both medical and non-medical) to the Boston Athletic Association to provide medical and other support for the Boston Marathon – in medical tents along the route and at the finish line. These volunteers were there to provide first aid and other assistance to the runners and spectators, but following the explosions, they were prepared and capable of delivering emergency first aid, helping to transport the injured, staffing temporary shelters and providing mental health support to those affected by the event.

- Three MRC Seasonal Leadership and Training Summits at which more than 500 MRC leaders were trained in topics such as disaster risk reduction, strategic road mapping, youth engagement, and sustainability planning to improve the quality and sustainability of the local MRC units.

Funding History

Fiscal Year	Amount
FY 2011	$11,925,000
FY 2012	$11,247,000
FY 2013	$10,672,000
FY 2014	$10,672,000
FY 2015 PB	$8,979,000

Budget Request

The FY 2015 President's Budget request is $8,979,000, which is -$1,648,000 less than FY 2014 Enacted Level. The FY 2015 request will continue to primarily support the cooperative agreement with the NACCHO and program support/assistance to MRC units through technical assistance, leadership training, networking opportunities, communications, and other assistance. Additionally, efforts will continue to reduce various administrative costs as outlined by the President's Executive Order 13589 – Promoting Efficient Spending: travel, information technology devices, printing, promotional items, and other opportunities.

Division of the Civilian Medical Reserve Corps - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
1.1 The acceptance of the MRC concept across the country is shown by the continued recruitment and retention of community members as MRC volunteers (# of MRC volunteers).	FY 2013: 205,920 Target: 205,000 (Target Exceeded)	205,000	205,000	0
1.2 MRC units participate in (and report) activities that strengthen local public health and improve emergency preparedness and response capabilities, such as supporting flu immunization clinics, screening for chronic diseases, promoting healthy lifestyles, assisting with National Preparedness Month events, training volunteers, and responding to local emergencies as needed. (# of activities reported).	FY 2013: 15,972 Target: 11,000 (Target Exceeded)	12,000	13,000	+1,000

Program/Measure	Most Recent Result	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
2.1 The MRC website is an important source of information for MRC leaders, volunteers and others (# of MRC website visits).	FY 2013: 355,143 Target: 270,000 (Target Exceeded)	300,000	310,000	+10,000
2.2 DCVMRC has provided guidance documents and training to assist with strategic planning, and has encouraged all MRC units to engage in strategic planning processes. (% MRC units indicating that they engage in strategic planning)	FY 2013: 80% Target: 80% (Target Met)	81%	82%	+1%

Performance Analysis

MRC is aligned with broader HHS and OASH Priorities:

- Creating Better Systems of Prevention: Local Medical Reserve Corps units are encouraged to conduct and support activities that address ongoing public health priorities and improve prevention efforts, such as childhood obesity and healthy lifestyle education, diabetes detection, hypertension screening, and flu immunizations.

- Eliminating Health Disparities: Local Medical Reserve Corps units are encouraged to conduct and support activities that address health disparities that occur by race and ethnicity, gender, education, income, geographic location, disability status, or sexual orientation.

- Protect the Health and Safety of Americans in Public Health Emergencies: Local Medical Reserve Corps units are encouraged to conduct and support activities that enable their community to prepare and respond to emergencies.

The MRC remains a strong, viable network of volunteers that are assisting their communities on a regular/daily basis. This is shown in the increasing numbers and breadth of reported activities. The program has seen significant growth since its inception in 2002, in both the number of units and in the number of volunteers, and while the rate of growth has begun to decrease, this is a positive sign as currently over 90% of the US population is in a jurisdiction covered by an MRC unit. While maintaining the volunteer base will always be a priority, the DCVMRC will focus on ways to improve the capabilities of MRC leaders and increase the sustainability of the nationwide MRC network. DCVMRC will continue to support MRC leaders, units, and volunteers through technical assistance, leadership training, networking opportunities, communications, funding and other necessary assistance.

PANDEMIC INFLUENZA

Budget Summary
(Dollars in Thousands)

Pandemic Influenza	FY 2013 Final *	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Budget Authority	-	115,009	170,009	+55,000
X-year (non-add)	-	*83,000*	*140,000*	*+57,000*
Annual (non-add)	-	*32,009*	*30,009*	*-2,000*
FTE	12	13	13	-

**FTE funding was provided by Pandemic Influenza carryover balances.*

Authorizing Legislation:
FY 2014 Authorization……Indefinite
Allocation Method……Direct Federal/Intramural, Contracts, Formula Grants/Cooperative Agreements, Competitive Grants/Cooperative Agreements, and Other

Program Description and Accomplishments

Influenza and other emerging infectious diseases with pandemic potential continue to mutate, evolve, and infect animals and humans, which pose continued significant threats to global public health and to the United States. To be prepared, HHS must invest in domestic pandemic preparedness efforts and work with key global partners to prepare for, prevent, detect, and respond to emerging pandemic threats.

HHS has made significant progress in enhancing pandemic preparedness for our nation and with international partners. Over the past few years, promising strides were made in the advanced development of high throughput rapid diagnostics, the development and production of seasonal, H5N1, and H7N9 vaccine seed strains, and new antigen-sparing adjuvants. The United States also has expanded domestic vaccine manufacturing surge capacity using nimble and flexible approaches coupled with modern manufacturing technologies. In addition, HHS continues to work with states to enhance their pandemic preparedness.

Since 2005, HHS has been funding the first stage of pandemic preparedness activities, including:

- Expanding and diversifying domestic vaccine production and surge capacity;
- Establishing and maintaining H5N1 pre-pandemic vaccine and antiviral drug stockpiles;
- Supporting optimization of high production yielding influenza vaccine seed strains and development of alternative vaccine potency and sterility assays to expedite influenza vaccine availability;
- Supporting advanced development and U.S. licensure of cell- and recombinant-based influenza vaccines and development of antigen sparing influenza vaccines and novel antiviral drugs towards U.S. approval;

- Conducting advanced development and Food and Drug Administration (FDA) clearance of point-of-care clinical diagnostics;

- Supporting development and FDA clearance of next generation portable ventilators;

- Stockpiling medical supplies and ventilators;

- Improving state and local preparedness;

- Expanding risk communication efforts;

- Enhancing FDA's regulatory science base;

- Increasing pandemic vaccine manufacturing capacity and enhancing manufacturing technical knowledge and capabilities in developing countries; and

- Expanding surveillance, research, and international collaboration efforts of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Office of the Assistant Secretary for Preparedness and Response (ASPR), and the Office of Global Affairs (OGA).

Recent Accomplishments that Strengthened Pandemic Influenza Preparedness
Following the release of the Department's *2010 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review* and the President's Council of Advisors on Science and Technology's (PCAST) *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* in August 2010, HHS took steps to efficiently execute the pandemic influenza preparedness priorities enumerated in the review.

Recent accomplishments include:

- ***Cell-based influenza vaccine:*** In November 2012, FDA licensed Novartis' Flucelvax, the first cell-based influenza vaccine in the United States. ASPR's Biomedical Advanced Research and Development Authority (BARDA) supported the development of this vaccine towards licensure and partnered with Novartis to build a state-of-the art domestic cell-based vaccine manufacturing facility that won the International Society for Pharmaceutical Engineering 2013 Best in Class Award for Process Innovation and Overall Winner for Best Pharmaceutical Facility in 2013. This achievement marked a significant milestone towards one of the major vaccine goals in the National Strategy for Pandemic Influenza (2005) by moving an incumbent vaccine industry from old technology towards a more rapid and reliable manufacturing platform. Additionally, Baxter submitted a Biologics License Application (BLA) to FDA in December 2013 for licensure of their cell-based seasonal influenza vaccine that BARDA has supported since 2006.

  In addition to improved reliability of raw material supply, more rapid and greater scalability, and more flexible manufacturing scheduling, cell-based influenza vaccines may be much closer in genetic and antigenic identity to circulating influenza viruses than their egg-based vaccine counterparts (as evidenced in 2013 by antigenic cartographic analysis of H3N2 vaccines). This new advantage with cell-based influenza vaccines may afford more effective vaccines for seasonal outbreaks. In addition, it will strengthen the nation's ability to produce a higher

volume of vaccines during an influenza pandemic in a shorter amount of time. Building upon this progress, cell-based influenza vaccine candidates are also under development as part of the current H7N9 vaccine response.

- ***Recombinant Vaccine:*** In January 2013, FDA licensed Protein Sciences' Flublok recombinant-based vaccine for seasonal influenza. BARDA supported the development of this recombinant-based vaccine since 2009 for seasonal and pandemic purposes. This is the first recombinant-based influenza vaccine licensed in the United States. It is essential to providing a more efficient and effective vaccine sooner for influenza pandemic as well as seasonal epidemics. Recombinant-based influenza vaccine candidates are also under development as part of the current H7N9 vaccine response.

- ***Expanded domestic influenza vaccine manufacturing surge capacity:*** To alleviate the paucity of domestic influenza vaccine manufacturing experienced in 2004-2005, BARDA supported the retrofitting of domestic manufacturing facilities for two companies as public-private partnerships to expand U.S. vaccine production capacity. Through this program, the vaccine manufacturing production of live, attenuated influenza vaccine was doubled in time to deliver vaccine for the 2009 H1N1 influenza pandemic. In 2012, the retrofitting of the second vaccine production facility was completed. This upgrade resulted in a nearly 50 percent increase in the influenza vaccine manufacturing capacity of this manufacturer.

- ***Innovation in advanced development and manufacturing:*** To fulfill one of the recommended initiatives in the Secretary's *2010 PHEMCE Review* and the PCAST report on influenza vaccine technology (2010), BARDA established three Centers of Innovation for Advanced Development and Manufacturing (CIADM). The Centers will provide on a routine basis advanced development and manufacturing assistance to developers of medical countermeasures (MCMs) for chemical, biological, radiological, and nuclear (CBRN) threats. The Centers will also be available to manufacture pandemic influenza vaccine in an emergency. These Centers will become operational beginning in FY 2014.

- ***Expedited vaccine availability:*** In September 2010, BARDA led a HHS initiative, with academia and industry partners, to improve influenza vaccine manufacturing and make vaccines available sooner. Support was directed toward optimization of high production yield vaccine seed strains and development of alternative novel vaccine potency and sterility assays. Using synthetic biology and novel reverse genetics donor partners, influenza vaccine seed strains, including H7N9 seeds, were available in fewer than 10 days as compared to weeks by classical methods. New sterility assays developed under this initiative have shortened assay time from 14 to 5 days. Alternative potency assays such as enzyme-linked immunosorbent assay (ELISA) and mass spectrometric assays are under evaluation with industry partners during the current H7N9 vaccine response.

- ***Expansion of vaccine capacity through the use of adjuvants:*** In November 2013, FDA licensed GlaxoSmithKline's Q-PAN H5N1 pandemic vaccine with AS03 adjuvant, which BARDA supported since 2007. This was the first adjuvanted pandemic influenza vaccine licensed in the United States. 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.

The effects of these adjuvants on H7N9 vaccine immunity are currently under evaluation as a part of the overall response.

- ***Addressing influenza antiviral drug resistance in critically ill populations:*** BARDA supports the advanced development of antiviral drugs for critically ill persons with influenza. There are still too few influenza antiviral drugs with new mechanisms of actions, which reduce drug resistance, and too few combined drug studies have been done. BARDA is supporting advanced development of additional influenza antiviral drugs with novel mechanisms of actions including host targets, easier usage, longer lasting effects, and possible co-administration with other influenza antiviral drugs. These antiviral drug candidates are also under evaluation against H7N9 viruses as part of the overall response.

- ***Simpler point-of-care diagnostics:*** In June 2012, FDA approved a breakthrough product – Simplexa, which is a point-of-care diagnostic device and assay for commercial U.S. marketing that detects influenza and respiratory syncytial viruses. The device can detect viruses in clinical samples within one hour. BARDA supported the development of this novel diagnostic product, which does not require clinical sample preparation.

- ***Development of rapid diagnostics:*** BARDA and CDC jointly began projects to develop rapid diagnostics for detection of seasonal and H5N1 viruses in point-of-care settings by healthcare providers and high throughput settings for use by clinical laboratories. The first 2009 H1N1 clinical case in the United States was detected with the diagnostic device developed under HHS contractual support for product development. FDA has cleared for use a number of technologies developed under these contracts.

- ***Increasing the supply of influenza antiviral drugs for the Strategic National Stockpile (SNS):*** The current national inventory of Federal and state stockpiles of influenza 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 Use Authorization. More than 1,200 persons received this drug during the H1N1 pandemic, and the remaining unused treatment courses are stored in the SNS. With the support of BARDA for the advanced development of peramivir, Biocryst filed a new drug application (NDA) with FDA in December 2013 for treatment of acute uncomplicated cases of influenza. This is the first NDA filed for a novel influenza antiviral drug since the approval of oseltamivir and Relenza in 1999. It advances the ability to deliver influenza antiviral drugs intravenously to hospitalized patients who may not be able to receive oral or inhalable therapeutics to treat influenza infection.

- ***Increasing vaccine manufacturing capacity in developing countries:*** Since 2006, BARDA has collaborated with the World Health Organization (WHO) to support building vaccine manufacturing facilities and training staff in developing countries. To date, more than 11 countries have received funding and training, seven flu vaccines have been licensed, and more than nine clinical trials have been conducted to evaluate pandemic H5N1 and H1N1 vaccine candidates produced in these countries. Four of these manufacturers are also developing H7N9 vaccine candidates to be able to respond against this new virus that is infecting people close to their borders. The current estimate of influenza vaccine manufacturing capacity afforded under this project to date is nearly 300 million vaccine doses in a year. The goal is to achieve manufacturing capacity in these countries of an estimated 500 million doses of pandemic influenza vaccine by 2015.

- ***Enhancing global pandemic preparedness:*** HHS' International Pandemic Influenza activities have substantially contributed to global health diplomacy in countries that are a priority for U.S. foreign policy goals. The Department has coordinated with National Security Council, Department of State (DOS), and other Departments and agencies for policy and technical coordination on international influenza. This coordination also has supported HHS's central leadership role in international influenza preparedness and response with WHO, other multi-lateral and international organizations (e.g. Asia-Pacific Economic Cooperation, the Association of Southeast Asian Nations, Organization of Islamic Cooperation, Developing Country Vaccine Manufacturers Network), and numerous foreign governments – particularly developing countries.

Key achievements include the following:

- Improved regulatory capacity for influenza vaccine safety and effectiveness in five developing countries: Indonesia, Mexico, Vietnam, Serbia, and Thailand;

- Strengthened diplomatic and political support for increased global surge capacity for influenza vaccine manufacturing through increasing sustainable influenza vaccine manufacturing capacity in developing countries;

- Supported the development, piloting, and application of an evidence-based assessment and evaluation tool used to collect longitudinal data in 42 developing countries – documenting the progress being made in increasing knowledge, skills, and capacities in influenza surveillance, response, and preparedness;

- Led logistical implementation of the Federal government's donation of H1N1 pandemic influenza vaccine to WHO, in collaboration with partners, vaccine manufacturers, international transport companies, the U.S. Agency for International Development, DOS, and the WHO; and

- Promoted global health security efforts and provided leadership and policy analysis in interactions with the White House, the WHO, the National Security Council, other Departments and agencies, non-governmental organizations, and bilateral and multilateral partners on multiple inter-related policy issues for global health security, including Countering Biological Threats efforts.

- Improved self-sustainability in developing countries for surveillance, detection and response of influenza and emerging threats affecting their countries and region through efforts directly supported to leverage global political will to make influenza initiatives more sustainable.

Lessons learned from the 2009 H1N1 influenza pandemic: In June 2012, HHS released two documents, *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance all Hazards Preparedness* and the *2009 H1N1 Influenza Improvement Plan.* The *Retrospective* is intended to stimulate discussion within HHS, with other Federal departments, and among other relevant organizations—both governmental and non-governmental—about how to build upon the successful elements of the response and concretely address areas that warrant improvement. The *Improvement Plan* is a refined blueprint that outlines next priorities for those aspects of pandemic influenza preparedness that are influenza-specific. It describes the ways in which those next steps need to be accomplished, informed

by the 2009 H1N1 influenza pandemic experience. Progress on implementing the improvement plan is monitored monthly.

HHS's response to H7N9 has been improved by the lessons learned. For example, new cell- and recombinant-based flu vaccines, generated by the need identified in the response to H1N1, have been licensed in time to respond to H7N9. Secondly, H7N9 vaccine seeds using biosynthetic methods were developed by Novartis as a result of the technology derived from the HHS Influenza Vaccine Manufacturing Improvement initiative to provide vaccines faster. Finally, three Centers were established in 2012. One of the Centers – the Novartis facility in Holly Springs, North Carolina – is playing a major role in H7N9 vaccine development and stockpile manufacturing.

Previous Funding for Pandemic Influenza Preparedness: Since FY 2006, Congress has appropriated $14 billion for pandemic influenza preparedness. In December 2005, Congress appropriated $3.3 billion in emergency supplemental funding for HHS for the first year of the HHS Pandemic Influenza Plan. In June 2006, Congress appropriated another $2.3 billion in emergency supplemental funding for the second year of the plan. In FY 2009, Congress appropriated $507 million for continuing support of pandemic influenza preparedness activities, followed by $7.65 billion for HHS to respond to the 2009 H1N1 influenza pandemic. In FY 2010, Congress appropriated $276 million for continuing support of pandemic influenza preparedness activities. Congress appropriated $65 million for FY 2011 to continue annual activities led by the Office of the Secretary. In FYs 2012 and 2013, all ongoing HHS influenza activities have been funded from existing balances. Congress appropriated $115 million in new funding for FY 2014.

Funding History

Fiscal Year	Amount
FY 2011	$26,179,000
FY 2012	$0
FY 2013	$0
FY 2014	$115,009,000
FY 2015 PB	$170,009,000

Budget Request

The FY 2015 request for the Department's Pandemic Influenza activities is $170,009,000, which is +$55,000,000 above the FY 2014 Enacted level. The request for ASPR totals $166,000,000. It includes $3,000,000 in annual funding for the Office of Policy and Planning's (OPP's) international pandemic preparedness activities and $163,000,000 for BARDA's programs. Of BARDA's total, $23,000,000 is annual funding and $140,000,000 is no-year funding. The BARDA request includes $45,000,000 to support the advanced development of antiviral drug candidates towards licensure and $73,000,000 for the development of new hemagglutinin stalk vaccine candidates for use as universal influenza vaccines. The request for Pandemic Influenza also supports OGA's international pandemic influenza activities by providing $4,009,000 in annual funding.

The FY 2015 Request builds on recent successes in pandemic preparedness. In 2007, during H5N1, the country relied on egg-based vaccines. In 2012, the first cell-based vaccine was approved (Flucelvax). In FY 2013, the first recombinant-based vaccine (Flublok) and the first adjuvanted vaccine (Q-Pan) were approved. The next step is the universal flu vaccine, for which funding is requested for FY 2015.

In recent years, ongoing annual flu activities have been funded exclusively from unobligated balances from previous years' appropriations. However, beginning with the FY 2014 appropriation and continuing with the FY 2015 Request, HHS will need additional funding to complete the goals defined in the *HHS Pandemic Influenza Plan 2005*, maintain national preparedness, and stay ahead of threats like the H7N9 influenza strain.

For FY 2015, the Department's key expenditures will support the following pandemic influenza activities:

- Development of new viral hemagglutinin stalk antigen-derived universal influenza vaccine candidates and existing antigen-sparing adjuvant containing pandemic influenza vaccine candidates; novel antiviral drugs directed against host targets, immunotherapeutics, diagnostic devices, and reusable respirators;

- Maintenance of a network of U.S.-based fill and finish manufacturers to supplement pandemic influenza vaccine manufacturers and to address drug shortages;

- Stockpiling of pre-pandemic influenza vaccines including H5N1 and H7N9 vaccines; and

- International leadership, technical expertise, oversight, policy and program coordination, and global health diplomacy in international pandemic preparedness and response.

Annual Funding Requests for FY 2015 ($30,009,000):

International Influenza Vaccine Manufacturing Infrastructure ($15,000,000): The International Influenza Vaccine Manufacturing program was established by BARDA in 2006 to improve global pandemic preparedness by helping developing countries build and operate in-country vaccine manufacturing facilities to add to the U.S. commitment to provide 10 percent of our pandemic influenza vaccine capacity for international pandemic needs. Since 2006, $59,700,000 has been obligated for this program. This investment has resulted in over $538,000,000 contributed from local governments and developing country manufacturers to achieve the program objectives. The request will support the final steps in completing the objectives of this project to build vaccine manufacturing infrastructure and provide technical training and support to ensure sustainability of this capacity in developing countries. The plan integrates three critical elements:

1. Sharing the costs of building vaccine manufacturing facilities to produce influenza and other vaccines in developing countries;

2. Training personnel from developing countries in U.S.-based vaccine manufacturing training programs on how to operate and regulate these facilities; and

3. Providing in-country assistance on the operation and regulation of these facilities and conducting clinical trials with influenza vaccines produced in these facilities.

ASPR requests $15,000,000 for FY 2015 for the International Influenza Vaccine Manufacturing Infrastructure program. This investment, combined with others, will continue to advance the clinical development of influenza vaccine from at least 11 developing country vaccine manufacturers. This funding level will also help gain licensure of influenza vaccines from at least seven developing country vaccine manufacturers, enhance technical skills and best practices through training in advanced

manufacturing, and provide in-country technical support to ensure sustainable production of high quality vaccine. The goal for the full production capability through this program is 500 million doses of pandemic vaccine from developing country vaccine manufacturers by 2015.

Diagnostics Advanced Development ($8,000,000): BARDA supports manufacturers who are developing novel influenza *in vitro* diagnostic (IVD) technologies and tests including isothermal nucleotide amplification, antiviral drug resistance detection, and specimen collection systems for point-of-care (POC) and near-patient laboratory settings. These diagnostics can rapidly provide health care providers with information affecting clinical management of patients. CDC also has a role in developing diagnostics. However, their role is different. CDC supports the development and manufacture of CDC-derived subtype-specific IVD tests for use in qualified laboratories (domestic and international public health partners). These diagnostic devices confirm seasonal and novel influenza virus infections by referral of samples from medical practices and laboratories, including established surveillance networks. Results from referral confirmation testing inform public health actions by defining virus characteristics, antiviral resistance, severity of disease in the population, and providing situational awareness. CDC and BARDA jointly will support development of new nucleotide rapid sequencing technologies for POC and Laboratory Response Network diagnostic usage in the coming years for influenza and emerging infectious diseases. Annual funding for BARDA will be used for the advanced development of rapid and specific multiplex diagnostic platforms so that:

1. U.S. laboratory network(s) (e.g., LRN) can readily distinguish influenza from non-influenza strains in respiratory panels;

2. Drug resistant viruses can be rapidly identified;

3. Devices can be tested to facilitate rapid CLIA-waiver for more general use; and

4. Improved methods can be developed for collecting samples from influenza patients in clinical settings.

***ASPR OPP's International Influenza activities ($3,000,000*)**: OPP will lead HHS' implementation of the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza with Canada and Mexico and the health security action plan for the Beyond the Border Initiative with Canada. OPP will collaborate with Mexico's Ministry of Health, Mexican Northern border states, and U.S. Southern border states to enhance cross-border International Health Regulations (IHR) capacities for public health emergency preparedness and response. OPP also will coordinate international preparedness efforts to address pandemic influenza and CBRN threats through the Global Health Security Initiative with the G7 countries, Mexico, the European Commission, and WHO. OPP will implement and exercise policy frameworks to guide the U.S. government's provision of international assistance; develop frameworks for receipt of international assistance during public health and medical emergencies; and continue to work with domestic and international stakeholders to identify and address legal, regulatory, and logistical barriers to sharing this assistance. OPP will continue to provide leadership and oversight of U.S. compliance with its obligations under the global health security framework of the IHR and will continue to collaborate with domestic and international partners to support the development and strengthening of IHR core capacities, supporting the President's Global Health Security agenda.

***Office of Global Affairs (OGA) International Influenza activities ($4,009,000)*:** Funding is requested to continue to provide leadership, technical expertise, oversight, policy and program coordination, and

global health diplomacy in international pandemic preparedness and response. Specific areas of work will include the expansion of medical, veterinary, and laboratory expertise and capacity abroad; strengthening of influenza networks to improve risk-communication and promote sustainability of influenza vaccine production in developing countries, enhancement of laboratory diagnostic capacity and technical capabilities; improvement of surveillance and response; support for international implementation of the core competencies of International Health Regulations critical to pandemic preparedness and response; promotion of and leadership for the U.S. Government global health security priorities; and, improved coordination of influenza surveillance, pandemic preparedness and response with the U.S. Government and other international efforts to counter biological threats regardless of cause whether natural, accidental, or intentional.

No-year Funding Requests for FY 2015 ($140,000,000):

Universal Influenza Vaccine Advanced Development ($73,000,000): Funding is requested to support advanced development of one to two vaccine candidates that may afford greater effectiveness against seasonal and pandemic influenza virus strains and/or may serve as universal influenza vaccine candidates affording cross-subtypic immunity. Several current vaccine candidates including viral hemagglutinin stalk-derived antigens are in early development in Phase 1 clinical trials supported jointly by BARDA and NIH's National Institute of Allergy and Infectious Diseases (NIAID). The hunt for a universal influenza vaccine has persisted for over 50 years, with notable failures in the 1980-90s using viral M2e and NP protein targets as universal flu vaccine candidates. The discovery of conserved regions on the influenza hemagglutinin protein that may elicit cross-neutralizing antibodies in 2010-2011 has led to the development of new universal influenza vaccine candidates over the past two years. These vaccine candidates, termed HA stalk vaccines, protect animals challenged with different influenza A virus subtypes (e.g., H1N1, H3N2, H5N1, etc.). NIH and BARDA are working currently with several investigators to develop and manufacture HA stalk vaccine candidates for Phase 1 clinical trials next year. By FY 2015, one or more of these vaccine candidates will be ready to transition to BARDA's advanced development support (i.e., Phase 2-3 clinical trials, commercial scale manufacturing development, optimization, and validation, etc.).

Advanced Development of Antiviral Drug Candidates ($45,000,000): This funding will support pivotal Phase 3 clinical trials for one new or existing novel antiviral drug candidates including those directed against host targets and not affected by the emergence of influenza viruses with neuraminidase drug resistance. With the emergence of H7N9 mutants resistant to oseltamivir in 2013, the importance of novel antiviral drugs with different mechanisms of action becomes paramount.

Vaccine Stockpiling ($10,000,000): This funding will cover the storage, analytical and clinical testing, maintenance, and replenishment of H5N1, H3N2v, H7N9, and other influenza vaccines and adjuvants in the national pre-pandemic influenza vaccine stockpile for pandemic preparedness. This stockpile – which includes more than 200 million doses of bulk and filled H5N1 vaccine, 125 million doses of bulk and filled adjuvants, and ancillary supplies – is reviewed annually to determine whether the appropriate vaccines are available to address circulating influenza viruses with pandemic potential. Other activities in the pre-pandemic influenza vaccine stockpiling program include: preparation of vaccine seed viruses for H5N1, H7N9, and other virus strains with pandemic potential; commercial scale production of these strains; and clinical testing of pre-pandemic influenza vaccine strains to determine the optimal dosage and doses for use at the onset of an influenza pandemic. These funds are required to maintain these stockpiles, which represent a total previous investment of more than $1.5 billion by the Federal government.

Fill and Finish Manufacturing Network ($10,000,000): This funding will maintain the readiness of a network established in 2013 for the formulation and fill and finish manufacturing of vaccines and biological products that will be needed in an influenza pandemic or other emergency surge response. These readiness activities will include annual formulation and fill and finish manufacturing of influenza vaccines or other products to meet the regulatory requirements for facility qualification. This network will supplement the existing manufacturing capacity of influenza vaccine manufacturers in an emergency and also serve the fill and finish manufacturing needs of the new Centers. Additionally, the aseptic sterile fill manufacturing facilities in this network may address domestic drug shortage outbreaks, as warranted.

Advanced Development of Improved Respiratory Protection Devices ($2,000,000): This funding will support BARDA's program to develop improved reusable respiratory protection devices and other personal protective equipment in an all-hazards approach for use during national health emergencies and pandemics.

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Thousands)

Object Class Code	Description	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
11.1	Full-time permanent	74,058	76,520	+2,462
11.3	Other than full-time permanent	-	-	-
11.5	Other personnel compensation	6	6	-
11.7	Military personnel	7,095	7,186	+91
11.8	Special personnel services payments	-	-	-
Subtotal	**Personnel Compensation**	**71,218**	**71,893**	**+675**
12.1	Civilian personnel benefits	29,623	30,393	+770
12.2	Military benefits	3,114	3,153	+39
13.0	Benefits for former personnel	-	-	-
Total	**Pay Costs**	**113,896**	**117,258**	**+3,362**
21.0	Travel and transportation of persons	10,408	10,099	-309
22.0	Transportation of things	577	577	-
23.1	Rental payments to GSA	17,630	17,663	+33
23.3	Communications, utilities, and misc. charges	1,166	845	-321
24.0	Printing and reproduction	115	108	-7
25.1	Advisory and assistance services	257,536	353,287	+95,751
25.2	Other services	35,478	35,208	-270
25.3	Purchase of goods and services from government accounts	1,271	1,269	-2
25.4	Operation and maintenance of facilities	119,636	103,505	-16,131
25.5	Research and development contracts	5,808	4,513	-1,295
25.6	Medical care	265,000	429,700	+164,700
25.7	Operation and maintenance of equipment	-	-	-
25.8	Subsistence and support of persons	23,060	25,686	+2,626
26.0	Supplies and materials	1,584	1,544	-40
31.0	Equipment	520	530	+10
32.0	Land and Structures	19	18	-1
41.0	Grants, subsidies, and contributions	-	-	-
43.0	Interest and Dividends	389,155	320,556	-68,599
44.0	Refunds	-	-	-
Total	**Non-Pay Costs**	**-**	**-**	**-**
Total	**Budget Authority by Object Class**	**1,243,430**	**1,422,936**	**+179,506**

SALARIES AND EXPENSES

(Dollars in Thousands)

Object Class Code	Description	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
11.1	Full-time permanent	74,058	76,520	+2,462
11.3	Other than full-time permanent	-	-	-
11.5	Other personnel compensation	6	6	-
11.7	Military personnel	7,095	7,186	+91
11.8	Special personnel services payments	-	-	-
Subtotal	**Personnel Compensation**	**81,159**	**83,713**	**+2,553**
12.1	Civilian personnel benefits	29,623	30,393	+770
12.2	Military benefits	3,114	3,153	+39
13.0	Benefits for former personnel	-	-	-
Total	**Pay Costs**	**103,681**	**106,913**	**+3,232**
21.0	Travel and transportation of persons	10,408	10,099	-309
22.0	Transportation of things	577	577	-
23.2	Rental payments to others GSA	17,439	17,466	+27
23.3	Communications, utilities, and misc. charges	1,144	823	-321
24.0	Printing and reproduction	110	108	-2
25.1	Advisory and assistance services	259,843	353,279	+93,436
25.2	Other services from non-Federal sources	36,198	35,208	990
25.3	Other goods and services from Federal sources	325	325	-
25.4	Operation and maintenance of facilities	121,534	104,449	-17,085
25.5	Research and development contracts	5,808	4,513	-1,295
25.6	Medical care	265,800	429,700	+163,900
25.7	Operation and maintenance of equipment	-	-	-
25.8	Subsistence and support of persons	23,435	25,711	+2,276
Subtotal	**Other Contractual Services**	**713,514**	**953,756**	**+240,242**
26.0	Supplies and materials	5,390	3,934	-1,456
Subtotal	**Non-Pay Costs**	**748,582**	**986,763**	**+238,181**
Total	**Salary and Expenses**	**852,263**	**1,093,676**	**+241,413**
Total	**Direct FTE**	**741**	**765**	**+24**

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT

Detail	FY 2013 Civilian	FY 2013 Military	FY 2013 Total	FY 2014 Civilian	FY 2014 Military	FY 2014 Total	FY 2015 Civilian	FY 2015 Military	FY 2015 Total
ASPR									
Direct	502	67	569	534	67	601	534	67	601
Reimbursable	-	-	-	-	-	-	-	-	-
Total, ASPR	**502**	**67**	**569**	**534**	**67**	**601**	**534**	**67**	**601**
Cybersecurity									
Direct	34	-	34	88	-	88	112	-	112
Reimbursable	-	-	-	-	-	-	-	-	-
Total, Cybersecurity	**34**	**-**	**34**	**88**	**-**	**88**	**112**	**-**	**112**
Office of Security and Strategic Information									
Direct	30	3	33	30	3	33	30	3	33
Reimbursable	-	-	-	-	-	-	-	-	-
Total, OSSI	**30**	**3**	**33**	**30**	**3**	**33**	**30**	**3**	**33**
Medical Reserve Corps									
Direct	1	6	7	1	6	7	1	6	7
Reimbursable	-	-	-	-	-	-	-	-	-
Total, MRC	**1**	**6**	**7**	**1**	**6**	**7**	**1**	**6**	**7**
Pandemic Influenza									
Direct	12	-	12	12	1	13	12	1	13
Reimbursable	-	-	-	-	-	-	-	-	-
Total, Pandemic Influenza	**12**	**-**	**12**	**12**	**1**	**13**	**12**	**1**	**13**
Total FTE	**579**	**76**	**655**	**665**	**77**	**742**	**689**	**77**	**766**

Average GS Grade	
FY 2011	13.2
FY 2012	13.2
FY 2013	13.2
FY 2014	13.2
FY 2015	12.9

DETAIL OF POSITIONS

(Dollars in Thousands)

Detail	FY 2013 Final	FY 2014 Enacted	FY 2015 President's Budget
Executive Level I	$179	$180	$183
Executive Level II	$1,751	$1,833	$1,833
Executive Level III	-	-	-
Executive Level IV	-	-	-
Executive Level V	-	-	-
Subtotal	**$1,930**	**$2,012**	**$2,016**
Total - Executive Level Salaries	**$1,930**	**$2,012**	**$2,016**
ES-6	2	2	2
ES-5	-	-	-
ES-4	-	-	-
ES-3	-	-	-
ES-2.	-	-	-
ES-1	-	-	-
Subtotal	**2**	**2**	**2**
Total - ES Salary	**$521**	**$524**	**$531**
GS-15	$660	$871	$21,045
GS-14	$23,507	$24,317	$24,623
GS-13	$7,807	$8,490	$8,214
GS-12	$4,555	$4,610	$4,610
GS-11	$1,323	$1,345	$1,345
GS-10	$83	$84	$84
GS-9	$796	$802	$802
GS-8	$114	$115	$116
GS-7	$154	$156	$156
GS-6	$22	$22	$22
GS-5	$113	$114	$114
GS-4	$16	$16	$16
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Total – GS Salary	**$39,150**	**$40,942**	**$61,147**
Average ES level	**6**	**6**	**6**
Average ES salary	**$261**	**$262**	**$266**
Average GS grade	**13.2**	**13.2**	**13.2**
Average GS salary	**$113**	**$110**	**$110**
Average Special Pay categories	$89	$89	$90

SIGNIFICANT ITEMS FOR INCLUSION IN THE FY 2015 CONGRESSIONAL JUSTIFICATION

Public Health Emergency Research:

The Committee recognizes that important infectious diseases research often must be conducted during a public health emergency and that the lack of clear Federal guidelines in this area presents barriers to researchers. The Committee encourages ASPR to consult with the Office of Human Research Protections and other HHS offices and agencies about establishing a public health emergency research review board. ASPR also should work to coordinate and strengthen research capacities between CDC, NIH, FDA, DOD, the VA, and the academic medical community.

Actions To Be Taken

In the past decade, numerous public health emergencies have highlighted the need for ongoing research efforts to improve preparedness and response, leading to improved recovery. This effort includes the ability to do rapid and appropriate human subjects review of clinical research protocols. In 2011, the National Biodefense Science Board recommended the creation of a Public Health Emergency Research Review Board (PHERRB) that could be activated rapidly during events for this purpose.

ASPR has worked collaboratively with the National Institutes of Health (NIH) in creating the infrastructure framework for the PHERRB. In fall 2013, ASPR and NIH finalized a charter and terms of reference for this national-level Institutional Review Board (IRB). The PHERRB operates, depending on the subject matter expertise required for the disaster event, by drawing on existing IRBs at 12 different NIH institutes.

In September 2012, ASPR held a conference to determine the infrastructure needs across the Federal government. The Departments of Defense (DOD), the Interior, and Veterans Affairs, and the Environmental Protection Agency participated. The White House Office of Science and Technology Policy also participated to support science preparedness research efforts. ASPR continues to lead this effort by initiating interagency coordination calls twice monthly. This coordination is helping to ensure information exchange and collaboration on joint programs. In this way, the broadest scope of disasters can be addressed.

Virtual Training:

The Committee continues to note the need for realistic virtual reality simulation training technologies at the local community level that will help prepare medical responders and hospitals for public health emergencies. The Committee encourages ASPR to develop core competencies and standardized curricula for virtual training using state-of-the-art, simulation medical response technology.

Actions To Be Taken

The Department agrees that, by leveraging technology, we can improve surge capacity and enhance community and hospital preparedness in the event of public health emergencies. However, as a precursor to the use of such technologies for preparedness training on a large scale, nationally-vetted and -approved disaster health professional core competencies or a curriculum should be established. Once these standards have been established, then the development of virtual and distributive training tools may help realize an overall reduction in the cost of training emergency responders and medical professionals nationwide.

- Our primary goal, as always, is to ensure that community officials, hospitals, emergency managers, and other emergency responders are prepared for the full spectrum of public health emergencies. Right now, face-to-face training is our conventional and preferred method, but we do use some simulation training methods when they are useful and appropriate. Through our investigations in the field of medical response training simulations, ASPR has identified existing state-of-the-art technologies that, with modification, have the potential to assist with the dissemination of national healthcare standards for preparedness, training, and response in public health and medical communities. As the Committee notes, simulation can be a useful, cost-effective tool to train a wide range of public health and medical professionals. Less experienced professionals can gain confidence and learn the procedures in a realistic, no-fault environment, while seasoned professionals can master new procedures and technologies in the ever-evolving environment of medicine.

The Department believes that a robust, hands-on simulation, driven by sophisticated and reliable technology, will enhance our teams' and individuals' abilities to expand preparedness, gain insights into our processes, and develop best practices in a virtual but realistic environment. Working in a simulated environment will allow public health and medical professionals to learn from making mistakes, without the need for intervention. By seeing the results of their actions, they will be able to gain powerful insights into the consequences of their actions and the need to get it right.

All training, be it in person or online, is designed to improve preparedness. To ensure that communities are prepared, the Hospital Preparedness Program (HPP) now focuses on community healthcare coalitions rather than just hospitals. Additionally, HPP has identified eight key preparedness capabilities, published in *The Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness.* This guidance helps emergency planners in states, local communities, and healthcare coalitions to identify gaps in preparedness, determine specific priorities, and develop plans for building and sustaining healthcare-specific capabilities. In addition to coalition formation, ASPR has key preparedness capabilities, including emergency operations coordination, information sharing, medical surge, and fatality management. For each capability, ASPR provides guidelines that emphasize capability-specific training. These capabilities could serve as the foundation for the necessary development of the health preparedness competencies and curricula described above.

Anthrax Vaccine

While the Committee remains concerned about the Nation's preparedness against biological threats, it recognizes that BARDA has made strides in developing and acquiring products to combat anthrax, including a next-generation recombinant anthrax vaccine. The Committee encourages the continuation of these targeted efforts toward a clinically advanced and affordable vaccine.

Actions To Be Taken

ASPR's Biomedical Advanced Research and Development Authority (BARDA) continues to support the development of enhanced and next generation anthrax vaccine candidates (a total of six) with funding and core service assistance for possible future procurement for the Strategic National Stockpile. BARDA is supporting the development of two projects to enhance existing Anthrax Vaccine Adsorbed (AVA) to reduce the amount of antigen and doses needed to mount an effective immune response. BARDA also supports the development of Emergent's BioThrax® for post-exposure prophylaxis against anthrax under Project BioShield, and the final Phase 3 clinical trials are underway. Under BARDA's new anthrax vaccine development strategy initiated in 2012, the focus of the program is supporting vaccine products superior to existing licensed AVA.

In addition, BARDA is supporting development of four next generation rPA anthrax vaccine candidates at various stages of development. The candidate from PharmAthene, which is the most mature in development, remains on clinical hold again by the Food and Drug Administration (FDA) due to product instability. The candidate is awaiting more results from product stability studies and improved potency assays before a Phase 1/2 clinical trial can be started using product made under a new process at a new manufacturer. The other candidates from Emergent, Pfenex, and Vaxin are completing necessary animal challenge, toxicology, and analytical studies to support Investigational New Drug filings and commencement of Phase 1 clinical trials in 2014 and 2015. Two of these candidates are using new adjuvants to reduce the amount of antigen and number of doses needed for protective immunity. Another candidate is using a new adenovirus virus-vector technology that may afford protective immunity following a single vaccine dose administered intranasally. In 2014, two next generation anthrax vaccine candidates are expected to receive technical assistance and manufacturing of clinical investigational lots in BARDA's Centers for Innovation in Advanced Development and Manufacturing prior to moving forward with human clinical trials.

Antimicrobial Development

The Committee is aware that CDC recently reported a four-fold increase in multidrug-resistant bacteria over the last 10 years. Unfortunately, existing treatment options are limited and few new drugs are likely to become available to address these bacterial threats in the near term. The Committee strongly encourages BARDA to prioritize its Broad Spectrum Antimicrobial program.

Actions To Be Taken

ASPR and BARDA initiated a new broad spectrum antimicrobial agent program in 2010 based on the need for new classes of antibiotics to treat patients exposed to biothreats causing plague, tularemia, glanders, melioidosis, and others, or to multi-drug resistant pathogens that may infect affected persons from other threats such as trauma induced by nuclear explosions. BARDA also understands that antimicrobial resistance will complicate the ability to save lives from other biothreats, ranging from anthrax to pandemic influenza. BARDA has supported four promising new antibiotic candidates, and several more candidates are under consideration presently.

A growing share of BARDA's Advanced Research and Development (ARD) budget supports the development of these new classes of antibiotics that may address biothreats and one of public health's major problems – antibiotic drug resistance. In fact, the FY 2015 Budget requests $79 million for these efforts as part of the President's new initiative to combat antimicrobial drug resistance.

The most mature candidate in the BARDA broad spectrum antibiotic portfolio range is a new aminoglycoside called Plazomicin (Achaogen). It has indications for plague, tularemia, and limited population antibacterial drug (LPAD) indication-carbapenem-resistant Enterobacteriaceae bloodstream infections (CRE). The pivotal Phase 3 multi-year efficacy study is on-going currently through a limited population regulatory pathway.

Another candidate is a new tetracycline (CUBRC/Tetraphase). This candidate has biodefense indications for treatment and post-exposure prophylaxis of anthrax, plague, and tularemia, and community and hospital-acquired infection indications including complicated intra-abdominal infection and Community-Acquired Bacterial Pneumonia. Phase 1 studies started in 2013 and are ongoing.

BARDA replaced the boron-based antibiotic candidate from GlaxoSmithKline (GSK) due to the rapid emergence of antimicrobial drug resistance in a Phase 2 clinical trial in 2012. However, BARDA reestablished a unique public-private partnership with GSK in May 2013 using Other Transaction Authority to support development of multiple GSK antibiotic candidates in a cost-sharing arrangement

for treatment of several biothreats such as anthrax, plague, and tularemia and to treat community- and hospital-acquired drug resistant infections.

In June 2013, BARDA partnered with Cempra to support development of solithromycin in pediatric populations. If approved, the drug would be the first orally-administrated antibiotic approved in decades to treat children who develop community-acquired bacterial pneumonia. This type of pneumonia is developed in the community rather than in a hospital. Studies of the drug's use in treating anthrax or tularemia will be conducted under the FDA Animal Rule and could provide additional treatment options for clinicians' use in a public health emergency involving these bioterrorism infections.

BARDA began a partnership in July 2013 with Basilea Pharmaceutica to support advanced research and development of BAL30072 for treatment of glanders and melioidosis and treatment of a broad range of multidrug-resistant Gram-negative bacteria commonly found in hospitals. The drug also has shown promise as part of a combination therapy with other licensed antibiotics in treating severe infections including hospital-acquired pneumonia, complicated intra-abdominal infections, cystic fibrosis lung infections, and complicated urinary tract infections.

Most recently, BARDA partnered with Rempex in February 2014 for the development of Carbavance. It will address glanders and melioidosis infections and to treat complicated urinary tract infections, hospital-acquired pneumonia, ventilator-acquired pneumonia, and carbapenem-resistant Enterobacteriaceae.

Additionally, BARDA is partnering with other Federal agencies – including DOD, NIH, FDA, and the Centers for Disease Control and Prevention – on new antibiotic sciences and technologies to lead a new national initiative to address antimicrobial drug resistance

Project BioShield Special Reserve Fund

The Committee directs BARDA to utilize this new multiyear contracting authority, providing for termination as appropriate in the event that funds are not made available in future fiscal years, to meet the known current and future national need for particular MCMs. The Committee believes that the multiyear contracts will provide a clear indicator to industry of the Federal Government's future support for medical countermeasure development, while at the same time promoting economy in the administration, performance, and operation of BARDA. The Committee requests that BARDA provide a 5-year spend plan for fiscal years 2014-2018, which shall be made public, detailing the funding amounts required to support advanced development contracts for these products.

Actions To Be Taken

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (P.L. 113-5) requires the Department to develop a five-year strategic plan on the medical countermeasure enterprise. This report will project and estimate PHEMCE-wide resources requirements on a five-year rolling basis and identify the hand-offs anticipated in the development cycle. This report will also provide information on project coordination and product transitions between agencies, and will serve to communicate priorities and resources needs to partner stakeholders. The Department is currently preparing this report for submission to the Committee.

TEXT VERSION OF ORGANIZATIONAL CHARTS

Assistant Secretary for Preparedness and Response

The Assistant Secretary for the Office of the Assistant Secretary for Preparedness and Response, Dr. Nicole Lurie, MD, MSPH, Rear Admiral, USPHS and Principal Deputy Assistant Secretary, Edward Gabriel, MPA, EMT-P, CEM, CBCP oversee the following:

- Chief Operating Officer (COO), Ben Goldhaber, MPA, Chief Operating Officer
- Office of Policy and Planning (OPP), Dr. Lisa Kaplowitz, MD, MSPH, Director
- Office of Acquisitions, Management, Contracts and Grants (AMCG), Jess Scarbrough, MSS, MBA, DACM, Director
- Office of Financial Planning and Analysis (OFPA), Jay Petillo, MPP, Director
- Office of Biomedical Advanced Research and Development Authority (BARDA), Dr. Robin Robinson, PhD, Director
- Office of Preparedness and Emergency Operations (OPEO), Don R. Boyce, JD, Director

Cybersecurity

The HHS Chief Information Security Officer, Kevin Charest, oversees the following:

- Program Management, Leslie Glaser
- HHS Deputy CISO, Sara Hall
    - Security Design & Innovation, Mike Levin, Director
        - Security Architecture
        - Cloud
        - Configuration Standards & Development
    - Cybersecurity Operations, Vacant, Director
        - Quality Assurance
        - Technology Support
        - CSIRC
        - Information Assurance/ISSO
    - Security Governance, Risk Management, & Compliance, Chris Bollerer, Director
        - Oversight & Compliance
        - Policy
        - Continuous Monitoring
        - Training & Awareness
        - Cybersecurity Workforce Planning
    - Security Services, Cindy Gagliano, Director
        - TIC Technical Program
        - ISSO Services
        - ISS LOB Services
- OS Deputy CISO, Johnny E. Davis, Jr.
    - Privacy, Julia White, Director
        - Enterprise Privacy Integration
        - OS Privacy
    - Information Systems Security Manager (ISSM) for Small OpDivs, John Richardson
    - OS Security Governance, Risk Management, & Compliance, David Tillman, Director

        - Plans & Policy
        - Workforce Management
        - Oversight & Compliance (FISMA)
    - OS Security Operations, Mark Deffenbaugh, Director
        - Design & Implementation
        - Operations & Maintenance
        - iCAM

Civilian Volunteer Medical Reserve Corps

The Director of the Civilian Volunteer Medical Reserve Corps, Captain Rob Tosatto, oversees the following:

- Operations Branch
    - Deputy Director, CDR Paul Reed
    - Program Officer, LTJG Katie Hager
    - Program Officer, Tracey Smith
- Training and Support Services Branch
    - Deputy Director, CDR Patrick Denis
    - Program Officer, LCDR Skip Payne
    - Program Officer, Vacant

Note: The Pandemic and All Hazards Preparedness Reauthorization Act of 2013 moved oversight and responsibility for the Civilian Volunteer Medical Reserve Corps to the Office of the Assistant Secretary for Preparedness and Response; this office is managed in the Office of the Assistant Secretary for Health (OASH).

Office of Security and Strategic Information

The Deputy Assistant Secretary for Security (Acting) and Secretary's Senior Intelligence Official (SSIO), Aida M. Perez, oversees the following:

- Chief of Staff, Carla McGregor, JD, MPH
- Directorate of Security, Dan Galik, Director
    - Division of Personnel Security, David Peterson, Associate Director
    - Division of Physical Security, Kory Whalen, Associate Director
    - Security Program Management (HSPD-12), Ken Calabrese, Associate Director
- Directorate of Intelligence and Counterintelligence, Aida Perez, Director
    - Division of Strategic Information, Mark Abdy, DVM, PhD, Associate Director
    - Division of Counterintelligence & Cyber Threat, Ricky Hill, Associate Director
    - Classified Security Program, Dennis McAuliffe, SSO

Note: OSSI coordinates Personnel, Physical, and Security Access Management services across the Department that are resourced by non-PHSSEF Funds.