DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2016

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committees

Contents

We are pleased to present the fiscal year (FY) 2016 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). This FY 2016 Budget request directly supports the United States' ability to prepare for, respond to, and recover from the consequences of a wide range of natural and man-made threats to public health. This request includes the FY 2016 Budget justifications for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Pandemic Influenza, Cybersecurity, and the Office of Security and Strategic Information (OSSI).

The United States must be prepared to effectively respond to and recover from public health emergencies and catastrophes. These emergencies include natural disasters such as tornadoes and hurricanes; pandemic influenza and emerging infectious diseases; and chemical, biological, radiological, and nuclear (CBRN) threats. ASPR's mission is to lead the country in preparing for, responding to, and recovering from these emergencies. ASPR works with partners to develop and acquire medical countermeasures (MCM) such as vaccines and therapeutic drugs, support communities' ability to withstand adversity, and improve the preparedness and integration of the U.S. health care system.

One of ASPR's primary responsibilities is to ensure that safe and effective MCMs are available to protect Americans from CBRN threats, pandemic influenza, and emerging infectious diseases (e.g., Ebola). The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which ASPR co-leads with a number of HHS partners, encompasses a host of complex and interdependent processes intended to ensure that the nation develops, acquires, and stockpiles safe and effective MCMs.

Through ASPR's Biomedical Advanced Research and Development Authority (BARDA) and with $5.6 billion in initial Project BioShield appropriations over the previous decade, the United States acquired 12 MCMs against CBRN threats by the end of 2013. Almost half of these MCMs also have a "peacetime" public health use. In 2012 and 2013, two of these CBRN MCMs became the first products approved under the Animal Efficacy Rule. In addition, since 2012, the Food and Drug Administration has approved six first-in-class vaccines, antiviral drugs, diagnostics, and medical devices for seasonal and pandemic influenza that BARDA supported.

Another worrisome threat to public health is antibiotic-resistant bacteria. The FY 2016 request increases funding for BARDA's important work carrying out the *National Strategy on Combating Antibiotic-Resistant Bacteria*. BARDA is supporting the development of the first new classes of antibiotics to treat multidrug-resistant pathogens often referred to as "superbugs". ASPR is using innovative public-private partnerships with small and large pharmaceutical and biotechnology companies to develop promising, cutting-edge antibacterial therapies that will improve patient care and preparedness nationwide.

This Budget also provides continued support to emergency preparedness and response. The nation also needs a health care system that is able to rapidly deliver coordinated and effective care during a disaster by integrating the health care, public health, and emergency management systems. Building and sustaining strong local and regional health care coalitions is vital to improving communities' preparedness for responding to disasters and other major events.

Since 2006, ASPR has led America's progress in public health emergency response. Hurricane Katrina exposed major problems in emergency management and response. Congress established ASPR to address these weaknesses. ASPR's Office of Emergency Management (OEM) and Hospital Preparedness Program (HPP) have modernized the federal emergency management infrastructure and strengthened states' and local communities' disaster response and recovery. In addition, through the Office of Policy and Planning, ASPR leads policy development, collaboration, and public health emergency management, response, and recovery throughout the nation and around the world.

The Budget includes $1.7 billion to support ASPR activities, which is an increase of +$535 million above FY 2015. The request includes $522 million for BARDA, of which $192 million supports efforts to address antibiotic resistance, and $646 million for Project BioShield. These investments will keep America on track to procure a dozen new CBRN MCMs by the end of 2018. The Budget also includes $170 million for activities within ASPR and the HHS Office of Global Affairs related to pandemic influenza and emerging infectious diseases. For example, ASPR's request includes funding to develop up to two vaccine candidates that may afford greater effectiveness against seasonal and pandemic influenza virus strains and may serve as "universal" influenza vaccines.

The request for ASPR also provides vital funding for public health emergency preparedness and response. The budget includes $255 million for HPP to support health care coalitions and $81 million for emergency management, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps.

The Budget also includes funding for two new initiatives. Informed by lessons learned from the Ebola response effort to-date and other recent response efforts, the FY 2016 Budget proposes the Public Health Emergency Response Initiative. This initiative would provide the Department with additional funding and flexibility needed for HHS to efficiently and effectively plan for and manage the response to public health emergencies. Secondly, as part of the Administration's commitment to incorporating evidence and evaluation into policy solutions, the Budget proposes the Effective Health Insurance Initiative. This new study will examine how changes in health insurance benefit packages impact health care utilization, costs, and outcomes. The goal of this study is to use the best methods to produce rigorous, actionable evidence about how to modernize the health care system in a way that improves outcomes while controlling costs.

The HHS Cybersecurity Program assures that all automated information systems throughout HHS are designed, operated, and maintained with the appropriate information technology security and privacy data protections. The FY 2016 Budget of $73 million support continued management and oversight of the Department's IT Security Program and to ensure compliance. This funding level will also contribute to sustaining prior year security investments, which are instrumental in enabling the completion of the security engineering and design work for the Trusted Internet Connection initiative, which provides greater security in the government's internet connections and facilitate the necessary infrastructure to implement Einstein for the entire Department.

Lastly, the Budget includes $7 million 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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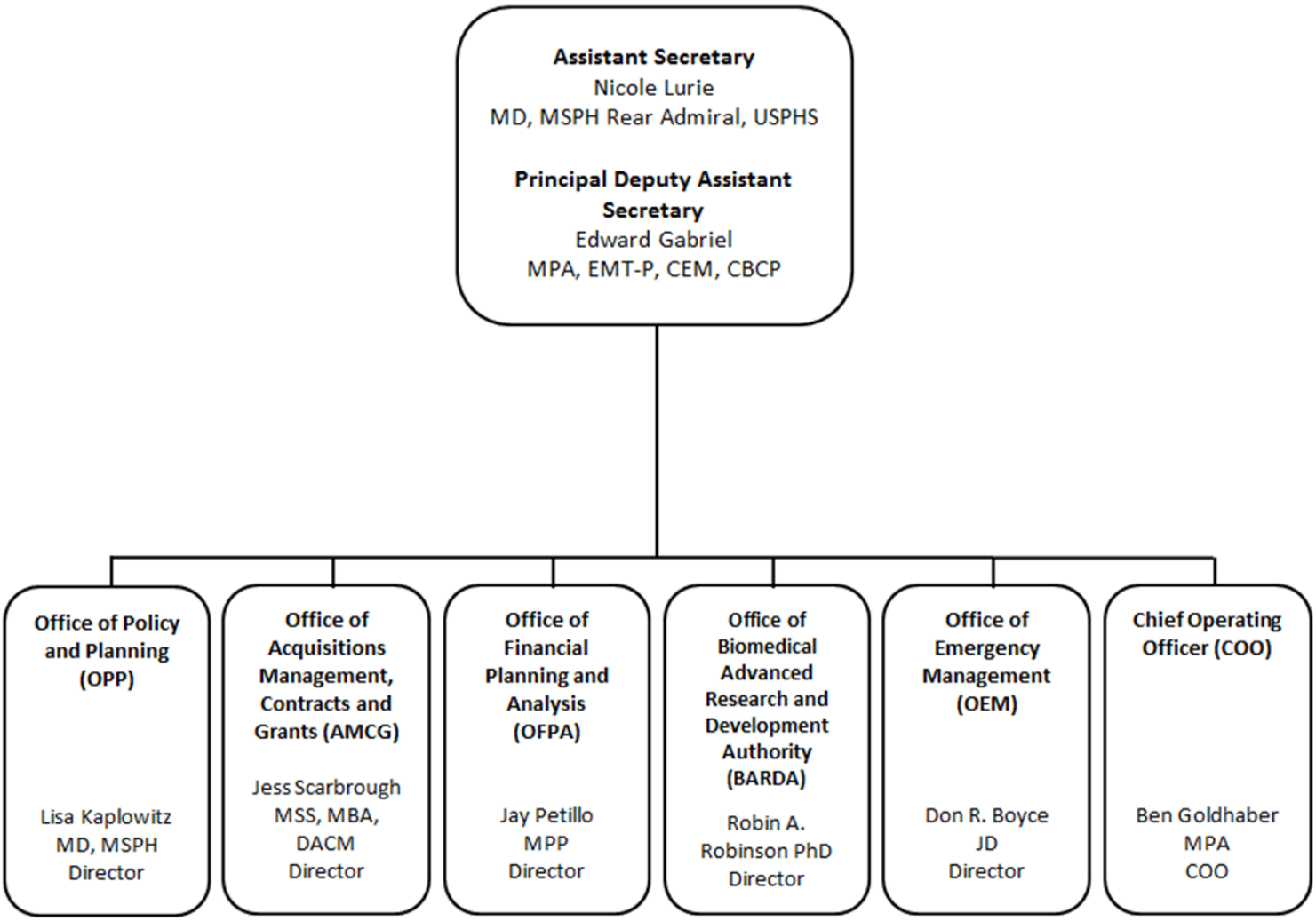
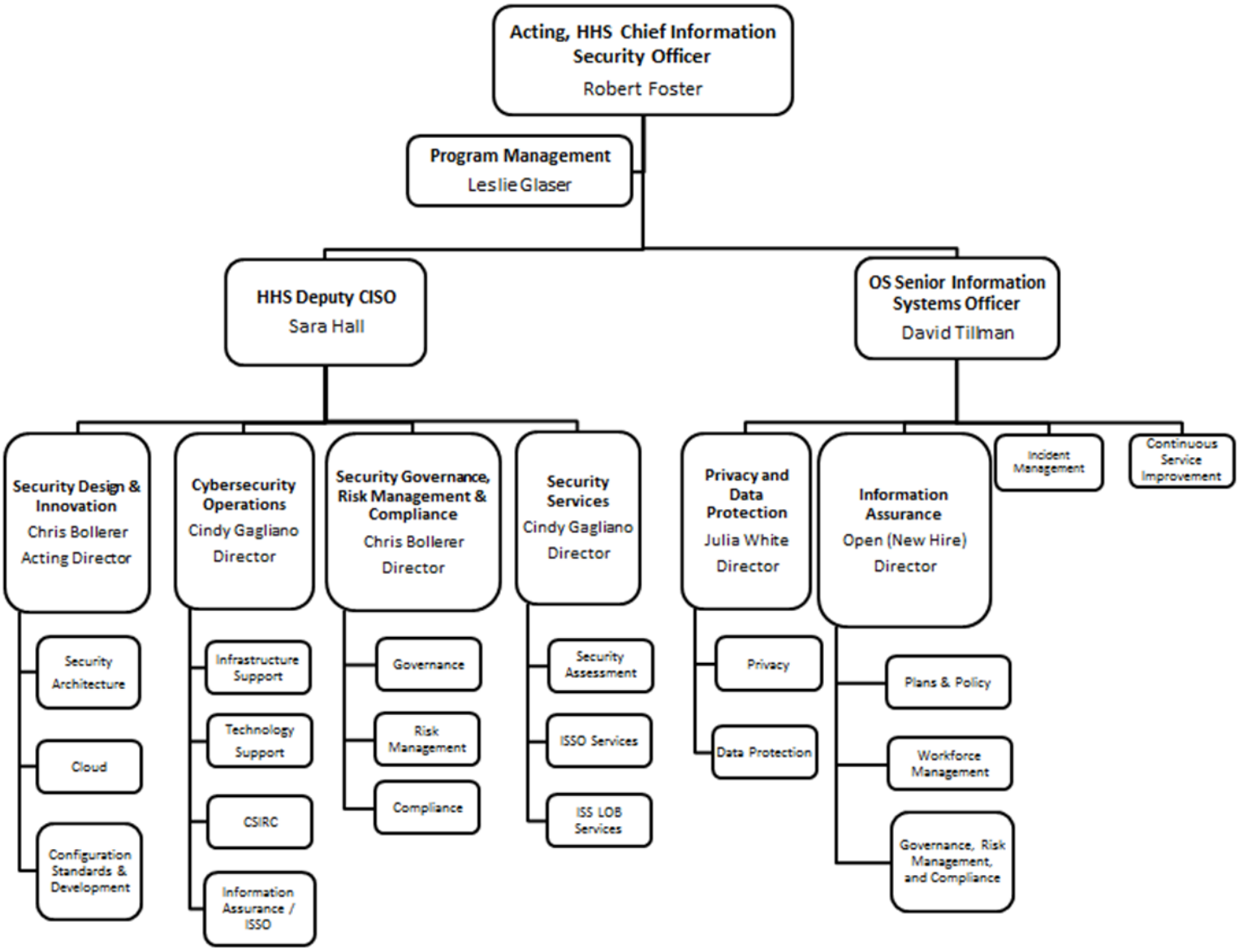
ORGANIZATIONAL CHARTS

Assistant Secretary for Preparedness and Response

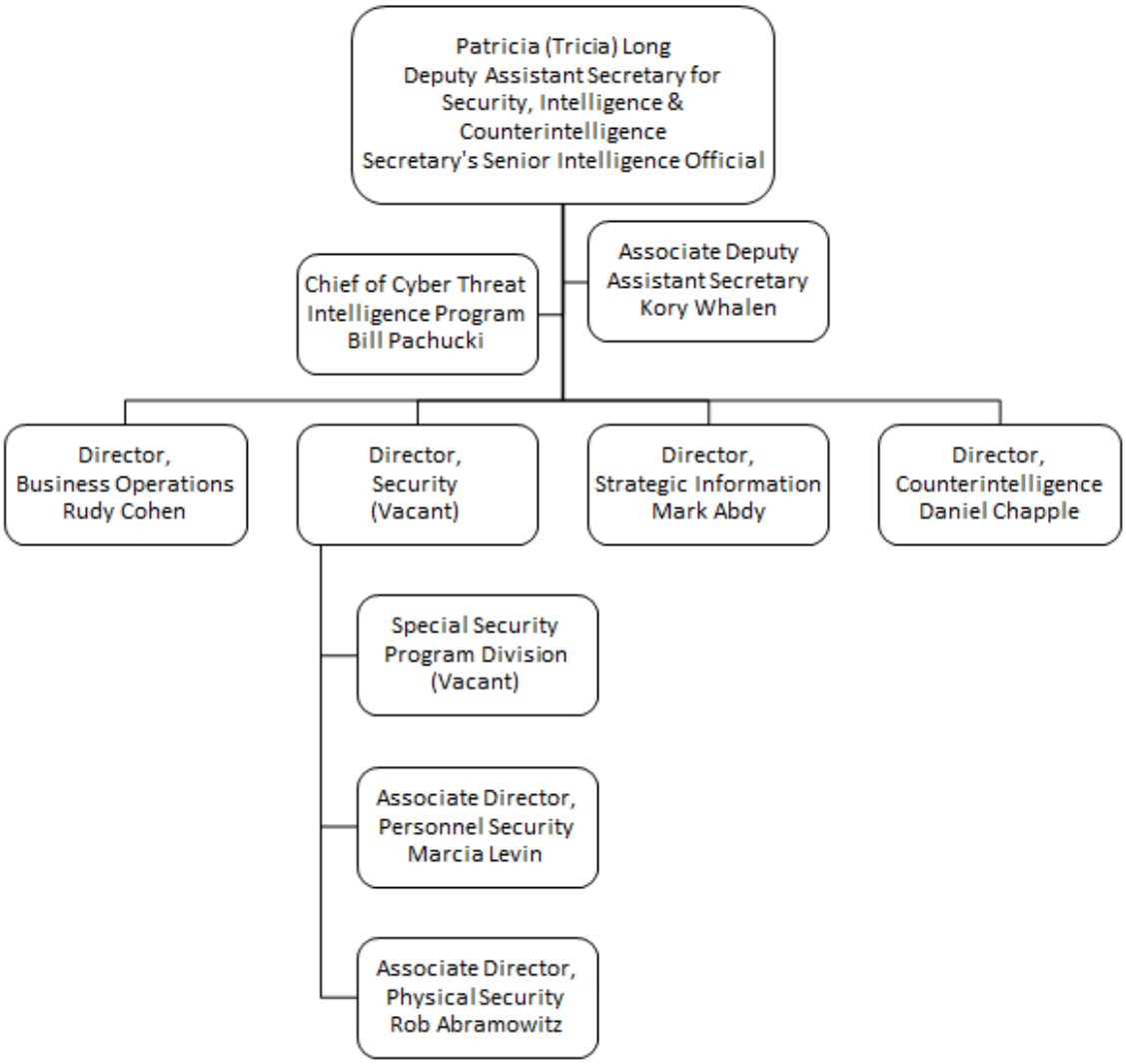


Cybersecurity



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.



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 threats from chemical, biological, nuclear, and radiological (CBRN) agents.

ASPR is a Staff Division in the Office of the Secretary. The Assistant Secretary 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. Furthermore, in 2009, the Secretary formally delegated to ASPR the authority to lead such preparedness activities and responses. ASPR takes a collaborative approach to fulfilling its federal preparedness, response, and recovery responsibilities. Within HHS, ASPR works with the Operating Divisions and other Staff Divisions.

In addition to its responsibilities as an advisor, planner, and leader for public health and medical emergency preparedness and response, ASPR has operational responsibilities for advanced research on and development of medical countermeasures (MCMs) against CBRN threats, pandemic influenza, and emerging infectious diseases like Ebola; and for coordinating the federal government's 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 continuously supports thorough, direct, and open communication with all stakeholders—federal, state, local, tribal, territorial and non-governmental organizations—to promote resilience. ASPR helps these stakeholders save lives, mitigate suffering, and preserve health. For example, ASPR's Office of Emergency Management (OEM) deploys behavioral health resources, lifesaving equipment, supplies and teams to support medical surge capacity after catastrophic natural disasters like a major hurricane. In addition, OEM sends subject matter experts to provide all hazards consultation and technical assistance to state and local authorities after public health emergencies like a chemical release.

Goal 2: Strengthen federal public health and medical preparedness, response, and recovery leadership and capabilities.

ASPR has several programs that contribute to achieving this goal. For example, in FY 2015, ASPR's OEM took over management and oversight of the Civilian Volunteer Medical Reserve Corps (MRC). Previously, MRC was part of the Office of the Assistant Secretary for Health. During FY 2016, ASPR will carefully examine what works well within the existing program and what should improve to make all MRC units more successful; will update MRC's mission, goals, and expectations for successful MRC units; and will develop a plan to ensure that these units can receive training to effectively contribute to disaster response when they are called to do so.

Goal 3: Promote an effective medical countermeasures enterprise.

The Biomedical Advanced Research and Development Authority (BARDA) and the Office of Policy and Planning's (OPP) Division of MCM Strategy and Requirements lead ASPR's efforts and achievements for this goal. During FY 2016, BARDA will continue to implement the *National Strategy on Combating Antibiotic-Resistant Bacteria*, which is a high priority for the Administration. BARDA will transition and support new antibiotic and diagnostic candidates from early to advanced development for biothreat and public health usages, especially for high-priority multi-drug resistant bacterial pathogens and Ebola. Further, BARDA will expand its initiatives to develop more effective influenza vaccines and immunotherapeutics, which it is launching in FY 2015. BARDA will support new innovations in continuous manufacturing of pharmaceutical products that may transform how pharmaceuticals are made. Lastly, through Project BioShield, BARDA will purchase multiple CBRN MCMs that have matured under BARDA's Advanced Research and Development program.

Goal 4: Strengthen ASPR's leadership role in coordinating and developing public health and medical emergency preparedness, response, and recovery policy.

OPP assists the ASPR in her leadership on this goal. ASPR's role extends not only across the United States, but also beyond our borders to ensure that our nation is prepared for any developing public health threat. For example, in FY 2016, OPP will continue to lead HHS and U.S. government engagement in international initiatives to prepare for and respond to pandemic influenza; CBRN threats; and other emerging or re-emerging infectious diseases (e.g. Ebola). ASPR/OPP leads the U.S. government's participation in the Global Health Security Initiative with the G7 countries, Mexico, the European Commission, and the World Health Organization.

Goal 5: Improve the preparedness and integration of health care delivery systems.

ASPR/OEM's Hospital Preparedness Program (HPP) is integral to improving the preparedness of the U.S. health care delivery system to respond to public health emergencies. Funding for HPP in FY 2016 will allow health care coalitions to engage in community-level planning, exercises, and training. The Budget also will support coalitions' operational costs, such as convening regular coalition meetings and maintaining staff members to facilitate disaster planning efforts, develop and implement exercises, and encourage other health care system partners to join coalitions. Preparedness planning through coalitions, which emphasize partnerships and collaboration, is more cost-effective than providing a small amount of grant funding to each individual health care facility or partner.

Goal 6: Improve management of the ASPR organization and investment in its people.

During 2014, ASPR continued 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. In 2016, ASPR will strengthen initiatives to promote a leadership and mentoring culture by expanding a career and leadership development program. This program will help to ensure that ASPR is capable of addressing evolving threats and emerging challenges to public health and implementing innovative solutions in the face of future disasters.

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.

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 2016 Budget request for the Public Health and Social Services Emergency Fund (PHSSEF) is $1,939,981,000 and 773 FTE. This level represents a program level increase of +$706,912,000, and +16 additional full time equivalent employees (FTE), relative to FY 2015. These funds will provide the necessary resources to:

- Support a comprehensive program to prepare for 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 Global Affairs.

Programmatic Increases (relative to FY 2015):

- **Assistant Secretary for Preparedness and Response (ASPR) (+$437 million, $1.5 billion total program level):** Within ASPR, the Budget supports the advanced development and procurement of medical countermeasures (MCMs), in addition to improvements in community preparedness and response for public health events. Notable activities include:
    - **Project BioShield (+$391 million, $646 million total):** FY 2016 funding will support the procurement of 7 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; adjuvanted anthrax vaccine for improved effectiveness and decreased maintenance costs over time; new cellular therapy to treat individuals exposed to radiation; and new therapeutics and vaccines for Ebola.
    - **Biomedical Advanced Research and Development Authority (+$49 million, $522 million total):** This increase in funding will support efforts to combat antibiotic-resistant bacteria ($192 million total, +$108 million above FY 2015) through the implementation of objectives outlined in the *National Strategy on Combating Antibiotic-Resistant Bacteria.* This funding will support new antibiotic and diagnostic candidates from early to advanced development for biothreat and public health usages, especially for high-priority multi-drug resistant bacterial pathogens. At this level, BARDA will fund three to five new partnerships, thereby increasing the number of MCM candidates in the development pipeline and, consequently, the probability of success in obtaining Food and Drug Administration approval of a new antimicrobial therapy by 2020.
- **Pandemic Influenza (+$98 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 universal influenza vaccines, international and domestic preparedness and response 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.

- **Cybersecurity (+$32 million, $73 million):** The Budget supports operational 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 funding would provide significant support to protecting the Department's information technology systems and safeguarding personally identifiable information, commercial propriety data, and scientific research of natural importance.
- **Public Health Emergency Response Initiative ($110 million total, new in FY 2016):** The FY 2016 Budget includes $110 million to be available until expended to respond to an urgent or emergency need that could cause severe consequences, but does not – or not yet – meet the criteria for a *Stafford Act* or public health emergency declaration, and in which rapid action would help mitigate the threat. This funding would be available after determination of the Secretary.
- **Effective Health Insurance Initiative ($30 million total, new in FY 2016):** The Budget includes $30 million to be funded through PHS Evaluation Funds for a new project to examine how changes in health insurance benefit packages impact health care utilization. This initiative will enable HHS to plan and initiate the study using state-of-the-art evaluation methods to address critical research questions that cannot be directly addressed through other means. The study will inform the development of health care models that work better for families and providers.

Programmatic Decreases (relative to FY 2015):

- **ASPR – Civilian Volunteer Medical Reserve Corps (-$3 million, $6 million total):** The Budget reflects the FY 2015 transfer of the Medical Reserve Corps from the Office of the Assistant Secretary for health to ASPR, per the 2013 *Pandemic and All-Hazards Preparedness Reauthorization Act*. The program decrease reflects administrative efficiencies that will be achieved by transitioning management to ASPR.

- **ASPR – Facility Efficiencies (-$652,000 below FY 2015; $105.5 million total):** Through FY 2013, ASPR had consolidated 90 percent of its staff into the renovated Thomas P. O'Neill Federal Building in Washington, DC. Since that time, ASPR has re-evaluated its facilities needs to identify additional efficiencies. This request level reflects further space efficiencies that ASPR plans to achieve. Programs that are affected include:
  - Operations (-$367,000 below FY 2015, $31 million total)
  - National Disaster Medical System (-$150,000 below FY 2015, $50 million total)
  - Preparedness and Emergency Operations (-$135,000 below FY 2015, $25 million total)

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 2015 Appropriations language.
- **Enhanced Transfer Authority:** To augment HHS' capability to respond rapidly to public health emergencies, the FY 2016 Budget proposes a general provision to increase the percentage of funding the Secretary may transfer among HHS' accounts during emergencies. This enhanced transfer authority will allow HHS to more rapidly assist states and local communities when a catastrophic event occurs.
- **Compensation for National Disaster Medical System Intermittent Employees:** The FY 2016 Budget proposes to specify the pay rate for compensating National Disaster Medical System

(NDMS) intermittent employees under the Federal Employees' Compensation Act (FECA) to be equivalent to the pay rate and coverage for full-time federal employees in a similar position when they are injured or become ill. The NDMS workforce includes more than 5,000 intermittent employees who comprise more than 80 regional and state-based teams. The injury rate among NDMS intermittent employees is low. The proposal supports these employees who assist the nation during public health emergencies, often working alongside federal employees who have greater FECA coverage. The proposal also will make NDMS a more attractive employer, which will help ensure that it maintains an adequate number of qualified individuals to respond to public health emergencies.

BUDGET BY STRATEGIC GOAL

(Dollars in Millions)

HHS Strategic Goals	FY 2014 Final	FY 2015 Enacted	FY 2016 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			**30**
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			30
3. Advance the Health, Safety and Well-Being of the American People	**1,235**	**1,233**	**1,910**
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	1,235	1,233	1,910
4. Increase Efficiency, Transparency and Accountability of HHS Programs	**16**		
4.A Ensure program integrity and responsible stewardship	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	**1,251**	**1,233**	**1,940**

ALL PURPOSE TABLE

(Dollars in Millions)

Activity	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Assistant Secretary for Preparedness and Response				
Preparedness and Emergency Operations	28.029	24.789	24.654	-0.135
National Special Security Events (non-add)	*4.950*	*5.000*	*5.000*	--
National Disaster Medical System	50.054	50.054	49.904	-0.150
Hospital Preparedness	255.060	254.555	254.555	--
Hospital Preparedness Program (non-add)	*254.555*	*254.555*	*254.555*	--
ESAR-VHP (non-add)	*0.505*	-	-	--
Medical Countermeasure Dispensing	4.950	-	-	--
Medical Reserve Corps /1	8.979	8.979	6.000	-2.979
Biomedical Advanced Research and Development Authority /2	413.494	473.000	521.732	+48.732
Ebola funding: Public Law 113-164 (non-add)	-	*58.000*	-	*-58.000*
Advanced Research and Development (non-add)	*272.712*	*271.000*	*269.732*	*-1.268*
Combating Antibiotic-Resistant Bacteria (non-add)	*81.000*	*84.000*	*192.000*	*+108.000*
Operations and Management (non-add)	*59.782*	*60.000*	*60.000*	--
Project BioShield	254.074	255.000	646.425	+391.425
Policy and Planning	14.877	14.877	14.877	--
Operations	31.305	31.305	30.938	-0.367
Subtotal, ASPR Program Level (non-pandemic influenza)	**1,060.822**	**1,112.559**	**1,549.085**	**+436.526**
Other Office of the Secretary				
Office of Security and Strategic Information	6.118	7.470	7.470	--
Cybersecurity	53.417	41.125	73.417	+32.291
HHS Lease Replacement	16.131	-	-	--
Subtotal, Other Office of the Secretary	**75.666**	**48.595**	**80.887**	**+32.291**
Pandemic Influenza				
ASPR No-Year Funding	82.597	39.906	140.000	+100.094
ASPR Annual Funding	28.000	28.000	26.000	-2.000
OGA Annual Funding	4.009	4.009	4.009	--
Subtotal, Pandemic Influenza	**114.606**	**71.915**	**170.009**	**+98.094**
Other PHSSEF Activities				
Emergency Response Initiative	-	-	110.000	+110.000
Effective Health Insurance Initiative	-	-	30.000	+30.000
Subtotal, Other PHSSEF Activities	-	-	140.000	+140.000
Total, PHSSEF Program Level	**1,251.094**	**1,233.069**	**1,939.981**	**+706.911**
Less Funds from Other Sources				
Effective Health Insurance Initiative (PHS Evaluation funds)	-	-	-30.000	+30.000
Subtotal, Less Funds from Other Sources	**-**	**-**	**-30.000**	**+30.000**
Total, PHSSEF Budget Authority	**1,251.094**	**1,233.069**	**1,909.981**	**+676.911**
FTE	**696**	**757**	**773**	**+16**

1/ Moved to ASPR from OASH in FY 2015. FY 2014 funding is reflected for comparability.

2/ Total reflects BARDA Ebola funds in the FY 2015 Continuing Resolution (PL 113-164) and does not reflect the $733 million in FY 2015 Ebola Emergency Response funding in PL 113-235.

FY 2016 PROPOSED APPROPRIATIONS LANGUAGE

(Relative to FY 2015 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, **[**$848,154,000] *$983,546,760*, of which [$415,000,000] *$521,732,000* shall remain available through September 30, [2016]*2017*, 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: *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, 2017]*until expended*: *Provided further, That in addition to amounts provided herein, $30,000,000 shall be made available under section 241 of the PHS Act for necessary expenses to initiate a longitudinal health insurance study, with such reimbursable amounts advanced and available until September 30, 2020.*

For expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act), [$255,000,000] *$646,425,000*, to remain available until expended.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic *or emerging infectious disease, including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools*, [$71,915,000] *$170,009,000*; of which [$39,906,000] *$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*, 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*.

For an additional amount for expenses necessary to provide immediate response to an urgent need, including a disease outbreak, a disaster, and an urgent or emergency public health care need,

$90,000,000 to be available until expended: Provided, That funds may be used for state and local emergency response: Provided further, That in addition to amounts provided herein, $20,000,000 shall be made available for preparedness or response activities, including for equipment and training, and shall be available until expended: Provided further, That the funds in this paragraph may be transferred at the discretion of the Secretary for the purposes provided in this paragraph to other accounts within the Department of Health and Human Services.

FY 2016 Proposed General Provisions

SEC. ___. (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.

SEC. ___. *WORK INJURY AND DISEASE COMPENSATION FOR NATIONAL DISASTER MEDICAL SYSTEM EMPLOYEES.*

Section 2812(d)(2) of the Public Health Service Act (42 U.S.C. 300hh-11(d)(2)) is amended—

(1) by redesignating the three sentences as subparagraphs (A), (B), and (C), respectively, and indenting accordingly;

(2) in subparagraph (A), as so redesignated, by striking "An" and inserting "IN GENERAL.—An";

(3) in subparagraph (B), as so redesignated, by striking "With" and inserting "APPLICATION TO TRAINING PROGRAMS.—With";

(4) in subparagraph (C), as so redesignated, by striking "In" and inserting "RESPONSIBILITY OF LABOR SECRETARY.—In"; and

(5) by adding at the end the following new subparagraphs:

"(D) COMPUTATION OF PAY.—In the event of an injury to such an intermittent disaster-response appointee, the position of the employee shall be deemed to be 'one which would have afforded employment for substantially a whole year,' for purposes of section 8114(d)(2) of such title.

"(E) CONTINUATION OF PAY.—The weekly pay of such an employee shall be deemed to be the hourly pay in effect on the date of the injury multiplied by 40, for purposes of computing benefits under section 8118 of such title."

SEC. ___. *In the event of a public health emergency declared under section 319 of the PHS Act, the Secretary of HHS may, during the duration of the emergency, transfer discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) which are appropriated in this Act for the current fiscal year for HHS between appropriations for costs of responding to and aiding in recovery from such public health emergency: Provided, That no appropriation may be reduced by more than 10 percent under this section: Provided further, That the Committees on Appropriations of the House of Representatives and the Senate shall be promptly notified of such transfers: Provided further, That this transfer authority is in addition to any other transfer authority.*

Appropriations Language Analysis

Language Provision	Explanation
Provided further, That in addition to amounts provided herein, $30,000,000 shall be made available under section 241 of the PHS Act for necessary expenses to initiate a longitudinal health insurance study, with such reimbursable amounts advanced and available until September 30, 2020.	This language provides funding for the proposed Effective Health Insurance Initiative through Public Health Service Evaluation funds. A multi-year (5 year) period of availability is requested because these funds are for long term evaluation purposes, which require more than a single year for planning and implementation.
For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic or emerging infectious disease, including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools, [$71,915,000] *$170,009,000; of which* [$39,906,000] *$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 clarifies that these funds are not the only HHS funds available for preparing for or responding to an influenza pandemic or emerging infectious disease. This language provides the authority to use FY 2016 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.
For an additional amount for expenses necessary to provide immediate response to an urgent need, including a disease outbreak, a disaster, and an urgent or emergency public health care need, $90,000,000 to be available until expended: Provided, That funds may be used for state and local emergency response: Provided further, That in addition to amounts provided herein, $20,000,000 shall be made available for preparedness or response activities, including for equipment and training, and shall be available until expended: Provided further, That the funds in this paragraph may be transferred at the discretion of the Secretary for the purposes provided in this paragraph to other accounts within the Department of Health and Human Services.	This language provides a total of $110 million to be available until expended to respond to an urgent or emergency need that could cause severe consequences, but does not necessarily -- or not yet -- meet the criteria for a *Stafford Act* or public health emergency declaration, and in which rapid action would be needed mitigate the threat. Within this total, up to $20 million would be available to prepare for such a response when speed is of concern for coordination, training, command and control, and other related needs.

Language Provision	Explanation
SEC. ___. *WORK INJURY AND DISEASE COMPENSATION FOR NATIONAL DISASTER MEDICAL SYSTEM EMPLOYEES.* *Section 2812(d)(2) of the Public Health Service Act (42 U.S.C. 300hh-11(d)(2)) is amended—* *(1) by redesignating the three sentences as subparagraphs (A), (B), and (C), respectively, and indenting accordingly;* *(2) in subparagraph (A), as so redesignated, by striking "An" and inserting "IN GENERAL.—An";* *(3) in subparagraph (B), as so redesignated, by striking "With" and inserting "APPLICATION TO TRAINING PROGRAMS.—With";* *(4) in subparagraph (C), as so redesignated, by striking "In" and inserting "RESPONSIBILITY OF LABOR SECRETARY.—In"; and* *(5) by adding at the end the following new subparagraphs:* *"(D) COMPUTATION OF PAY.—In the event of an injury to such an intermittent disaster-response appointee, the position of the employee shall be deemed to be 'one which would have afforded employment for substantially a whole year,' for purposes of section 8114(d)(2) of such title.* *"(E) CONTINUATION OF PAY.—The weekly pay of such an employee shall be deemed to be the hourly pay in effect on the date of the injury multiplied by 40, for purposes of computing benefits under section 8118 of such title."*	This language would ensure equitable workers' compensation coverage under the Federal Employees Compensation Act (FECA) for National Disaster Medical System intermittent employees when they are activated for training or deployment.
SEC. ___. *In the event of a public health emergency declared under section 319 of the PHS Act, the Secretary of HHS may, during the duration of the emergency, transfer discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) which are appropriated in this Act for the current fiscal year for HHS between appropriations for costs of responding to and aiding in recovery from such public health emergency: Provided, That no appropriation may be reduced by more than 10 percent under this section: Provided further, That the Committees on Appropriations of the House of Representatives and the Senate shall be promptly notified of such transfers: Provided further, That this transfer authority is in addition to any other transfer authority.*	This language provides the Secretary with the authority to transfer up to 10 percent of appropriated funds for emergency response purposes. The authority may only be used during a declared public health emergency.

AMOUNTS AVAILABLE FOR OBLIGATION

(In Dollars)

Detail	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget
Annual Appropriation	464,299,000	460,163,282	486,823,760
Rescissions	-	-	-
Sequester Order	-	-	-
Transfers	+10,599,000	-	-
Subtotal, Adjusted Annual Appropriation	**474,898,000**	**460,163,282**	**486,823,760**
Multi-Year Appropriation	425,000,000	478,000,000	526,732,000
Supplemental (PL 113-235)	-	+733,000,000	-
Rescissions	-	-	-
Sequester Order	-	-	-
Transfers	-1,606,000	-	-
Subtotal, Multi-Year Appropriation	**423,394,000**	**1,211,000,000**	**526,732,000**
No-Year Appropriation	354,131,000	294,906,000	896,425,000
Rescissions	-	-	-
Sequester Order	-	-	-
Transfers	-1,328,566		
Subtotal, No-Year Appropriation	**352,802,434**	**294,906,000**	**896,425,000**
Total, Adjusted Budget Authority	**1,251,094,434**	**1,966,069,282**	**1,909,980,760**
Unobligated balance, start of the year	1,435,813,078	97,021,201	
Unobligated balance, end of the year	97,021,201		
Total Obligations	**1,338,791,877**		

SUMMARY OF CHANGES

(Dollars in millions)

FY 2015	
Total Estimated Budget Authority	1,233
(Obligations)	1,474
FY 2016	
Total Estimated Budget Authority	1,910
(Obligations)	1,619
Net Change	**+677**

Increases	**FY 2016 PB FTE**	**FY 2016 PB BA**	**FY 2016 +/- FY 2015 FTE**	**FY 2016 +/- FY 2015 BA**
Assistant Secretary for Preparedness and Response				
Biomedical Advanced Research and Development Authority (BARDA)	155	522	--	+49
Project BioShield	-	646	--	+391
Hospital Preparedness Program	49	255	+5	--
Subtotal, ASPR Increases			**+5**	**+440**
Other Office of the Secretary				
Cybersecurity	123	73	+11	+32
Subtotal, Other Office of the Secretary Increases			**+11**	**+32**
Pandemic Influenza				
No-year Flu Funds	-	140	--	+100
Subtotal, Pandemic Influenza			**--**	**+100**
Public Health Emergency Response Initiative	-	110	--	+110
Total Increases			**+16**	**+683**

Decreases	**FY 2016 PB FTE**	**FY 2016 PB BA**	**FY 2016 +/- FY 2015 FTE**	**FY 2016 +/- FY 2015 BA**
Assistant Secretary for Preparedness and Response				
Preparedness and Emergency Operations	86	25	--	-0.14
National Disaster Medical System	115	50	--	-0.15
Medical Reserve Corps	6	6	--	-2.98
Operations	135	31	--	-0.37
Subtotal, ASPR Decreases			**--**	**-4**
Pandemic Influenza				
Annual Flu Funds	5	30	--	-2
Subtotal, Other Office of the Secretary Decreases			**--**	**-2**
Total Decreases			**--**	**-6**

Net Change in Program Level			**+16**	**+677**

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Thousands)

Activity	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget
Bioterrorism and Emergency Preparedness	1,120,357	1,161,154	1,739,972
Pandemic Influenza	114,606	71,915	170,009
Buildings and Facilities	16,131	-	-
Total Budget Authority	**1,251,094**	**1,233,069**	**1,909,981**
Total FTE	**696**	**757**	**773**

AUTHORIZING LEGISLATION

(Dollars in Thousands)

Details	2015 Authorized	2015 Enacted	2016 Authorized	2016 President's Budget
Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)		1,233,069		1,939,981

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				
Appropriation			1,389,813	1,233,069
Supplemental Appropriation				733,000
FY 2016				
Estimate	1,909,981			

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Summary of Request

Budget Summary
(Dollars in Thousands)

ASPR	FY 2014 Final /2	FY 2015 Enacted /3	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority /1	1,171,419	1,180,465	1,715,085	+534,620
Ebola Emergency Funding (non-add)	-	*58,000*	-	*-58,000*
FTE	588	607	612	+5

1/ These amounts include ASPR's portion of pandemic influenza funding.
2/ In FY 2015, the Civilian Volunteer Medical Reserve Corps (MRC) moved to ASPR from the Office of the Assistant Secretary for Health. For comparability, FY 2014 funding for MRC is also included in this table.
3/ Congress appropriated $733 million in one-time emergency funding to the Public Health and Social Services Emergency Fund (PHSSEF) for the U.S. Government response to contain, treat, and prevent the spread of Ebola. This funding is not reflected in this total. This emergency funding includes $157 million for ASPR's Biomedical Advanced Research and Development Authority and $576 million to be allocated by the Secretary.

The fiscal year (FY) 2016 Budget Request for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is $1,715,085,000, which is +$534,620,000 above FY 2015.

ASPR has contributed significantly to the nation's improvements in public health emergency management since 9/11 and Hurricane Katrina. ASPR and its federal, state, and local partners have built a nimble, flexible infrastructure that allows the nation to respond to all hazards.

Some of the most troubling threats to Americans' health and security are chemical, biological, radiological, and nuclear (CBRN) agents; pandemic influenza; and emerging infectious diseases (e.g., Ebola). Through ASPR's Biomedical Advanced Research and Development Authority (BARDA) and $5.6 billion in initial Project BioShield appropriations, our nation acquired 12 medical countermeasures (MCM) against the CBRN threats by the end of FY 2013. Almost half of these MCMs also have a "peacetime" public health use. In 2012 and 2013, two of these CBRN products became the first products approved under the Animal Efficacy Rule. In addition, since 2012, the Food and Drug Administration has approved six first-in-class vaccines, antiviral drugs, diagnostics, and medical devices for seasonal and pandemic influenza. BARDA and its partners also are supporting rapid research on and development of several promising vaccines and therapeutic MCMs against Ebola. This expedited response to the West African Ebola outbreak beginning in 2014 and the rapid development and stockpiling of vaccine against a new strain of avian influenza (H7N9) in China in 2013 demonstrates how far the nation has come during the last decade.

ASPR has led our nation's progress in public health emergency response. Hurricane Katrina exposed major problems in emergency management and response. Congress established ASPR after Hurricane Katrina, and addressing these weaknesses has been one of ASPR's most important missions. Through the Office of Emergency Management (OEM) and the Hospital Preparedness Program (HPP), ASPR modernized the federal emergency management infrastructure and strengthened states' and local communities' disaster response and recovery. In addition, through the Office of Policy and Planning

(OPP), ASPR leads policy development, collaboration, research on MCMs, and public health emergency management, response, and recovery throughout the nation and around the world.

ASPR's goals for FY 2016 are to sustain this critical mission and achieve new successes in public health emergency management. The request supports these goals.

Programmatic Increases:

- **BARDA (+$48.7 million above FY 2015; $521.7 million total):** The FY 2016 Budget includes a total of $521,732,000 for BARDA's advanced research on and development of MCMs against CBRN threats. This level includes $192 million (+$108 million above FY 2015) for the Administration's *National Strategy on Combating Antibiotic-Resistant Bacteria*. BARDA will continue using innovative public-private partnerships with pharmaceutical and biotech companies to develop antibacterial therapies.
- **Project BioShield (+$391.4 million above FY 2015; $646.4 million total):** The FY 2016 Budget includes $646,425,000 to procure 7 new MCMs against CBRN agents, including Ebola vaccines, and additional quantities of some existing MCMs that are part of the nation's stockpile. The request aims to keep the United States on track to procure 12 new CBRN MCMs by the end of FY 2018.
- **Pandemic Influenza (+$98.1 million above FY 2015; $166.0 million total[1]):** The FY 2016 Budget includes $166,000,000 for ASPR's advanced research and development of MCMs against pandemic influenza and its work on global pandemic preparedness. The request supports the advanced development of up to two vaccine candidates that may afford greater effectiveness against seasonal and pandemic influenza virus strains. The candidates may serve as "universal" influenza vaccines.

Programmatic Decreases:

- **Facility Efficiencies (-$652,000 below FY 2015; $105.5 million total[2]):** Through FY 2013, ASPR had consolidated 90 percent of its staff into the renovated Thomas P. O'Neill Federal Building in Washington, DC. Since that time, ASPR has re-evaluated its facilities needs to identify additional efficiencies. This request level reflects further space efficiencies that ASPR plans to achieve.
- **Civilian Volunteer Medical Reserve Corps (-$3.0 million below FY 2015; $6.0 million total):** The FY 2016 Budget includes $6,000,000 for the Civilian Volunteer Medical Reserve Corps (MRC). MRC moved to ASPR from the Office of the Assistant Secretary for Health in FY 2015. The transfer is consistent with statutory requirements included in the 2013 *Pandemic and All-Hazards Preparedness Reauthorization Act*. The request level (-$2,979,000 below FY 2015) reflects program changes and efficiencies that will follow the move to ASPR.

General Provisions:

- **Multiyear Contracting Authority:** The FY 2016 Budget sustains a general provision included in the FY 2015 Omnibus that allows BARDA to modify requirements of its existing multiyear contracting authority. This authority provides BARDA flexibility to enter into long-term procurement contracts for MCMs while operating within annual budgets.

[1] This total does not reflect PHSSEF funding for the Office of Global Affairs' pandemic influenza activities ($4,009,000).
[2] The Budget reduces funding for three accounts—Preparedness and Emergency Operations (OEM), National Disaster Medical System (OEM), and Operations (ASPR-wide)—by a total of -$652,000.

- **Enhanced Transfer Authority:** To augment HHS' capability to respond rapidly to public health emergencies, the FY 2016 Budget proposes a general provision to increase the percentage of funding the Secretary may transfer among HHS' accounts during emergencies. This enhanced transfer authority will allow HHS to more rapidly assist states and local communities when a catastrophic event occurs.
- **Compensation for National Disaster Medical System Intermittent Employees:** The FY 2016 Budget proposes to specify the pay rate for compensating National Disaster Medical System (NDMS) intermittent employees under the Federal Employees' Compensation Act (FECA) to be equivalent to the pay rate and coverage for full-time federal employees in a similar position when they are injured or become ill. The NDMS workforce includes more than 5,000 intermittent employees who comprise more than 80 regional and state-based teams. The injury rate among NDMS intermittent employees is low. The proposal supports these employees who assist the nation during public health emergencies, often working alongside federal employees who may qualify for greater FECA coverage. The proposal also will make NDMS a more attractive employer, which will help ensure that it maintains an adequate number of qualified individuals to respond to public health emergencies.

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

In FY 2014, 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 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	28,029	24,789	24,654	-135
National Special Security Events/Public Health Emergencies (non-add)	*4,950*	*5,000*	*5,000*	--
FTE	76	86	86	--

Authorizing Legislation:
FY 2016 Authorization.....PAPHRA
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

The programs, initiatives, and people of the Office of Emergency Management (OEM) work together to save and sustain lives by supporting communities as they prepare for, respond to, and recover from public health and medical impacts of emergencies and disasters. Funding for the Preparedness and Emergency Operations (PEO) activity supports OEM.

Whether OEM is deploying behavioral health resources or lifesaving equipment, supplies, and teams to support medical surge capacity after a catastrophic hurricane or sending subject matter experts to provide all-hazards consultation or technical assistance to state and local authorities after a chemical release, OEM continuously supports thorough, direct, and open communication with all stakeholders – federal, state, local, tribal, territorial and non-governmental organizations. OEM helps these stakeholders save lives, mitigate suffering, and preserve health.

ASPR's OEM is vital to fulfilling HHS' responsibilities for public health emergencies. HHS is the coordinator and primary agency for Emergency Support Function (ESF) 8 (Public Health and Medical) of the National Response Framework. HHS also leads the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework. ASPR/OEM leads these functions within HHS. OEM provides leadership and support for all major public health and medical incidents.

OEM has led and supported HHS' efforts to respond to and mitigate the lasting impacts of public health and medical emergencies for several years. For example, OEM supported responses to Hurricanes Katrina, Rita, and Wilma in 2005; Ike and Gustav in 2007; and Sandy in 2012. OEM also responded to the earthquake in Haiti in 2009; the Deepwater Horizon oil spill in 2010; tornadoes in 2012 that crippled the health infrastructure in Oklahoma and Missouri; and mass shooting incidents in 2013. For each of these responses, OEM provided targeted and specific information related to the impact each incident had on the supporting health infrastructure to ensure a continuation of health care for the public. OEM also provided coordination of all federal assets and capabilities to limit duplication of efforts and ensure the federal government addressed requests from state and local partners timely and appropriately.

OEM also directed and managed the deployment of National Disaster Medical System (NDMS) teams to manage health care requirements as systems required surge support to treat the affected populations.

In addition, OEM recently supported a number of other important incidents with public health and medical implications. Throughout 2014, OEM supported the Department of Homeland Security's Customs and Border Protection's (CBP) officers as they provided health screening for an influx of unaccompanied children crossing the U.S. border. OEM/NDMS personnel augmented CBP's efforts and provided senior HHS leaders and other government officials with up-to-date information.

OEM also continues to support America's preparedness for and response to the West African Ebola outbreak. In coordination with the Centers on Disease Control and Prevention (CDC), OEM is leading the development of a federal interagency senior leadership brief that goes to the White House National Security Staff and the Domestic Resilience Group. In addition, OEM's Division of Planning is collaborating with partners to continue an ongoing review of domestic Ebola preparedness and response plans and modifies them as needed. This important plan outlines how the federal government is and will continue to respond to Ebola domestically. In addition, OEM/NDMS developed safety guidelines for the U.S. Public Health Service mission in Africa, and NDMS headquarters personnel developed training requirements that will enhance system readiness in the future. The training will ensure that when NDMS is activated to provide support for any wide-scale disease outbreak, teams are able to provide clinical care as needed and required.

During and after each response, OEM captures lessons learned and incorporates them into existing practices and procedures. In addition, to better serve stakeholders, effectively strengthen disaster preparedness and response capabilities, and fulfill its missions, OEM developed a strategic plan in 2014 that establishes organizational priorities through 2020. Using its 2014 Strategic Plan as a guide, OEM is:

- Promoting the development of a strong, well-trained workforce ready to provide an effective response to disasters and emergencies;
- Helping the public understand how they can care for themselves during an emergency;
- Ensuring resources are invested where they are most needed; and
- Improving communications among all sectors, from government emergency response to private-sector and community-based organizations.

To better support its varied programs and initiatives, in April 2013, OEM reorganized into ten divisions covering the full spectrum of emergency management responsibilities. The ten divisions work together to assist communities in building and maintaining resilience in the face of disasters. The divisions are:

1. Planning
2. Resilience and Infrastructure Coordination
3. National Healthcare Preparedness Program
4. Fusion
5. Operations
6. Logistics
7. Tactical Programs
8. National Disaster Medical System
9. Regional and International Coordination
10. Recovery

Preventing and Mitigating the Adverse Health Effects of Disasters and other Emergencies

To support nimble, flexible, adaptable, coordinated, and consolidated responses to public health and medical incidents, OEM's Division of Planning develops both deliberate and crisis action plans. Deliberate operational planning is a highly-structured process that engages managers and staff among the various federal agencies in a methodical development of a fully-coordinated, complex plan for all contingencies and the transition to and from active events. In contrast, crisis action planning is based on current events and is conducted in time-sensitive situations and emergencies. These plans provide for the coordination of federal public health, health care delivery, and emergency response systems to minimize and/or prevent health emergencies from occurring. Further, these plans assist in detecting and characterizing health incidents; providing medical care and human services to those affected; reducing the public health and human services effects on the community; and enhancing community resilience to respond to a disaster. In both deliberate and crisis action planning, OEM's Division of Planning provides senior-level decision makers with recommended courses of action to support HHS' mission.

All plans provide a solid foundation that eases the transition to national-level responses during public health emergencies. Plans ensure that the ASPR, as the Secretary's lead for coordinating HHS' response, has the systems, response infrastructure, and logistical support necessary to coordinate the HHS' operational response to catastrophic incidents, acts of terrorism, or any public health and medical threat or emergency that requires federal augmentation.

The All Hazards Plan provides an integrated national strategic- and operational-level view of the public health and medical preparedness, response, and recovery actions HHS may execute, as the lead for ESF 8, in a natural or man-made disaster. The All Hazards Plan describes the federal public health and medical functional area missions and how each function is accomplished. The assignment of resources, situational awareness, and coordination are very important to success. Scenario-specific annexes to this plan, such as the one for pandemic disease, describe how HHS will coordinate and conduct activities at the national level as the lead agency in the federal public health and medical response to an emerging threat. The annexes to the All Hazards Plan address HHS' capabilities, essential tasks, and resources by the phase of response. They also specify requirements for ESF 8 and other federal partners who support HHS in carrying out its response mission. The planning process builds on previous HHS and interagency pandemic planning efforts.

OEM also supports efforts to ensure that operations and business support functions will continue to provide critical services that protect and save lives in a worst-case scenario. In accordance with federal and presidential directives, OEM's Division of Resilience and Infrastructure Coordination is responsible for leading the effort to ensure the continuation of HHS' essential functions during all hazards. The Department's Continuity of Operations (COOP) program serves the Office of the Secretary (OS) and other HHS staff and operating divisions by developing and managing a unified HHS COOP program. COOP also handles the day-to-day operations and implementation of the OS Continuity Program. OEM refines the required planning documents, as needed, within the scope of HHS' unified COOP Program. These documents include a component COOP plan template, an HHS headquarters COOP plan, an ASPR COOP plan, and a COOP Personnel Implementation Guide—which provides concise guidance for all HHS personnel during a COOP activation based on their individually-assigned positions.

In 2014, the COOP program reviewed and facilitated several continuity-focused test, training, and exercise events. In July 2014, OEM participated in the White House's annual continuity exercise. Working and planning with all other components and senior leaders, the HHS COOP program achieved the highest possible scores from the Department of Homeland Security's Federal Emergency Management Agency (FEMA). In 2014, OEM continued its work with other parts of HHS on plan development, exercises, and seminars relating to devolution and reconstitution.

In FYs 2013 and 2014, OEM integrated the COOP programs of disparate HHS components into an integrated HHS COOP Program. This integration allowed HHS to implement a comprehensive continuity program while eliminating redundancies and addressing gaps in a cost-effective manner. OEM also has primary responsibility for HHS' implementation of the National Communications System Directive (NCSD) 3-10. This directive establishes the minimum continuity communications requirements for all executive branch agencies. ASPR serves as the HHS lead to ensure that all communication capabilities HHS must possess at headquarters and alternate sites are available and functional for continuity of operations activities. As a result of OEM's leadership of the NCSD 3-10 testing, HHS has achieved 100 percent compliance in testing and associated metrics. OEM has also increased HHS' emergency communications capabilities, including the management and implementation of Wireless Priority Service for continuity personnel, procurement and installation of high-frequency and in-transit communications, and a nearly-tenfold increase in bandwidth capacity at the HHS COOP site. These capabilities allow HHS to develop and maintain a strong, redundant communications capability while reducing costs.

Leading Response Operations from Headquarters

Early detection is critical to mitigating events that have the potential to significantly impact public health. OEM supports the surveillance of emerging threats and incidents 24 hours a day, seven days a week. The Secretary's Operation Center (SOC) monitors information from federal, state, local, territorial, tribal, private-sector, non-profit, and international partners to identify potential or emerging threats to public health. For analysis of trends and data, the SOC leverages expertise within OEM's Division of Fusion to build reports that inform decision-makers about potential events. Both the Division of Fusion and the SOC monitor media reports, various official information systems, and other information streams to be well-informed about potential or evolving threats and developing situations. OEM has evolved as technology has changed. For example, OEM monitors new forms of social media to understand public fears and knowledge. Then, OEM is able to respond before it is too late to help change the trajectory.

The SOC is strengthening relationships with other programs, offices, and private-sector partners by including such partners as soon as emergencies occur. These partners include OEM's Critical Infrastructure Protection (CIP) program and HHS' Office of Security and Strategic Information, the Food and Drug Administration, and CDC. Partners outside HHS include the Department of Defense, the World Health Organization, 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 public health departments. The SOC supports an open communication exchange to maintain situational awareness before, during, and after an incident. Open and ongoing information exchanges and communication among these partners throughout the continuum of preparedness, response, and recovery help maintain a comprehensive common operating platform and decision support system for the Secretary and the ASPR. The SOC has also enhanced its web platform, Web EOC, to improve incident management, reporting, and compatibility with other users.

As mentioned above, OEM's Division of Fusion analyzes data and integrates information from multiple internal and external sources. The division performs near-real time analysis using tools including MedMap, Fusion Analytics, HavBed, and Social Media Analytics. These tools allow the division to track emerging threats and health system resources, such as available hospital beds. The Division of Fusion's analysis provides decision-makers with the information they need to be better during public health emergencies. This information leads to more-informed and rapid responses, and helps OEM better tailor resource needs to events.

The Division of Fusion is OEM's source for in-depth information, analysis, and synthesis. They report on trends and salient points that go beyond the traditionally-reported information. Earlier this year, the division launched the "Now Trending" website (http://nowtrending.hhs.gov/). This site, which resulted from a challenge competition, is a tool for health departments and other entities to use as an indicator of potential health issues emerging in their population, to build a baseline of trend data, and to engage the public on trending health topics. In addition, SOC Geographic Information System (GIS) staff are developing routine procedures for integrating electricity-dependent population data into GIS products ahead of and during disaster events. This will allow these populations to be rapidly identified, and assisted, in an emergency. This initiative started as a pilot, but will move to full implementation so that the SOC will be able to manage and be responsible for monitoring these populations.

The SOC and the Division of Fusion work in concert to ensure that clear, timely, reliable, valid, and comprehensive information and analysis is submitted to ASPR, partner agencies, and other HHS leaders. One example of this collaboration was in the aftermath of the Boston Marathon bombings in April 2013. After the bombings, the SOC quickly gathered real-time information from both traditional and non-traditional sources and facilitated situational awareness for public health stakeholders throughout the federal government. Simultaneously, the SOC and the Division of Fusion analyzed medical resources in the Boston area, monitored social media, and used GIS and mapping resources to develop resource utilization estimates and help guide planning efforts. This collaboration is an integral part of OEM's ability to be a trusted source for situational awareness information.

When an incident that requires or may require significant federal support is identified, OEM rapidly shifts its focus to response by providing necessary surge support to state and local partners. All ten OEM divisions have supporting roles in a response and work together to address issues that arise. OEM supports responses to both catastrophic and small-scale public health and medical incidents at the request of state and local partners. OEM is also available to help with routine events that have the potential to become a large public health incident. In addition to its deployable assets, OEM has a robust structure in place to coordinate information sharing, decision-making, and operational support at the headquarters level to guide the use of its assets to ensure processes are efficient and meet requirements in the field.

OEM's operations have included large responses such as to Hurricane Sandy, international operations such as the response to the Haiti earthquake, and nontraditional mental health missions such as the responses to the 2012 Sandy Hook Elementary School shootings in Connecticut and the 2013 Boston Marathon bombings. In 2014, ASPR/OEM supported the response to severe weather incidents, provided health screening support for the influx of thousands of unaccompanied children crossing the southern U.S. border, and the outbreak of Ebola virus disease in West Africa. ASPR/OEM also monitored and supported numerous other smaller, localized events and public gatherings.

Recently, OEM has tracked and analyzed a number of smaller incidents with the potential to significantly impact public health. When the SOC identifies such incidents, HHS/ASPR headquarters staff identify potential assets for deployment and prepare to support requests for assistance. Headquarters staff communicate directly with OEM's Regional Emergency Coordinators (REC), who serve as the points of contact for OEM within the ten regions and with state and local officials before, during, and after emergencies.

OEM also coordinates and provides information to other federal partners to ensure that all assets are organized and ready in case federal support is required. Sometimes, these events—including tornadoes, severe winter weather, and flooding events—do not require federal support to mitigate public health impacts because states are adequately prepared and able to respond on their own. Those incidents demonstrate that state and local partners have successfully prepared for large-scale public health

emergency events. OEM has successfully deployed subject matter experts to support state and local partners when incidents call for creative solutions. These deployments have had great success and likely diminished the unnecessary deployment of large federal teams.

In addition to unpredictable incidents, OEM supports a number of routine events by providing medical teams who can respond with public health assistance if needed. These National Special Security Events (NSSE) include the following: the President's annual State of the Union Address; annual Independence Day celebrations in Washington, DC; North Atlantic Treaty Organization summits; quadrennial national political conventions; the National Football League's annual Super Bowl; and quadrennial Presidential Inaugurations.

HHS also uses NSSE funding to support other events that may not be anticipated but require rapid responses or that are not authorized under the *Stafford Act* for reimbursement from FEMA, like U.S. State Funerals. For example, in December 2012, ASPR used NSSE funding to rapidly deploy mental health support to Connecticut after the Sandy Hook Elementary School shootings. In April 2013, ASPR used NSSE funding to provide mental health support to disaster responders after the Boston Marathon bombings. In May 2014, ASPR used NSSE funding to provide public health and medical support to the unaccompanied children from Central America who crossed the border with Mexico into the Rio Grande Valley of Texas. ASPR also provided NSSE funding to CDC in 2014 to respond to and prepare for Ebola.

Improving Future Responses Using Information on Public Health and Lessons Learned

To enhance operations and improve future responses to public health and medical incidents, OEM creates corrective action plans based on recommendations from past responses and refines procedures and capabilities for future actions. OEM's Division of Tactical Programs leads the after-action reporting, prioritization, and corrective-action process for all of ASPR's response programs and assets. The division incorporates a systematic approach to ensure ASPR is poised to achieve success in preparing for, responding to, and recovering from public health and medical incidents.

OEM has a formal system to capture lessons learned and track associated corrective actions to strengthen the health and emergency response systems in place for future events. Following each response, when appropriate, ASPR meets with its HHS, federal, state and local partners. OEM also conducts staff-level engagements and meetings to identify root causes and opportunities to improve.

Lastly, OEM's Division of Tactical Programs provides subject matter expertise in analysis and implementation of lessons learned. The division conducts exercises to enhance response and improve operational expertise. The division is comprised of three branches. The Center for Tactical Medicine Branch, through its Counter-Narcotics and Terrorism Operational Medical Support Program, promotes a federal standard of excellence in providing high-quality training for tactical emergency medicine to federal, state, local, tribal, and territorial responders. Through its support of federal law enforcement agencies, this branch helps to "protect the protectors."

Through its Training, Exercise and Lessons Learned (TELL) Branch, the Division of Tactical Programs focuses on the well-established "plan, train, exercise/respond, and evaluate" model. TELL Branch promotes and validates preparedness and response capabilities within HHS. TELL Branch conducts training, validates preparedness levels and response capabilities through exercises, and uses the corrective actions program to tie training and exercises together.

The Chemical, Biological, Radiologic, Nuclear and Explosives (CBRNE) Branch of the Division of Tactical Programs coordinates and provides medical and health-related CBRNE subject and operational expertise across the spectrum of ASPR preparedness and response. The CBRNE Branch recognizes, anticipates,

and evaluates gaps in the nation's medical and public health response systems. In addition, through cooperative professional interaction with both internal and external entities, the branch develops innovative, evidence-based interventions that strengthen the nation's medical and public health emergency response, including regional medical countermeasure initiatives. During preparedness and in response to an accidental or intentional CBRNE incident, the CBRNE Branch provides leadership, advice, and guidance regarding strategic, technical, and operational issues; medical and public health impacts; and interventions.

Funding History

Fiscal Year	*Amount*
FY 2012	$29,583,000
FY 2013	$27,984,000
FY 2014[3]	$28,029,000
FY 2015 Enacted	$24,789,000
FY 2016 Budget	$24,654,000

Budget Request

The FY 2016 Budget includes $24,654,000 for Preparedness and Emergency Operations activities (which supports the Office of Emergency Management, or OEM). This request level is -$135,000 below FY 2015. The request supports OEM's ability to immediately respond to a public health emergency or medical incident when called on to do so. The reduction reflects efficiencies that OEM will achieve following an ASPR-wide analysis of facilities utilization.

The FY 2016 request includes $5,000,000 in no-year funding to prepare for and respond to National Special Security Events (NSSE), public health emergencies, and other events that are not eligible for assistance from the Department of Homeland Security's Federal Emergency Management Agency under the *Stafford Act*. As noted above, NSSE funding supports the activation of coordination personnel and response teams for planned events such as the President's annual State of the Union address and the quadrennial national political conventions. NSSE funding also supports less frequent events like the response to the Ebola outbreak. For instance, HHS anticipates supporting the Papal visit to the United States in 2015.

[3] Reflects the reduction of -$50,000 for the FY 2014 Secretary's permissive transfer.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
National Disaster Medical System

Budget Summary
(Dollars in Thousands)

ASPR National Disaster Medical System	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	50,054	50,054	49,904	-150
FTE	109	115	115	--

Authorizing Legislation:
FY 2016 Authorization.....PAHPRA
Allocation Method .....Direct Federal/intramural, contracts

Program Description and Accomplishments

States and local partners have significantly invested in preparedness initiatives over the last decade and are demonstrating their resilience to public health and medical incidents as a result. Most recently, communities have responded without federal assistance to destructive tornadoes and storms, explosions, and outbreaks. In each incident, ASPR's Office of Emergency Management (OEM) prepared and monitored the situation in case assistance was requested.

When an event overwhelms state and local capabilities, OEM's National Disaster Medical System (NDMS) provides surge support and assists state and local communities in treating people affected by the event. State and local officials can request federal resources to augment medical care. NDMS functions under the authorities of the *Public Health Service Act*. It is a coordinated partnership between HHS and the Departments of Veterans Affairs, Homeland Security, and Defense. NDMS has provided assistance to communities impacted by public health and medical emergencies ranging from small severe weather incidents to catastrophic hurricanes and tornadoes.

OEM/NDMS augments the nation's medical response capability during actual or potential public health emergencies through a partnership with 1,800 hospitals and a workforce of more than 5,000 intermittent employees who comprise more than 80 regional and state-based teams. NDMS remains the single most critical and effective medical resource that provides surge support should an event occur that overwhelms the nation's health infrastructure. NDMS teams include clinical providers; emergency medical service professionals including physicians, nurses, advanced practice providers; and other support staff. NDMS is capable of providing medical, veterinary, and mortuary response; patient movement; and definitive care.

NDMS teams include:

- ***Disaster Medical Assistance Teams (DMATs):*** Provide a range of medical capabilities, including stabilizing emergency care to communities affected by disaster. These teams include physicians, advanced practice clinicians, nurses, paramedics and non-clinical support staffing and are comprised to deploy in modular units of 24, 36, or 48 personnel to accomplish the specific mission needs of a local community.

- ***International Medical Surgical Teams (IMSURTs)*:** Provide stabilizing surgical care and can be deployed domestically or internationally. The IMSURTs have a similar composition to DMATs. However, they are staffed by surgical/critical care providers. IMSURTs typically deploy in concert with one or more DMATs for post-surgical/critical care treatment and support.
- ***Disaster Mortuary Assistance Teams (DMORTs)*:** Support a community that has experienced a mass-fatality event. DMORTs respond with providers to assist and support local resources, including full mortuary staffing capabilities and a victim identification team to facilitate combining post- and anti-mortem data to identify victims' remains.
- ***National Veterinary Response Teams (NVRTs)*:** Deliver disaster medical care for large and small animals upon request. NVRTs are primarily composed of veterinarians and animal health technicians to facilitate the stabilization of animal populations affected by a disaster.

Since NDMS was formed in 1989, it has been activated and deployed on approximately 300 occasions to provide medical, mortuary, and veterinary support for both natural and man-made events. These events include hurricanes (Katrina, Ike/Gustav, and Sandy), tornadoes (Joplin, MO), international earthquakes (Iran and Haiti), flooding (Red River, ND, and Tarboro, NC), acts of terrorism (the 1999 Oklahoma City bombings, September 11th terrorist attacks, and 2013 Boston Marathon bombings), airline crashes (American Airlines Flight 587), behavioral health emergencies (the 2012 Sandy Hook Elementary School shootings), major fires (Rhode Island disco), and environmental crises (Exxon Valdez and the Deepwater Horizon). Additionally, NDMS has provided contingency medical support for national high profile events and National Security Special Events (NSSE) such as Presidential Inaugurations, quadrennial national political conventions, and State Funerals.

NDMS's recent initiatives and accomplishments include the following:

- Throughout 2014, NDMS supported efforts to enhance domestic readiness and preparedness for Ebola. Staff of the NDMS Chief Medical Officer program, including safety professionals, developed safety guidelines for the U.S. Public Health Service mission in Africa. NDMS also determined what resources were needed for domestic responses to Ebola that include its personnel. In addition, NDMS headquarters personnel developed training requirements that will enhance system readiness in the future. The training will ensure that when NDMS is activated to provide support for any wide-scale disease outbreak, teams are able to provide clinical care as needed and required.
- In 2013, NDMS entered into an agreement with the Center for Domestic Preparedness in Anniston, Alabama. This partnership supports fundamentals training for the Disaster Medical Assistance Teams. It also tests their skills at the conclusion with a disaster-scenario setting. NDMS anticipates that it will have the opportunity to use additional training venues in the future, which will increase cost-effectiveness and efficiency.
- NDMS is undergoing a major transition to enhance its response capabilities for greater flexibility and scalability. NDMS has initiated a comprehensive process to begin "typing," or categorizing, Disaster Medical Assistance Teams consistent with the National Incident Management System (NIMS), based on their capacity to treat patients. This process will improve ASPR's ability to both plan for and use the teams in an effective and consistent manner that complements existing medical infrastructure in an impacted community.

- National Veterinary Response Teams have fashioned themselves to be modular and smaller. The changes offer a smaller operational format but one that can be easily adjusted to support mission needs.
- NDMS created teams that will enhance patient movement of critical care patients during disasters. NDMS developed these Mobile Acute Care (MAC) teams based on lessons learned from Hurricane Katrina. For example, highly-skilled medical professionals support patients at flight lines until they can be evacuated, minimizing mortality risk at that vulnerable point in evacuation.

OEM's Division of Logistics leads the supporting components for NDMS and ensures that equipment is where it is needed to provide an effective response. It is a complex, coordinated effort to move and set up teams, supplies, and equipment. Success requires support from regional mission support center warehouse and storage facilities that can get resources ready and deployed at a moment's notice. The Division of Logistics manages and maintains over $85 million worth of response material and supplies including: vehicle fleets; medical, lab, pharmacy, and mortuary caches; communication kits; and shelter systems. Division subject matter experts provide critical services to support medical cache composition, structure, staging, and other logistical components for NDMS teams in the field.

Following are examples of some recent Division of Logistics initiatives and accomplishments:

- Led an interagency working group that conducted a comprehensive requirements study on the nation's Federal Medical Stations. The study resulted in a more appropriate design that allows NDMS to meet national response requirements.
- Implemented a web-based asset management system. It provides real-time tracking of ASPR's response resources, including maintenance and lifecycle replacement requirements. This system is helping NDMS achieve better efficiency and accuracy in procuring and managing material.
- Deployed hundreds of tons of material in support of numerous NSSEs—including U.S. Capitol ceremonies, and support for medical and mental health management during the 2012 Sandy Hook Elementary School and 2013 Boston Marathon emergency responses.
- Led an intra-agency working group that restructured and consolidated several different types of mobile medical capability kits in one efficient Mobile Life-saving Kit to enhance preparedness and response, and bridge capability gaps in care and resources that NDMS discovered during Hurricane Sandy.
- Rehabilitated over 700 tons of material and supplies deployed for Hurricane Sandy. These materials consisted of medical supplies and equipment, information technology and telecommunications equipment, and vehicles and ground support equipment. During rehabilitation, the equipment was serviced to return it to a deployable status. The Division of Logistics, in coordination with state partners and HHS response teams, was able to enhance NDMS's mobile medical cache capabilities and address several lessons learned from the Hurricane Sandy deployment.

NDMS's 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. Within its recently published strategic plan, OEM determined that one of its objectives is to conduct ongoing gap analyses of resources, tools, and processes and provide best practices for solving complex problems more effectively and efficiently. OEM established a working group and has begun to develop a process

to prioritize existing capabilities and address current threats, both natural and human-caused hazards, that impact public and medical health. OEM will use this process to assess risk and vulnerability to develop and set capabilities to reduce gaps.

OEM's Division of Regional and International Coordination also plays an important role for NDMS. Regional Emergency Coordinators (REC) who are located around the country build and maintain relationships with state, tribal, and local officials and health care representatives. These relationships support an effective, informed, and coordinated federal emergency response when one is requested. During emergencies, the RECs are the points of contact for information flowing within the regions to and from state and local partners. The RECs help inform deployments so that OEM provides only the capabilities and assets that are useful to the requestor. The RECs also function as command and control during responses because of their proximity to the event and existing relationships with the public health, medical, and emergency management agencies requesting support. When overseas require a response from NDMS, the International Program Branch ensures linkages with partners in the Department of State and the U.S. Agency for International Development. For example, the branch's work continues to be instrumental in responding to the Ebola outbreak in West Africa.

Additionally, the RECs serve as ASPR Regional Administrators. As the senior federal public health and medical preparedness and response official in one of the ten regions, a Regional Administrator performs essential functions for HHS in several major areas: prevention, mitigation, response, recovery, and agency-wide coordination. These functions directly and indirectly support the work of HHS and other federal agencies.

OEM's Divisions of NDMS, Logistics, and Regional and International Coordination all work together to ensure that the right support is provided to communities in need. Due in large part to innovative thinking, finding efficiencies and support by a dedicated staff, OEM continues to provide surge support when requested even though there are challenges in years with multiple events.

Funding History

Fiscal Year	*Amount*
FY 2012	$52,735,000
FY 2013	$49,708,000
FY 2014	$50,054,000
FY 2015 Enacted	$50,054,000
FY 2016 Budget	$49,904,000

Budget Request

The FY 2016 Budget includes $49,904,000 for the National Disaster Medical System (NDMS), which is -$150,000 below FY 2015. The request level supports continued NDMS operations and regional emergency coordination to prepare for and respond to public health emergencies. The request also provides funding for medical response assets, including NDMS teams, supplies, and equipment. The reduction reflects efficiencies that OEM will achieve following an ASPR-wide analysis of facilities utilization.

Specifically, the request funds NDMS cache maintenance, including medical and pharmaceutical supplies, information technology, and communications capabilities. NDMS will begin replacing critical equipment such as defibrillators, ventilators, and emergency response vehicles to sustain the current readiness posture nationwide.

The request also supports further development of policies and procedures related to training standards, objectives, and cycles. NDMS will emphasize regional training and exercises to more than 80 NDMS response teams. Training and exercises will include Disaster Medical Assistance Teams, Disaster Mortuary Operational Response Teams, National Veterinary Response Teams, and other specialty teams across the country. An effective multiyear training and exercise program to ensure employees are ready to respond is a significant and critical investment to ensure that the care delivered by NDMS is consistently high-quality and will mitigate the risk that is inherent in the direct medical care mission.

FY 2016 funding also will be directed to preparedness planning and response operations to continue to identify requirements for public health and medical needs using a "whole community" approach. OEM reaches out to federal and state partners to identify those requirements. Additionally, OEM will use the request to quantify the assets and other capabilities needed to meet ASPR's preparedness and response mission as the lead for ESF 8.

ASPR National Disaster Medical System - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Percent of new NDMS intermittent staff who complete psychological first aid training	FY 2014 = 100%	100%	100%	--

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Medical Countermeasure Dispensing

Budget Summary
(Dollars in Thousands)

ASPR Medical Countermeasure Dispensing	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	4,950	-	-	--
FTE	-	-	-	--

Authorizing Legislation:
FY 2016 Authorization.....PAPHRA
Allocation Method ..... Competitive grant/cooperative agreement; direct Federal/intramural, contracts

Program Description and Accomplishments

On December 30, 2009, the President issued Executive Order (EO) 13527. That EO made it the policy of the federal government to plan and prepare for the timely provision of medical countermeasures (MCM) to the American people in the event of a biological attack. The government would do so through a rapid federal response in coordination with state, local, territorial, and tribal governments. The EO'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 EO tasked HHS and the United States Postal Service (USPS) to develop an initial pilot to test distribution of MCMs using USPS volunteers. In 2011, HHS and USPS entered into a Memorandum of Understanding (MOU) establishing the National Postal Model for five jurisdictions in the United States to test such distribution capabilities. The federal government provided funding to the five jurisdictions–Boston, Philadelphia, Louisville, San Diego, and Minneapolis/St. Paul–to support planning, exercises, and implementation of the model. As of July 31, 2013, there were approximately 1,600 U.S. postal workers who, in the event of an anthrax attack, could be called upon to deliver antibiotics to 125 ZIP codes covering approximately 2 million households.

Under the terms of the National Postal Model, MCMs were pre-placed for USPS participants and their household members to keep at work and in their homes. These MCMs consisted of doxycycline hyclate kits. The MCMs were required to be replaced (or refreshed) as the medication expired, approximately every two years. Thus, the model requires dedicated funding to sustain operational capacity.

In FY 2014, HHS received $5,000,000 to support MCM dispensing. After careful examination of the lessons learned from past investments in a USPS distribution model, HHS and USPS determined that, going forward, funding would be used to enhance state and local planning. Specifically, HHS will invest in regional capabilities to advance state and local planning to ensure that capabilities and mechanisms exist to support MCM distribution to all communities nationwide.

Funding History

Fiscal Year	*Amount*
FY 2012	-
FY 2013	-
FY 2014[4]	$4,950,000
FY 2015 Enacted	-
FY 2016 Budget	-

Budget Request

ASPR requests no funding for MCM dispensing for FY 2016, which is the same level as FY 2015. Because of the limited ongoing costs, the multi-year funding in the FY 2014 appropriation is sufficient to support FY 2016 activities. 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 MCM distribution models, HHS is committed to offer support, share best practices, and assist the planning activities.

Medical Countermeasure Dispensing - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Target	The original goal had been to expand to 2 additional cities.	No additional cities. ASPR remains available to assist jurisdictions that allocate their own resources to this planning.	No additional cities. ASPR will remain available to assist jurisdictions that allocate their own resources to this planning.	Same
Result	For FY 2014, there were no expansions. ASPR contributed to state and local planning.	In progress		

[4] Reflects the reduction of -$50,000 for the FY 2014 Secretary's permissive transfer.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Civilian Volunteer Medical Reserve Corps

Budget Summary
(Dollars in Thousands)

ASPR Civilian Volunteer Medical Reserve Corps	FY 2014 Final /1	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	8,979	8,979	6,000	-2,979
FTE	7	6	6	--

1/ The Medical Reserve Corps (MRC) moved to ASPR from the Office of the Assistant Secretary for Health in FY 2015. However, FY 2014 funding and FTE for MRC are also included in this table.

Authorizing Legislation:
FY 2016 Authorization.....PAHPRA
Allocation Method .....Direct Federal/intramural, contracts

Program Description and Accomplishments

The Civilian Volunteer Medical Reserve Corps (MRC) is a national network of tens of thousands 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 units have supported various community public health missions, participated in local and regional exercises across the nation, and have provided support during emergencies. Each MRC unit is unique in what it can provide before, during, and after emergencies as well as to support public health missions.

In March 2002, the Office of the Surgeon General within the Office of the Assistant Secretary for Health (OASH) established MRC as a demonstration project. The *Pandemic and All-Hazards Preparedness Act* authorized MRC as an ongoing program in 2006. In 2013, the *Pandemic and All-Hazards Preparedness Reauthorization Act* (PAHPRA) assigned authority and responsibility for the program to ASPR. With the publication of a revision to the Federal Register Notice on November 26, 2014, MRC formally moved from the Office of the Assistant Secretary for Health (OASH) to ASPR. Since that time, MRC has supported an ongoing assessment of state and local expectations of MRC units. Going forward, ASPR will use the results of this assessment to ensure the MRC network is integrated into preparedness and response activities so that all units can contribute to their communities before, during, and after public health and medical incidents.

Funding History

Fiscal Year	*Amount*
FY 2012[5]	$11,247,000
FY 2013	$10,672,000
FY 2014[6]	$8,979,000
FY 2015 Enacted	$8,979,000
FY 2016 Budget	$6,000,000

[5] The Office of the Assistant Secretary for Health administered the Medical Reserve Corps until FY 2015.
[6] Reflects the reduction of -$1,693,000 for the FY 2014 Secretary's permissive transfer.

Budget Request

The FY 2016 Budget includes $6,000,000 for the Civilian Volunteer Medical Reserve Corps (MRC), which is -$2,979,000 below FY 2015. The request level reflects the final steps necessary to integrate the program into ASPR. In FYs 2015 and 2016, ASPR will work with OASH and other partners to:

1. Carefully examine what works well within the existing program and what should improve to make all MRC units more successful;
2. Update MRC's mission, goals, and expectations for successful MRC units; and
3. Develop a plan to ensure that MRC units can receive training to effectively contribute to disaster response when they are called upon to do so.

MRC units' capabilities vary greatly according to geographical region and local investments. In addition, while there is a standard mission and vision for the MRC network, there is not a standard set of capabilities that all MRC units are required to meet.

ASPR will establish a new mission statement and standard set of capabilities and reliability standards for all MRC units based on the findings of an ongoing evaluation. These changes will set the course for MRC going forward and promote consistency throughout the network. ASPR will leverage its existing programs and infrastructure, along with these changes, to yield efficiencies, savings, and a more effective MRC. ASPR also will support training opportunities from regional coordination offices to ensure MRC units are prepared for a variety of public health emergencies. Finally, ASPR will begin increasing involvement of MRC units during public health emergencies based on the particular circumstances and capabilities at the time of the event.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Hospital Preparedness Program

Budget Summary
(Dollars in Thousands)

ASPR Hospital Preparedness Program	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	255,060	254,555	254,555	--
ESAR-VHP/ 1 (non-add)	*505*	-	-	--
FTE	41	44	49	+5

1/ This amount does not include funding for Ebola preparedness and response from the emergency appropriation to the Public Health and Social Services Emergency Fund.
2/ ESAR-VHP is the Emergency System for Advance Registration of Volunteer Health Professionals.

Authorizing Legislation:
FY 2016 Authorization.....PAPHRA
Allocation Method .....Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments

The Office of Emergency Management (OEM) is capable and poised to immediately respond to requests for assistance from state and local partners. However, more prepared and resilient communities can reduce the need for deploying federal assets and shorten the response and recovery phase, making the overall costs of disasters far less than they would have been otherwise.

OEM's Hospital Preparedness Program (HPP) is critical to community health and medical preparedness efforts. HPP builds resilience in local communities' health care systems by increasing their ability to maintain health care operations, even in the face of an emergency. HPP has provided more than $4 billion to partners since 2002. The return on these investments has enabled communities to handle smaller events on their own, thereby decreasing the burden on federal resources and shortening the response timeframe and any corresponding federal resource commitments.

Investing in Local Preparedness

For much of its history, HPP supported the purchase of critical resources needed to respond to disasters. Some of these resources are specific medical resources and others are communication systems, registry, patient tracking, information sharing, and credentialing systems that require sustainment. Without this funding, many states would be unable to properly respond and save lives without other federal support. Because of HPP investments, in recent years, there have been many demonstrations of communities that were able to respond with little to no federal support at the time of an event:

- **Ebola Outbreak:** During 2014 and continuing in 2015, HPP has supported efforts to prepare for and respond to Ebola should the virus become wide-spread in the United States. Through the funding provided in the FY 2015 Emergency Ebola Appropriations, ASPR is working with HHS and other partners, including CDC, to aggressively implement a national strategy and education plan. This plan will ensure that the nation's health care system, providers, and workers are strong, prepared, and resilient to respond to any isolated domestic or medically-evacuated case of

Ebola. This summer, HPP rapidly released guidance, training documents, and checklists to ensure that all elements of our health care system have access to timely and accurate information on Ebola. The information ranges from patient receiving and detection, and use of personal protective equipment (PPE), to waste management and disposal. Additionally, ASPR has conducted numerous webinars and sent letters that have reached tens of thousands of health care workers across our nation. These webinars not only provide information but also address questions in real-time or with follow-up documents. Furthermore, HHS is leveraging these opportunities to share other guidance as it becomes available.

- **Tornadoes:** When an EF5 tornado (the most damaging level of tornado) touched down in Joplin, Missouri, in May 2011, St. John's Regional Medical Center (Mercy) was seriously damaged. Because of the investments made using HPP funding, Mercy immediately responded, offered care to injured people, and cooperatively evacuated patients to Freeman Hospital and other regional facilities. Within 48 hours, Mercy had an alternate care site established and was providing ambulatory care. A few weeks earlier, tornadoes of similar scale touched down in Tuscaloosa, Alabama. The community used regional response plans, including pediatric referral plans, and pediatric mass-casualty supplies funded by HPP. Two years later, an EF5 tornado touched down in Moore, Oklahoma. The community was able to respond and recover with little federal support.

- **Pandemic Influenza:** During the 2009 H1N1 influenza pandemic, HPP activities allowed facilities to share resources, such as vaccines and N95 masks, to maintain consistent supplies and draw on caches of materials. Communities also activated surge-capacity plans to accommodate inpatient and outpatient demand, including screening hundreds of patients per day in triage tents outside hospitals (for example, in Atlanta, Georgia). HPP partners also developed common regional and state policies for infection-control practices, visitor policies, and other guidance.

- **Hurricane Sandy:** During Hurricane Sandy, the State of New Jersey deployed two Mobile Satellite Emergency Department Units funded in part by HPP. These units helped to relieve surge issues because medical professionals used them as triage and treatment facilities. At one point, these units replaced a level 2 trauma center's emergency department after it was rendered inoperable by flooding. In addition, the establishment and staffing of specific Medical Needs Shelters alleviated stress on hospital emergency departments.

  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 during Hurricane Sandy. The city used evacuation sleds purchased with HPP funds to evacuate 20 infants and other patients at New York University. In addition, the city used HPP funding to purchase radios that assisted patient evacuation, blankets that kept patients warm, and headlights to illuminate evacuation routes.

- **Medical Surge:** Using a combination of HPP and the Federal Emergency Management Agency's (FEMA) Urban Areas Security Initiative funding, the Commonwealth of Pennsylvania established Surge Medical Assistance Response Teams (SMART). In addition to doctors, nurses, and emergency medical technicians, SMART has the ability to provide mobile back-up power, medical supplies, telemetry, and portable heat and air conditioning systems. Pennsylvania used SMART for 17 events between 2008 and 2013. SMART has demonstrated a full return on investment in just five years.

- **Fungal Meningitis Outbreak:** Between October 2012 and February 2013, health care facilities in Michigan treated 243 cases of fungal meningitis, part of a nationwide outbreak caused by contaminated epidural steroid injections. As the number of cases increased and complex diagnostic and treatment challenges emerged, Michigan's health care coalitions became critical

responders to the outbreak. Coalition partners shared information on bed availability, distributed evolving patient care guidelines, and participated in weekly webinars to broadly distribute clinical updates. The coalitions also shared resources—including specialists and pharmaceuticals— and identified additional staffing resources, including 95 health care professionals from the state's volunteer registry. The Michigan health care coalitions' proactive approach to pre-identifying hospitals with resources matched to patients' needs prevented this challenge from requiring federal support. Massachusetts recently reported a similar experience in managing multiple drug shortages that resulted from the closure of contaminated compounding pharmacies.

- **Chemical Explosion:** In April 2013, an ammonium nitrate explosion occurred at a fertilizer facility in West, Texas, killing 15 people and injuring 160 others. More than 300 residents and responders sought treatment at local hospitals. In addition, a local nursing home was damaged by the explosion, requiring an emergent evacuation of more than 130 elderly residents. Less than two weeks prior to the explosion, the nursing home held an evacuation drill. That preparation allowed the facility and its coalition partners to safely and rapidly evacuate and identify receiving sites for all residents after the explosion. Further, the region's hospitals had a plan to immediately surge to make available 20 percent of its beds following a disaster. Through HPP-supported training and exercises, all coalition partners were able to successfully implement the surge plan, allowing the region and the state to handle the emergency without requiring federal health care response assets.

- **Boston Marathon Bombings:** In April 2013, a terrorist attack in the form of bombings at the Boston Marathon resulted in 264 injured patients and three fatalities. Within 20 minutes of the attack, Massachusetts General Hospital was able to rapidly make available 30 beds in its emergency department to prepare for the patient surge, and EMS dispatchers were able to evenly distribute patients to facilities that could appropriately care for their injuries. HPP-funded disaster preparedness exercises in the weeks before the marathon helped coalitions and state partners to enhance communication, identify gaps in preparedness, and implement corrective actions to close gaps, boosting local resilience. Further, HPP has funded trainings for clinicians and hospital staff in Massachusetts since 2002. A local hospital administrator noted that, because of these trainings and exercises, Boston had a more effective response than it would have ten years ago.

All of these past investments are reducing requests for federal assistance and mitigate the lasting impacts of disasters on communities throughout the nation. HPP is a critical cornerstone for the nation's health care infrastructure to be adequately prepared for a wide-range of public health and medical incidents.

Supporting Coalitions, Leveraging Assets, and Bringing Partners Together

In 2012, to support a more sustainable and comprehensive solution to build and maintain health care facility surge capacity, HPP shifted from supporting equipment procurement and focusing on individual hospitals to focusing on building community and regional coalitions of health care providers. Health care coalitions are networks of health care organizations and public- and private-sector partners in a defined geographic region who work together to prepare for, respond to, and recover from disasters. These networks aim to enhance the movement of information, resources, and patients across the community so that its health care system that can absorb casualty and incident demands that would otherwise be overwhelming. Coalitions have a diverse membership, including hospitals, emergency medical services, long-term care facilities, dialysis centers, behavioral health, public health departments, emergency management, and law enforcement.

Specifically, a health care coalition is a formal collaboration among health care organizations and public and private-sector partners who work together to prepare for, respond to, and recover from an emergency, mass-casualty or catastrophic health event. These coalitions emphasize coordination of activities, rather than a "unified command" of all public and private medical and health assets in a geographical area. Individual coalitions maintain their individual management autonomy during an incident response. However, the coalitions participate in information sharing and incident planning to promote consistent management strategies within an established jurisdiction or geographical area. Health care coalitions can provide capacity that exceeds a facility's independent efforts, and they are able to better utilize the full community's resources to target needs of a specific event.

As a multi-agency coordinating body, a health care coalition assists with mitigation, preparedness, response, and recovery activities related to disaster operations. Activities include planning, organizing, equipping, and training coalition members to respond to and recover from a disaster. To improve response, coalitions plan and conduct exercises and after-incident or after-exercise evaluations of both large and smaller events. During responses, coalitions provide multi-agency coordination, advice on decisions made by incident management, information sharing for situational awareness, and resource coordination. The more optimal the health care coalition's response, the less likely it is that state or federal resources will need to be deployed during incidents.

HPP funding allows coalitions to engage in community-level planning, exercises, and trainings for the health care system. The funding also covers coalitions' operational costs, such as convening regular coalition meetings and maintaining staff members to facilitate disaster planning efforts, develop and implement exercises, and encourage health care system partners to join coalitions. Preparedness planning through coalitions, which emphasize partnerships and collaboration, is more cost-effective than providing a small amount of grant funding to each individual health care facility or partner.

Today, nearly 16,000 health care facilities and community partners participate in health care coalitions nationwide. These coalitions are already demonstrating their value to response and recovery from public health and medical incidents. Investments in coalitions as described above have resulted in additional systems development, exercises, collaborative partnerships, and information-sharing that have contributed to more positive outcomes during local disasters as demonstrated by the following:

HPP-sponsored health care coalitions prepare for emergencies by building core capabilities that are necessary for the health care system to respond to various types of incidents, regardless of the specific hazard that may cause an emergency. HPP developed a set of capabilities that awardees leverage to identify gaps and better target investments. These capabilities are designed to facilitate and guide joint Emergency Support Function (ESF) 8 preparedness planning and ultimately assure safer, more resilient, and better-prepared communities. HPP provides technical assistance to awardees to assist with health care coalition and capability development, through its field project officers which are assigned to each region and other ASPR subject matter experts. These capabilities include:

1. **Health Care System Preparedness** is the ability to prepare for, respond to, and recover from incidents that have a public health and medical impact in the short- and long-term. The health care system role in community preparedness involves coordination with emergency management, public health, mental/behavioral health providers, community and faith-based partners, state, local, and territorial governments. Health care system preparedness is achieved through a continuous cycle of planning, organizing and equipping, training, exercises, evaluations, and corrective actions.

2. **Health Care System Recovery** is collaboration with emergency management and other community partners—for example, public health, business, and education—to develop efficient processes and advocate for the rebuilding of public health, medical, and mental/behavioral health systems to at least a level of functioning comparable to pre-incident levels and improved levels where possible. The focus is an effective and efficient return to normalcy or a new standard of normalcy for the provision of health care delivery to the community.

3. **Emergency Operations Coordination** is the ability to engage with incident management at the Emergency Operations Center or with on scene incident management during an incident to coordinate information and resource allocation for affected health care organizations. This is done through multi-agency coordination representing health care organizations or by integrating this coordination into plans and protocols that guide incident management to make the appropriate decisions. Coordination ensures that the health care organizations, incident management, and the public have relevant and timely information about the status and needs of the health care delivery system in the community.

4. **Fatality Management** is the ability to coordinate with organizations to ensure the proper recovery, handling, identification, transportation, tracking, storage, and disposal of human remains and personal effects; certify cause of death; and facilitate access to mental/behavioral health services for family members, responders, and survivors of an incident. Coordination also includes the proper and culturally sensitive storage of human remains during periods of increased deaths at health care organizations during an incident.

5. **Information Sharing** is the ability to conduct multijurisdictional, multidisciplinary exchange of public health and medical related information and situational awareness between the health care system and local, state, federal, tribal, and territorial levels of government and the private sector. This capability includes the sharing of health care information through routine coordination for dissemination to the local, state, and federal levels of government and the community in preparation for and response to events or incidents of public health and medical significance.

6. **Medical Surge** is the ability to provide adequate medical evaluation and care during incidents that exceed the limits of the normal medical infrastructure within a community. This encompasses the ability of health care organizations to survive an all-hazards incident, and maintain or rapidly recover operations that were compromised.

7. **Responder Safety and Health** is the ability of health care organizations to protect the safety and health of health care workers from a variety of hazards during emergencies and disasters.

8. **Volunteer Management** is the ability to coordinate the identification, recruitment, registration, credential verification, training, engagement, and retention of volunteers to support health care organizations with the medical preparedness and response to incidents and events.

Examinations of major public health and medical emergencies reveal exceptionally complex management scenarios. This complexity is true for all hazard types and is apparent even in events without large numbers of physically injured and ill patients. Medical evaluation and treatment of incident victims require many complicated tasks that extend beyond hands-on medical care and are dispersed across a wide range of resources. By helping to build and sustain health care coalitions, HPP helps communities to better collect, analyze, and manage a large amount of complex information to determine incident parameters and response needs. This collective coordination of information is needed to rapidly and accurately determine patient distribution and numbers, the range of injury and illness caused by the hazard, recommendations for evaluation and treatment, the post-impact condition of public health and medical assets, and response considerations. The coordination processes and health care capabilities promoted by HPP's coalitions are designed to limit community morbidity and mortality after exposure to a hazard.

Evaluating and Researching How to Improve Preparedness

HPP uses its evaluation team to monitor awardee status, generate program improvements, conduct research and inform policy. The Science Healthcare Preparedness Evaluation and Research (SHARPER) Branch evaluates services. OEM/HPP's SHARPER Branch is placing ever more emphasis on science and evidence to propel an agenda of more rigorous analysis, evidence based technical assistance, and integrated learning and research.

ASPR's Emergency Care Coordination Center (ECCC) shares this heightened interest in evaluation. ECCC aims to improve the health care system's response to disasters and public health emergencies by strengthening day to day systems of emergency care. ECCC focuses efforts on developing an emergency care system that is patient- and community-centered, integrated into the health care system as a whole, and focused on delivering high-quality care.

There is substantial synergy between HPP's focus on health care coalition development and the activities of ECCC. Current initiatives include improving situational awareness for patients, pre-hospital providers, and emergency managers by improving transparency around the acute care capabilities of hospitals; understanding how acute unscheduled care is managed across different types of providers (primary care, urgent care, emergency medical services, and hospital-based emergency care); and developing innovative ways to measure the effectiveness of systems of care for emergency care outcomes. ECCC provides a critical bridge between the private-sector health care delivery system, federal partners focused on health care delivery and quality (such as the Agency for Healthcare Research and Quality, the Centers for Medicare & Medicaid Services [CMS], and the Health Resources and Services Administration) and HPP. Demonstrating the bi-directional link between preparedness and improved day to day emergency care outcomes creates synergies throughout HHS.

OEM is employing quality improvement to streamline business processes and reduce unnecessary burden on HPP awardees. In July 2012, HPP developed new provisional program measures that align with the health care preparedness capabilities and the new strategic direction to build community health care coalitions. Program measurement activities describe and illustrate an awardee's progress toward meeting the goals and achieving program outcomes. Through the measurement redevelopment process, OEM has reduced the number of measures and awardee burden by 80 percent.

Coincident with the focus on coalitions, OEM developed a refined set of program performance measures for the awardees in 2013 and 2014 to begin establishing a meaningful baseline and a stable set of indicators will remain consistent and comparable through FY 2017. Stable measures will help ensure that HPP can monitor incremental awardee progress over the course of the project period. In FY 2015, HPP is continuing to develop incremental milestones that tie to program performance measures and

quantify objective performance targets informed by emerging data, evidence, and science related to the achievement of the eight key capabilities. These activities will ensure continued alignment with overarching health care preparedness strategies and guidance.

ASPR is using CMS data to examine the effects of disasters on clinical and economic outcomes for providers and patients, and to evaluate trends in the health care system during disasters, such as patient flow patterns. OEM/HPP and ASPR's Office of Policy and Planning have also teamed with CMS to support the CMS Proposed Rule to establish national emergency preparedness requirements for participating providers and suppliers. This rule will help to ensure that providers and suppliers adequately plan for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. This rule will complement the strides HPP has made in building health care system capabilities by providing requirements that better prepare providers and suppliers to meet needs in disasters and other emergencies, and by establishing more uniform and rigorous requirements.

The SHARPER Branch and ECCC are working to improve their technical assistance to states and local communities. ASPR uses data from HPP program evaluations and measurements, along with detailed feedback from awardees, to tailor technical assistance to meet the needs of each awardee, and to determine the effectiveness of the technical assistance provided. OEM is committed to expeditiously providing the required technical assistance to help communities to connect with the right resources and experts—whether improving the preparedness of its HPP awardees, coordinating the immediate health and medical response needs of at-risk communities, or promoting the recovery of communities after a disaster. OEM uses evidence-based applications, technology, and proven best practices to help states and communities build enhanced capacity and improve their knowledge and effectiveness. OEM develops and disseminates appropriate, action-oriented technical assistance, which may include:

- Interactive websites;
- Participant and instructor training manuals;
- Curricula;
- Interactive training materials;
- Online training programs and courses;
- Webinars and virtual technical assistance;
- Call centers;
- Conference presentations;
- Toolkits and guidance documents;
- Continuing Education Units;
- Databases; and
- Site exchanges.

Recovering from Disasters and Other Public Health Emergencies

In addition to its diverse preparedness and response missions, OEM provides support for community recovery. OEM's Division of Recovery leads HHS/ASPR in coordinating federal health and social services efforts to support communities' recovery from emergencies and disasters. Under the National Disaster Recovery Framework (NDRF), HHS is the coordinating agency for the Health and Social Services (H&SS) Recovery Support Function (RSF). The H&SS RSF has identified nine core mission areas: (1) public health; (2) health care services impacts; (3) behavioral health impacts; (4) environmental health impacts; (5) food, drug, and regulated medical product safety; (6) social services impacts; (7) referral to social services/disaster case management; (8) long-term recovery impacts to first responders; and (9) children in disasters. HHS is also a Supporting Organization to four of the other five RSFs.

The Division of Recovery is responsible for coordination efforts among HHS and other federal partners. The division also conducts pre-disaster health and social services recovery planning, and promotes systematic improvements in health and social services recovery planning. For example, the Division of Recovery is beginning a major effort with the ASPR Regional Emergency Coordinators and federal, state, and local partners in developing a catastrophic earthquake plan for the San Francisco Bay area. Also, ASPR and its partners in the Departments of Housing and Urban Development, and Veterans Affairs; along with the Robert Wood Johnson Foundation have provided funding for the Institute of Medicine to issue a report identifying key activities across a range of sectors that impact and/or improve the health and public health outcomes in a community recovering from a disaster and to develop recommendations for their implementation. The final report is expected in March 2015.

During an emergency or disaster, OEM's Division of Recovery engages as part of the Emergency Management Group to maintain situational awareness and gather information about disaster impacts that could affect the recovery of the community or communities. Recovery staff may be formally activated under the NDRF by the Federal Emergency Management Agency (FEMA) or by another department or agency (as was the case in 2012 when HHS was activated by the Department of Agriculture to support needs of the widespread drought). Activation can require deployment to the impacted areas. When the H&SS RSF is activated, HHS is responsible for appointing a recovery field coordinator whose role is to work with primary and supporting agencies and organizations, as well as 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.

In more recent disasters, the division provided technical assistance and informal support without a formal activation. The last formal activation of the H&SS RSF was for Hurricane Sandy. That engagement continues under an interagency agreement with FEMA. The division also engaged with partners regarding the flooding in Colorado in September 2013, the drought in California in 2014, and the tornadoes across the South and Midwest including Mississippi and Arkansas in April 2014.

Protecting Critical Public Health Infrastructure

HPP's resources not only support grants to health care facilities but also support other critical efforts to promote public health preparedness and resiliency. One such program is the Critical Infrastructure Protection (CIP) Branch within OEM's Division of Resilience and Infrastructure Coordination. CIP contributes to community resilience by working with businesses to protect health care and public health critical infrastructure from all hazards. Through a public- and private-sector partnership, CIP analyzes infrastructure risks; prioritizes actions to mitigate those risks; and shares information related to risk management with private sector, state, local, tribal, and territorial partners. The program fulfills HHS' responsibilities under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience; and Executive Order (EO) 13636, Enhancing Critical Infrastructure Cybersecurity.

In FY 2013, CIP worked closely with private-sector partners to develop an Infrastructure of Concern (IOC) list for the health care and public health sectors. 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 performed a similar analysis for cyber-dependent critical infrastructure, which was added to the IOC list. CIP also enhanced its information sharing initiative by moving 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.

CIP's partnerships and information sharing capabilities have played a valuable role in keeping partners informed of emerging infrastructure threats. In 2013, CIP worked through trade association partners to share information with hospitals on a series of telephony denial of service attacks that have caused telecommunications disruptions in more than 90 health care facilities to date. The advisory provided background on the attacks, recommendations for response, and contact information for the Federal Bureau of Investigation. Additionally, CIP worked with the Department of Homeland Security and the Food and Drug Administration to develop and share information with health care providers on a set of newly discovered vulnerabilities in Internet-connected medical devices. In 2014, CIP worked with its federal and private-sector partners to assess the severity of an ongoing national shortage of saline solution that threatened to impact patient care. In all of these cases, the pre-existing private-sector partnership provided a solid platform on which to communicate essential information during a crisis to support the resilience of health care and public health communities.

Registering Volunteer Health Professionals in Advance

Lastly, HPP funding has supported the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) in prior years. ESAR-VHP is a national network of state-based volunteer programs that pre-register 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. Having supported the registration of more than 262,000 volunteers, ESAR-VHP has enhanced community resilience.

Following are examples of some recent ESAR-VHP accomplishments:

- Oklahoma's integrated ESAR-VHP and Medical Reserve Corps (MRC) program continues to enhance response capabilities at the local level. In response to the May 2013 tornadoes in Oklahoma, 209 volunteers contributed 2,932 hours, saving the state an estimated $88,019. Communication with such a large number of volunteers and managing their response activities would not have been possible without the ESAR-VHP/MRC database registry.
- In April 2013, the Los Angeles Disaster Health Care Volunteers conducted a full-scale exercise to test volunteer deployment procedures and the overall management of volunteer health professionals at local health care facilities. The exercise met and exceeded the volunteer management capability, including coordinating, notifying, organizing, assembling, and demobilizing volunteers. More than 150 volunteers were deployed to eight health care facilities throughout the county. For the first time, local health care facilities exercised and explored issues related to receiving volunteers, including receiving and assigning volunteers.

ESAR-VHP received no funding for FY 2015, and HHS requests no funding for ESAR-VHP for FY 2016. Previously, funding supported one full-time equivalent (FTE) employee to provide technical assistance and to visit states needing assistance in establishing the program. Any additional federal support will be covered by other ASPR/OEM resources.

Funding History

Fiscal Year	*Amount*
FY 2012	$379,639,000
FY 2013	$358,231,000
FY 2014	$255,060,000
FY 2015 Enacted	$254,555,000
FY 2016 Budget	$254,555,000

Budget Request

The FY 2016 Budget includes $254,555,000 for the Hospital Preparedness Program (HPP), which is the same as FY 2015. This funding will support grants to states for community health care coalitions, program management and administration of HPP, and other activities including evaluation, critical infrastructure protection, and recovery. Most of these funds (approximately 90 percent) will support grants to states to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Grantees and their community health care coalitions will further their work, begun in FY 2012, to implement and become fully prepared in all eight capabilities outlined in *Health Care Preparedness Capabilities: National Guidance for Healthcare System Preparedness*.

The request will strengthen public health emergency preparedness in several ways:

- **Enhanced Planning:** States and other awardees use HPP funding to enhance collective system planning and response by health care coalitions, hospitals, and other health care organizations at the state, local, and territorial levels.
- **Increased Integration:** HPP facilitates the integration of public- and private-sector medical planning and assets to increase the preparedness, response, and surge capacity of health care coalitions, hospitals, and other health care organizations.
- **Improved Infrastructure:** Awardees use HPP awards and special initiative grant funding to improve the state, local, and territorial infrastructures that help health care coalitions, hospitals, and other health care organizations to prepare for public health emergencies.

Estimates of HPP awards are provided on the following two pages.

ASPR Hospital Preparedness Program - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Percentage of States with heightened health care coalition engagement in statewide/regional exercises. (Outcome)	N/A	30%	During FY 2015, HPP will receive data and report on the FY 2015 targets. At that time, HPP will establish new measures to inform program guidance.	N/A
Percentage of States with established operational health care coalitions. (Outcome)	N/A	50%	During FY 2015, HPP will receive data and report on the FY 2015 targets. At that time, HPP will establish new measures to inform program guidance.	N/A

ASPR Hospital Preparedness Program Grant Awards by Recipient

(estimated amounts in dollars)

HPP Grants	FY 2014 Final	FY 2015 Enacted Estimate /1	FY 2016 President's Budget Estimate	+/- FY 2015
Alabama	$3,237,341	$3,231,541	$3,231,541	--
Alaska	$913,025	$948,583	$948,583	--
Arizona	$4,007,263	$3,985,942	$3,985,942	--
Arkansas	$2,004,404	$2,014,696	$2,014,696	--
California	$23,324,282	$23,204,454	$23,204,454	--
City of Chicago	*$2,695,627*	*$2,736,924*	*$2,736,924*	--
Colorado	$3,223,094	$3,230,913	$3,230,913	--
Connecticut	$2,478,410	$2,467,952	$2,467,952	--
Delaware	$1,068,469	$1,061,248	$1,061,248	--
District of Columbia	$951,425	$951,550	$951,550	--
Florida	$11,648,741	$11,661,603	$11,661,603	--
Georgia	$5,970,165	$5,941,199	$5,941,199	--
Hawaii	$1,217,945	$1,220,804	$1,220,804	--
Idaho	$1,218,950	$1,217,406	$1,217,406	--
Illinois	$8,743,125	$8,867,636	$8,867,636	--
Indiana	$4,115,905	$4,127,659	$4,127,659	--
Iowa	$2,083,867	$2,091,263	$2,091,263	--
Kansas	$2,078,328	$2,068,884	$2,068,884	--
Kentucky	$2,873,535	$2,900,747	$2,900,747	--
Los Angeles	*$9,155,699*	*$9,197,167*	*$9,197,167*	--
Louisiana	$3,150,334	$3,137,439	$3,137,439	--
Maine	$1,076,998	$1,078,955	$1,078,955	--
Maryland	$4,943,757	$4,916,220	$4,916,220	--
Massachusetts	$4,228,980	$4,240,648	$4,240,648	--
Michigan	$6,065,597	$6,086,643	$6,086,643	--
Minnesota	$3,526,348	$3,520,091	$3,520,091	--
Mississippi	$2,168,560	$2,174,085	$2,174,085	--
Missouri	$3,780,117	$3,766,903	$3,766,903	--
Montana	$917,530	$910,977	$910,977	--
Nebraska	$1,372,877	$1,376,638	$1,376,638	--
Nevada	$1,928,013	$1,917,424	$1,917,424	--
New Hampshire	$1,113,252	$1,104,016	$1,104,016	--
New Jersey	$5,820,991	$5,835,689	$5,835,689	--
New Mexico	$1,517,542	$1,507,698	$1,507,698	--
New York	$9,825,062	$9,617,523	$9,617,523	--
New York City	*$7,841,384*	*$7,928,385*	*$7,928,385*	--
North Carolina	$6,183,490	$6,144,992	$6,144,992	--
North Dakota	$875,113	$877,391	$877,391	--
Ohio	$7,442,831	$7,459,074	$7,459,074	--
Oklahoma	$2,605,636	$2,602,048	$2,602,048	--

1/ The FY 2015 Enacted column is an estimate. It does not include emergency funding for Ebola preparedness and response. Final amounts of regular and Ebola funding will be released in Funding Opportunity Announcements in the spring of 2015.

ASPR Hospital Preparedness Program Grant Awards by Recipient - Continued

(estimated amounts in dollars)

HPP Grants	FY 2014 Final	FY 2015 Enacted Estimate /1	FY 2016 President's Budget Estimate	+/- FY 2015
Oregon	$2,534,407	$2,523,559	$2,523,559	--
Pennsylvania	$8,118,396	$8,131,994	$8,131,994	--
Rhode Island	$951,741	$969,418	$969,418	--
South Carolina	$3,107,080	$3,091,113	$3,091,113	--
South Dakota	$859,947	$858,655	$858,655	--
Tennessee	$4,048,785	$4,059,780	$4,059,780	--
Texas	$15,859,228	$15,821,740	$15,821,740	--
Utah	$1,918,379	$1,925,825	$1,925,825	--
Vermont	$900,000	$898,240	$898,240	--
Virginia	$6,188,517	$6,295,382	$6,295,382	--
Washington	$4,211,758	$4,220,025	$4,220,025	--
West Virginia	$1,383,580	$1,380,775	$1,380,775	--
Wisconsin	$3,641,719	$3,611,886	$3,611,886	--
Wyoming	$840,991	$836,173	$836,173	--
States Subtotal	**$223,958,540**	**$223,955,579**	**$223,955,579**	**--**
Indian Tribes	-	-	-	--
Migrant Program	-	-	-	--
American Samoa	$278,408	$278,128	$278,128	--
Guam	$352,993	$352,520	$352,520	--
Marshall Islands	$266,504	$267,111	$267,111	--
Micronesia	$275,664	$275,479	$275,479	--
Northern Marianas Islands	$269,970	$270,652	$270,652	--
Palau	$255,069	$255,101	$255,101	--
Puerto Rico	$2,503,028	$2,506,617	$2,506,617	--
Virgin Islands (US)	$339,824	$338,814	$338,814	--
Territories Subtotal	**$4,541,460**	**$4,544,421**	**$4,544,421**	**--**
Total States/Territories	**$228,500,000**	**$228,500,000**	**$228,500,000**	**--**
TOTAL RESOURCES	**$228,500,000**	**$228,500,000**	**$228,500,000**	**--**

1/ The FY 2015 Enacted column is an estimate. It does not include emergency funding for Ebola preparedness and response. Final amounts of regular and Ebola funding will be released in Funding Opportunity Announcements in the spring of 2015.

ASPR Hospital Preparedness Program: Summary of Grant Awards

(estimated amounts in dollars)

HPP Grants	FY 2014 Final	FY 2015 Enacted Estimate	FY 2016 President's Budget Estimate
Number of Awards	62	62	62
Average Award	$3,570,313	$3,570,312	$3,570,312
Range of Awards	$255,069 -$23,324,282	$255,101 -$23,204,454	$255,101 -$23,204,454

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 2014 Final	FY 2015 Enacted /1	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	413,494	473,000	521,732	+48,732
Ebola funding: Public Law 113-164 (non-add)	-	*58,000*	-	*-58,000*
Advanced Research and Development (non-add)	*272,712*	*271,000*	*269,732*	*-1,268*
Combating Antibiotic-Resistant Bacteria (non-add)	*81,000*	*84,000*	*192,000*	*+108,000*
Operations and Management (non-add)	*59,782*	*60,000*	*60,000*	--
FTE	154	155	155	--

1/ Congress also appropriated $157 million for ASPR's Biomedical Advanced Research and Development Authority for advanced development of several promising Ebola vaccine and therapeutic medical countermeasure candidates.

Authorizing Legislation:
FY 2016 Authorization.....PAHPRA
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

Many serious health threats facing our nation come from naturally-occurring events like pandemic influenza and emerging infectious diseases like Ebola. 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 (MCM) against these threats, including vaccines, therapeutic products, diagnostics, medical devices, and non-pharmaceutical agents. These MCMs constitute the country's "medicine cabinet" to prepare appropriately for and respond effectively to these threats.

HHS' 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 America needed to acquire and stockpile MCMs that were vital to mitigating or preventing the effects of CBRN threats, and it took action by establishing Project BioShield (BioShield) in 2004. BioShield supports the late-stage development and purchase of available CBRN MCMs. It serves as an incentive to pharmaceutical and biotechnology companies to develop new MCMs. The 2006 *Pandemic and All-Hazards Preparedness Act* (PAHPA) modified BioShield's authorization. PAHPA created ASPR to coordinate federal MCM activities and the Biomedical Advanced Research and Development Authority (BARDA) to support advanced development, innovation, and procurement of MCMs for CBRN threats, pandemic influenza, and emerging infectious diseases like Ebola.

BARDA's mission is to support advanced development and make available MCMs to protect the nation from man-made and natural public health emergencies. BARDA does so through product development

and innovation, building manufacturing infrastructure, core service assistance, and product acquisition. Because these products require significant development over time at high risk and significant cost, large investments made now will greatly impact the nation's preparedness a decade later. BARDA shepherds MCM candidates from early development, supported by other federal agencies or industry, into advanced development and eventually Food and Drug Administration (FDA) approval. BARDA's goals and accomplishments enumerated below address key elements set forth in the 2011 BARDA Strategic Plan and align with the 2014 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP) and other national plans (please see ASPR's Office of Policy and Planning portion of the request for additional information).

Building a Replete, Robust, and Formidable MCM Development Pipeline

ASPR/BARDA and the PHEMCE have evolved together and 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 reliable pipeline of MCM candidates that could be purchased, stockpiled, and approved by FDA. 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 advanced development to regulatory approval. BARDA's mandate is to support development and acquisition of MCM candidates across the so-called "valley of death" through manufacturing scale-up and optimization, and animal and clinical trial testing until the products are approved by FDA. BARDA may procure these CBRN MCMs and store them in the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile (SNS) or other sites. Prior to BARDA's authorization, few commercial markets existed for MCMs, which led to sole dependence on government support by developers and manufacturers.

Following the 2009 H1N1 influenza pandemic, HHS launched a review of the PHEMCE. That review recommended the nation transition from a "one bug, one drug" approach for 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 disease, and that MCM development and manufacturing would benefit greatly from enhancing its structure and governance.

Since 2006, BARDA has created a robust and formidable product development pipeline comprised of more than 85 MCM candidates for CBRN threats. BARDA has used this pipeline to furnish the SNS with 12 new MCMs since 2004 under BioShield. FDA approved two of these MCMs, Raxibacumab® anthrax antitoxin and HBAT® botulinum antitoxin, in FY 2013 under the Animal Efficacy Rule. These MCMs were the first novel products approved under this authorization and program. At the current five-year authorized level, BARDA expects a dozen 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 and novel public-private partnerships with industry and academia, and supported the development of innovative products and technologies. For example, through BARDA's support, new next-generation ventilators that are more portable, easier to use, and less expensive are under development.

***National Strategy on Combating Antibiotic-Resistant Bacteria* (CARB)**

In the area of broad spectrum antimicrobials, BARDA is supporting the development of the first new classes of antibiotics to treat multidrug resistant pathogens, such as carbapenem-resistant *Enterobacteriaceae* and methicillin-resistant *Staphylococcus aureus* (MRSA). BARDA is doing so through

novel partnerships with small and large pharmaceutical companies. To date, BARDA has partnered with six companies for development of nine antibiotic candidates to treat infections caused by biothreats (e.g., plague) and multidrug-resistant pathogens in communities and hospital settings. BARDA's antimicrobial investments contribute to efforts across the Department to address the objectives included in the Administration's high priority plan: the *National Strategy on Combating Antibiotic-Resistant Bacteria*.

For example, in May 2013, BARDA established a new partnership with a major large pharmaceutical company to develop a portfolio of new antimicrobial drugs for biothreats (e.g. plague) and multidrug resistant pathogens (e.g. MRSA) in community and hospital settings using Other Transaction Authority (OTA) afforded ASPR under the 2013 *Pandemic and All-Hazards Preparedness Reauthorization Act* (PAHPRA). Four antibiotic candidates are under development in this cost-sharing partnership. It has revitalized interest in this business sector to meet the worsening antimicrobial drug resistance crisis.

BARDA and the National Institutes of Health (NIH) are jointly funding a $20 million award supporting the CARB Initiative. NIH is working to design a public competition to be announced by the end of FY 2015 for the accelerated development of an affordable, accurate, and rapid diagnostic test to be used by health care providers to identify highly-resistant bacterial infections at the point of patient care (please see below for additional information on BARDA's antibiotic-resistance activities).

Enhancing Public-Private Partnerships for Innovation in Development and Manufacturing

BARDA is also pursuing other successful public-private partnerships with industry, academia, non-governmental organizations and other federal and state government agencies. In 2012, BARDA entered into partnerships with industry and academia to establish three new Centers for Innovation in Advanced Development and Manufacturing (CIADM).

These CIADMs address the PHEMCE Review's recommendation for flexible manufacturing. As an important part of BARDA's core assistance programs (additional information on other assistance programs below), the CIADMs assist CBRN MCM developers on a routine basis in the developing and manufacturing candidate products from Phase I through FDA approval. During public health emergencies such as pandemic influenza, the CIADMs, which are partnered with influenza vaccine manufacturers, will manufacture vaccines or other biological products at commercial scale to meet national demand. Finally, the CIADMs have workforce development programs to provide formal and applied training in flexible manufacturing and other innovative technologies to future MCM developers. Many development and manufacturing services provided by the CIADMs became operational in FY 2014 for two sites and will become operational at the third site in FY 2015.

The CIADMs are already demonstrating their value. In 2013, one of the CIADMs developed, manufactured, tested, and stockpiled vaccine in record time in response to the lethal avian influenza, H7N9 virus, outbreaks in China. In 2014-2015 the CIADMs also are participating in BARDA's response to the Ebola epidemic in West Africa by expanding the production of Ebola monoclonal antibody therapeutic candidates produced in tobacco plants and Chinese hamster ovary (CHO) mammalian cells for clinical trials and eventual usage in affected West African countries and elsewhere.

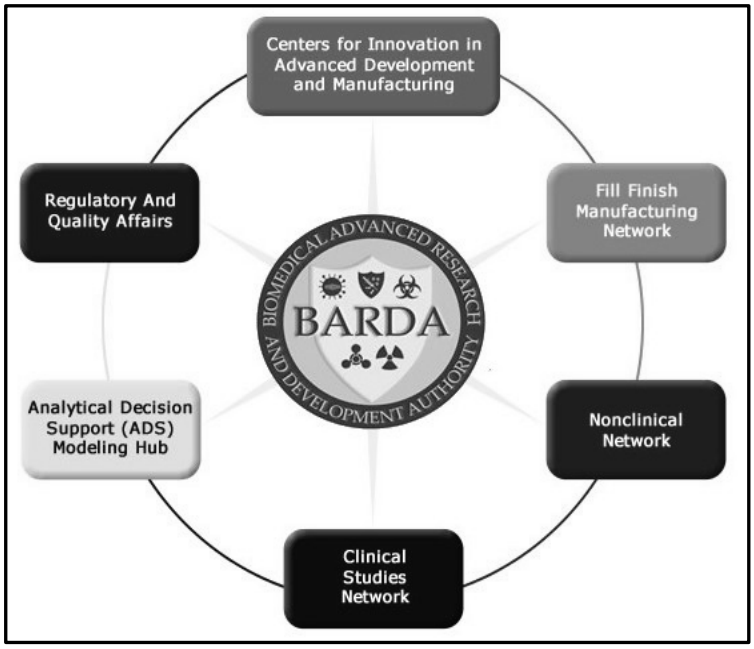
Providing Core Service Assistance to MCM Developers

The PHEMCE Review recommended that partners provide not only financial help to MCM developers but also technical and regulatory assistance. BARDA's Strategic Plan set a goal to provide assistance to developers through core assistance programs in critical areas including animal and clinical studies to obtain safety and efficacy data and manufacturing optimization, validation, and scale-up for clinical

studies and commercial launch. As noted above, the CIADMs are an important part of this core assistance.

In 2011, BARDA established the Non-Clinical Studies Network. This network is comprised of 17 laboratories in the United States and the United Kingdom that have performed 34 studies supporting the natural history of CBRN events in multiple animal models and the safety and efficacy afforded by different MCMs supportive of FDA approval.

In 2013, BARDA established a Fill-Finish Manufacturing Network (FFMN) to assist MCM developers with final drug product manufacturing (for example, aseptic syringe and vial filling, and lyophilization) and to support national pandemic influenza vaccine manufacturing efforts and other public health emergencies. The FFMN is comprised of four domestic manufacturers with a broad set of capabilities to address every day and emergency needs. In 2014, the FFMN filled container vials of Ebola monoclonal antibody therapeutic candidates for upcoming clinical trials in the United States and West Africa. In 2015, this work will continue, and the FFMN will reinitiate a pilot program with FDA to address the U.S. drug shortage crisis by performing fill-finish manufacturing on three drugs in chronic short supply in the United States.



Lastly, in 2014, BARDA established a Clinical Studies Network (CSN) to provide clinical study services from designing clinical protocols to managing clinical trial sites. The five domestic clinical research organizations in the CSN will provide these services to MCM developers partnered with BARDA and backfill the National Institutes of Health's (NIH) clinical study capabilities in a public emergency, as requested. In 2014 and continuing in 2015, BARDA is partnering with CDC to conduct a clinical trial in Sierra Leone, using BARDA's Clinical Studies Network, to evaluate the safety and efficacy of Ebola vaccine candidates. In 2015, BARDA plans to use the CSN to test the immunogenicity of H5N1 pre-pandemic influenza vaccine lots stored for more than eight years in national stockpiles.

Together, these four core service assistance programs—the CIADMs, Non-clinical Studies Network, FFMN, and CSN—work in concert with BARDA's internal technical, regulatory, and modeling expertise to provide comprehensive assistance to developers. This core assistance mitigates many inherent risks associated with MCM development and manufacturing.

Developing Medical Countermeasures for CBRN Threats

Since its inception, BARDA has prioritized the development and procurement of MCMs for the CBRN threats and pandemic influenza. BARDA's CBRN programs have focused on developing MCMs to meet the requirements determined to be necessary to address the 21 Material Threats identified by the Department of Homeland Security (DHS).

In 2009, BARDA issued its first Broad Agency Announcement (BAA) to expand its partnerships with industry and solicit a broader range of potential products and candidates for advanced research and development. Subsequently, BARDA issued special instructions to prioritize a range of product areas including the following: anthrax vaccines and antitoxins; therapeutic MCMs 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. The July 2013 BAA for development of CBRN MCMs stated BARDA's goals and priorities, which align with the BARDA Strategic Plan and the PHEMCE SIP.

During 2015, BARDA will announce new BAAs for CBRN, pandemic influenza, and innovation. These BAAs will serve as BARDA's public announcements of MCM goals and priorities through FY 2017. The FYs 2014 and 2015 budgets focused on how BARDA would address remaining CBRN MCM development gaps, including MCMs for viral hemorrhagic fevers (Ebola and Marburg viruses), biodiagnostics for biothreats and multidrug-resistant pathogens, chemical antidotes and treatments including those for chemical burns, thermal and radiation burn therapies, blood products, and broad spectrum antimicrobial drugs. BARDA may amend the BAAs to adjust to changes in threats, requirements, priorities, medical approaches, or transformational product discoveries.

The following are highlights of BARDA's progress on specific CBRN MCM portfolios:

Anthrax:

In the anthrax MCM portfolio, BARDA has made multiple investments totaling over $1 billion since 2004 in the development and acquisition of two major MCM types: vaccines and antitoxins. First, BARDA's 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 (i.e. poor vaccine stability). BARDA's anthrax vaccine development strategy is to seek a new vaccine with properties that improve upon the currently-licensed BioThrax vaccine (that is, inactivated whole organism vaccine). BARDA is supporting development of four enhanced AVA anthrax vaccine products using adjuvants, lyophilized formulations, expanded domestic manufacturing capacity, and next-generation recombinant anthrax protective antigen(PA)-based vaccines. One next generation anthrax vaccine development project was down-selected in 2014 due to lack of product stability.

Recent clinical study results with the anthrax AVA vaccine formulated with CpG adjuvant have shown that only two doses of the CpG- adjuvanted vaccine are needed rather than the usual three doses of anthrax AVA vaccine to reach the same level of post-exposure protective immunity. Initial preliminary results from recent NIH studies with different dosages and dose regimens for the anthrax AVA vaccine in human immunogenicity studies and nonhuman primate challenge studies indicate that less antigen or fewer doses of AVA vaccine may be feasible. If these data hold true following further analysis, then these results may afford expansion of the SNS's anthrax vaccine stockpile post-event under Emergency Usage Authorization (EUA). EUA allows the use of unapproved medical products or unapproved uses of approved medical products in the case of a public health emergency.

In FY 2015, BARDA anticipates Emergent's submission of a Biologic License Application (BLA) to FDA for BioThrax: an anthrax AVA vaccine with a post-exposure prophylaxis indication. Additionally, a supplemental BLA submission is expected in FY 2016 for this vaccine manufactured in Emergent BioSolutions' new facility in Baltimore, Maryland. In this new facility, Emergent will have a four- to six-fold greater manufacturing capacity than in its current facility, which will increase vaccine availability.

Second, the BARDA anthrax antitoxin program is a mature venture comprised of three antitoxin products (two monoclonal antibodies and one polyclonal antibody product) to treat persons exposed to anthrax who do not respond to antibiotic treatments. BARDA continues to support late-stage development of a second anthrax monoclonal antibody product that may have greater efficacy, allow for storage of freeze-dried product at room temperature, with intramuscular administration. The other monoclonal antibody and polyclonal antibody products have been procured under BioShield and delivered to the SNS.

One of these antitoxins (Raxibacumab) was approved by FDA in 2012. This FDA approval applies to the treatment of individuals who are symptomatic with anthrax or for prophylaxis and is approved for pediatric dosing. Raxibacumab is the first novel product approved under FDA's Animal Efficacy Rule and the first FDA-approved product developed and purchased solely with BioShield funding. This achievement is a significant milestone for both BioShield and the PHEMCE. BARDA expects FDA approval of the other two anthrax antitoxins in 2015.

Smallpox:

BARDA has a mature smallpox MCM program. The program has achieved this level through investments in the development and acquisition of smallpox vaccine and antiviral products since 2006. Under BioShield, BARDA has supported late-stage development, procured, and delivered to the SNS the IMVAMUNE smallpox MVA vaccine for persons with HIV or atopic dermatitis, and the ST-246 smallpox antiviral drug for treatment of persons with smallpox symptoms. Both products may be used post-event under EUA.

In 2013, Bavarian Nordic completed a large Phase III study to evaluate lot-to-lot consistency and safety of IMVAMUNE. Final results are pending. The pivotal clinical study to determine non-inferiority to ACAM2000 smallpox vaccine, which is already licensed by FDA, commenced in 2014. Both studies are necessary to support licensure of the product currently stockpiled in the SNS. IMVAMUNE was licensed in the European Union and Canada in 2013 based on studies supported by BARDA. Additionally, BARDA is supporting the development of freeze-dried formulation of the smallpox MVA vaccine that may afford significantly greater shelf life and lower stockpiling costs. In FY 2016, BARDA anticipates submission of a BLA for licensure of IMVAMUNE (liquid frozen product) and to have sufficient data to transition purchase of the lyophilized product under BioShield.

In addition to smallpox vaccines, the United States has a goal of developing and acquiring two smallpox antivirals to treat individuals symptomatic with disease. The development of two antiviral drug candidates also has the potential to mitigate the emergence of drug resistance during an outbreak. BARDA has supported the advanced development of two smallpox antiviral drug candidates. One of these products has demonstrated broad spectrum antiviral activity (efficacy against smallpox and other DNA viruses), which may provide a commercial market to enhance product and company sustainability. The other smallpox antiviral drug candidate (ST-246), which transitioned in development from NIH to BARDA in 2008, has been supported under BARDA's ARD and BioShield programs.

BARDA has worked with both manufacturers and FDA to develop rabbitpox and ectromelia animal challenge models to support approval of both products. In FY 2014, BARDA shared the data from the rabbitpox model with the FDA. This rabbitpox animal model can now be used by both sponsors in non-clinical studies to evaluate their respective drug candidates in support of FDA approval. This collaborative effort is an example of pre-competitive data sharing among industry and government partners to advance the overall field; understanding that we can accomplish more when we work together. In FY 2015, BARDA is continuing to support the development of both smallpox antiviral

drug candidates, and the second antiviral drug candidate will be sufficiently mature for BioShield acquisition.

Broad Spectrum Antimicrobials:

As discussed above, BARDA is also addressing biothreats and antimicrobial resistance. BARDA is building a broad-spectrum antimicrobial drug program and technologies and platforms with multi-use potential. This program is comprised of MCM candidates that would allow our nation to respond to biothreats including anthrax, plague, tularemia, typhus, melioidosis, and glanders. This effort is critical because antimicrobial drug resistance can complicate America's ability to respond to a public health emergency (for example, natural disaster, bioterror agent exposure, burns, blast wounds, or an outbreak of a multi-drug resistant infection). Lastly, antimicrobial drug resistance is a continuing crisis that has led to a Presidential Initiative to stave off a possible catastrophic post-antibiotic era.

As part of the National Strategy for Combating *Antibiotic*-Resistant Bacteria, BARDA and the NIH's National Institute of Allergy and Infectious Diseases (NIAID) are accelerating basic and applied research and development for new antibiotics, other therapeutics, and vaccines and diagnostics to detect these emerging pathogens. BARDA and NIAID will expand collaborative efforts to advance innovative research on antibiotic resistance by hosting research forums to facilitate the creation of public-private partnerships and launching a "biopharmaceutical incubator" that allows academic institutions and start-up companies to explore creative, early-stage research ideas that could lead to development of new antibacterial drugs or therapies.

In FY 2010, BARDA awarded its first contract for the advanced development of a next-generation aminoglycoside against plague and tularemia, with an aspirational goal of developing a product that would have other important public health uses. The product is also being evaluated as a potential treatment for carbapenem-resistant Enterobacteriaceae in an ongoing Phase III clinical trial. Achaogen and BARDA are sharing the costs of this clinical trial to evaluate the efficacy of plazomicin for carbapenem-resistant Enterobacteriaceae (CRE) infections under a limited-population antibacterial drug guidance with FDA. The safety data from this trial will support the biothreat indication of this drug to treat plague and tularemia infections.

In the past few years, BARDA further expanded its antibacterial portfolio with five advanced research and development contracts to support candidate small molecule therapies with the potential to address biothreat indications and the broader public health threat of antimicrobial resistance. BARDA's current program stands at nine candidates with six industry partners. Two of these candidates address the threats of glanders and melioidosis, for which there are currently no antibiotics in the SNS formulary. BARDA has advanced four antimicrobial candidates from the pipeline forward into pivotal Phase III clinical trials. Several of these antibiotic candidates are intended for the treatment of drug-resistant Gram-negative bacterial infections, addressing a high-priority area of current unmet medical need.

In addition, in FY 2013, BARDA entered into an innovative public-private partnership with one company using OTA. This was HHS' first use of OTA provided by PAHPA. This agreement supports advanced development of a portfolio of antibacterial drug candidates, each with a unique and unprecedented mechanism of action. It mitigates BARDA's risk by supporting multiple products in development as opposed to just one candidate as traditional contracts do. In addition, there is flexibility to move compounds in or out of the portfolio as technical or business risks materialize. Finally, overall development costs are shared by the company and BARDA, meaning development risks are also shared.

Another antimicrobial drug project that BARDA initiated in FY 2013 is the development of pediatric formulations for solithromycin. MCM development for at-risk populations is a key BARDA function mandated under PAHPA. In 2015 results from pivotal Phase III clinical trials showed that solithromycin was well-tolerated and efficacious for treating community-acquired bacteria pneumonia caused by antibiotic drug-resistant bacteria. In FYs 2015 and 2016, BARDA will continue to support existing candidates with promise and may expand the antibacterial program.

Viral Hemorrhagic Fevers:

Viral Hemorrhagic Fevers (VHF) caused by the Ebola and Marburg Viruses are biological threat agents of concern and global public health threats. The current epidemic of Ebola in West African countries, which the World Health Organization declared a Public Health Emergency of International Concern on August 8, 2014, has highlighted the severity of the disease, the extreme difficulties in providing adequate medical care, preventing disease transmission, and the need to accelerate the early-stage development of the filovirus MCM candidates in the development pipeline. Ebola is an emerging infectious disease with high mortality (20-70 percent) and a select agent and biothreat such that the Department of Homeland Security issued a Material Threat Assessment in 2006.

The PHEMCE developed product-specific requirements for filovirus vaccines and therapeutics that have guided HHS investments towards product development. In 2014, BARDA began support for the development and manufacturing of three Ebola vaccine candidates and multiple tobacco- and CHO mammalian cell-based Ebola monoclonal antibody therapeutic candidates. BARDA's support of Ebola vaccine candidate development will ensure commercial-scale production of more thermostable vaccines for potential mass vaccine campaigns in West Africa when positive Phase II/III results are available; additionally vaccine clinical studies will be supported in 2015 primarily using Emergency Ebola Response Resources provided in PL 113-235. These antibody candidates include ZMapp, on which BARDA is supporting clinical safety and efficacy trials in 2015 as part of BARDA's Ebola response.

Biodiagnostics:

In FY 2013, BARDA started a project supporting development of a biodiagnostic platform technology to detect infection with biothreat pathogens. In FY 2015, BARDA will continue to support advancing the development of existing candidates and expand the portfolio as promising candidates are identified and based on the availability of funds. New biodiagnostics will address multiple biothreats to identify markers of early infection for point-of-care usage.

Radiological and Nuclear Threats:

The treatment of Acute Radiation Syndrome (ARS) remains one of the most difficult due to the effects of radiation on the entire body of the person exposed. Effective treatment requires MCMs targeted to several organ systems (that is, blood, gastrointestinal, skin, lung, and neural) and the ability to accurately quantify a person's exposure in the field. Also, development of a deep-view thermal imaging device was started in FY 2013 to assist in the debridement of thermal burns. The imaging system has enabled general surgical debridement of burns as effectively as a highly skilled burn surgeon, enhancing response capabilities during a large event due to the small number of U.S. burn surgeons.

To support the early development of a wide variety of therapeutic MCMs for neutropenia (a 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 (GI) 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 under 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 and can be used under 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. The U.S. government will have immediate access to the acquired doses when necessary.

In FY 2015, BARDA will continue to support development of promising candidates for ARS, burns, and blood products. Projects for thermal and radiation burns have the potential to seek diverse alternative indications-for-use and bolster their commercial sustainability. Projects initiated in FY 2012 and 2013 have shown significant progress, and funding for these promising candidates will continue in FYs 2015 and 2016. BARDA will expand the portfolio of candidate products based on the availability of funds from down selection of existing programs that have failed to meet scientific milestones for safety and efficacy. In FY 2015, BARDA will fund late-stage development and procurement of a thermal burn cellular therapy (autologous skin replacement) and a thermal burn ointment to accelerate healing that are expected to mature sufficiently for BioShield.

Biodosimetry:

The amount of radiation an individual has absorbed 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 absorbed. Initially, BARDA awarded contracts to ten biodosimetry device producers for the development of biomarkers, assays, and point-of-care and high-throughput diagnostics. In FY 2014, BARDA continued to support six of the most promising candidates from this portfolio. All have shown biomarker feasibility and transitioned to an advanced stage of product development. Five of these candidates have developed acceptable instrumentation strategies essential for completion of product development.

BARDA continues to work with the sponsors to push them to partner with large diagnostic companies; utilizing their existing platforms to enhance potential use of these products during an incident. In FY 2015, one of these point-of-care biodosimetry devices using lateral flow and genomics technologies is anticipated to mature sufficiently for late stage development and procurement under BioShield.

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), were

reported in *The New England Journal of Medicine*. The results indicate 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 under BioShield for late stage development and procurement of midazolam to Meridian Medical Technologies (a Pfizer company). 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; adding a new capability to treat children with easy-to-use auto injectors. Midazolam demonstrated superior efficacy as an anti-convulsive drug to diazepam in the RAMPART clinical trial conducted by the Department of Defense and published in 2012. Midazolam is available at the same cost as diazepam but is also available, unlike diazepam, for pediatric populations in an auto-injector format.

Also, in September 2013, BARDA awarded a contract under BioShield to repurpose a commercially-available burn and wound dressing to treat chemical burns. If approved, this product would be the first ever approved specifically to treat the effects of sulfur mustard. The product is also being developed for burns caused by radiation. The result will be one product that can be carried by first responders and used to treat burns and open wounds regardless of their source.

Finally, the PHEMCE agreed to include "decontamination" as an MCM category. 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 participated in decontamination trials underway in the United Kingdom. Data collected at these demonstrations is being used to inform experiments and studies to inform a scientifically-supported guidance document for best practices in mass-casualty decontamination, which is expected in 2015. Removal of chemical agents is the most effective way to mitigate the short- and long-term effects of exposure to these agents. BARDA will emphasize supporting new candidate products under ARD to address the threat of chemical agents in FY 2015, as promising candidates are identified and based on the availability of funds.

Product Innovation:

Consistent with several Strategic Plan 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 the PHEMCE Review and the President's Council of Advisors on Science and Technology (PCAST) report 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 2012-2014, two new projects, which focused more recently on drug delivery

technologies, were added to the portfolio as other projects completed. BARDA has prioritized radiation and nuclear MCM efforts to address specific technological needs and opportunities that may contribute to the success of BARDA's mission. In FY 2015, BARDA will fund a new project on dry freezing technologies for MCMs.

Animal Studies:

Support in FYs 2012-2014 has resulted in numerous studies to evaluate potential and existing product candidates in animal challenge studies. Many of these studies will provide essential data to be used in advancing products through the regulatory pathway toward FDA approval. BARDA has supported over 22 programs under this effort, and the work will continue through FY 2015.

Through this network, BARDA continues to support the development of animal models, assays, reagents, and studies for such threats as anthrax, smallpox, plague, glanders, chemical agents and ARS. BARDA is using the network as core service assistance to test manufacturers' product candidates in proof of concept studies, provide the results to manufacturers, and inform decisions about whether to support the development of new MCMs. BARDA continues to use this network to evaluate the repurposing of 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 FYs 2013 and FY 2014, this network supported proof-of-concept studies to evaluate candidate MCMs and repurposing studies of commercially-available products. In FY 2015, BARDA will conduct utilization studies to provide supplemental data for products in the SNS and repurposing studies for MCMs against chemical threats. BARDA also will continue animal model development studies to support advancement of products currently in BARDA's portfolio. Additionally, BARDA will continue in 2015 to utilize the Non-Clinical Studies Network to conduct non-human primate challenge studies with Ebola viruses to evaluate the safety and efficacy of promising Ebola monoclonal antibody and small molecule therapeutic candidates. If necessary, BARDA will utilize the Non-Clinical Studies Network to perform additional Ebola vaccine challenge studies in non-human primates to support licensure of these products, if insufficient data emerge from Phase II and III efficacy studies in West Africa.

Funding History

Fiscal Year	*Amount*
FY 2012[7]	-
FY 2013	-
FY 2014[8]	$413,494,000
FY 2015 Enacted[9]	$473,000,000
FY 2016 Budget	$521,732,000

[7] Funding for FYs 2012 and FY 2013 was supported by unobligated balances from prior year appropriations
[8] Reflects the reduction of -$1,506,434 for the FY 2014 Secretary's permissive transfer.
[9] This amount includes $58,000,000 provided for BARDA for Ebola activities by the FY 2015 Continuing Resolution. This amount does not include $157,000,000 in emergency funding provided for BARDA's Ebola activities by the FY 2015 Omnibus.

Budget Request

The FY 2016 Budget includes $521,732,000 for advanced research on and development (ARD) of medical countermeasures (MCM) by the Biomedical Advanced Research and Development Authority (BARDA), which is +$48,732,000 above FY 2015.

The request includes $192 million to support efforts to combat antibiotic-resistant bacteria (+$108 million above FY 2015). During FY 2016, BARDA will continue to implement objectives outlined in the *National Strategy on Combating Antibiotic-Resistant Bacteria* (CARB) by supporting new antibiotic and diagnostic candidates from early to advanced development for biothreat and public health usages, especially for high-priority multidrug-resistant bacterial pathogens. BARDA will continue using innovative public-private partnering mechanisms to form relationships with pharmaceutical and biotech companies developing antibacterial therapies with the goal of stimulating the therapeutic pipeline. BARDA will continue to invest in novel antibiotic candidates using new mechanisms of action (unprecedented candidates such as DNA gyrase inhibitors) and improved existing classes of antibiotics with enhanced properties against drug resistance and other properties (e.g., aminoglycosides). Further, BARDA will invest in non-traditional innovative antimicrobial therapies including phage-induced bacterial lysis, immunotherapies targeting common bacterial targets, immunomodulators that may down-regulate harmful responses associated with bacterial infections, and small molecule drugs that inhibit bacterial virulence factors. These therapies may be used in high-risk persons entering long-term hospitalized settings.

At the request level for efforts to combat antibiotic-resistant bacteria, BARDA will fund three to five new partnerships, thereby increasing the number of MCM candidates in the development pipeline and, consequently, the probability of success in obtaining FDA approval of a new antimicrobial therapy by 2020. BARDA will de-emphasize non-traditional contracting approaches, such as OTA, in favor of the formation of additional public-private partnerships for the development of unprecedented and existing classes of small molecule antimicrobial therapies. BARDA also may consider limited investment in proven technological approaches (e.g., monoclonal antibodies) to prevent or treat drug-resistant bacterial infections.

The request also includes $21 million to support the annual operating costs for the three CIADMs, which are becoming operational on a rolling basis in FYs 2014 and 2015. The CIADMs will afford cost-savings for multiple CBRN MCM projects. BARDA's Non-clinical Studies Network will use $10 million to continue the development of animal models that are essential to support licensure or approval of CBRN MCMs, which require supportive data for FDA approval under the Animal Efficacy Rule. Further work is critical in evaluating MCM candidates' efficacy for ARS sub-syndromes, including skin and lung and chemical agents. Furthermore, BARDA's Clinical Studies Network will receive $2 million to maintain the medical infrastructure to conduct planned clinical trials evaluating key MCMs.

The FY 2016 Budget also supports the advanced development of the highest priority MCMs against all 12 threats identified by DHS and prioritized in the PHEMCE SIP. Specifically, ASPR requests funding for investments in new projects in the following programs, in addition to broad spectrum antimicrobials:

1. Anthrax – Redirect existing candidates in the vaccine portfolio toward CIADM assistance;
2. Biodiagnostics – Develop devices to quantify the level of exposure to biological agents;
3. Viral Hemorrhagic Fevers – Develop existing and next-generation antiviral drug and vaccine candidates against Ebola and Marburg viruses;
4. Radiation – Develop replacement candidates to address the six illnesses resulting from injuries from radiological or nuclear events, including thermal burns; and
5. Chemicals – Develop new antidotes to treat exposure to chemical agents such as mustard gas.

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 or replete with promising candidates. The near-term objective is to finalize the licensure of anthrax vaccine absorbed for post-exposure prophylaxis; expected in 2015. However, new starts may only occur if existing programs fail to meet milestones associated with safety or efficacy. New starts also may be limited 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.

ARD funding for late-stage development will be directed toward a lyophilized smallpox MVA vaccine for immunocompromised persons, a cellular therapy for neutropenia associated with ARS, a biodosimetry device based on gene expression, a chemical antidote, an enhanced anthrax vaccine with CpG adjuvant, and a second smallpox antiviral drug.

ASPR BARDA - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Provide technical assistance to MCM manufacturers through BARDA's core assistance programs.	N/A	N/A	Nonclinical Studies Network: +4 projects Centers for Innovation in Advanced Development and Manufacturing: +2 projects Fill/Finish Manufacturing Network: +3 projects Clinical Studies Network: +1 project	Nonclinical Studies Network: +4 projects Centers for Innovation in Advanced Development and Manufacturing: +2 projects Fill/Finish Manufacturing Network: +3 projects Clinical Studies Network: +1 project
Result				
Status				

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

	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Target	CBRN Licensed = +2; EUA = +2 Pan Flu/EID Licensed = +2; EUA = +0	CBRN: Licensed = +4; EUA = +2. Pan Flu/EID: Licensed = +5; EUA = +3	CBRN: Licensed = +2; EUA = +5. Pan Flu/EID: Licensed = +2; EUA = +3	CBRN Licensed= -2 EUA =+3 Pan Flu/EID Licensed = +3 EUA = +3
Result	CBRN EUA = 3; ST-246 antiviral for smallpox became accessible and Neupogen and Leukine, anti-neutropenia cytokines for radiation treatment under EUA by FDA. Another package (Neulasta) was submitted but not acted on during the performance period. CBRN licensed = 2; Licensed by FDA are 1) Raxibacumab, the first anthrax antitoxin, and 2) HBAT, the first botulinum antitoxin. Both projects were supported by Project BioShield and approved under the FDA's Animal Efficacy Rule. Pan Flu licensed = 6; Licensed by FDA are: 1) Flucelvax, the first cell-based seasonal influenza vaccine, 2) FluBlØk, the first recombinant-based seasonal influenza vaccine, 3) QPAN H5N1 vaccine, the first adjuvanted pandemic influenza vaccine in the U.S. 4) Aura, a next generation portable ventilator for adults, 5) Simplexa, PCR-based point-of-care diagnostic for influenza and respiratory syncytial virus, and 6) Rapivab (peramivir), the first intravenously-administered single dose influenza antiviral drug; had been available under EUA previously.			
Status	Target Exceeded	In progress		

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Project BioShield

Budget Summary
(Dollars in Thousands)

ASPR Project BioShield	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	254,560	255,000	646,425	+391,425
FTE	-	-	-	--

Authorizing Legislation:
FY 2016 Authorization.....PAHPRA
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

The medical countermeasures (MCM) pipeline has never held more promise than it does today. Innovation, enhanced partnerships with small and large companies and sustained investments throughout the last decade have resulted in the addition of 12 new MCMs through Project BioShield for national preparedness and stockpiling through FY 2013. These MCMs afford greater national preparedness against the medical consequences of anthrax, botulism, smallpox, radiological and nuclear agents, and chemical threats.

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. Project BioShield (BioShield) authorities were further delineated, clarified, and extended by the 2006 *Pandemic and All-Hazards Preparedness Act* and the 2013 *Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).*

From FYs 2004-2013, BARDA spent $3.4 billion of the original Special Reserve Fund (SRF) to purchase 12 novel MCMs under BioShield. Additionally, over the same period, BARDA used the remaining $2.2 billion of the original SRF appropriations to establish a robust and formidable CBRN MCM development pipeline comprised of more than 85 product candidates.

In FY 2013, the Food and Drug Administration (FDA) approved two of the 12 products that BARDA developed and procured under BioShield. FDA approved Raxibacumab®, an anthrax antitoxin, 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. FDA approved Heptavalent botulinum antitoxin (HBAT®) in March 2013 for treating of individuals with confirmed or suspected botulism intoxication. FDA approval included dosing for pediatrics as well. Both antitoxins were the first novel MCMs against these threats approved by FDA.

BARDA added three new MCMs under BioShield in FY 2013: Neupogen, Leukine, and Midazolam. These products treat hematopoiesis associated with Acute Radiation Syndrome (ARS) and convulsions resulting from chemical agent exposure, respectively.

In FY 2014, BARDA used the first new appropriations to the SRF to replenish expiring stockpiles of anthrax antitoxins, including a new monoclonal antibody and smallpox MVA vaccine for immunocompromised persons. In addition, two MCM developer submitted applications to FDA. In July, Cangene/Emergent submitted a Biologic License Application (BLA) for anthrax immunoglobulin (AIG), an anthrax antitoxin derived from human plasma. In September, Amgen submitted a New Drug Application (NDA) for Neupogen in support of an ARS indication.

FY 2015 appropriations provide funding for BARDA to maintain existing stockpiles of anthrax antitoxins and smallpox MVA vaccine and to add two new MCMs: thermal burn skin replacement (autologous cell therapy) and a lateral flow point-of-care biodosimetry device to measure radiation exposure. With these investments in prior years and 2015, the nation's level of preparedness for CBRN threats has been greatly enhanced as compared to 2004, when BioShield commenced.

For FYs 2015-2016, BARDA anticipates that there will be multiple regulatory filings to FDA for approval of several MCMs developed and procured under BioShield. In October 2014, Emergent submitted its BLA for Anthrax Vaccine Absorbed (AVA) in support of a post-exposure prophylaxis indication. BARDA expects additional submissions of BLAs or NDAs for a third anthrax antitoxin and the smallpox MVA vaccine.

With continued funding support for FYs 2016-2018, BARDA anticipates maintaining current capabilities, capacities, and preparedness previously established under BioShield and the late-stage development and procurement of 12 new MCM products developed in BARDA's ARD programs. These procurements will further enhance our nation's preparedness against new threats. In addition, it is essential for BARDA to work with sponsors to support post licensure/approval commitments and requirements requested by FDA and required for products licensed under the Animal Efficacy Rule. As products achieve FDA approval, these additional studies have been conducted. In addition, it is important for BARDA to support relabeling activities of products stored in the Strategic National Stockpile to ensure the products are properly labeled as they move from Investigational New Drug status to approval and are granted expiration.

New MCMs emerging from the current BARDA development pipeline that are mature enough for late-stage development and procurement under BioShield and qualify for utilization in an event under Emergency Use Authorization from FYs 2014-2018 include the following products:

- Next generation artificial skin replacement therapy for definitive care treatment of thermal and radiation burns (FY 2015);
- Antimicrobial drug-impregnated mesh dressings for point-of-care treatment of thermal and radiation burns (FYs 2017-2018);
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biothreats (FYs 2017-2018);
- Gene expression- and other technology-based biodosimetry devices for quantitative measurement of ionizing radiation exposure in affected persons following a nuclear event (Initial procurement FY 2016 and additional funds will be necessary in FY 2016);
- Chemical antidotes for cyanide poisoning and highly-volatile nerve agents (FYs 2016-2018);
- Multiple therapies using cell-based, recombinant protein, and small molecule technologies for treatment of hematopoietic, skin/lung, and gastrointestinal illnesses associated with ARS (FYs 2016-2018);

- Next-generation anthrax vaccine and adjuvanted enhancement to the current anthrax vaccine (FYs 2016-2018);
- New lyophilized MVA smallpox vaccine for "at-risk" individuals which will provide a significant life-cycle costs savings (FY 2016);
- A second smallpox antiviral drug fulfilling the Public Health Emergency Medical Countermeasures Enterprise requirement for two smallpox antiviral drug products (FY 2015);
- A monoclonal anthrax antitoxin that is currently being developed under ARD to improve the life-cycle management costs for stockpiling this type of MCM (FY 2015); and
- Therapeutics and vaccines for Ebola currently funded under ARD, which will be evaluated for efficacy in the United States and West Africa (FY 2016).

Funding History

Fiscal Year	*Amount*
FY 2012[10]	-
FY 2013	-
FY 2014[11]	$254,560,000
FY 2015 Enacted	$255,000,000
FY 2016 Budget	$646,425,000

Budget Request

The FY 2016 Budget includes $646,425,000 for Project BioShield, which is +$391,865,000 above FY 2015. At the request level, the Biomedical Advanced Research and Development Authority (BARDA) will be able to make the following procurements to increase the United States' preparedness for chemical, biological, radiological, and nuclear threats:

1. **New lyophilized smallpox MVA vaccine ($132 million):** The new smallpox vaccine will replace expiring stockpile of existing frozen liquid smallpox MVA vaccine for immunocompromised persons. The new lyophilized formulation developed in BARDA's Advanced Research and Development program may provide two-fold increase in shelf life and significant life-cycle management costs savings (3–5 million doses).
2. **New cellular therapy ($137.6 million):** This new cellular therapy will be used to treat the hematopoietic illness associated with ARS. This therapy may be used in conjunction with anti-neutropenia cytokines and in patients that are refractive to anti-neutropenia cytokines. Funds will support Phase III studies and vendor managed inventory (VMI) because the product will have a commercial indication (5,000 to 15,000 treatment courses).
3. **New autologous skin replacement and debridement therapy ($34.8 million):** The new skin therapies will be used for definitive care treatment of thermal and radiation burns experienced in persons exposed to a nuclear or other fire event. Funds would support pivotal clinical studies to

[10] Funding for FYs 2012 and FY 2013 came from unobligated balances in the Special Reserve Fund, so there were no appropriations those years.
[11] Reflects the reduction of $925,640 for the Secretary's transfer.

support the thermal burn indication. Products have the potential for VMI because they will have a commercial market for thermal burns (2,000–10,000 treatment courses).

4. **New biodosimetry devices and reagents ($66 million):** New point-of-care (POC) biodosimetry devices (100–300 POC instruments) using gene expression assays and associated reagents (100,000–300,000 test reagent kits) will be procured to determine an individual's level of exposure to ionizing radiation. For high-throughput biodosimetry devices, funds will support the purchase of reagents (100,000–200,000 test reagent kits) using existing platform devices in clinical diagnostic labs and the upgrade of existing devices to incorporate the new diagnostic test.

5. **New adjuvanted anthrax vaccine absorbed (AVA-CpG) ($200 million):** The adjuvanted vaccine has the potential to provide protective immunity in two doses and provides increased kinetics of immune response decreasing regimen schedule significantly. Cost savings afforded by this new anthrax vaccine formulated with a new adjuvant will be realized due to both antigen- and dose-sparing. A 33 percent increase in the size of the anthrax vaccine stockpile will be realized by the reduction in number of doses of vaccine per regimen from the current three doses down to two doses; more doses of vaccine per vial will be realized with the reduction in the quantity of vaccine antigen per dose by using the adjuvant. The stability of the anthrax vaccine with the adjuvant may be extended, increasing the shelf life from five years to nearly twice that duration. Thus, replenishment of this vaccine in the stockpile will be less often resulting in less lifecycle costs over five and ten year horizons (4–5 million doses).

6. **New chemical antidotes ($20 million):** Small molecule drug repurposed to mitigate the potential longer term effects of exposure to highly volatile nerve agent(s) or products to treat chemical burns on skin. The request supports final clinical studies and procurement of product to add to CHEMPACKs that are forward-deployed by the SNS (100,000–1,000,000 treatment courses).

7. **New therapeutics and vaccines for Ebola ($56 million):** Immunotherapeutic or small molecule drugs to treat individuals infected with Ebola and vaccines to prevent the spread of disease or as post-exposure prophylaxis (6,000-12,000 treatment courses of therapeutics and 500,000-1 million doses of vaccine).

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 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	14,877	14,877	14,877	--
FTE	66	66	66	--

Authorizing Legislation:
FY 2016 Authorization.....PAHPRA
Allocation Method .....Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments

ASPR's Office of Policy and Planning's (OPP) mission is twofold. First, OPP advises the Assistant Secretary on policy options and approaches to support, strengthen, and sustain the nation's domestic and international public health and health care emergency preparedness and response capabilities. Second, OPP facilitates the development, implementation, and evaluation of organizational, federal, and national strategies, policies, and strategic plans related to domestic and international public health emergency preparedness and response. OPP's programs directly support HHS' strategic goals of strengthening health care; spurring scientific knowledge and innovation; and advancing the health, safety, and well-being of the American people.

OPP's integrated policy approach spans three functional policy components: 1) strategic planning and evaluation, 2) preparedness policy, and 3) response and recovery policy. OPP leads or co-leads strategic planning efforts through the development and implementation of several congressionally-mandated strategies and policies, including the National Health Security Strategy (NHSS) and Implementation Plan, the Public Health and Medical Situational Awareness Strategy and Implementation Plan, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan, the Strategic National Stockpile (SNS) Annual Review, the Pandemic Influenza Implementation Plan, including guidance on temporarily reassigning state and local public health personnel during emergencies, and the overall implementation of other mandates in the 2013 *Pandemic and All-Hazards Preparedness Reauthorization Act* (PAHPRA).

OPP's scientific subject-matter experts develop medical countermeasure (MCM) requirements and related policy directives for chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases such as Ebola. Their work requires the focused application of scientific and analytical skills to identify and resolve complex policy problems. OPP also develops and manages processes designed to gather the best evidence from hundreds of domestic and international scientific and operational subject matter experts to support ASPR's mission, and leads the Federal coordination of Science Preparedness, an initiative aimed at creating an evidence base of research information gathered in the aftermath of disasters to promote resilience and better inform response to future disasters. OPP's policy response supports HHS' Disaster Leadership Group (DLG) response activities, engages in activities that promote effective and efficient emergency response systems,

improves access to emergency care, addresses the behavioral health needs of disaster survivors and responders and the access and functional needs of at-risk individuals, enhances community resilience, increases coordination of national health and medical assets, and aligns incentives within the federal government, and with state and local governments, the private sector, and the general public.

Guiding National Health Security

OPP leads HHS and U.S. government stakeholders to bolster policy and planning efforts that support development, implementation, and evaluation of the NHSS. This strategy integrates health security planning across national and global health security missions, recognizing that many interrelated systems are needed to support national health security. Some of these interrelated systems include health care, public health, behavioral health care, and emergency management systems. They also include other systems that address elements essential to maintaining public health, such as clean water, food, housing, the environment (including a safe food supply and animal health), and access to health care. OPP coordinates, analyzes, and implements relevant laws and regulations, proposed policies, HHS and national strategies, presidential directives, and executive orders to enhance health security.

Addressing At-Risk Individuals, Behavioral Health, and Community Resilience

OPP provides its partners, stakeholders, and response assets with education and guidance to implement policies and practices that address the access and functional needs of at-risk individuals, the behavioral health needs of disaster survivors and responders, and individual and community health and resilience. OPP also ensures the contents of the SNS take into account at-risk populations; disseminates and updates best practices of outreach and care of at-risk individuals before, during, and following a public health emergency; and ensures that information HHS distributes by during public health emergencies is released and communicated effectively. OPP also chairs the Health Subcommittee of the Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities; co-chairs the Children's HHS Interagency Leadership on Disasters Working Group; and leads the National Advisory Committee for Children and Disasters.

Further, OPP implements the HHS Disaster Behavioral Health and Disaster Human Services Concepts of Operations during emergencies. OPP also convenes federal stakeholders to provide a common operating picture regarding needs, and identifies and delivers informational resources, technical assistance, and behavioral health support to assist disaster survivors and responders. OPP leads community health resilience policy development and analysis, convenes interagency working groups such as the federal Community Health Resilience Coalition, and engages in public-private partnerships to integrate health and wellness into national resilience initiatives and projects.

Providing Global Leadership on Pandemic Influenza and Other Threats

In FY 2016, OPP will continue to lead U.S. engagement in international initiatives to prepare for and respond to pandemic influenza, CBRN threats, and emerging infectious diseases such as Ebola. OPP coordinates these international preparedness and response efforts, serving as the U.S. government lead for the Global Health Security Initiative (GHSI) with the G7 countries, Mexico, the European Commission, and the World Health Organization (WHO), and by implementing a new GHSI strategic framework. OPP leads HHS' implementation of the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza with Canada and Mexico, as well as the health security actions in the Beyond the Border Initiative with Canada.

Through these partnerships and other bilateral and multilateral initiatives, OPP engages domestic and international stakeholders to identify and address the legal, regulatory, and logistical barriers to deploy

public health and medical assets across borders during emergencies, including MCMs, public health and medical personnel, and samples of non-influenza pathogens with pandemic potential. OPP collaborates with the White House National Security Council, other U.S. government, and international partners to complete action packages of the Global Health Security Agenda—in particular, those with objectives related to the development of frameworks for the international deployment of medical countermeasures and personnel during emergencies.

In addition, OPP will continue to develop, assess, implement, and exercise policies to guide U.S. international assistance during public health and medical emergencies. This work includes guidance for receiving, considering and responding to requests for the international deployment of personnel and/or MCMs during influenza pandemics and other international medical and public health emergencies. HHS used this guidance to direct responses to requests for international assistance related to H7N9 influenza, Middle East Respiratory Syndrome Coronavirus, and the Ebola outbreak in West Africa.

OPP also oversees the functioning of the U.S. International Health Regulations (IHR) National Focal Point (NFP) by leading U.S. government-wide efforts to assess potential Public Health Emergencies of International Concern (PHEICs) within the United States and to provide notification to WHO and the international community. The U.S. IHR NFP has notified WHO of 65 potential PHEICs. The IHR NFP provides policy advice and support to U.S. domestic partners on assessing potential PHEICs and leads efforts to monitor and report on U.S. domestic implementation and compliance with the IHR. Similarly, OPP works with international partners and U.S. border states to build IHR-related capacities to assess, verify, and monitor public health events.

Further, OPP leads HHS' policy coordination for pandemic influenza and other emerging infectious diseases. These responsibilities include interagency coordination for pandemic planning and response. OPP is developing and formalizing requirements for pandemic MCMs. OPP also will provide a capability, similar to the Influenza Risk Assessment Tool, for assessing the risk of emerging infectious disease threats to inform the needs for development, large-scale production and/or stockpiling of MCMs. OPP coordinates federal influenza policy, supports HHS' DLG response activities, and initiates evaluation and implementation of influenza plans and policies.

OPP continues to lead the implementation of the 2009 H1N1 Influenza Improvement Plan, which shares the Secretary's priorities for pandemic influenza preparedness post-H1N1. More than 60 percent of the actions in the H1N1 Improvement Plan are complete. They include the improvement of surveillance and characterization capabilities, significant gains in vaccine development, and a five-year non-pharmaceutical intervention research agenda.

Enhancing Biosafety and Biosecurity

In 2014, incidents involving biological select agents and toxins raised serious safety and security policy issues. OPP has expanded, intensified, and accelerated efforts to strengthen biosafety and biosecurity by examining ways to reinforce policies and practices. OPP also provides oversight of federally-supported facilities that conduct life science research. OPP continues to develop and implement policies to mitigate risks posed by the misuse of life science research and serves as chair of the Interagency Biorisk Management Working Group to highlight the importance of continuing efforts to strengthen biorisk management. OPP also supports the Federal Experts Security Advisory Panel, which is working to enhance the security of select agents and toxins, and supports efforts to promote outreach and education to inform scientists, biosafety professionals, institutional officials and the public on biorisk management. In addition, OPP supports a range of efforts on international bioengagement, and collaborates with Canadian colleagues to advance biosafety, biosecurity, and pathogen security under the Beyond the Border initiative.

Coordinating Health Care Systems Policy

OPP provides policy expertise and guidance to advance federal, state and local government as well as private sector capacities to respond to disasters and public health emergencies. Primary policy issues include finance and reimbursement, workforce, measurement, evaluation and quality standards, data analytics, regionalization, integration and coalitions, health information technology, electronic medical records and telehealth, disaster and public health emergency preparedness. OPP contributes to building strong, sustainable, and resilient health care systems through policy evaluation and strategic initiatives. OPP evaluates and makes policy recommendations to support integrated and scalable health systems that align with the NHSS's second goal to strengthen and sustain health and emergency response systems. OPP engages in activities that promote wider use of interoperable electronic health records, improve access to emergency care, and aligns incentives in support of this goal.

OPP works closely with ASPR/OEM's Hospital Preparedness Program (HPP) and other partners, including HHS' Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology, to promote strong public health, health care, and emergency response systems. OPP also works to promote an emergency care system that is patient- and community-centered, integrated into the broader health care system, high-quality, and prepared to respond in times of public health emergencies. OPP provides guidance and direction to state and regional stakeholders on forming comprehensive coalitions that include representation from hospital and health care systems, behavioral health care providers, and human service organizations in order to better leverage expertise and capacity in limited resource environments. OPP participates in a variety of workgroups and committees that support the coordination of health care policies, including those for bystander care and community first-based first aid, long-term care preparedness, health care coalitions, private health insurance, acute care and active shooters.

To respond to the Ebola outbreak in West Africa, ASPR/OPP worked with the Centers for Disease Control and Prevention (CDC) and other partners to develop and release guidelines to ensure that the nation's health care system, providers, and health care workers are prepared to respond to Ebola and other serious communicable diseases. ASPR and CDC rapidly released resource materials guidance, training documents, and checklists to help ensure that all elements of the U.S. health care system have access to timely and accurate information that ranges from patient receiving and detection, use of personal protective equipment, and waste management and disposal.

OPP will continue the development of no-notice drills for hospitals and coalitions to assess the ability to meet the immediate bed availability goals for medical surge as well as address the needs of those psychologically injured placing additional demands on emergency and hospital systems. In collaboration with CMS, OPP has utilized limited administrative claims data to evaluate the impact of prolonged power outages on health care delivery, and individuals that rely on electricity-dependent medical equipment and health care services, by mapping this data for the purpose of sharing with state and local health department emergency planning and response teams.

OPP also worked with the Association of State and Territorial Health Officials to identify the legal and regulatory barriers to expand the roles of Emergency Medical Service providers. In addition, OPP conducted a study of private health insurance company disaster coverage in collaboration with America's Health Insurance Plans to gain better understanding of disaster health insurance coverage. OPP is also involved in the needs of children during disasters. Specifically, they co-chair the Children's HHS Interagency Leadership on Disasters Working Group and lead the new National Advisory Committee for Children and Disasters.

Promoting an Effective Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

OPP leads coordination of the PHEMCE and provides policy and strategic direction on MCM-related issues. HHS established the PHEMCE in 2006 to coordinate federal efforts to respond to CBRN threats, pandemic influenza, and other emerging infectious diseases. The PHEMCE's mission is to advance national civilian preparedness for these threats by coordinating MCM-related activities within HHS and in cooperation with PHEMCE partners. ASPR leads the PHEMCE, which also includes three primary HHS partners: CDC, FDA, and NIH. The PHEMCE also includes several interagency partners: the Departments of Agriculture, Defense, Homeland Security, and Veterans Affairs. Together, the PHEMCE partners work to optimize the nation's preparedness for large-scale public health emergencies by researching, developing, acquiring, stockpiling, and effective using MCMs.

HHS implemented the PHEMCE governance structure in 2006 and revised it in 2011 to support coordination and collaborative decision-making of MCM efforts across federal departments. OPP implemented many of the governance recommendations arising from HHS' 2010 PHEMCE Review and continues to provide the management and operational services for the PHEMCE at the strategic and policy level (Enterprise Senior Council), the operational level (Enterprise Executive Committee), and the subject-matter expertise level (Integrated Program Teams).

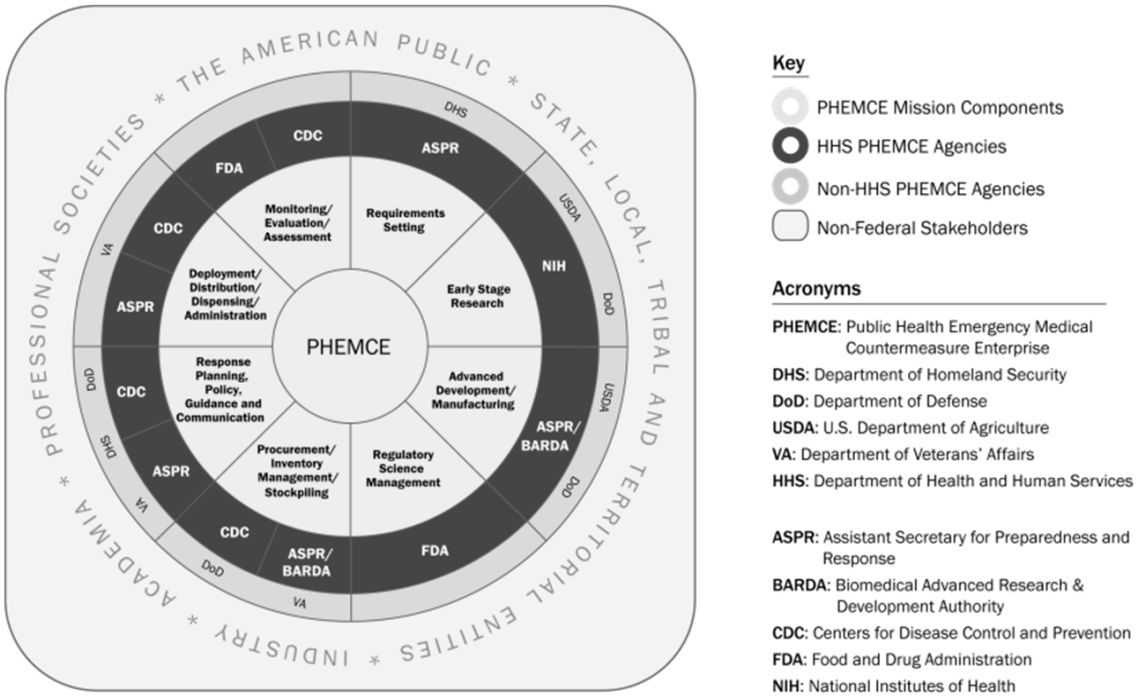
Strategically, in collaboration with other ASPR offices, OPP leads development of the annual PHEMCE Strategy and Implementation Plan, which provides the blueprints that the partners follow to make the best use of available resources and enhance national health security. ASPR/OPP worked with partners to develop the prioritization framework that the PHEMCE uses to support optimal allocation of resources to address the high-priority threats. OPP is working closely with subject-matter experts across the federal government to examine the current and targeted MCM preparedness levels and inform future resource allocation decisions.

OPP leads the development of scenario-based analyses, integrated capabilities documents, research requirements, and product-specific requirements documents that identify the critical MCMs needed to support civilian public health emergency preparedness. OPP works with partners to ensure alignment of early research, advanced development, acquisition activities, and effective distribution, deployment, dispensing, and administration of federal MCMs. These requirements increase civilian preparedness to prevent or mitigate the adverse health impacts of CBRN agents and pandemic influenza, by informing MCM research, advanced development, stockpiling, and utilization efforts across the PHEMCE.

The PHEMCE has made significant progress in supporting the effective utilization at all levels of critical MCMs. For example, ASPR/OPP and its CDC partners have hosted meetings and workshops to develop updated clinical guidance for anthrax and botulism MCMs under mass-casualty conditions and MCMs for the hematopoietic sub-syndrome of Acute Radiation Syndrome.

OPP co-leads with CDC the SNS Annual Review. The SNS Annual Review is a continuous process that optimizes the contents of the SNS through a comprehensive examination of its holdings. The Annual Review identifies and prioritizes formulary gaps and recommends additions or modifications to the contents of the SNS. This review helps to insure that stockpiled MCMs are those that will best support the health security of the nation.

The Public Health Emergency Medical Countermeasures Enterprise



OPP also supports implementation of the White House National Security Council's *National Strategy for Countering Biological Threats*. OPP coordinates HHS' implementation of this strategy's objectives and reporting requirements. OPP helps to develop policies to mitigate "dual use" risks posed by the misuse of knowledge, information, and technologies related to life science research. OPP also helps to strengthen pathogen security by enhancing domestic and international laboratory biosafety, biocontainment, and biosecurity oversight and outreach.

Improving ASPR's Strategic Planning and HHS' Administrative Preparedness

OPP also leads ASPR's strategic planning, which identifies strategic priorities and facilitates the processes to monitor, review, and report on implementation of ASPR's Strategic Plan. OPP represents ASPR in HHS' strategic planning process. ASPR was an integral stakeholder in developing the 2014 HHS Strategic Plan (including Goal 3F: Protect Americans' Health and Safety During Emergencies and Foster Resilience to Withstand and Respond to Emergencies). OPP also provides coordination, management, and operational services for the National Preparedness and Response Science Board (formerly, the National Biodefense Science Board).

ASPR also has partnered with the Office of the Assistant Secretary for Financial Resources to address HHS' Administrative Preparedness. This initiative seeks to ensure that fiscal and administrative authorities and practices that govern funding, procurement, contracting, hiring, and legal capabilities necessary to mitigate, respond and recover from public health threats and emergencies can be accelerated, modified, streamlined, and accountably managed. Following the identification of lessons learned from the H1N1 influenza pandemic, OPP has been leading ASPR in identifying and implementing activities to increase the speed and efficiency with which HHS and its state and local partners can secure, disburse, and accountably manage emergency funds, especially in support of events to which the *Stafford Act* does not apply. ASPR also has partnered with CDC, and state and local public health

officials to improve administrative preparedness for awardees of CDC's Public Health Emergency Preparedness program and ASPR's HPP. In May 2014, OPP successfully conducted an ASPR tabletop exercise with HHS partners, including CDC and ASFR, to assist in identifying gaps to address to increase administrative preparedness. OPP currently is monitoring HHS' administrative preparedness in deploying resources to respond to the Ebola outbreak in West Africa, including emergency funding.

Finally, OPP leads and ensures that ASPR meets all requirements under PAHPRA and tracks all HHS deliverables to Congress. For example, in 2014, ASPR/OPP transmitted to Congress a Public Health and Medical Situational Awareness Strategy.

Funding History

Fiscal Year	*Amount*
FY 2012	$15,674,000
FY 2013	$15,674,000
FY 2014	$14,877,000
FY 2015 Enacted	$14,877,000
FY 2016 Budget	$14,877,000

Budget Request

The FY 2016 Budget includes $14,877,000 for the Office of Policy and Planning (OPP), which is the same as FY 2015. The request will support OPP's activities described above, which are aligned with all six goals in ASPR's Strategic Plan.

In FY 2016, OPP will engage with national stakeholders to drive implementation and evaluate the progress of the second National Health Security Strategy (NHSS) and Implementation Plan, released in January 2015. Priorities will include efforts to better integrate health care organizations into coalitions; enhance state and local coordination; integrate disaster behavioral health into preparedness, response and recovery; identify and disseminate 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 health care coalitions. OPP will provide coordination, management, and operational services for the National Preparedness and Response Safety Board and the National Advisory Committee for Children and Disasters. 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.

OPP will lead global health security efforts and pandemic preparedness as part of the NHSS Implementation Plan. OPP will continue to work with domestic and international stakeholders to identify legal, regulatory, and logistical barriers for providing international assistance during public health emergencies. OPP also will develop policy frameworks to address these barriers and to guide the federal government's actions during these events. OPP will oversee the implementation of the health security actions under the Beyond the Border Initiative with Canada, will lead the implementation of the trilateral and multi-sectorial North American Plan for Animal and Pandemic Influenza, and will coordinate international preparedness efforts to address chemical, biological, radiological, and nuclear events, pandemic influenza, and infectious disease threats through the Global Health Security Initiative. OPP will continue to provide leadership and oversight for the federal government's compliance with U.S. obligations under the International Health Regulations, and will also support core capacity development in partner countries under the Global Health Security Agenda.

OPP also supports efforts to strengthen biosafety and biosecurity. OPP participates in, and in some cases leads, working groups intended to develop and implement policies and plans that strengthen biosafety and biosecurity and provide oversight of U.S. government-supported facilities that conduct life sciences research. OPP leads efforts to promote transparency and broader awareness about the evolving nature of biological agents that can be hazardous, and how to handle and use these agents safely and securely.

OPP also will continue to work with partners in the Public Health Emergency Medical Countermeasures Enterprise. OPP will work with other ASPR offices, the National Institutes of Health, the Food and Drug Administration, CDC, and state, local, tribal and territorial partners to define civilian medical countermeasure (MCM) requirements that meet the nation's needs. OPP will work with the Analytic Decision Support in the Biomedical Advanced Research and Development Authority to reduce the unmitigated risk inherent in the advanced development of MCMs. In coordination with CDC, OPP will continue to work to develop clinical guidance and utilization policies for MCMs. OPP also will help determine the best methods for distributing and dispensing MCMs to the public.

Finally, OPP will contribute to building strong, sustainable, and resilient health care systems through policy evaluation and strategic initiatives that align with the NHSS's second goal, which is to strengthen and sustain health and emergency response systems. OPP will also provide policy expertise and guidance to advance the capacities of federal, state, and local governments, as well as private-sector organizations, to respond to disasters and public health emergencies.

ASPR Office of Policy and Planning - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Establish and coordinate implementation of national strategies for public health and medical preparedness and response.	FY 2014: OPP has published and is now implementing a number of strategy documents, including: The Public Health and Medical Situational Awareness Strategy (May 2014) as required by PAHPRA; ASPR's revised Strategic Plan; and The *National Preparedness Report* released annually by FEMA.	Publish the 2010-14 National Health Security (NHS) Review and the 2015-2018 NHS Strategy and Implementation Plan. Publish the Public Health and Medical Situational Awareness Implementation Plan.	Continue the process of implementing and evaluating progress for the 2015-2018 NHSS, including the establishment of a Strategic Guidance Committee structure and annual report on progress towards NHS.	N/A

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Operations

Budget Summary
(Dollars in Thousands)

ASPR Operations	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Budget Authority	31,305	31,305	30,938	-367
FTE	135	135	135	--

Program Description and Accomplishments

The Operations activity funds 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, IO provides 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.

The Office of the Chief Operating Officer (COO)

In support of Emergency Support Function (ESF) 8, COO administers organizational operations, including management of communications and public and media affairs; workforce development; facility operations and real estate administration; records and information management; technology management; information technology integration; emergency and routine travel; legislative affairs; and the Executive Secretariat. COO continues 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. Also, consistent with Executive Order 13589 (Promoting Efficient Spending), COO is instituting a number of strategic efforts to monitor and contain costs for the services it administers. These efforts include the incorporation of quality improvement systems for business management.

In 2016, COO will strengthen initiatives to promote a leadership and mentoring culture through an expansion of a career and leadership development program that helps to ensure ASPR is capable of addressing evolving threats and emerging challenges to public health and implementing 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 integrity and quality. Lastly, COO will leverage innovative communication tools and technologies—including social networking and crowd source media—to enhance community connectedness and empower individuals to take action during public health and medical emergencies.

The Office of Acquisitions Management, Contracts, & Grants (AMCG)

AMCG provides acquisitions, grants, and assistance oversight and support to each office within ASPR. AMCG is ASPR's leader for managing the awarding of contracts, grants, cooperative agreements and Other Transaction Authority agreements. The majority of AMCG's support is for ASPR's Biomedical Advanced Research and Development Authority (BARDA) and Office of Emergency Management (OEM). However, AMCG also provides acquisition and grant support to ASPR's other offices. AMCG provides functional support including requirements analysis, operations development, support acquisition strategy development, and tracking of milestones.

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 ESF 8. AMCG's Division of Acquisition Program Support provides a wide range of program management support to the Assistant Secretary and direct program support to BARDA and OEM. This support includes the ASPR Acquisition Management System, which includes procurement oversight and control tools such as "Decision Gate," event-driven In-Process Reviews, and Milestone Decision Reviews of applicable contracts. AMCG also supports ASPR with Earned Value Management, auditing, cost and price analysis, and the development and execution of various acquisition-related training programs.

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 annual planning under a multi-year strategy, measuring performance and correcting course when necessary. OFPA carries out its responsibilities by formulating, monitoring, and evaluating budgets and financial plans to 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 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 to directly support HHS responders and stakeholders in the event of a public health emergency. When the HHS Emergency Management Group (EMG) 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 the Federal Emergency Management Agency 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.

Finally, OFPA ensures the 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 that could impede the completion of a mission and to develop strategies for ensuring effective and efficient operations.

Funding History

Fiscal Year	*Amount*
FY 2012	$32,981,000
FY 2013	$31,304,000
FY 2014	$31,305,000
FY 2015 Enacted	$31,305,000
FY 2016 Budget	$30,938,000

Budget Request

The FY 2016 Budget includes $30,938,000 for ASPR's Operations, which is -$367,000 below FY 2015. The request is integral to achieving ASPR's goals and to the success of all of ASPR's activities. The request supports staff salaries for key support staff in 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 implementation of mandates included in the *Pandemic and All-Hazards Preparedness Reauthorization Act* and other relevant legislation.

ASPR Operations - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Improve strategic communications effectiveness.)	FY 2014: Continued improvement in ASPR's central infrastructure for public web communications to support interagency collaboration. 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
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)

Office of Information Security	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	53,417	41,125	73,417	+32,292
FTE	70	112	123	+11

Authorizing Legislation:
FY 2016 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.

As cyber threats continue to multiply and become more complex, the need for enhanced controls and threat management strategies will continue to amplify. The evolving cyber threat landscape coupled with the rapid proliferation of information assets, the increased mobility of the HHS workforce, and the need to derive value and intelligence from information assets have forced HHS to redefine its approach for managing and protecting information assets. A mature cybersecurity workforce – equipped with the appropriate training, education, and skill sets – is vital to managing the evolving threats to these information assets and adequately implementing the controls necessary for protecting information assets. Although OCIO has the capacity to drive secure resolutions to many of these challenges, ongoing stakeholder engagement is the critical success factor that will ensure these solutions are lasting and continue to strengthen HHS' risk posture. Our mission is to secure the Program by ensuring access to innovative technologies and thought leadership that enable Program objectives and allow HHS to provide better, more secure services to the public.

The OCIO leadership embraces a business-centric, collaborative approach that is crucial to effectively addressing the evolving cyber threat environment, increased sophistication of attacks, and rapid proliferation of information assets without impeding or inhibiting OpDiv missions and business objectives. Accordingly, Office of Information Security (OIS) FY 2015-18 strategic goals are geared towards threat management, information protection, workforce maturity, and stakeholder engagement.

The implementation of these goals will enhance HHS' threat awareness and information protection capabilities. This collaborative approach is crucial to effectively addressing the evolving cyber threat environment in HHS by transforming the current cybersecurity workforce and engaging internal and external stakeholders in a meaningful way to provide innovative recourses, solutions and services to HHS Programs.

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 the Department of Homeland Security (DHS).

The Cybersecurity Program is comprised of four sub-programs, Computer Security Incident Response Center (CSIRC), Trusted Internet Connection (TIC), Endpoint Security Tools and Federal Information Security Management Act (FISMA) Program Management.

Computer Security Incident Response Center:

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. Continued expansion of the Cybersecurity Operations across the Department will continue through FY 2016 and will 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. In FY 2014, Information Sharing Memorandums with the Veterans Affairs Network and Security Operations Center (VA-NSOC) and the Department of Defense (DoD) SPAWAR NSOC to establish the Healthcare Threat Operations Center (HTOC) and account activation requests for VA-NSOC and SPAWAR NSOC for further growth of the HTOC were completed. In addition, CSIRC continued the development and installation of OpDiv Security Enclaves within the Food and Drug Administration (FDA) and the Office of Inspector

General (OIG). In FY 2014, the HHS OCIO/OIS Computer Security Incident Response Center (CSIRC) tools processed approximately 700 billion base events. Of these events, approximately 3.5 million alerts were generated. The CSIRC received 10,576 security incident reports.

Trusted Internet Connection:

The Budget invests in engineering, implementation work and the ongoing operations and maintenance of the Trusted Internet Connections (TIC), 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 four physical TIC locations (Bethesda, Maryland, Ashburn, Virginia, Atlanta, Georgia and Albuquerque, New Mexico) became operational in FY 2013, while adding the special monitoring technologies provided by DHS (Einstein). In 2Q FY 2015, the Department is expected to complete the cutover to TIC of all OpDiv internet circuits into its infrastructure. At the end of FY 2014, 98 percent of the Department's internet traffic had been cut over to the TIC. In addition, the TIC Virtual Private Network (VPN) migration and integration of Cloud Services will begin and continue into FY 2016.

Endpoint Security Tools:

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. In FY 2014, the program procured enterprise wide licenses for digital investigation technology to be deployed across all OpDivs, procured a service desk cloud capability to enhance asset, configuration, and problem management functions in support of CSIRC mission and the enclaves and continued enterprise deployments of security incident and event management, firewalls, web proxies, and security analytics.

Federal Information Security Management Act Program Management:

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 in November 2014. With the issuance of updated guidance from NIST – specifically, NIST Special Publication (SP) 800-53 Revision 4, *Security and Privacy Controls for Federal Information Systems and Organizations* - which updated and expanded the 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. HHS was the first agency to grant a FedRAMP ATO in FY 2013 with four subsequent ATOs granted in FY 2014.

The Department of Homeland Security (DHS) Continuous Diagnostics Management (CDM) initiative is driving HHS to adopt an automated, continuous monitoring capability. The DHS CDM program provided over $16 million in security capabilities and tools to the Department. In particular, Indian Health Services (IHS) was able to salvage its vulnerability management program, the National Institute of Health (NIH) was able to better implement its continuous monitoring, the Centers for Medicare and Medicaid Services (CMS) was able to enhance its web vulnerability programs in support of the Affordable Care Act (ACA). Tools included database vulnerability, source code analysis, vulnerability management, and

configuration management. The tools allowed the Department to begin to normalize capabilities and processes and directly improve the security posture of the OpDivs and the Department as a whole.

As part of this initiative, DHS is providing a number of 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 standardizing continuous monitoring fundamentals across HHS so that senior management and IT staff can make risk based decisions based off 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 NIST.

As HHS continues to build a strong technological foundation in response to the growing business demands and the need to rely on advanced technology (e.g., cloud computing) to create operational efficiencies, we must drive the necessary strategic initiatives to ensure this foundation is "open, agile and secure." By open, we mean that solutions are accessible to anyone with approved credentials; by agile, we mean the technology is adaptable and capable of changing based on business needs; and by secure, we mean the information assets are adequately protected at all times.

HHS embraces a business-centric, collaborative approach that is crucial to effectively addressing the evolving cyber threat environment, increased sophistication of attacks, and rapid proliferation of information assets without impeding or inhibiting the HHS mission and business objectives. Accordingly, our Information Security strategic goals are geared towards threat management, information protection, workforce maturity, and stakeholder engagement.

Funding History

Fiscal Year	*Amount*
FY 2012	$39,924,000
FY 2013	$37,884,000
FY 2014[12]	$53,417,000
FY 2015 Enacted	$41,125,000
FY 2016 Budget	$73,417,000

Budget Request

The FY 2016 request for the HHS Cyber Security Program is $73,417,000, an increase of $32,292,000 above FY 2015.

[12] Includes $12,292,000 transferred to the Cybersecurity program from the FY 2014 Secretary's permissive transfer.

The FY 2016 Budget 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 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 and fund 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.

Program	FY 2014	Enacted FY 2015	Request FY 2016
CSIRC	$16,744,000	$10,700,000	$18,363,000
TIC	$18,521,000	$12,400,000	$32,611,000
Endpoint Security Tools	$4,300,000	$4,300,000	$4,300,000
FISMA	$13,852,000	$13,718,000	$18,143,000
Total	**$53,417,000**	**$41,125,000**	**$73,417,000**

Computer Security Incident Response Center (CSIRC); and Security Incident Response & Situational Awareness ($18,363,000): The request is $7,663,000 above the FY 2015 Enacted Budget. The increase will be used to fund the Security Information and Event Management (SIEM) refresh as the existing equipment was scheduled for refresh in May 2014, through various security updates on the existing equipment the need to refresh was prolonged into FY 2016. SIEM is the core security tool and the hub and most critical piece of critical infrastructure. Should the equipment go end-of-life with no refresh, the Original Equipment Manufacturer will not support the equipment and the current tools will stop functioning creating increased risks of cyber-attacks and security breaches. The request level will also allow 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 DHS 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 OpDiv networks. Numerous attacks have been minimized Department-wide as a result of CSIRC's capabilities, in many cases before the attacks occurred within those networks. The FY 2016 request invests in security technologies including enterprise network intrusion detection and prevention solutions, network traffic analysis tools, SIEM solutions, data 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.

The FY 2016 request will also allow for the ongoing operations 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. OIS partnered with the HHS Office of Security and Strategic Information (OSSI) to operationalize the Cyber Threat Analysis Center (CTAC), to increase operational awareness and information dissemination to OpDivs. The CTAC establishes and maintains capabilities to provide intelligence support and counterintelligence analysis for the HHS cybersecurity efforts. In addition, OSSI

provides oversight of the Department's cyber incident prevention, warning, detection, forensics, response, and remediation, in coordination with ASA/OCIO and the CSIRC.

Trusted Internet Connection (TIC) ($32,611,000): The request is $20,211,000 above the FY 2015 Enacted Budget. The implementation of four physical TIC sites in FY 2013 and FY 2014 allowed the Department to align with DHS initiatives to provide greater security in the government's internet connections and facilitate the necessary infrastructure to implement Einstein for the entire Department. Additionally, the 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), network traffic analysis, and SIEM. Finally, the TIC provides core capabilities for the Department's continuous monitoring plan. In 2Q FY 2015, the Department is expected to complete the cutover to TIC of all OpDiv internet circuits into its infrastructure. At the end of FY 2014, 98% of the Department's internet traffic had been cut over to the TIC with the exception of an extremely small amount of IHS (West) traffic.

In FY 2016, an additional $20,211,000 in funding is requested to upgrade the routers, switches and security tools to 100 gigabytes (Gb) in order to provide traditional monitored internet access, and meet the needs of the ever-increasing bandwidth demands from Cloud related applications and services that pass through the HHS TIC Access Points (TICAPS) out to the internet. Initial bandwidth analyses demonstrate that third party site-to-site VPNs and new initiatives such as HHS Cloud Services will have significant impacts on the size of the existing internet circuits and the current TIC infrastructure. The increase in the TIC core network capacity hardware will allow HHS to flex from a 10Gb network (currently) all the way up to a 100Gb network with no further hardware upgrades. This is a critical consideration when one looks at the cost of Internet Service Provider (ISP) levels of hardware. It is projected that in FY 16 and beyond, the HHS TICAPs could see bandwidth demands outside of the current infrastructure capacity.

Endpoint Protection Security Tools ($4,300,000): The request is flat with the FY 2015 Enacted Budget. 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 additional solutions to counter malicious software (malware) and other sophisticated computer viruses and worms that continue to plague government computer systems. The Cybersecurity Program 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 2016 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.

FISMA Program Management ($18,143,000): The request is $4,418,000 above the FY 2015 Enacted Budget. The additional resources requested in FY 2016 support the organizational maturation of the Privacy and Governance programs 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.

Cybersecurity - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Asset management: What percentage of assets are covered by an automated capability (scans/device discovery processes) to provide enterprise-level visibility into asset inventory information for all hardware assets?	FY 2014 Target: 95.0% FY 2014 Actual: 93.0%	95.0%	95.0%	--
Configuration management: What is the percentage of applicable hardware assets with each kind of operating system software that have an automated capability to identify deviations from the approved configuration baselines and can provide visibility at the organization's enterprise level?	FY 2014 Target: 90.0% FY 2014 Actual: 69.0%	90.0%	95.0%	+5.0%
Vulnerability management: What percentage of hardware assets are evaluated using an automated capability that identifies NIST National Vulnerability Database vulnerabilities (CVEs) present with visibility at the organization's enterprise level?	FY 2014 Target: 95.0% FY 2014 Actual: 77.0%	95.0%	95.0%	--
Boundary protection: What percentage of the required TIC 2.0 Capabilities are implemented? 100%	FY 2014 Target: 100.0% FY 2014 Actual 100.0%	100.0%	100.0%	--
FISMA System Inventory Compliance: Percentage of systems with current Security Authorization to Operate (ATO).	FY 2014 Target: 95.0% FY 2014 Actual: 90.0%	95.0%	95.0%	--

ASSISTANT SECRETARY FOR ADMINISTRATION
Office of Security and Strategic Information

Budget Summary
(Dollars in Thousands)

Office of Security and Strategic Information	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	6,118	7,470	7,470	--
FTE	33	33	33	--

Authorizing Legislation:
Allocation Method ..... Direct Federal

Program Description and Accomplishments

The Office of Security and Strategic Information (OSSI) was established in 2007 and in 2012 was designated by the Secretary of Health and Human Services (HHS) as a Federal Intelligence Coordinating Office (FICO). In this capacity, OSSI coordinates the sharing and safeguarding of classified national security information between HHS and its operating divisions across the Department 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 public health, terrorism, weapons of mass destruction, 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 relevant Executive Orders, Presidential Directives and policy guidance.

OSSI Program objectives include increasing the Department's security awareness and the ability to respond swiftly and effectively to national security threats. These objectives are achieved by characterizing security threats and vulnerabilities, identifying and assessing trends and patterns across the Department's operational environment, and developing and evaluating mitigation strategies. OSSI as a FICO manages all intelligence and counterintelligence activities for the Department and the programs are resourced with PHSSEF funds. In addition, OSSI coordinates all security services across the Department and the security programs are resourced by non-PHSSEF funds.

The Intelligence and Counterintelligence Directorates within OSSI provide policy guidance and manage the Department's programs for intelligence and counterintelligence, respectfully. The programmatic areas within these Directorates include identification and analysis of national security threats from terrorism, weapons of mass destruction or health threats, management of classified and secure facilities, coordination with federal agencies and partners via the Information Sharing Environment, and counterintelligence initiatives. The HHS counterintelligence program is a robust enterprise that integrates key elements to identify and mitigate potential vulnerabilities to our personnel, facilities and systems. The counterintelligence operating environment covers foreign visitor and foreign travel monitoring, the insider threat program, employee security and awareness training, the conducting of inquiries and assessments, supply chain risk analysis, and the establishment of mitigation strategies and actions to defend against insider or external threats.

Operational Environment

As the leader in the U.S. for medical research, medical product and pharmaceutical regulation, as well as the administrator for billions of program dollars supporting health and human services programs domestically and internationally, as well as the principal repository for personal medical and health related data, HHS is a primary target for cyber-attacks, and theft of intellectual property, technical data or sensitive information from insider threats, or foreign intelligence services or actors.

To identify the requirements for establishing the framework for an effective counterintelligence program at HHS, in 2011 OSSI collaborated with the ODNI and requested that the Office of the National Counterintelligence Executive (ONCIX) conduct a Department wide risk assessment. The risk assessment resulted in a set of recommendations for management actions to address the vulnerabilities identified in the report which pose the most serious risks to our operations, assets, and national security impacts. The main areas to be incorporated into the framework which now form the HHS Counterintelligence Program include counterintelligence analysis and assessments, insider threats, cyber threat intelligence, and risks to the acquisition and supply chain.

To begin addressing these gaps, OSSI established a cadre of security, intelligence and counterintelligence professionals to acquire, synthesize, and report on open source and classified information and assesses its usefulness in supporting and furthering HHS missions. OSSI utilizes all-source classified and unclassified information from Intelligence Community and to the extent possible, incorporates information from other stakeholder organizations into its work. In addition, OSSI represents HHS on a number of external committees and councils responsible for interagency coordination on security threats, intelligence and counterintelligence issues, including the sharing and safeguarding of national security information. As a member of the White House Information Sharing and Access, Interagency Policy Committee, OSSI ensures full Department compliance with the Administration's information sharing policies, procedures, guidelines, rules, and standards. Through a delegation of authority from the Secretary, the Deputy Assistant Secretary of OSSI has original classification authority for national security information and material produced by any HHS component

Funding History

Fiscal Year	*Amount*
FY 2012	$6,448,000
FY 2013	$6,118,000
FY 2014	$6,118,000
FY 2015 Enacted	$7,470,000
FY 2016 Budget	$7,470,000

Budget Request

The FY 2016 Budget includes $7,470,000 for OSSI, which is the same as the FY 2015 Enacted level. This funding level will provide the necessary support to the HHS Defensive Counterintelligence and Insider Threat Program initiatives commenced in FY 2012, FY 2013 and FY 2014, 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. The Cyber Threat Analysis Unit, although operationally managed under OSSI, serves to enhance the operations of the HHS Computer Security Incident

Response Center (CSIRC) and is therefore reflected in the baseline allocation for the PHSSEF IT Security FY 2016 Budget.

The security, intelligence, and counterintelligence programs managed by the OSSI enable a nation-wide Departmental response capability that provides senior leadership with science-based, intelligence-informed, threat reporting. OSSI is also working with the HHS operating and staff divisions to conduct counterintelligence inquiries and assessments to resolve allegations or suspicious activities by, or on behalf of, foreign entities. OSSI is developing protocols for suspicious activity reporting and guidelines for case management to manage and preserve information that may require follow-on FBI or the Office of the Inspector General (OIG) actions, as appropriate. In addition, OSSI Counterintelligence inquiries and assessments seek to identify insider (lone wolf) threats to HHS personnel, information, critical infrastructure and systems. Counterintelligence inquiries and assessments can uncover information that identifies threats and mitigates Departmental risk and allows a full range of Departmental response options, including referral to law enforcement agencies and the provision of support during OIG and /or FBI investigations.

Strengthening the Department's Defensive Counterintelligence Program HHS has established a Counterintelligence program as an integrated enterprise across the Department that detects threats and identifies risks and vulnerabilities to HHS personnel, information, facilities, systems and operational missions. Executive Order 13587 dated October 2011 mandated that federal departments and agencies establish a Counterintelligence program focused on identifying and mitigating foreign intelligence activity and threats to classified information and systems in support of the National Counterintelligence Strategy. The OSSI Intelligence and Counterintelligence Directorate created and the Deputy Secretary signed in November 2012, the HHS Counterintelligence Policy. This new policy focuses on protecting the integrity of the Department's mission in support of national security objectives. The principal goal of HHS' Counterintelligence program is to identify and disrupt insider or external threats that could detrimentally impact our employees, facilities, information, systems or operational mission.

The HHS defensive Counterintelligence program was established with FY 2012 PHSSEF resources and is built upon four critical pillars: 1) a counterintelligence strategy to develop capabilities and enhance awareness; 2) an integrated insider threat program; 3) a cyber-threat analysis unit with forensic capabilities; and 4) a supply chain risk assessment program.

OSSI Intelligence & Counterintelligence Initiatives:

1. Defensive Counterintelligence Program: The HHS 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. At present, the Counterintelligence Directorate is lacking the ability to perform the full range of analytical and assessment functions across the ten regions due to limited personnel resources. 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.

The additional funding would enable OSSI to enhance support to Operating Divisions at headquarters and enable support at the regional level. OSSI will conduct counterintelligence inquiries and assessments and continue to enhance its insider threat program and identify and develop the necessary tools to better integrate data across classified networks and synthesize analytic programs for a robust

analytical capability. These tools are needed to effectively protect and conduct the counterintelligence mission and to serve as a department-wide platform and conduit to identify, analyze and capture case information and also allowing the operating divisions to protect and share information to mitigate risks and vulnerabilities to our operations, personnel, information, systems and facilities.

2. Insider Threat Program: Integral factors within an Insider Threat Program include, but are not limited to, the ability to conduct risk and threat assessments, enhance analytic capabilities, to deliver extensive foreign travel briefings, and to maintain a comprehensive Foreign Visitor Tracking System.

- Risk assessments are dual-faceted under an Insider Threat Program and they focus on two key areas:
  - 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.
  - Counterintelligence threat assessments which examine threat information and identify personnel, system or organizational vulnerabilities to make informed determinations about the likelihood and consequence of the loss or compromise of critical assets, including classified or sensitive information and systems. Presently the program is lacking an adequate threat assessment and analytical function that is critical to ensuring the information gathering and dissemination of potential threat data across HHS.

- Development and maintenance of the HHS foreign travel briefings and monitoring is labor intensive because it requires both pre- and post-travel briefings, analytical assessments, and trend reporting. In order to enhance this program and streamline the analytical processes, OSSI will use the funding to add full time resources to developing required training modules and conduct briefings for HHS personnel. The focus of the program is to provide security and counterintelligence briefings to key Departmental personnel who hold national security clearances in an effort to raise awareness of the threats and mitigate the vulnerabilities related to overseas travel.

- Tracking and monitoring of trends of foreign visitors to HHS facilities information will be used to build the required Counterintelligence training modules for HHS personnel in order to raise awareness on potential threats and vulnerabilities to HHS personnel, information, facilities systems, and critical infrastructure.

3. System Upgrades: The present Sensitive Compartmented Information Facility (SCIF) infrastructure was built in 2011, and with the subsequent growth of OSSI, requires expansion and the necessary improvements and upgrades to promote a more efficient and effective working environment. In order for OSSI intelligence and counterintelligence analysts to effectively conduct their job and provide timely and current threat information to policymakers, they are required to work in a SCIF and have access to the Joint Worldwide Intelligence Communications System (JWICS). The JWICS system must reside within a SCIF. The majority of an OSSI analyst's time must be spent on JWICS and currently, the analysts do not each have their own workstation or JWICS terminal. This requires that they have to share each other's JWICS system, thus significantly negatively impacting the timeliness and quality of their work. Expanding and upgrading the SCIF that was established in 2011 would permit at least ten more analyst's access to their own workstations and thus increase efficiency and productivity, and ultimately better serve our policymakers.

PANDEMIC INFLUENZA

Budget Summary

(Dollars in Thousands)

Pandemic Influenza	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	110,597	67,906	170,009	+98,094
ASPR No-Year Funding (non-add)	*82,597*	*39,906*	*140,000*	*+100,094*
ASPR Annual Funding (non-add)	*28,000*	*28,000*	*26,000*	*-2,000*
OGA Annual Funding (non-add)	*4,009*	*4,009*	*4,009*	--
FTE	-	5	5	--

Authorizing Legislation:

FY 2016 Authorization.....PAPHRA

Allocation Method ..... Direct Federal/Intramural, Contracts, Formula Grants/Cooperative Agreements, Competitive Grants/Cooperative Agreements, and Other Direct Federal/Intramural, Contracts

Program Description and Accomplishments

Influenza and other emerging infectious diseases with pandemic potential continue to mutate, evolve, and infect animals and humans, posing continued significant threats to global public health and to the United States. To be prepared, invests in domestic pandemic preparedness efforts and works 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 our international partners. Over the past few years, America has made promising strides in the development and licensure of new seasonal and pandemic influenza vaccines using modern technologies; the development and approval of new single-dose influenza antiviral drugs; the advanced development and clearance of high-throughput rapid diagnostics; the development and production of H5N1 and H7N9 vaccine pre-pandemic vaccine stockpiles; and the expansion and increased flexibility of domestic and international vaccine manufacturing surge capacity. In addition, HHS continues to work with states to enhance their pandemic preparedness.

Since December 2005, HHS has been funding fundamental medical countermeasures (MCM) for pandemic preparedness activities. HHS has made significant progress improving vaccines and manufacturing technologies. The Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) has supported:

- Development of new cell- and recombinant-based influenza vaccines, and antigen-sparing vaccines leading to Food and Drug Administration (FDA)-licensure of:
  - Flucelvax (2012), the first cell-based seasonal influenza vaccine in the United States,
  - FluBlØk (2013), the first recombinant-based seasonal influenza vaccine in the United States, and
  - QPan H5N1 vaccine (2013), the first U.S. adjuvanted pandemic influenza vaccine.
- Optimization of high yielding vaccine seed strains and alternative potency and sterility assays to expedite influenza vaccine availability;

- Development of novel antiviral drug candidates for severe cases of influenza leading to the FDA approval (2014) of the first intravenously-administered single dose influenza antiviral drug - Rapivab (peramivir), which has been accessible under Emergency Use Authorization (EUA) since 2009;
- Development and FDA clearance (2012) of a *Polymerase Chain Reaction (PCR)*-based rapid point-of-care clinical diagnostics (Simplexa) for detecting influenza and respiratory syncytial viruses and their regulatory science base;
- Development and FDA clearance (2012) of next generation portable ventilators (Aura);
- Multi-fold expansion of domestic influenza vaccine production for pandemic preparedness by retrofitting older manufacturing plants (2007-2011) and helping to build new, state-of-the art, and award-winning manufacturing facilities (2009-2012) through BARDA's public-private partnerships with industry; and
- Establishment of three Centers for Innovation in Advanced Development and Manufacturing (2012), the Fill-Finish Manufacturing Network (2013), and the Clinical Studies Network (2014). HHS called on this infrastructure to develop, produce, test, and stockpile H7N9 vaccines in 2013 and Ebola vaccine and monoclonal antibody therapeutic candidates in 2014. The Ebola development will continue in 2015. Together, these efforts have expanded the national development and manufacturing infrastructure for vaccines, antibodies, and other products for pandemic influenza and emerging infectious diseases like Ebola.

HHS also has worked with partners to improve preparedness at the local, state, and international levels. Specifically, HHS has improved manufacturing technical knowledge and capacity in developing countries; surveillance, research, and international collaboration; risk communication efforts; and stockpiling of personal protective devices, ventilators, medical supplies, and MCMs such as vaccines, adjuvants, and antiviral drugs.

Strengthening Pandemic Influenza Preparedness

Following the release of HHS' 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 effectively and efficiently execute the pandemic influenza preparedness priorities. Recent accomplishments include the following:

- ***Cell-based influenza vaccines:*** In November 2012, FDA licensed Novartis' Flucelvax®, the first cell-based influenza vaccine in the United States. This vaccine will be available for pandemic vaccine production for the 2015 U.S. influenza season. BARDA supported the development of this vaccine towards licensure and partnered with Novartis to build a state-of-the-art, domestic cell-based influenza vaccine manufacturing facility that won the International Society for Pharmaceutical Engineering Best-in-Class Award for Process Innovation and was Overall Winner for Best Pharmaceutical Facility in 2013. This achievement marked a significant milestone toward one of the major vaccine goals in the National Strategy for Pandemic Influenza (2005) by moving an incumbent vaccine industry from old technology toward a more rapid and reliable manufacturing platform. Additionally, Baxter submitted a Biologic License Application to FDA in December 2013 for licensure of its cell-based seasonal influenza vaccine, which BARDA has supported since 2006. Lastly, cell-based influenza vaccines were a big part of HHS' H7N9

response in 2013, which included rapid vaccine development using new biosynthetic technology, manufacturing, clinical studies, clinical studies, and stockpiling.

Cell-based influenza vaccines have advantages over egg-based counterparts. These advantages include better raw material supply reliability, more rapid and greater scalability, and more flexible manufacturing scheduling. In addition, cell-based influenza vaccines may be much closer in genetic and antigenic identity to circulating influenza viruses than egg-based vaccines, as evidenced recently 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. Moreover, it will certainly strengthen the nation's ability to produce a higher volume of vaccines during an influenza pandemic in a shorter amount of time. For example, the H7N9 inactivated subunit cell-based influenza vaccine was developed and manufactured by Novartis with BARDA support in 2013 three to four weeks sooner than the egg-based inactivated subunit H1N1 vaccine in 2009 in the United States.

- ***Recombinant Vaccines:*** Recombinant-based influenza vaccines do not depend on the availability of influenza virus isolates, the ability of the new influenza virus strain to grow in eggs or cells, or the availability of eggs. Thus, development and manufacturing of recombinant-based influenza vaccines is much faster in an outbreak or pandemic. In January 2013, FDA licensed Protein Sciences' FluBlØk® 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 more and better vaccine sooner for influenza pandemic and seasonal epidemics. Recombinant-based influenza vaccines were the first developed, manufactured, and clinically tested in HHS' H7N9 vaccine response in 2013, which illustrates the rapidity and flexibility of this technology. Currently, pivotal Phase III clinical trials for seasonal influenza vaccine candidates are planned for 2015.
- ***Expanding vaccine capacity through the use of adjuvants:*** In November 2013, FDA licensed GlaxoSmithKline's Q-PAN H5N1 pandemic vaccine with AS03 adjuvant, which BARDA has supported since 2007. This vaccine 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 were instrumental to producing an immunogenic vaccine during our H7N9 vaccine response in 2013. Advanced development of a fourth pandemic influenza vaccine using adjuvants was added to the BARDA portfolio in 2014.
- ***Innovation in advanced development and manufacturing:*** To fulfill one of the recommended initiatives in the PHEMCE Review and the PCAST report on influenza vaccine technology (2010), BARDA established three CIADMs. The CIADMs will provide on a routine basis advanced development and manufacturing assistance to developers of MCMs for CBRN threats. The CIADMs are on track to offer this assistance to at least two CBRN MCM developers in 2014. The CIADMs also will be available to manufacture pandemic influenza vaccine in an emergency with a portion of that manufacturing surge capability coming online in FY 2016. (see also the section on BARDA)
- ***Expedited vaccine availability:*** Since September 2010, BARDA has led an HHS initiative, including academia and industry partners, to improve influenza vaccine manufacturing and make pandemic influenza vaccines available sooner. Support is directed toward optimizing high-

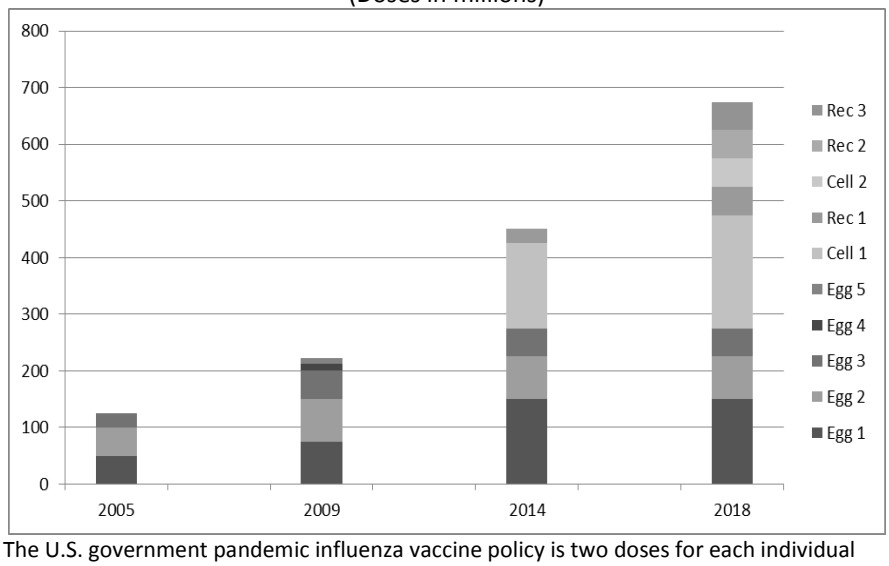
production yield vaccine seed strains and developing alternative novel vaccine potency and sterility assays. Using synthetic biology and novel reverse genetics donor partners, influenza vaccine seed strains—including H7N9 seeds—have been made available in less than 10 days, as compared to weeks by classical methods. New sterility assays developed through 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. Mass spectrometry was also developed and implemented at World Health Organization (WHO) Essential Regulatory Laboratories to accelerate the availability of vaccine potency testing reagents and speed vaccine release by two or more weeks.

- ***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 and public-private partnerships to expand U.S. vaccine production capacity. Through this effort, the vaccine manufacturing production rate of live, attenuated influenza vaccine doubled. That step enabled delivery of vaccine for the 2009 influenza pandemic. In 2012, the retrofitting of the other vaccine production facility was completed, which allowed for a nearly 50 percent increase in its influenza vaccine manufacturing capacity. In 2013, the United States realized a two-fold increase in domestic pandemic influenza vaccine manufacturing surge capacity with the commercial scale production of H7N9 vaccines at Novartis' cell-based vaccine manufacturing facility in North Carolina. That facility became a CIADM in 2012. These improvements bring U.S. manufacturing surge capacity for pandemic influenza vaccines closer to the ultimate goal of providing a rapid and adequate supply.

  The chart below displays the increase in U.S. domestic surge capacity to manufacture influenza vaccines.

ASPR/BARDA Multifold Expansion of Domestic Flu Vaccine Manufacturing Surge Capacity

(Doses in millions)



The U.S. government pandemic influenza vaccine policy is two doses for each individual (approximately 600 million doses) within four months of the onset of an influenza pandemic (Rec = Recombinant Vaccines; Cell = Cell-based Vaccines; Egg = Egg-based Vaccines).

- ***Increasing vaccine manufacturing capacity in developing countries:*** Since 2006, BARDA has collaborated with the WHO to support building vaccine manufacturing facilities and train staff in developing countries. To date, this collaboration has provided funding and training to 11

countries, has led to the licensure of seven influenza vaccines, and has supported more than nine clinical trials to evaluate pandemic H5N1 and H1N1 vaccine candidates produced in these countries. Four of these manufacturers developed H7N9 vaccine candidates to be able to respond against this new virus that is infecting people close to their borders. The current estimate of developing countries' influenza vaccine manufacturing capacity afforded under this project is nearly 300 million doses in a year. The goal is to achieve manufacturing capacity in these countries of an estimated 500 million doses of vaccine in 2016.

- ***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 to 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, and advantages such as reduced risk of resistance, expanded treatment windows, and possible co-administration with other influenza antiviral drugs. These antiviral drug candidates are under evaluation against H5N1 and H7N9 viruses as part of the pandemic response. In December 2014, FDA approved the usage of Rapivab™ (peramivir) for single-dose intravenous administration in persons with influenza in hospitalized settings. BARDA had supported development of this drug candidate since 2007.
- ***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. This level fully meets the requirement for stockpiling antiviral drugs. Additionally, a small federal stockpile of peramivir was established during the 2009 H1N1 pandemic to treat critically ill persons under EUA. 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, in 2014, FDA approved the first single-dose intravenously-administered influenza antiviral for use in hospitalized settings. 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.
- ***More rapid point-of-care diagnostics:*** In June 2012, FDA approved the breakthrough product – Simplexa; a point-of-care diagnostic device and assay for commercial U.S. marketing to detect 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. The Simplexa diagnostic detects influenza and respiratory syncytial virus in clinical samples as a moderate complex point-of-care diagnostic device. The device uses PCR technology with greater sensitivity and faster turn-around (less than one hour) than currently-marketed products.
- ***Simpler rapid diagnostics:*** ASPR/BARDA and CDC jointly began projects to develop rapid diagnostics for detection of seasonal and H5N1 viruses in point-of-care (POC) settings by health care 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. While the Simplexa diagnostic device supported by BARDA uses PCR technology, which has greater sensitivity and faster turn-around than currently-marketed products, other influenza rapid diagnostic device candidates under development with BARDA use different technologies. These devices use different technologies,

such as lateral flow immunoassays, for both POC and high-throughput applications, thereby achieving greater sensitivity and more accuracy for more respiratory pathogens in less time.

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

  HHS' 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 U.S. donation of H1N1 pandemic influenza vaccine to WHO and the response to the H7N9 Flash Appeal for support to WHO, in collaboration with partners in HHS, vaccine manufacturers, international transport companies, DOS, the U.S. Agency for International Development (USAID), and WHO;
  - Ensured policy coherence and program coordination across all HHS OPDIVs and STAFFDIVs engaged in global health security, particularly international influenza activities; and
  - Promoted global health security efforts and provide leadership for HHS in interactions with the White House, various federal 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.

- ***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.

ASPR/BARDA'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. 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, one of the CIADMs mentioned above—the Novartis facility in North Carolina—is playing a major role in H7N9 vaccine development and stockpile manufacturing.

Funding History

Fiscal Year	*Amount*
FY 2012[13]	-
FY 2013	-
FY 2014[14]	$114,606,000
FY 2015 Enacted	$71,915,000
FY 2016 Budget	$170,009,000

Budget Request

The FY 2016 Budget includes $170,009,000 for pandemic influenza activities, which is +$98,094,000 above FY 2015. The FY 2015 Enacted level for pandemic influenza activities ($72 million total) is -$98.1 million below the FY 2015 Budget. This FY 2015 reduction below the request level impedes HHS' ability to maintain existing programs for pre-pandemic influenza vaccine stockpiling and development of influenza antiviral drugs and immunotherapeutics, which are central programs to address critical vulnerabilities for U.S. pandemic preparedness. Furthermore, the reduced funding will disrupt the planned universal influenza vaccine advanced development program and erode progress that was made for transition and further development of an existing promising vaccine candidate (i.e., novel chimeric HA influenza vaccine candidate) that NIH and BARDA jointly support.

Given the FY 2015 Enacted level, the FY 2016 request is even more vital to the nation's pandemic preparedness.

Annual Funding Request for FY 2016 ($30,009,000):

Diagnostics Advanced Development ($10,000,000): BARDA will use this annual funding for the advanced development of rapid and specific multiplexed diagnostic platforms for use in near-patient settings, such as physician's office laboratories, or centralized laboratories, to enable faster and more reliable differentiation of influenza infection from other respiratory diseases, identification and/or genotyping of non-seasonal influenza strains, identification of drug resistant viruses, and improved clinical sample collection techniques. Performance of influenza diagnostic tests available in the marketplace will also be evaluated to ensure an appropriate quality of care and pandemic preparedness is maintained. These funds will be sufficient to support advanced development of one point of care diagnostic platform and of sequencing base diagnostics.

Fill-Finish Manufacturing Network ($13,000,000): This funding for BARDA will maintain the readiness of a network established in 2013 for the formulation and fill-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

[13] Activities in FYs 2012 and 2013 were supported by unobligated balances of prior-year appropriations.
[14] Reflects the reduction of -$402,926 for the Secretary's FY 2014 permissive transfer.

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 CIADM facilities. Additionally this BARDA Network will work with FDA to address drug shortages based on the results of a pilot program initiated in FY 2015.

***ASPR's Office of Policy and Planning (OPP) International Pandemic Influenza Activities ($3,000,000*)**: OPP will continue to 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 actions in the Beyond the Border Initiative with Canada. OPP also will coordinate international preparedness efforts to address pandemic influenza, emerging infectious diseases, and CBRN threats through the GHSI with the G7 countries, Mexico, the European Commission, and WHO. OPP will complete the development and oversee the implementation and exercising of policy frameworks to guide the U.S. government's provision and receipt of international assistance during public health and medical emergencies. Furthermore, OPP will continue to work with domestic and international stakeholders to identify and address legal, regulatory, and logistical barriers to assistance. OPP will continue to provide leadership and oversight of U.S. compliance with its obligations under the global health security framework of the International Health Regulations (IHR), including collaborations with domestic and international partners to support the development and strengthening of IHR core capacities.

Office of Global Affairs' (OGA) International Pandemic Influenza Activities ($4,009,000): This funding will allow OGA to continue to provide leadership, oversight, policy and program coordination, and global health diplomacy in international pandemic preparedness and response. The Office of Global Affairs has had remarkable success over the past several years providing policy and technical coordination on international influenza as well as for inter-related issues of influenza, the animal-human interface, and global health security. U.S. domestic pandemic preparedness is dependent on HHS' continued leadership and investments with key global partners in international settings to prepare, prevent, detect, and respond to emerging influenzas and other viruses with pandemic potential. HHS will support global, multilateral, bilateral, and inter and intra-government initiatives to ensure the United States, other countries, and international organizations use the most effective approaches to better prepare for and respond to a pandemic. Areas of work will include 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 U.S. government global health security priorities; and, improved coordination of influenza surveillance, pandemic preparedness and response with 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 2016 ($140,000,000):

Vaccine Stockpiling ($20,000,000): BARDA requests $20,000,000 to cover the storage, analytical and stability testing, and maintenance of H5N1, 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, more than 40 million doses of H7N9 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. These funds are required to maintain these existing stockpiles, which represent a total previous investment of more than $1.75 billion by the federal government and to

prepare for emerging pandemic threats. Because the FY 2015 Enacted level for pandemic influenza is inadequate, BARDA will not be able to fund activities on newly-awarded stockpile contracts that are required to maintain the existing stockpile program critical for a swift and nimble pandemic response.

Universal Influenza Vaccine Candidates ($75,000,000): BARDA requests $75 million to support the advanced development of up to two vaccine candidates that may afford greater effectiveness against a diverse group of influenza virus strains and/or may include "universal" influenza vaccine candidates that afford cross-subtypic and longer lasting immunity, as well as serve as a primer vaccine for future influenza pandemics. Several current vaccine candidates including viral hemagglutinin stalk-derived antigens are in early development in Phase I clinical trials supported jointly by BARDA and the 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 2010-2011 discovery of conserved regions on the influenza hemagglutinin protein, which may elicit cross-neutralizing antibodies, has led to the development of new "universal" influenza vaccine candidates over the past two years. These vaccine candidates, called HA stalk vaccines, protect animals challenged with different influenza A virus subtypes (i.e. H1N1, H3N2, H5N1, etc.). NIAID and BARDA are working currently with several investigators to develop and manufacture HA stalk vaccine candidates for Phase I clinical trials next year. Because of inadequate FY 2015 appropriations for pandemic influenza, BARDA will not be able to transition many influenza vaccine candidates fully toward advanced development or support later-stage clinical development. Therefore, the FY 2016 request will be critical to launch and sustain scientific advancements of these novel and promising technologies to lead to more effective influenza vaccines. By FY 2016, several of these vaccine candidates will be ready to transition toward BARDA's advanced development support (including Phase II and III clinical trials, commercial-scale manufacturing development, optimization, and validation).

Advanced Development of Influenza Immunotherapeutics ($45,000,000): In the last three years, monoclonal antibodies have emerged as a new class of antivirals with novel mechanisms of action compared to the current licensed antivirals. These human monoclonal antibodies are broadly neutralizing across influenza A Group 1 and Group 2 strains. The antibodies inhibit viral replication by binding to highly-conserved regions on the hemagglutinin stalk. Their novel mechanism of action also makes them less vulnerable to the emergence of resistance. These monoclonal antibodies have demonstrated safety in humans and an expanded treatment window, allowing for treatment later in the course of infection. The request will help fill a significant unmet medical need by advancing two programs toward licensure for the treatment of the severely-ill hospitalized population. The FY 2016 request will be critical to prevent the loss of momentum to accelerating this new class of drugs.

Proposed Language Change:

While influenza continues to be an issue of concern, it is not the only pandemic that poses a threat to the health of Americans nor of the global community. In recent years, Middle East Respiratory Syndrome-Coronavirus (MERS-CoV), Severe Acute Respiratory Syndrome (SARS), and Ebola have materialized as concrete threats that challenge the capacity of health systems just as influenza does; all of these pandemics require the same infrastructure, programs and policies to mount effective responses. In the face of these emerging threats, HHS' role of response and coordination of the U.S. Government's health diplomacy and political engagement with multilateral and bilateral partners is needed. Existing appropriations language has limited the Department's ability to use these funds for such purposes. Influenza is only one of many pandemic threats we face at this time. Addressing all of those implies an approach that requires health system strengthening and policy development that

ultimately give us the ability to fight all of them, not just one. Maintaining existing language for pandemic funding inhibits HHS' ability to address the broader threats to global health security.

Modification of pandemic appropriations language (see page 16) to include pandemic influenza and other emerging infectious disease threats would allow ASPR and OGA to provide a more efficient and effective response and better coordinate across the Department and the U.S. Government.

Without such a change in language, HHS' ability to address pandemic threats other than influenza would be limited, which weakens the U.S. Government's engagement with and ability to influence multilateral organizations and our bilateral partners. Recent experience with the Ebola crisis in West Africa has demonstrated the urgent need to respond quickly and decisively, and in a well-coordinated fashion. Broadening this language would enable the Department to better lead U.S. Government engagement with multilateral and bilateral partners focused on preventing pandemic threats, to coordinate interagency responses to international requests, and ultimately to better protect the health of Americans.

Pandemic Influenza – Outputs and Outcomes Table

	Most Recent Result	FY 2015 President's Budget	FY 2016 Target	+/- FY 2015 PB
Target	N/A	N/A	ASPR/BARDA: Ensure a domestic pandemic influenza vaccine manufacturing surge capacity to produce at least 500 million vaccine doses within six months of the onset of an influenza pandemic.	
Result	N/A	N/A	N/A	N/A
Status	N/A	N/A	N/A	N/A

PUBLIC HEALTH EMERGENCY RESPONSE INITIATIVE

Budget Summary

(Dollars in Thousands)

Emergency Response Initiative	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
Budget Authority	-	-	110,000	+110,000
FTE	-	-	-	--

Authorizing Legislation:

FY 2016 Authorization.....PHS Act

Allocation Method ..... Direct Federal/Intramural, Contracts, Formula Grants/Cooperative Agreements, Competitive Grants/Cooperative Agreements, and Other Direct Federal/Intramural, Contracts

Background

Since 9/11, considerable work across the Department has focused on preparedness, response, and recovery efforts. These efforts have remained a work in progress, requiring identification of strategies that have been effective and opportunities to strengthen our efforts based on lessons learned from each event.

The government response to Ebola has highlighted the need for a more effective and coordinated response to significant public health crises that require immediate or sustained large-scale responses – particularly those that cross state and international boundaries – that may not immediately meet the three major declaration thresholds. Informed by lessons learned from the Ebola response effort to-date and other recent response efforts, the FY 2016 Budget proposes additional funding for HHS for strengthening the nation's capability to plan for and manage the response to public health emergencies. In conjunction with this funding request, the Department has identified immediate opportunities to improve flexibility through additional authorities to strengthen the nation's capability to plan for and rapidly respond to urgent public health needs that may require both domestic and international response capabilities.

Opportunity for Improved Response:

Lack of Immediate Funding Available: The Public Health Emergency Fund, authorized by the Public Health Service Act, has no balance and can only be accessed in a declared public health emergency. There is no other immediate and flexible no-year funding available to ensure a timely response to an urgent event and no such fund for an event that does not meet the threshold for a public health emergency declaration. The lack of dedicated and flexible funding impeded the Department's ability to respond more quickly to control the spread of Ebola at its source in West Africa.

Funding History

Fiscal Year	*Amount*
FY 2012	-
FY 2013	-
FY 2014	-
FY 2015 Enacted	-
FY 2016 Budget	$110,000,000

Budget Request

The FY 2016 Budget includes $110,000,000 to be available until expended to respond to an urgent or emergency need that could cause severe consequences, but does not – or not yet – meet the criteria for a *Stafford Act* or public health emergency declaration, and in which rapid action would help mitigate the threat. This funding would be available at the discretion of the Secretary.

Within this total, up to $20,000,000 would be available to prepare for such a response when speed is of concern for coordination, training, command and control, and other related needs. Whether we have an infectious disease outbreak (e.g., influenza or Ebola) or other public health crisis, having this fund accessible will enable HHS to respond rapidly. The Budget includes not less than $90 million in an emergency fund for immediate federal, state, or local response needs in the United States or internationally and that could be used for purposes including emergency staffing, laboratory equipment, countermeasures, and rapid state and local response in an emergency to protect human health.

EFFECTIVE HEALTH INSURANCE INITIATIVE

Budget Summary

(Dollars in Thousands)

Health Insurance Evaluation Initiative	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/-FY 2015
PHS Evaluation Funds	-	-	30,000	+30,000
FTE	-	-	-	--

Authorizing Legislation:

FY 2016 Authorization.....Indefinite

Allocation Method .....Direct Federal, Contract

Program Description and Accomplishments

As part of the Administration's commitment to incorporating evidence and evaluation into policy solutions, the Budget proposes a new project to examine how changes in health insurance benefit packages impact health care utilization, costs, and outcomes. The goal of this study is to use the best methods to produce rigorous, actionable evidence about how to modernize the health care system in a way that improves outcomes while controlling costs.

This new project will use a gold standard randomized controlled trial study design to update the Health Insurance Experiment, a pioneering trial funded by the then-Department of Health, Education, and Welfare that has shaped the structure of health insurance plans ever since. The healthcare landscape has changed considerably since the original study was conducted, and new information is needed to develop the best policy for today's health care consumers.

The original Health Insurance Experiment was groundbreaking. Starting in the early 1970s, the study tested alternative health insurance designs by randomly assigning voluntary participants into insurance plans with different payment models and levels of cost sharing. The use of random assignment is a rigorous way to examine the impact of policies, but it is rarely used in applied public policy research. After observing years of participant enrollment in the health plans, the study's results showed the effect of different levels of cost sharing on hospital visits, doctor office visits, and health care spending. For example, the researchers found that higher levels of required cost sharing decreased participants' use of both effective and ineffective health services, but did not demonstrably impact the quality of care received (Brook et al., 2006). The study prompted increased use of cost sharing in private health insurance, and still provides the best available evidence on health insurance designs. The study's results became a resource for policymakers and insurers to understand how changes in health insurance benefit packages would affect health care quality, health outcomes, and costs.

Funding History

Fiscal Year	*Amount*
FY 2012	-
FY 2013	-
FY 2014	-
FY 2015 Enacted	-
FY 2016 Budget	$30,000,000

Budget Request

The FY 2016 request for the Effective Health Insurance Initiative is $30 million of Public Health Service Evaluation funds to support a new effort to rigorously identify modern health insurance plan designs that maximize health status and quality, while controlling costs. HHS will launch a longitudinal study to inform the development of health care models that work better for families and providers. The results of the study could potentially help patients become better health care consumers by appropriately using treatments that prevent health declines, hospitalizations and complications, and by using fewer treatments that provide limited health benefit.

Much has changed in health care and health insurance since the 1970s. Despite innumerable changes in health care treatment, delivery, and regulations in the four decades since the original Health Insurance Experiment study was conducted, the study remains the gold standard for policymakers and insurers to understand how changes in health insurance can improve health care quality, health outcomes, and avoid unnecessary health care costs. Currently, economists have to apply one-size-fits-all behavioral estimates across all types of insurance markets and populations even though that may not always be appropriate. For example, the effect of cost sharing on health care use, spending, and health status likely differs depending on the type of service (prescription drug, physician, hospital), the type of provider network (open or narrow), or population (low income, chronically ill). Although recent studies have developed useful evidence in these areas, these studies have been limited to a narrow change or population (for example, a change to prescription drug cost sharing within a single employer), and have not used a randomized design that ensures that the results will be generalizable and replicable when scaled to larger populations. This study will address key limitations to using the original study's results to design today's policies and health insurance plans.

This study has enormous potential to inform policy that will improve health and reduce spending among the privately and publicly insured populations. In the context of private health plans covering 177 million Americans, public programs covering tens of millions more, and private health insurance spending projected to grow beyond $1.1 trillion in 2016, it is more important than ever that policymakers have accurate ways to design health care policies that will reduce spending while improving health. Addressing these questions is critically important for private and public coverage. For example, better care designs for high cost, chronically ill patients could result in cost savings and health benefits for private and public payers. Due to the broad applicability of the questions this study will address, even small innovations resulting from this project could lead to significant savings.

This project will inform better policy by providing information on key recent features of today's health care system that were not evaluated in the original study. First, the new study will take into account the substantial changes in health care treatment and delivery since the 1970s, including the growth of post-acute care services, prescription drug use, high deductible health plans, health savings accounts, managed care, value-based incentives, and the establishment of the standardized essential health benefits and health care marketplaces. Furthermore, substantial changes are under way to improve care coordination, and the effect of cost sharing is not known in these evolving delivery settings. The study will take advantage of advances in quality and outcome measurement to examine the impacts of interest with today's proven methods. Finally, this study will provide an opportunity to examine populations, such as those with chronic illness or low-incomes, where targeted findings could provide particular improvements. Understanding these distinctions would allow insurers and policy makers to design more effective policies and more accurately estimate the costs and impacts of policy proposals.

As private health plans and public programs expand coverage and work to provide access to high quality, high value care to hundreds of millions of Americans, this study would provide current, comprehensive data on which benefit designs are most effective, and for which populations. This evidence will help

assess issues of critical importance to delivery system and payment reform. Potential issues addressed by the study include:

- How do varied levels of insurance deductibles, copayments, co-insurance, and out-of-pocket maximums affect health spending, utilization, and outcomes?
- How do other ways of affecting utilization, such as management of benefits, affect cost, quality, and outcomes?
- Do health plans' limited networks, prior authorization, and care coordination activities do a better or worse job of managing care than cost sharing? Are these approaches mutually reinforcing or can they substitute for one another?
- How can insurance benefit packages be designed to maximize affordability for vulnerable groups such as persons with multiple chronic conditions or low incomes, while still supporting access to high quality health care?
- How can insurance plans improve the value enrollees receive from health spending? Are there effective ways to help guide people's decisions toward higher value services?
- To what extent do the effects of insurance benefit design vary across regional health care markets, provider types, and delivery settings?

The requested funds will enable HHS to plan and initiate the study using rigorous evaluation methods to answer critical research questions that cannot be directly addressed through other means. The study will employ a longitudinal design framework in which the health care behaviors of participating individuals and families will be assessed for a minimum of two years. In order to permit such longitudinal analyses, to be large enough to apply to a variety of insurers, and to ensure a statistically robust design, the study will require adequate funding.

The Agency for Healthcare Research and Quality, in collaboration with the Office of the Assistant Secretary for Planning and Evaluation, will lead this project. These agencies have extensive experience in program evaluation and health services research, including ASPE's implementation of the original Health Insurance Experiment. The new study will be implemented through external research contracts and will operate according to the highest standards of research methods and protections for participant privacy and wellbeing.

In preparing to launch a new experimental examination of health insurance design and its impacts, HHS will conduct a review of the literature on demand response and how it has changed since the 1970s; review a number of natural experiments that have used rigorous quasi-experimental techniques; perform an assessment of measurement and data requirements for conducting a focused experimental study; and examine strategies for implementing randomized studies that assesses behavior under relevant institutional arrangements.

A multi-year (5 year) period of availability is requested because these funds are for long term evaluation purposes, which require more than a single year for planning and implementation.

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Thousands)

Object Class Code	Description	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
11.1	Full-time permanent	76,124	79,345	+3,221
11.3	Other than full-time permanent	-	-	--
11.5	Other personnel compensation	112	118	+6
11.7	Military personnel	6,614	6,586	-28
11.8	Special personnel services payments	-	-	--
Subtotal	**Personnel Compensation**	**82,849**	**86,048**	**+3,199**
12.1	Civilian personnel benefits	30,422	31,548	+1,126
12.2	Military benefits	2,834	2,845	+11
13.0	Benefits for former personnel	-	-	--
Total	**Pay Costs**	**116,106**	**120,442**	**+4,336**
21.0	Travel and transportation of persons	6,137	6,187	+50
22.0	Transportation of things	521	521	--
23.1	Rental payments to GSA	17,506	17,559	+53
23.3	Communications, utilities, and misc. charges	710	843	+133
24.0	Printing and reproduction	105	105	--
25.1	Advisory and assistance services	266,000	516,498	+250,498
25.2	Other services	26,029	29,567	+3,538
25.3	Purchase of goods and services from government accounts	67,622	110,423	+42,801
25.4	Operation and maintenance of facilities	4,017	4,022	+5
25.5	Research and development contracts	429,258	713,901	+284,643
25.6	Medical care	-	-	--
25.7	Operation and maintenance of equipment	19,737	72,077	+52,340
25.8	Subsistence and support of persons	570	570	--
26.0	Supplies and materials	1,258	1,548	+290
31.0	Equipment	475	527	+52
32.0	Land and Structures	18	18	--
41.0	Grants, subsidies, and contributions	277,000	315,173	+38,173
43.0	Interest and Dividends	-	-	--
44.0	Refunds	-	-	--
Total	**Non-Pay Costs**	**1,058,963**	**1,679,539**	**+620,576**
Total	**Budget Authority by Object Class**	**1,233,069**	**1,909,981**	**+676,912**

SALARIES AND EXPENSES

(Dollars in Thousands)

Object Class Code	Description	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
11.1	Full-time permanent	76,124	79,345	+3,221
11.3	Other than full-time permanent	-	-	--
11.5	Other personnel compensation	112	118	+6
11.7	Military personnel	6,614	6,586	-28
11.8	Special personnel services payments	-	-	--
Subtotal	**Personnel Compensation**	**82,849**	**86,048**	**+3,199**
12.1	Civilian personnel benefits	30,422	31,548	+1,126
12.2	Military benefits	2,834	2,845	+11
13.0	Benefits for former personnel	-	-	--
Total	**Pay Costs**	**116,106**	**120,442**	**+4,336**
21.0	Travel and transportation of persons	6,137	6,187	+50
22.0	Transportation of things	521	521	--
23.2	Rental payments to others GSA	17,506	17,559	+53
23.3	Communications, utilities, and misc. charges	710	843	+133
24.0	Printing and reproduction	105	105	--
25.1	Advisory and assistance services	266,000	516,498	+250,498
25.2	Other services from non-Federal sources	26,029	29,567	+3,538
25.3	Other goods and services from Federal sources	67,622	110,423	+42,801
25.4	Operation and maintenance of facilities	4,017	4,022	+5
25.5	Research and development contracts	429,258	713,901	+284,643
25.6	Medical care	-	-	--
25.7	Operation and maintenance of equipment	19,737	72,077	+52,340
25.8	Subsistence and support of persons	570	570	--
Subtotal	**Other Contractual Services**	**813,233**	**1,447,058**	**+633,825**
26.0	Supplies and materials	1,258	1,548	+290
Subtotal	**Non-Pay Costs**	**839,470**	**1,473,821**	**+634,351**
Total	**Salary and Expenses**	**955,576**	**1,594,263**	**+638,687**
Total	**Direct FTE**	**757**	**773**	**+16**

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT

Detail	FY 2014 Civilian	FY 2014 Military	FY 2014 Total	FY 2015 Civilian	FY 2015 Military	FY 2015 Total	FY 2016 Civilian	FY 2016 Military	FY 2016 Total
ASPR									
Direct	519	69	588	535	72	607	540	72	612
Reimbursable	-	-	-	-	-	-	-	-	-
Total, ASPR	**519**	**69**	**588**	**535**	**72**	**607**	**540**	**72**	**612**
Cybersecurity									
Direct	70	-	70	112	-	112	123	-	123
Reimbursable		-	-	-	-	-	-	-	-
Total, Cybersecurity	**70**	**-**	**70**	**112**	**-**	**112**	**123**	**-**	**123**
Office of Security and Strategic Information									
Direct	30	3	33	32	1	33	31	2	33
Reimbursable	-	-	-	-	-	-	-	-	-
Total, OSSI	**30**	**3**	**33**	**32**	**1**	**33**	**31**	**2**	**33**
Pandemic Influenza									
Direct	4	2	5	3	2	5	3	2	5
Reimbursable	-	-	-	-	-	-	-	-	-
Total, Pandemic Influenza	**4**	**2**	**5**	**3**	**2**	**5**	**3**	**2**	**5**
Total FTE	**623**	**74**	**696**	**682**	**75**	**757**	**697**	**76**	**773**

Average GS Grade	
FY 2014	13
FY 2015	14
FY 2016	14

DETAIL OF POSITIONS

Detail	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Budget
Executive Level I	-	-	-
Executive Level II	8	8	8
Executive Level III	-	-	-
Executive Level IV	-	-	-
Executive Level V	1	1	1
Subtotal	**9**	**9**	**9**
Total – Executive Level Salaries	**$1,986,812**	**$1,958,941**	**$1,960,204**
ES-6	2	1	1
ES-5	-	-	-
ES-4	-	-	-
ES-3	-	-	-
ES-2.	-	-	-
ES-1	1	1	1
Subtotal	**3**	**2**	**2**
Total – ES Salary	**$319,029**	**$258,219**	**$274,301**
GS-15	130	130	132
GS-14	200	210	213
GS-13	121	132	135
GS-12	69	68	70
GS-11	29	32	32
GS-10	1	1	1
GS-9	14	14	14
GS-8	3	3	3
GS-7	11	11	11
GS-6	-	4	4
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Total – GS Salary	**$66,120,085**	**$71,555,497**	**$72,929,349**
Average ES level	**ES II**	**ES II**	**ES II**
Average ES salary	**$151,622**	**$160,316**	**$165,677**
Average GS grade	**13**	**14**	**14**
Average GS salary	**$108,267**	**$108,970**	**$109,928**
Average Special Pay categories	**$131,097**	**$156,190**	**$157,781**

SIGNIFICANT ITEMS FOR INCLUSION IN THE FY 2016 CONGRESSIONAL JUSTIFICATION

PER THE OMNIBUS (P.L. 113-235) L-HHS APPROPRIATIONS COMMITTEE REPORT

SIGNIFICANT ITEM

(#99, PAGE #85) Project Bio-Shield - The agreement is committed to ensuring the nation is adequately prepared against chemical, biological, radiological, and nuclear attacks. The agreement recognizes a public-private partnership to develop medical countermeasures (MCMs) is required to successfully prepare and defend the nation against these threats as has been demonstrated in the decade since the initiation of the Project BioShield Special Reserve Fund (SRF). Where there is little or no commercial market, the agreement supports the goal of an explicit commitment by the Government to biodefense medical countermeasures, such as was provided during fiscal years 2004-2013 by the initial SRF. Although the agreement cannot provide the authorized 5-year amount of $2,800,000,000, it continues to support the procurement of MCSs. Further, the agreement requests the agency provide an update in the fiscal year 2016 congressional budget on how it can support training and simulated events to prepare for the coordinated management and utilization of medical countermeasures.

RESPONSE

The SRF funding is not available for training or to conduct simulated events.

However, the Department of Health and Human Services (HHS)—and the Office of the Assistant Secretary for Preparedness and Response (ASPR), in particular—will continue working with federal and other partners to support training and simulations to prepare for the coordinated management and use of MCMs. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan of 2014 establishes many goals related to developing additional federal operational and response plans.

The PHEMCE coordinates federal efforts to enhance MCM preparedness for chemical, biological, radiological and nuclear threats (CBRN), pandemic influenza, and emerging infectious diseases like Ebola. ASPR leads the PHEMCE, which includes three other primary HHS partners: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health. The PHEMCE also includes other federal partners: DHS and the Departments of Agriculture, Defense, and Veterans Affairs (VA).

Over the next five years—through the leadership of ASPR and CDC, and supported by other federal partners and external experts—the PHEMCE will leverage the lessons learned at all levels of government from previous incident responses to develop and share MCM response strategies, clinical utilization guidelines, and an MCM concept of operations (CONOPs) with end-users such as first responders, physicians, nurses, other allied health professionals, local and hospital laboratory directors, and state and local emergency planners. ASPR will collaborate with PHEMCE partners to ensure MCM strategies and clinical guidelines are appropriately captured in federal and regional all-hazards emergency response planning processes. ASPR will assess, streamline, and enhance deployment and sustainment protocols and tracking processes.

First responders are critical in supporting and assisting communities as they recover from the impacts of public health and medical incidents, including events during which MCMs are used. Planning for protecting first responders is primarily done at the state and local levels, but all PHEMCE agencies will continue to provide general recommendations, modeling projections, and other supporting information

to guide such planning efforts. For example, recently, a federal interagency working group that included subject matter experts from DHS and HHS issued *Guidance for Protecting Responders' Health during the First Week Following a Wide-Area Aerosol Anthrax Attack*. This guidance provides recommendations for protecting first responders and addresses pre- and post-event vaccination, the proper use of personal protective equipment, and personal decontamination processes. In addition, HHS and DHS recently collaborated on a letter to first-responder occupational health care providers to promote the implementation of a program to provide MCMs to first-responder personnel prior to a biological event. In this correspondence, federal officials outlined the benefits of such a program and suggested how it could be implemented by individual first responders' contacting their personal health care providers to obtain prescriptions for recommended antimicrobial drugs. States, local organizations, or individual first responders may pay the cost of the MCMs.

CDC's Division of State and Local Readiness (DSLR) currently provides state, local, territorial and tribal planning guidance and conducts annual reviews with state and local MCM stakeholders. The 2014 document, "Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness," provides detailed MCM planning guidance for state and local preparedness programs. In 2015, CDC/DSLR will implement a new method of reviewing state and local MCM operational readiness using the Operational Readiness Review (ORR). The ORR replaces the legacy Technical Assistance Review assessment tool.

Through ongoing collaborative efforts with other PHEMCE partners and external stakeholders, FDA will work to modernize the legal, regulatory, and policy frameworks to facilitate the development and availability of MCMs; enhance pre-event planning; and foster rapid MCM deployment and use in public health emergencies. In addition, VA's Office of Public Health will lead an effort to study and streamline closed Points of Dispensing as a means to distribute MCMs during a public health crisis.

Also, by the end of FY 2019, the PHEMCE will develop the following strategies, guidance, and other documents to facilitate national public health emergency response for high-priority threats:

- Planning guidance for patient decontamination in a mass-exposure chemical incident (FY 2015);
- An assessment of state and local capacity to utilize cytokines for Acute Radiation Syndrome (ARS)-associated neutropenia following the use of an improvised nuclear device (FY 2015);
- National response strategies for anthrax (FY 2015), botulism, glanders and melioidosis, and smallpox (FY 2016);
- Clinical practice guidelines for MCMs to address chemical agents, smallpox, anthrax, and botulism in the near-term and ARS-associated neutropenia (by the end of FY 2018); and
- CONOPs for MCMs to address neutropenia (FY 2018), and glanders and melioidosis (FY 2018).

HHS prioritizes the implementation of corrective actions to learn from past responses and continue to refine procedures and capabilities. This analysis of past responses and potential corrective actions includes MCMs. By prioritizing corrective actions in this way, HHS improves responses and mitigates lasting effects of public health and medical emergencies. ASPR's Office of Emergency Management leads a corrective action process for all of ASPR's response programs and assets that incorporates a systematic approach to ensure HHS is poised to achieve success in preparedness, response, and recovery from public health and medical incidents.

ASPR has a formal system in place to capture lessons learned and ultimately leverage them to strengthen the health and emergency response systems in place. Following each response, ASPR conducts professional discussions between HHS response entities and state, local, and interagency

partners through participation in interagency committees, and staff engagements and meetings. Through these channels, HHS identifies any issues with the response and their cause. This internal corrective action process informs DHS's Federal Emergency Management Agency's after-action and lessons-learned reports.