DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2017

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committees

Contents

We are pleased to present the Fiscal Year (FY) 2017 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2017 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 and includes the FY 2017 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).

ASPR protects health to save lives after disasters. To do this, ASPR strengthens day-to-day public health and health care systems nationwide so they can withstand public health emergencies and disasters. ASPR supports state and local health departments, health care coalitions, medical providers, and emergency managers in preparing for incidents that impact health. When disaster strikes, ASPR assists state and local governments with public health and medical response, helping communities recover quickly and become healthier and more resilient.

The public outcry over the lack of vaccines, diagnostics, and drugs for the Ebola epidemic in 2014 and for the H1N1 influenza pandemic in 2009 demonstrates the immediacy with which the American people expect their government to respond and protect public health from new infectious diseases. To meet public demand, protect health, and save lives in the next pandemic or disease epidemic, the Federal government must continue to take action and maintain momentum to develop new medical countermeasures – vaccines, drugs, diagnostics, and devices – so they are available immediately when needed, as well as work domestically and internationally to establish and implement the policies, procedures, training, drills, and plans necessary for the nation to be resilient when faced with pandemics. The innovation, enhanced partnerships with small and large companies, and sustained investments made possible under Project BioShield and funding provided for Pandemic Influenza preparedness over the last decade have led to medical countermeasures critical to national health security. These advances continue to boost the nation's readiness to respond to the medical consequences of anthrax, botulism, smallpox, radiological and nuclear agents, chemical, and emerging diseases. The medical countermeasure pipeline holds more promise today than ever.

ASPR's advanced research and development program bridges gaps in national preparedness that no other federal agency does: the late stages of development necessary to reach licensure of medical products that prevent, diagnose, or treat illnesses or injuries from chemical, biological, radiological, and nuclear threats; from emerging infectious diseases; and from the growing public health threat of antimicrobial resistance, all of which hold dire consequences for American and global health. Made possible through support for Project BioShield, the United States acquired 12 MCMs against chemical, biological, radiological, and nuclear (CBRN) threats over the past decade. Notably, almost half of these MCMs also have a "peacetime" public health use. Since 2012 and 2013, two of these CBRN MCMs became the first products approved under the Animal Efficacy Rule; two additional CBRN MCMs were licensed in 2015. In addition, since 2012, the Food and Drug Administration has approved eight pioneering vaccines, antiviral drugs, diagnostics, and medical devices for seasonal and pandemic influenza that ASPR supported.

ASPR provided medical countermeasure responses to recent public health emergencies in the U.S. and globally. In 2013 ASPR led the development, manufacturing, and clinical testing of new vaccines in record time as part of the HHS response to the deadly avian influenza H7N9 outbreak in China. In 2014-2015 ASPR, with federal and industry partners, supported advanced development of 12 vaccine, antiviral, immunotherapeutic, and diagnostic candidates as part of the Ebola response. Additionally ASPR's core service assistance programs provided support of animal and clinical studies including Ebola vaccine clinical studies with the CDC in Sierra Leone. In 2016 ASPR is working with partners to develop and evaluate MERS-CoV therapeutic candidates in Saudi Arabia. These and other achievements by the PHEMCE demonstrate how far America has come in MCM preparedness and response capabilities during the last decade.

The reality of antibiotic-resistant bacteria affects the country every day and represents a critical gap in our ability to effectively respond to a naturally occurring or bioterrorist event. This request continues to fund ASPR's important work in carrying out the National Strategy to Combat Antibiotic-Resistant Bacteria (CARB Initiative). ASPR is supporting the development of the first new classes of antibiotics to treat multidrug-resistant pathogens that are sometimes called 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 across the United States.

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

The FY 2017 budget request for ASPR is $1.4 billion, which is a decrease of -$102 million below the FY 2016 enacted budget and an increase of +$188 million above FY 2015, after excluding emergency funding for Ebola preparedness and response. The request provides:

- $862 million for BARDA, including $512 million for Advanced Research and Development which also includes $192 million for the CARB initiative; and $350 million for Project BioShield procurements of MCMs.
- $125 million for activities by ASPR and the HHS Office of Global Affairs to develop new diagnostics tools, vaccines, immunotherapeutics and support international preparedness for pandemic influenza and emerging infectious diseases
- $255 million for the Hospital Preparedness Program to support cooperative agreements with state, local, and territorial health departments to improve surge capacity and enhance community health care coalitions
- $86 million for Federal emergency management, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps, including an increase of +$5 million to fund the training of NDMS deployable personnel to ensure a knowledgeable and prepared workforce
- $46 million for ASPR's policy; planning; acquisitions, grants, and financial management; administrative operations; and leadership

The HHS Cybersecurity program maintains the security of an array of unique systems and sensitive data within the Department, including, HHS grants systems, for which the Department is the largest grant-

maker, and many systems are utilized across the Federal government; personally identifiable information and health records; and, sensitive biodefense research and proprietary data. The Budget sustains the FY 2016 Enacted level, which has afforded the Cybersecurity program with a sustainable base budget. The Budget helps support a more nimble, flexible operating level to address ongoing Cybersecurity concerns and to prepare for the future challenges that accompany rapidly changing technologies. The Department continues to assess evolving requirements and support for HHS specific needs as cyber threats becoming increasingly complex.

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.

Nicole Lurie
Assistant Secretary for Preparedness and Response, MD, MSPH Rear Admiral, USPHS

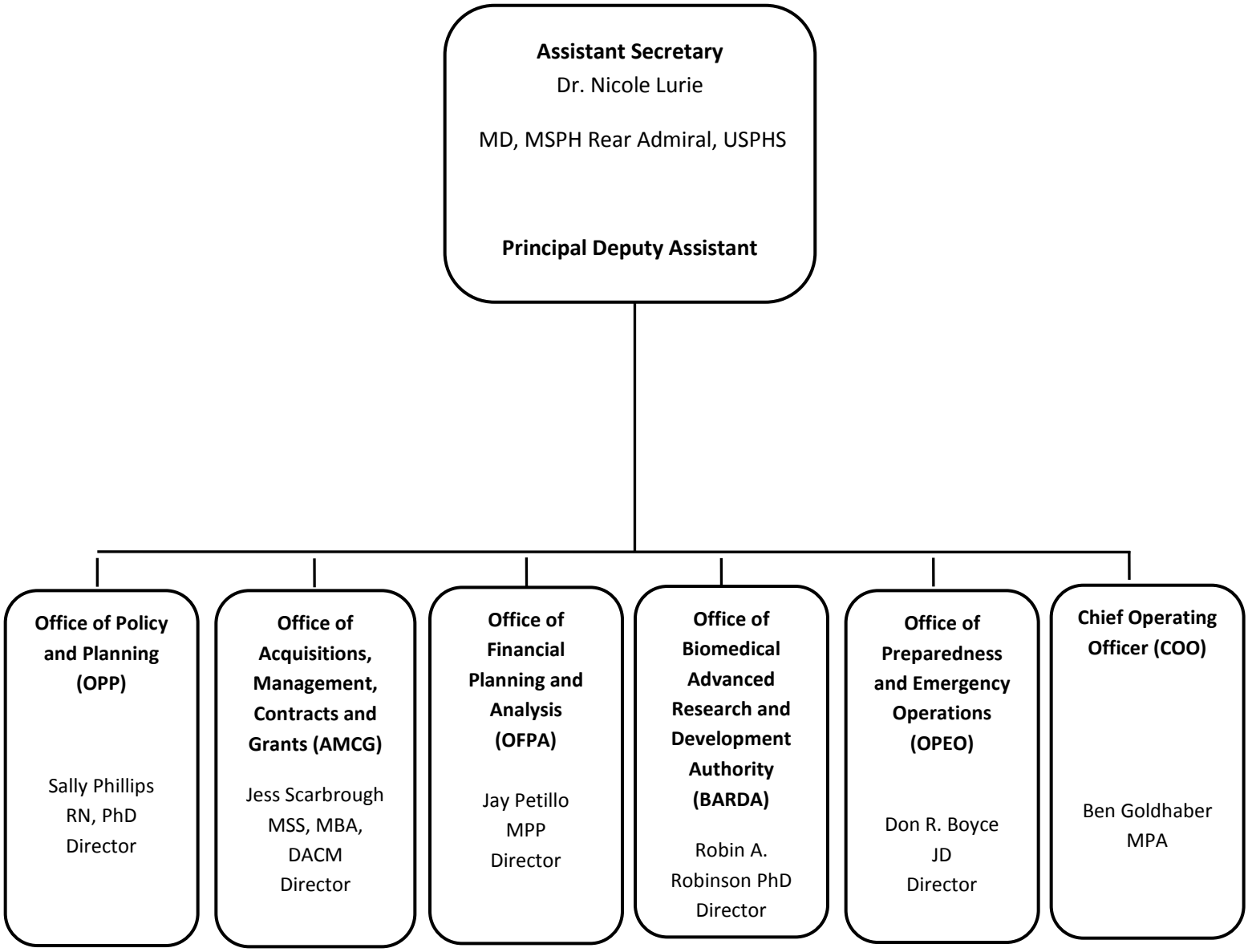
Colleen Barros
Acting Assistant Secretary for Administration

Sara Hall
HHS Chief Information Security Officer

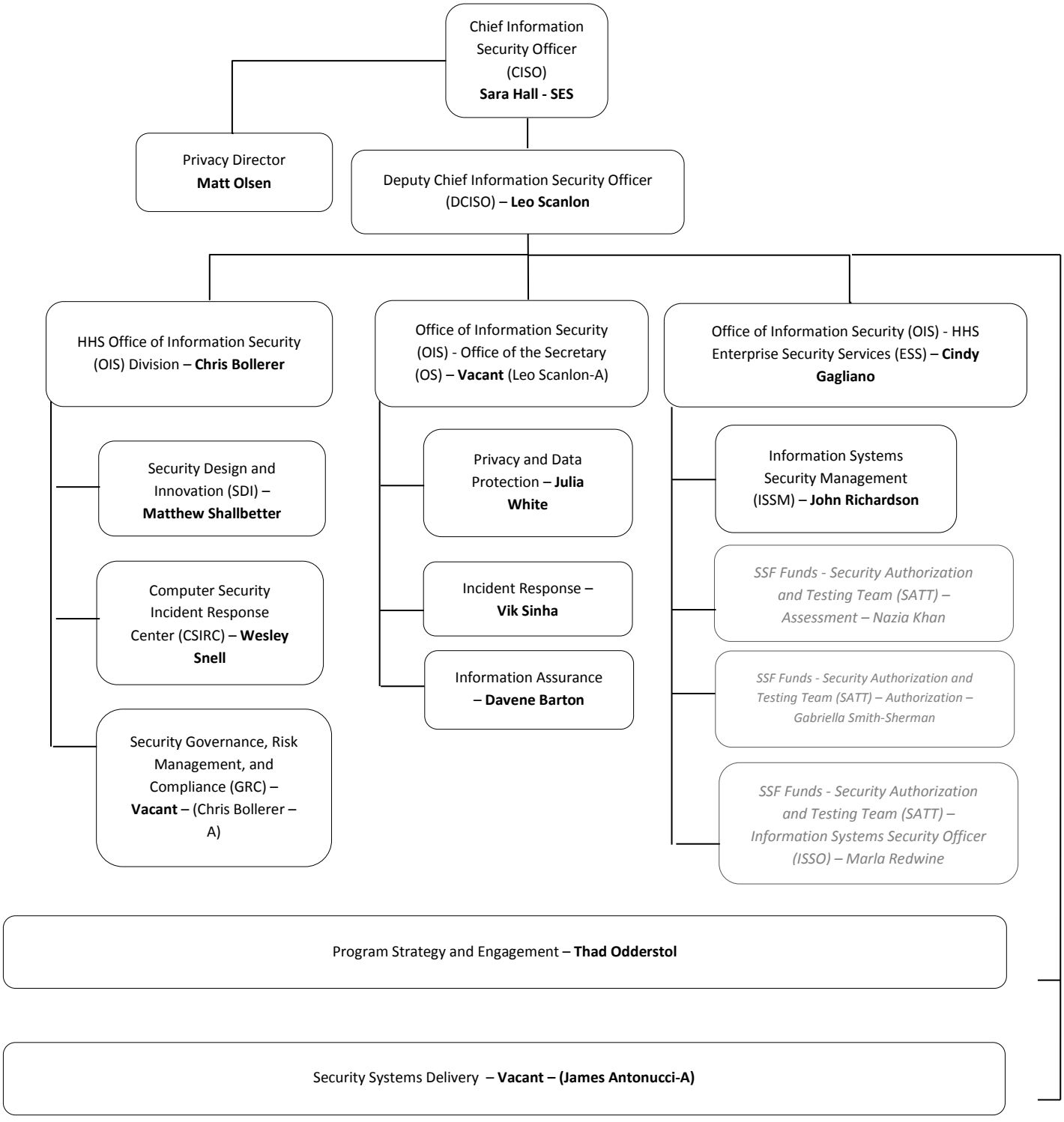
Patricia A Long
Deputy Assistant Secretary for Security, Counterintelligence
Secretary's Senior Intelligence Official

ORGANIZATIONAL CHART

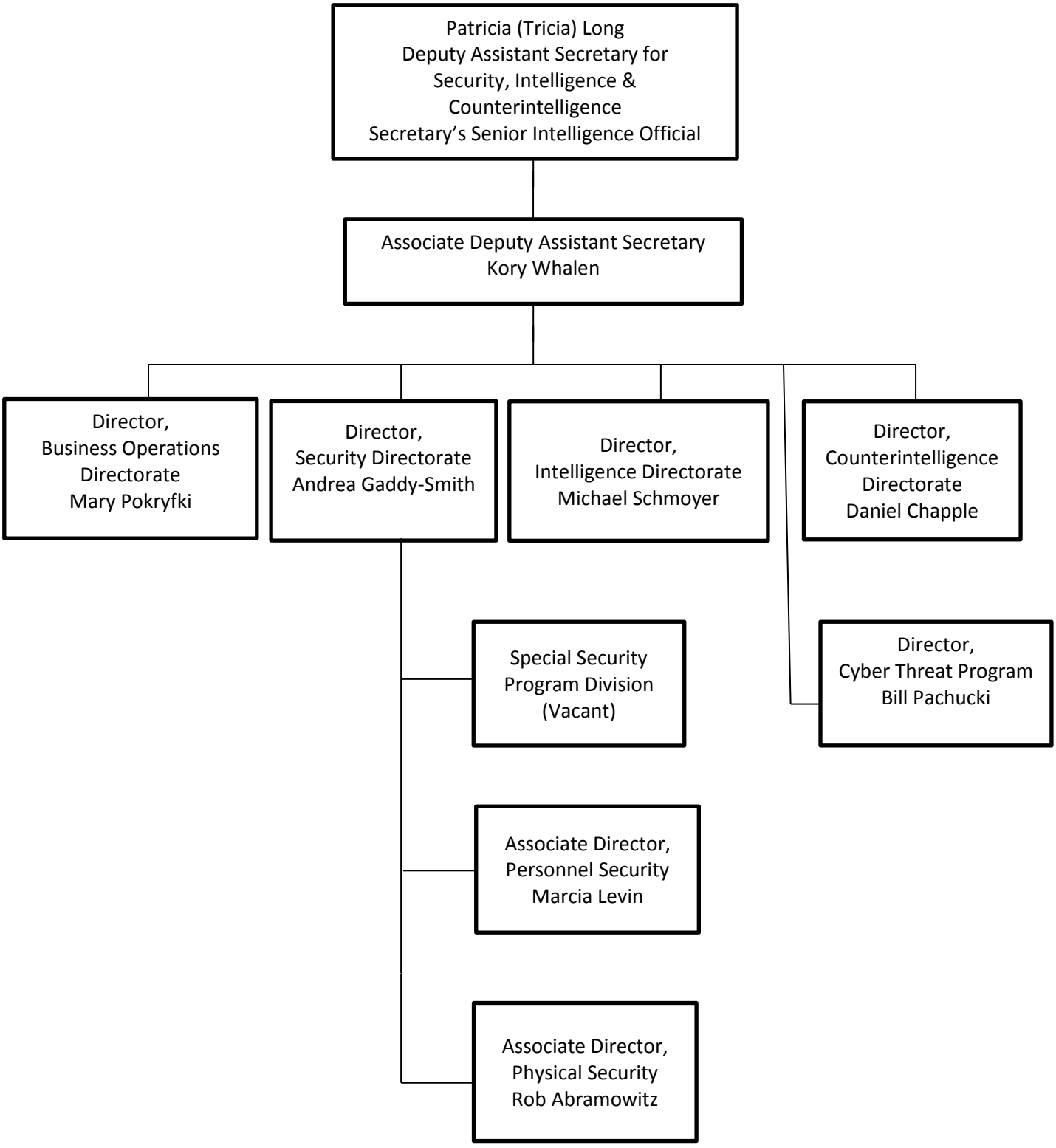
Assistant Secretary for Preparedness and Response



Cybersecurity



Office of Security and Strategic Information



INTRODUCTION AND MISSION

The Public Health and Social Services Emergency Fund supports the Department's cross-cutting efforts to improve the nation's preparedness against naturally occurring and man-made health threats. The following programs are supported by this Fund.

Assistant Secretary for Preparedness and Response:
The Office of the Assistant Secretary for Preparedness and Response (ASPR) is a leader in preparing America's communities to respond to and recover from public health and medical disasters and emergencies. These events include natural disasters, pandemic diseases, and man-made threats from chemical, biological, nuclear, and radiological (CBRN) agents. ASPR is a Staff Division in the Office of the Secretary, and the ASPR serves as the principal advisor to the Secretary on public health and medical emergency preparedness and response, including incidents covered by the National Response Framework. ASPR takes a collaborative approach to the Department's preparedness, response, and recovery responsibilities by working with Operational Divisions and Staff Divisions across the Department to coordinate preparedness and response activities. In addition, ASPR has operational responsibilities for the advanced research and development of medical countermeasures (MCMs) and for coordination of the Federal public health and medical response to such incidents.
ASPR's mission is to lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting our communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security.
ASPR's Strategic Implementation Plan is guided by six major goals:

- **Goal 1 – Promote resilient communities, fostering a nation able to withstand and recover from public health emergencies.** ASPR's Hospital Preparedness Program (HPP) supported the infrastructure necessary to enable Pennsylvania hospitals to treat over 200 patients injured during an Amtrak train derailment that was traveling from Washington DC to NYC. Health care coalition members activated a response platform to track and triage patients, facilitating proper distribution of patients and preventing any single hospital from being overburdened. This coordinated response saved lives, improved care, and increased accountability.

- **Goal 2 – Strengthen Federal public health and medical preparedness, response, and recovery leadership and capabilities.** ASPR's National Disaster Medical System supported efforts to enhance domestic readiness and preparedness for Ebola Viral Disease. NDMS Operational staff developed and supported the Centers for Disease Control and Prevention (CDC) and US Public Health Service in training response personnel.

- **Goal 3 – Promote an effective medical countermeasures enterprise.** Since its inception in 2007, ASPR's Biomedical Advanced Research and Development Authority (BARDA) has supported advanced research and development of more than 190 CBRN and pandemic influenza MCM product candidates. From 2006 through 2016, BARDA advanced development programs have developed 16 of CBRN MCM candidates, including four recently for treatment of thermal burns, into maturity for purchase under Project BioShield. BARDA also is leading the development of 12 medical countermeasures - vaccines, immunotherapeutics, antiviral drugs, and diagnostics - in response to the Ebola epidemic. Many of these Ebola MCMs are in Phase 2/3 clinical trials since early 2015.

- **Goal 4 – Strengthen ASPR's leadership role in coordinating and developing public health and medical emergency preparedness, response, and recovery policy.** ASPR's Office of Policy and Planning (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. OPP will lead global health security efforts and pandemic preparedness as part of the NHSS Implementation Plan

- **Goal 5 – Improve the preparedness and integration of health care delivery systems.** HPP continues its focus on improving the preparedness of community healthcare coalitions. Today, nearly 24,000 health care facilities and community partners participate in health care coalitions nationwide. Coalitions are multi-agency coordinating bodies that plan, organize, equip, and train together to face any public health emergency that they may face.

- **Goal 6 – Improve management of the ASPR organization and investment in its people.** ASPR is continuing to strategically invest in its internal management and operations to promote a more flexible and nimble organization that is better able to adapt to threats affecting public health. In 2017, ASPR will strengthen initiatives to promote a leadership and mentoring culture that will prepare future leaders to address evolving threats and emerging challenges.

Cybersecurity:
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. Additionally, OSSI provides cyber threat intelligence across the Department that identifies potential and actual malicious cyber incidents that allows HHS to protect, mitigate and respond to these threats as part of its information security efforts.

Office of Security and Strategic Information:
The Office of Security and Strategic Information (OSSI) provides strategic information, intelligence, counterintelligence, insider threat, cyber threat intelligence and special security (classified information) and communications security support across the Department. OSSI is also responsible for the Department's physical security, emergency management and personnel security, programs. OSSI Program objectives include increasing the Department's security and threat awareness and its ability to respond swiftly and effectively to national and homeland security threats, as well as public health emergencies. These objectives are achieved by OSSI's continued engagement internally and externally with Federal partners and others, its ability to analyze all-source intelligence/information to identify potential threats and vulnerabilities, ongoing programs that identify and assess trends and patterns across the Department's operational environment, and developing and evaluating mitigation strategies. OSSI is responsible for the safeguarding of all classified information, equipment and facilities across the Department and as HHS' Federal Intelligence Coordinating Office it manages all intelligence, counterintelligence, insider threat, and cyber threat intelligence activities for the Department – all of these programs are resourced with PHSSEF funds.

Pandemic Influenza:
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 2017 Request for the Public Health and Social Services Emergency Fund (PHSSEF) is $1,431.117 million. The Request represents a program level decrease of -$101.841 million relative to the FY 2016 enacted level. The funds requested will provide the necessary resources to:

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

The Budget provides funds for programs within the Office of the Secretary, and specifically for the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Office of the Assistant Secretary for Administration (ASA). This justification also requests funding for the Department's pandemic influenza activities.

Programmatic Increases (relative to the FY 2016 Enacted Budget):

- **National Disaster Medical System (+$5 million, $55 million total):** The increase in funding will support enhanced preparedness and response training efforts, specifically by shortening the training timeline and moving closer to the goal of completing retraining every two years. Training will be targeted to teams most in need of basic training to meet minimum standards, and to teams for which additional specialized training would fill gaps in the NDMS. Training will be available to the National Disaster Medical teams, as well as the Medical Reserve Corps and Commissioned Corps as applicable.

- **Pandemic Influenza (+$53 million, $121 million total):** The funding level reflects the maturation of the pandemic influenza program while maintaining modest progress in the key areas of universal flu vaccine and immunotherapy product advanced development.

Programmatic Decreases (relative to the FY 2016 Enacted Budget):

- **Project BioShield (-$160 million, $350 million total):** At this level, funding will support the highest priority procurements including five medical countermeasures.

BUDGET BY STRATEGIC GOAL

HHS Strategic Goals	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget
1.Transform Health Care			
1.A Make coverage more secure			
1.B Improve health care quality and patient safety			
1.C Emphasize primary & preventative care, link to prevention			
1.D Reduce growth of health care costs promoting high-value			
1.E Ensure access to quality culturally competent care			
1.F Promote the adoption of health information technology			
2. Advance Scientific Knowledge and Innovation			
2.A Accelerate scientific discovery to improve patient care			
2.B Foster innovation at HHS to create shared solutions			
2.C Invest in sciences to improve food & medical product safety			
2.D Increase understanding of what works in health & services			
3. Advance the Health, Safety and Well-Being of the American People	**1,233**	**1,532**	**1,431**
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	1,233	1,532	1,431
4. Increase Efficiency, Transparency and Accountability of HHS Programs			
4.A Ensure program integrity and responsible stewardship			
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	**1,233**	**1,252**	**1,431**

Public Health and Social Services Emergency Fund
FY 2017 All Purpose Table

(Dollars in Thousands)

Program	FY 2015	FY 2016	FY 2017	
	Final/1	Enacted	President's Budget	+/- FY 2016 Enacted
Assistant Secretary for Preparedness and Response (ASPR):				
Preparedness and Emergency Operations	24.789	24.654	24.654	--
National Special Security Events (non-add)	*5.000*	*5.000*	*5.000*	--
National Disaster Medical System	50.054	49.904	55.054	+5.150
Hospital Preparedness	254.555	254.555	254.555	--
Hospital Preparedness Program Grants and Administration (non-add)	*254.555*	*254.555*	*254.555*	--
Medical Reserve Corps	8.979	6.000	6.000	--
Biomedical Advanced Research and Development Authority	473.000	511.700	511.700	--
Ebola Anomaly Funding: Public Law 113-164 (non-add)	*58.000*	-	-	--
Advanced Research and Development (non-add)	*271.000*	*259.700*	*259.700*	--
Combating Antimicrobial Resistance (non-add)	*84.000*	*192.000*	*192.000*	--
Operations and Management (non-add)	*60.000*	*60.000*	*60.000*	--
Project BioShield	255.000	510.000	350.000	-160.000
Office of Policy and Planning	14.877	14.877	14.877	--
Operations	31.305	30.938	30.938	--
Subtotal, ASPR Budget Authority	1,112.559	1,402.628	1,247.778	-154.850
ASPR Pandemic Influenza:				
No-Year Pandemic Influenza	39.906	40.000	111.000	+71.000
Annual Pandemic Influenza	28.000	27.991	10.000	-17.991
Subtotal, Pandemic Influenza Budget Authority	67.906	67.991	121.000	+53.009
Subtotal, ASPR Program Level	**1,180.465**	**1,470.619**	**1,368.778**	-101.841
Subtotal, ASPR Budget Authority -All Resources	***1,180.465***	***1,470.619***	***1,368.778***	-101.841

Program	FY 2015	FY 2016	FY 2017	
	Final/1	Enacted	President's Budget	+/- FY 2016 Enacted
Other Office of the Secretary:				
Pandemic Influenza	4.009	4.009	4.009	--
Annual funding (non-add)	*4.009*	*4.009*	*4.009*	--
Cybersecurity	41.125	50.860	50.860	--
Office of Security and Strategic Information	7.470	7.470	7.470	--
Subtotal, Other Office of the Secretary	**52.604**	**62.339**	**62.339**	--
PHSSEF Total:				
HHS Pandemic Influenza Budget Authority	71.915	72.000	125.009	+53.009
Annual Pandemic Influenza	*32.009*	*32.000*	*14.009*	-17.991
No-Year Pandemic Influenza	*39.906*	*40.000*	*111.000*	+71.000
All Other Budget Authority	1,161.154	1,460.958	1,306.108	-154.850
Total, PHSSEF Budget Authority	**1,233.069**	**1,532.958**	**1,431.117**	**-101.841**
Total, PHSSEF Program Level	**1,233.069**	**1,532.958**	**1,431.117**	**-101.841**
FTE				
ASPR	607	612	612	--
OGA	5	5	5	--
OSSI	20	33	33	--
Cybersecurity	77	123	139	+16
Total FTE, PHSSEF	**709**	**773**	**789**	**+16**

1/ This program moved to ASPR beginning with fiscal year 2015, consistent with the Pandemic and All-Hazards Preparedness Reauthorization Act, which assigned responsibility for it to the Assistant Secretary for Preparedness and Response. The FY 2016 totals reflect the HHS reallocation to continue the operation of this program in ASPR.

FY 2017 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, [$950,958,000] *$956,108,000*, of which $511,700,000 shall remain available through September 30, [2017]*2018*, 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, 2018]*until expended*: *Provided further, That up to 10 percent of the amounts made available in this paragraph to support advanced research and development pursuant to section 319L of the PHS Act may also be used to supplement funds provided in the second paragraph for the purposes provided herein.*

For expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act), [$510,000,000] *in addition to any other amounts available in the Special Reserve Fund, $350,000,000*, to remain available until expended: *Provided further, That paragraphs (1) and (7)(C) of subsection (c) of section 319F-2 of the PHS Act, but no other provisions of such subsection, shall apply to such security countermeasures procured with funds made available under this heading: Provided further, That up to 10 percent of the amounts provided in this paragraph may also be used to supplement funds provided in the first paragraph to support advanced research and development pursuant to section 319L of the PHS Act*.

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*, [$72,000,000] *$125,009,000*; of which [$40,000,000] *$111,000,000* 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 to 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*.

FY 2017 Proposed General Provisions

SEC. 221. Section 1204(9) of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796b) is amended—(1) in subparagraph (C)(ii) by striking "or"; (2) in subparagraph (D), by striking the period and inserting ";or"; and (3) by adding the following new subparagraph: "(E) an intermittent-disaster response appointee of the National Disaster Medical System under section 2812 of the Public Health Service Act who is performing official duties of the Service, if those official duties are determined by the Secretary of Health and Human Services to be hazardous duties.".

SEC. 222. 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 (as defined pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) which are appropriated in this Act for the current fiscal year for the Department of Health and Human Services 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 $5,000,000 of the amounts made available to support emergency operations shall remain available [through September 30, 2018]*until expended*:	This language makes $5,000,000 of funds for emergency operations available until expended.
Provided further, That up to 10 percent of the amounts made available in this paragraph to support advanced research and development pursuant to section 319L of the PHS Act may also be used to supplement funds provided in the second paragraph for the purposes provided herein.	This language provides permissive authority for ASPR to transfer up to 10% of the amounts appropriated for BARDA to BioShield. Such transferred amounts may be used to supplement funding for purposes of the BioShield appropriation.
For expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act), [$510,000,000] *in addition to any other amounts available in the Special Reserve Fund, $350,000,000*, to remain available until expended:	This language appropriates $350,000,000 (in addition to amounts in the Special Reserve Fund) for procuring security countermeasures.
Provided further, That paragraphs (1) and (7)(C) of subsection (c) of section 319F-2 of the PHS Act, but no other provisions of such subsection, shall apply to such security countermeasures procured with funds made available under this heading:	The language provides for the Secretary of Health and Human Services to use funds appropriated for Project BioShield procurements that are in addition to Special Reserve Funds and clarifies that use of the additional funds does not require special approval procedures that are unique to use of the Special Reserve Fund.
Provided further, That up to 10 percent of the amounts provided in this paragraph may also be used to supplement funds provided in the first paragraph to support advanced research and development pursuant to section 319L of the PHS Act.	This language provides permissive authority for ASPR to transfer up to 10% of the amounts appropriated for BioShield to BARDA. Such transferred amounts may be used to supplement funding for purposes of the BARDA appropriation.

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*, [$72,000,000] *$125,009,000*; of which [$40,000,000] *$111,000,000* 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 to 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 transfer funding to other appropriation accounts within HHS.
SEC. 221. Section 1204(9) of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796b) is amended— *(1) in subparagraph (C)(ii) by striking "or";* *(2) in subparagraph (D), by striking the period and inserting ";or"; and* *(3) by adding the following new subparagraph:* *"(E) an intermittent-disaster response appointee of the National Disaster Medical Service under section 2812(d) of the Public Health Service Act who is performing official duties of the Service, if those official duties are determined by the Secretary of Health and Human Services to be hazardous duties.".*	The language would provide catastrophic disability and death benefits under the Public Safety Officers' Benefits Act of 1976 (PSOB) to HHS intermittent federal employees during response to a public health emergency or during an authorized training exercise. This would align benefits with the same coverage received by other federal responders (e.g., law enforcement, firefighters, ambulance crews, and emergency management officials).
SEC. 222. In the event of a public health emergency declared under section 319 of the PHS Act, the Secretary may, during the duration of the emergency, transfer discretionary funds (as defined pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) which are appropriated in this Act for the current fiscal year for the Department of Health and Human Services 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 appropriated funds for emergency response and recovery purposes. The modified notification requirements would allow transfers to be executed quickly once the emergency arose. The maximum percentage that an appropriation may be reduced would, at this level, enable the execution of a transfer late in the fiscal year when broad-based transfers are not practical. The authority could only be used during a declared public health emergency.

AMOUNTS AVAILABLE FOR OBLIGATION

(In Dollars)

Detail	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget
Annual Appropriation	518,163,000	466,258,000	453,417,000
Rescissions	-	-	-
Sequester Order	-	-	-
Transfers	-	-	-
Subtotal, Adjusted Annual Appropriation	**460,163,282**	**466,258,000**	**453,417,000**
Multi-Year Appropriation	420,000,000	516,700,000	516,700,000
Supplemental (PL 113-235)	+733,000,000	-	-
Rescissions	-	-	-
Sequester Order	-	-	-
Transfers	-16,075,000	-	-
Subtotal, Multi-Year Appropriation	**1,136,925,000**	**516,700,000**	**516,700,000**
No-Year Appropriation	294,906,000	550,000,000	461,000,000
Rescissions	-	-	-
Sequester Order	-	-	-
Transfers	-20,050,000		
Subtotal, No-Year Appropriation	**274,866,000**	**550,000,000**	**461,000,000**
Total, Adjusted Budget Authority	**1,929,954,000**	**1,532,958,000**	**1,431,117,000**
Unobligated balance, start of the year	568,400,000	414,330,035	
Unobligated balance, end of the year	414,003,035		
Total Obligations	1,951,000,000		

Summary of Changes

(Dollars in Millions)

	FY 2017 FTE	FY 2017 BA	FY 2017 +/- FY 2016 FTE	FY 2017 +/- FY 2016 BA
Increases:				
Assistant Secretary for Preparedness and Response				
National Disaster Medical System.....	115	55.054	--	+5.150
Subtotal, ASPR Increases.....	115	55.054	--	+5.150
Pandemic Influenza				
ASPR No-Year Influenza Funds.....	0	111.000	--	+71.000
Subtotal, Pandemic Influenza Increases.....	0	111.000	--	+71.000
Total Increases.....	115	166.054	--	+76.150
Decreases:				
Assistant Secretary for Preparedness and Response				
Project Bioshield.....	0	350.000	--	-160.000
Subtotal, ASPR Decreases.....	0	350.000	--	-160.000
Pandemic Influenza				
ASPR Annual Influenza Funds.....	0	27.991	--	-17.991
Subtotal, Pandemic Influenza Decreases.....	0	27.991	--	-17.991
Total Decreases.....	0	377.991	--	-177.991
Net Change in Program Level.....	**16**	**1431.117**	**--**	**-101.841**

Budget Authority by Activity

(dollars in thousands)

Activity	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget
Bioterrorism and Emergency Preparedness	1,161,154	1,460,958	1,306,108
Pandemic Influenza	71,915	72,00	125,009
Total Budget Authority	**1,233,069**	**1,532,598**	**1,431,117**

Authorizing Legislation

Details	2016 Enacted	2017 President's Budget
Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)	**1,532,598**	**1,431,117**

APPROPRIATIONS HISTORY

(Dollars in Thousands)

Details	Budget Estimates to Congress	House Allowance	Senate Allowance	Appropriations
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				
Appropriation				1,532,958
FY 2017				
Estimate	1,431,117			

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Summary of Request

Budget Summary
(Dollars in Thousands)

ASPR	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Program Level	1,112,559	1,402,628	1,247,778	-154,850
Budget Authority (non-add)	*1,180,465*	*1,470,619*	*1,368,778*	*-101,841*
Other Sources (non-add)	-	-	-	-
FTE	607	612	612	612

1/ Totals include ASPR's portion of pandemic influenza funding. In FY 2015, the Civilian Volunteer Medical Reserve Corps moved from the Office of the Assistant Secretary for Health to ASPR. That transition accounts for the differences in ASPR's FY 2015 funding and FTE levels from the original FY 2015 President's Budget.

The Fiscal Year (FY) 2017 Budget Request for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is $1,368,778. The request is a decrease of -$101,841 below the FY 2016 enacted budget level.

America has made great strides in public health emergency management since 9/11 and Hurricane Katrina. Since its establishment, HHS/ASPR has been leading that progress. ASPR and its federal, state, and local partners have built a nimble, flexible infrastructure that allows the nation to respond to all hazards. Chemical, biological, radiological, and nuclear (CBRN) threats; pandemic influenza; and emerging infectious diseases are some of the most troubling threats to Americans' health and security. With the help of ASPR's BARDA and $5.6 billion in initial Project BioShield appropriations, our nation has acquired 12 medical countermeasures (MCM) against these threats. Almost half of these MCMs have a "peacetime" public health use. In addition, when a worrisome new avian influenza strain (H7N9) emerged in China last year, ASPR and its HHS partners supported rapid research, development, and stockpiling of vaccine should the strain ever reach the United States. This rapid response demonstrates how far the nation has come.

ASPR has also 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, and research on MCMs, public health emergency management, response, and recovery throughout the nation and around the world.

HHS/ASPR's goals for FY 2017 are to sustain the mission and achieve new successes in public health emergency management. The FY 2017 Budget proposes funding for three program areas which will contribute significantly to advances in public health emergency management:

- Project BioShield: The Budget requests $350 million to procure five MCMs. At this level, BARDA will procure one new antibiotic presently in BARDA's ARD program which may be able to replace existing antibiotics in the Strategic National Stockpile that have become obsolete due to antimicrobial drug resistance. Also, BARDA will procure a new biodiagnostic device and for diagnosing anthrax. This addresses a major gap for diagnosing a large number of individuals who may have been exposed to anthrax after an incident. To complement the point-of-care diagnostic supported under BioShield in FY 2016, BARDA will procure a new high-throughput biodosimetry diagnostic device which allows verification of actual levels of exposure to ionizing radiation to better inform clinical care of patients. Funds will also support late-stage development and acquisition of products to partially address the PHEMCE requirement for Ebola.

- Combating Antimicrobial Resistant Bacteria: The Budget requests $192 million for activities that contribute to the President's CARB initiative. The request maintains the significant investment proposed in the FY 2016 President's Budget. BARDA will continue utilizing innovative public-private partnering mechanisms to form relationships with pharmaceutical and biotech companies developing antibacterial therapies. These partnerships will explore novel and improved antibiotics and non-traditional antimicrobial therapies. At this funding level, BARDA anticipates that at least one of these awards will be for a nontraditional antibacterial therapy (e.g. monoclonal antibody, microbiome modulation, etc.), in alignment with the CARB National Strategy.

- Universal Influenza Vaccines: The Budget requests $65 million to support the partial advanced development of one vaccine candidate that may afford greater effectiveness against seasonal and pandemic influenza virus strains or may serve as a "universal" influenza vaccine candidate affording cross-subtypic immunity. The development and potential licensure of more effective, or universal, influenza vaccines will address the omnipresent need for a vaccine that may provide "influenza immunity for life" and transform our pandemic influenza preparedness readiness and response capabilities. This request for universal influenza vaccine advanced development reflects the strategic transition of vaccine candidates in early development from NIAID to BARDA for advanced development with potentially more effectiveness and universal properties.

Other Increases above the FY 2016 Enacted Level:

- National Disaster Medical System (+$5,150,000 above the FY 2016 enacted budget level; $55,054,000 total): The increase in funding will support enhanced preparedness and response training efforts, specifically by shortening the training timeline and moving closer to the goal of completing retraining every two years. Training will be targeted to teams most in need of basic training to meet minimum standards, and to teams for which additional specialized training would fill gaps in the NDMS. Training will be available to the National Disaster Medical teams, as well as the Medical Reserve Corps and Commissioned Corps as applicable.

- Pandemic Influenza (+$53,009,000 above the FY 2016 enacted budget level; $121,000,000 total): The Budget requests $25 million to support the advanced development of a new kind of treatment for influenza: broadly reactive immunotherapeutics, including monoclonal antibodies and immune modulators. It also requests $21 million to develop, maintain and conduct clinical studies with the pre-pandemic influenza vaccine stockpile. This total includes the $65 million highlighted above for universal influenza vaccine development.

Decreases below the FY 2016 Enacted Budget Level:

- Project BioShield (-$160,000,000 below the FY 2016 enacted budget level; $350,000,000 total): BARDA prioritizes its planned investments to ensure that the highest priority procurements are completed within this lower level of resources. At the requested level, BARDA will be able to five procurements which reflect the highest priority countermeasures for FY 2017.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Preparedness and Emergency Operations

Budget Summary
(dollars in thousands)

ASPR Preparedness and Emergency Operations	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**24,789**	**24,654**	**24,654**	**--**
National Special Security Events/Public Health Emergencies (non-add)	*5,000*	*5,000*	*5,000*	*5,000*
FTE	86	86	86	--

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

Program Description and Accomplishments

ASPR strives to mitigate suffering due to illness and injury, preserve health, and expedite recovery through the development of resilient communities. It maintains situational awareness and monitors national and international public health and medical disasters. When ASPR responds to emergencies, the organization deploys subject matter experts, medical personnel, and supporting medical caches of lifesaving equipment to disaster areas. During times of relatively minor response activities or "peacetime," ASPR works to enhance its internal preparedness and capabilities through training, education, and coordination with federal, state, local, territorial, and tribal partners. This includes working with these partners through direct and open communication. As a result, ASPR's partners and other stakeholders continue to improve in emergency planning, by conducting exercises and collaborating within a broad health services network. This work has saved lives before, during, and after disasters.

ASPR is vital to fulfilling the U.S. Department of Health and Human Services' (HHS) responsibilities for public health emergencies. HHS is the coordinator and primary agency for Public Health and Medical Emergency Support Function 8 (ESF-8) of the National Response Framework and the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework and can serve as the Lead Federal Agency in coordinating the federal and medical response to public health emergencies. ASPR leads these functions within HHS and the federal government, and also holds the designation as the lead federal agency for these components in the Emergency Support Function Leadership Group as well as the Recovery Support Function Leadership Group. Through these functional designations, ASPR provides critical operational leadership and support for all major public health and medical incidents on behalf of the federal government.

To support its integrated programs and initiatives, ASPR's Office of Emergency Management (OEM) leads 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 – coordinates ESF-8 response and short-term recovery planning among all levels of government and in coordination with federal partners.

2. Resilience and Infrastructure Coordination – leads continuity of operations planning within ASPR and HHS and manages the critical infrastructure protection program of the healthcare and public health sector.
3. National Healthcare Preparedness Program – provides leadership, guidance, and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve resilience and surge capacity of the healthcare system.
4. Fusion – captures, analyzes, and interprets information before, during, and after an emergency to ensure decision-makers receive timely and updated situational analysis and information.
5. Operations – leads deployments and exercises, and provides informed situational awareness of all emergencies and events, both domestic and international.
6. Logistics – provides strategic and operational logistical preparedness, planning and support of public health and medical responses through the preparation, sustainment and deployment of trained staff, equipment and other response resources.
7. National Disaster Medical System – augments the nation's medical response capability.
8. Regional and International Coordination – provides critical collaboration and timely coordination before, during, and after national and global public health incidents
9. Recovery – leads the coordination of federal health and social services efforts to support communities' recovery from emergencies and disasters.
10. Tactical Programs – coordinates and provides medical and health-related subject and operational expertise.

OEM has led and supported HHS' efforts to respond to and mitigate the lasting impacts of public health and medical emergencies over the past ten 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; the Oklahoma and Missouri tornadoes in 2012 that crippled the health infrastructure of those impacted areas; the mass shooting incidents in Connecticut in 2013; the Boston Marathon bombing in 2013; the Washington state mudslides in 2014; the Yellowstone River Oil spill; Super Typhoon Dolphin; and many more events impacting the health of individuals and the public overall. In addition, OEM supports a number of planned events including: the President's annual State of the Union Address; the Peace Officer's Memorial, Independence Day celebrations in Washington, DC; the Papal Visit in 2015; the upcoming 2016 United Nations General Assembly, and Democratic and Republican National Conventions. OEM coordinates all federal assets and capabilities specific to the health and medical components of emergency management to leverage all available resources and to ensure the federal government addresses requests from state and local partners in a timely and appropriate fashion.

OEM has supported a number of other important incidents with public health and medical implications. OEM assisted the Administration for Children and Families (ACF) meet their responsibilities to provide for the health and medical needs of children and families coming to the United States through the Mexican border. ACF's previously established capabilities were not sufficient to build the needed emergency management coordination structure or to meet the record breaking number of immigrant children entering into the United States. OEM, with ACF, engaged with the Department of Homeland Security (DHS) Federal Emergency Management Agency (FEMA) to coordinate the response to this life threatening crisis. The command and control structure for this emergency included DHS Customs and Border Protection's (CBP), HHS Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Department of Defense. It was operated out of the FEMA Headquarters, as directed by the President of the United States, but included HHS as a lead agency in the response. OEM provided subject matter experts to FEMA Headquarters and provided liaison support with OEM staff to ACF. Additionally, OEM supported oversight and the actual

implementation of medical care to the children through activation of the National Disaster Medical System (NDMS) and U.S. Public Health Service (USPHS) officers. These critical assets provided health screening for an influx of unaccompanied children crossing the U.S. border. OEM and NDMS personnel augmented CBP's efforts and provided senior HHS leaders and other government officials with up-to-date information.

Most recently, OEM has been engaged in the Ebola Virus Disease outbreak, where it played a critical role in compiling and providing information to the White House on behalf of the federal government response during the emerging and sustained crisis. OEM also deployed NDMS staff to work in CDC's Operations Center as subject matter experts. Additionally, OEM coordinated and facilitated direct support to the U.S. Agency for International Development (USAID) Mission and to USPHS officers deployed to Africa. OEM's NDMS personnel developed safety guidelines for the USPHS mission in West Africa, and determined specific training requirements related to the Ebola outbreak. OEM's Division of Planning collaborated with federal partners to develop a US Government Ebola Virus Disease Plan for the national framework of federal partner response roles and responsibilities, and continues to support the regional and healthcare system review of domestic Ebola preparedness and response plans. These plans outline how the federal government, States, and healthcare systems will continue to respond to Ebola domestically. In addition, OEM produced a daily Senior Leadership Brief for leaders across the entire federal government, providing twice-daily critical information to the National Security Staff, as well as directly to the President of the United States. OEM supported hospitals and health care coalitions through the National Hospital Preparedness Program, and provided support to the nation's health care infrastructure through the Critical Infrastructure Program. OEM has moved quickly to award grants totaling nearly $200M to enhance the medical capability of the national health care footprint to prepare for epidemics such as Ebola. Lastly, OEM is actively working to identify lessons learned related to domestic preparedness and international response. Sponsored the independent HHS Ebola Lessons Learned Review and the companion internal HHS Ebola Lessons Learned Review to evaluate the HHS response to the West Africa Ebola outbreak.

To better serve stakeholders and strengthen disaster preparedness and response, OEM has developed a strategic plan that establishes organizational priorities through 2020. Using its 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.

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 supports the development of 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, multi-faceted 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 of OEM's plans provide a solid foundation that, when needed, 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.

OEM's Division of Planning began developing an All-Hazards Plan soon after the release of Presidential Policy Directive 8 in September 2011. The development of the All-Hazards Plan was in conjunction with the development of the National Response Framework and the Federal Interagency Operations Plan. The base portion of the All-Hazards Plan and functional appendices were completed in April 2014. Scenario-specific annexes to this plan, such pandemic influenza, hurricane, earthquake, anthrax, and improvised nuclear device planning, 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. These annexes 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.

To ensure that HHS plans are up to date, accurate and inclusive, OEM is conducting a plan validation exercise on each All-Hazards Plan annex. OEM uses this process to capture corrective actions and adjust annexes, as needed, to enhance planning considerations. Plan validation exercises were recently completed for Anthrax and Earthquake scenarios to the All-Hazards Plan.

OEM's Division of Planning also collaborates with federal partners in the development of interagency plans. The Planning Division coordinated the HHS input to the updates for the Strategic National Risk Assessment, National Response Framework, ESF #8 Annex, and Federal Interagency Operations Plan. The Planning Division also co-led with FEMA in the development of the Biological Incident Annex and participated in the Power Outage Incident, Food and Agriculture Incident Annex and Mass Evacuation Incident Annex creation. In addition to these plans for catastrophic incidents, the Planning Division supports a number of routine events by developing National Support Plans for consequence management.

OEM efforts also ensure, that in a disaster, business support functions continue to provide critical services that protect and save lives. In accordance with federal and presidential directives, OEM's Division of Resilience and Infrastructure Coordination ensures the continuation of HHS' essential functions during all hazards. The Department's Continuity of Operations (COOP) and Continuity of Government (COG) programs serve the Office of the Secretary (OS) and other HHS staff and operating divisions with an overall goal of building and managing unified HHS COOP and COG programs. Similarly, OEM handles the day-to-day operations and implementation of the OS Continuity Program, to include maintaining a continuity facility in a state of constant readiness. OEM also refines the required planning documents, as needed, within the scope of HHS' unified COOP and COG Programs.

In FYs 2014 and 2015, the COOP program reviewed and facilitated several continuity-focused test, training, and exercise events. In July 2014 and April 2015, OEM participated in the White House's annual continuity exercise. Working and planning with all other HHS 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 April 2015, OEM hosted a tabletop exercise for HHS senior leadership that focused on identifying vulnerabilities due to reliance upon critical infrastructure and strategies to address these vulnerabilities. The exercise also incorporated the transition of Deputy Secretaries within HHS to ensure succession of leadership. Likewise, 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 separate HHS components into an integrated HHS COOP Program. In FY 2015, this integration continued and allowed HHS to implement a comprehensive continuity program while eliminating redundancies and addressing gaps in a cost-effective manner. OEM also has the primary responsibility for HHS' implementation of Executive Order 13618. 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 this monthly communications testing, HHS finally attained 100 percent compliance in testing and associated metrics, and has maintained that score for five straight quarters. OEM 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 Public Health and Medical Emergency Response Operations

Early detection is critical to mitigating events that have the potential to significantly impact public health. OEM supports the surveillance of emerging threats and critical incidents, nationally and internationally, 24 hours a day, seven days a week. The Division of Operations manages the Secretary's Operation Center (SOC) and 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, staff leverage expertise within OEM's Division of Fusion to build reports informing decision-makers about potential events. Both the Divisions of Fusion and Operations monitor media reports, various official information systems, and other information streams to be well-informed about potential or evolving threats and developing situations.

To implement this operational mission effectively, the OEM Divisions of Operations and Fusion work together to ensure clear, timely, reliable, valid, and comprehensive information and analysis is submitted to ASPR, partner agencies, and other HHS leaders. OEM operations personnel strengthen relationships with other programs, offices, and private-sector partners by including them as soon as emergencies occur. They also support an open communication exchange to maintain situational awareness before, during, and after an incident. Ongoing information exchanges and communication help maintain a comprehensive common operating platform and decision support system for the Secretary and the ASPR.

The Division of Fusion analyzes data and integrates information from multiple internal and external sources and performs near-real time analysis using tools including the Geographic Information System (GIS)-based GeoHEALTH Platform, Fusion Analytics, HAVBED, and social media analytics. These tools allow the division to track emerging threats with public health and medical impacts as well as the status of health system resources, such as available hospital beds. This analysis provides decision-makers with the resources they need to be informed during public health emergencies. This transformation of data

into knowledgeable situation awareness leads to more-targeted and rapid responses, and helps OEM better tailor resource needs to events.

One example of this collaboration was the Boston marathon bombing. The Division of Fusion noticed a spike in on-line social network activity – alerting staff in the SOC immediately as the event was occurring. OEM collaborated with regional partners and subject matter experts to quickly rule out a radiation threat. This resulted in no time lapse whatsoever from identification to information sharing. In the aftermath of the Boston Marathon bombings in April 2013, OEM staff 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, staff analyzed medical resources in the Boston area, monitored social media, and used Geographic Information System (GIS)-based mapping resources to develop resource utilization estimates and help guide planning and response efforts. One of the results of this effort was that OEM was able to quickly deploy a needed Behavioral Health Response Unit to support the primary responders at the request of the Commonwealth of Massachusetts. This series of achievements and response to a critical need was identified as a best practice by the Commonwealth of Massachusetts in their report to Congress in the aftermath of the Bombing. A more recent example occurred when Fusion received a request to research cyber bullying related to the Umpqua Community College (UCC) shooting. Using social media analytic tools, Fusion combed through the data and within 24 hours provided a report categorizing and summarizing the main themes of those expressing "blame" via social media. The information was shared with the Roseburg Behavioral Health leadership; the findings provided actionable information and supported the behavioral health leadership in refocusing their attention on bigger picture behavioral health priorities.

In 2014, the Division of Fusion 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. Most recently, the Fusion GIS team developed and launched the GIS-based tool GeoHEALTH Platform in 2015. The GeoHEALTH Platform is an enhanced application of ASPR's previous GIS tool MedMap, and it incorporates information from numerous sources both internal and external to HHS. GeoHEALTH is able to display many different datasets and information feeds (including local data feeds) in a dynamic environment to provide all involved with a more complete aggregation of data, allowing for coordinated decision making and response. The GIS team has integrated many open datasets and made them available through GeoHEALTH for all users. A key example of this was the integration of electricity-dependent population data. Fusion was able to aggregate and remove sensitive information from electricity-dependent population datasets and load them into the GeoHEALTH Platform for use ahead of and during disaster events. Viewing this information geospatially allows responders to rapidly identify, and assist, these populations in an emergency. The interactive mapping capabilities within GeoHEALTH allow for this data to be viewed at the state, county and zip code level and can be used to mitigate the lasting impacts of disasters.

When an incident that requires 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 prior to and when they arise. OEM's assets are nimble, flexible, and adaptable to ensure that the support provided meets the requirement. This flexibility enables OEM to support responses to both catastrophic and small-scale public health and medical incidents at the request of state and local partners.

To support a response, the Operations Division oversees and manages the Incident Response Coordination Team (IRCT), made up of members of the NDMS, the USPHS and ASPR Regional Emergency Coordinators (RECs). The IRCT is a rapidly deployable, competent and agile command and control element within the area of operations that is essential to the success of a response and/or recovery operation. OEM maintains two IRCT's that are all scalable in size and function to ensure it meets the needs of a disaster, incident, emergency or event.

OEM also coordinates and provides medical and health-related Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) subject and operational expertise across the spectrum of ASPR preparedness and response. CBRNE subject matter experts recognize, anticipate, and evaluate gaps in the Nation's medical and public health response systems. In addition, through cooperative professional interaction with both internal and external entities, personnel develop 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 a CBRNE incident, personnel provide leadership, advice, and guidance regarding strategic, technical, and operational issues; medical and public health impacts; and interventions.

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. Such events, referred to as National Special Security Events (NSSE), include the following: the President's annual State of the Union Address; Independence Day celebrations in Washington, DC; North Atlantic Treaty Organization summits; the United Nations General Assembly; quadrennial national political conventions and quadrennial Presidential Inaugurations.

HHS also uses NSSE funding to support other events that are not anticipated but require rapid responses and that are not authorized under the *Stafford Act* for reimbursement from FEMA, like evolving disasters that have a public health concern. For example, ASPR has used NSSE funding to rapidly deploy mental health support to Connecticut after the Sandy Hook Elementary School shootings, mass shootings in Roseburg, Oregon, and 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. Resources from the PHSSEF were provided from NSSE funding to CDC in 2014 in advance of passage of an emergency appropriation 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 training, exercise and corrective action efforts ensures each program and Division in OEM is fully prepared to meet the needs of the Nation and that they are able to seamlessly and effortlessly work together to prepare for, respond to and recover from a man-made or natural disaster. Specifically, to enhance operations and improve future responses to public health and medical incidents, OEM focuses on the well-established "plan, train, exercise/respond, and evaluate" model. Staff promotes and validates preparedness, response and recovery capabilities within HHS. Staff conducts training, validates preparedness levels and response capabilities through exercises, and uses the corrective actions program to tie training and exercises together.

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 and conducts an After-action review and subsequent report. OEM also conducts staff-level engagements and meetings to identify root causes and opportunities to improve.

Significant lessons learned and corrective actions activities in FY 2015 include:

- Conducted IRCT training sessions to ensure response staff are knowledgeable to respond effectively within the HHS framework when deployed with an Incident Response Coordination Team.
- Identified and implemented corrective actions for improvements to our support and execution to National Special Security Events, Hurricane response and a wide variety of exercises.
- Sponsored the independent HHS Ebola Lessons Learned Review and the companion internal HHS Ebola Lessons Learned Review to evaluate the HHS response to the West Africa Ebola outbreak.
- Utilizing the Noble Lifesaver Patient Movement Project, ASPR developed and implemented on-line training across the patient movement continuum and conducted three patient movement workshops, enhancing understanding and preparedness for federal, state, and local partners in the patient movement enterprise.
- Led the design, planning and coordination for HHS participation in 21 major exercises including:
    - The "SOCAL Rocks" exercise with the State of California, which focused on the public health and medical issues surrounding an southern California earthquake;
    - Re-engineered Noble Lifesaver Patient Movement Project and conducted three patient movement workshops across the Nation, enhancing understanding and preparedness in the patient movement enterprise
    - Developed and enacted the Nimble Challenge no-notice exercise project, designed to focus on specific processes within the emergency management spectrum. A significant portion of the little or no notice drills targeted rapid senior leader decision making and implementation of those decisions.
    - Support to National Security Council Staff (NSCS) Senior Level Exercises designed to strengthen interagency coordination during complex incidents by addressing policy issues, validating incident response mechanisms, and testing the Federal Government's preparedness.
    - Multiple International exercise support to the Global Health Security Initiative, the NAPAPI, and Global Health Security Agenda projects
    - The HHS/ASPR/OEM Plans validation exercise series designed to examine and crosswalk various annexes to the HHS All-Hazards Plan to validate the planning effort and to identify and capture any unresolved policy issues. In their role as the HHS lead for exercises, the Exercise Team supported the design, development and conduct of three international exercises involving 8 different countries,
    - An ASPR-wide exercise in support of streamlining policy, administrative and finance processes during an emergency response and;
    - A policy based exercise to help validate the Prescription Medication Preparedness Initiative.

Funding History

Fiscal Year	*Amount*
FY 2013	$27,984,000
FY 2014[1]	$28,029,000
FY 2015	$24,789,000
FY 2016 Enacted	$24,654,000
FY 2017 PB	$24,654,000

Budget Request

The FY 2017 Budget includes $24,654,000 in budget authority for Preparedness and Emergency Operations activities. This request is consistent with the FY 2016 enacted level. The request supports OEM's ability to immediately respond to a public health emergency or medical incident when called on to do so.

The FY 2017 request includes $5,000,000 in no-year funding to prepare for and respond to NSSEs, public health emergencies, and other events that are not eligible for assistance under the *Stafford Act*. As noted above, NSSE funding supports the activation of personnel and response teams for planned events such as the President's annual State of the Union address and the Presidential inauguration. NSSE funding also supports less frequent events, such as the immediate response to the Ebola outbreak and the September 2015 Papal visit to the United States.

[1] 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)

National Disaster Medical System	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**50,054**	**49,904**	**55,054**	**+5,150**
FTE	115	115	115	--

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

Program Description and Accomplishments

When disaster strikes, ASPR is called upon to support communities with critical medical services to protect public health and help communities recover faster. The National Disaster Medical System (NDMS) is vital to these efforts. NDMS' mission is to assist communities with medical services after a disaster or public health emergency and to support the Department of Defense in cases of a surge in military casualties that could overwhelm the military medical system. Since its establishment, NDMS has responded to over 300 incidents to support communities both domestically and internationally. NDMS provides assistance to communities impacted by public health and medical emergencies ranging from severe weather incidents to terrorist acts. For each incident, NDMS deploys trained medical teams with hundreds of thousands of previous patient encounters. NDMS is a unique asset positioned and authorized to deliver essential medical services when requested by a community or partner federal agency.

Operating under the ASPR Office of Emergency Management (OEM), NDMS augments the Nation's medical response capability during actual or potential disasters and public health emergencies with a workforce of more than 6,000 intermittent federal employees who comprise more than 80 teams. NDMS teams include clinical providers and 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 support; definitive care; and behavioral health support.

NDMS teams include:

- ***Disaster Medical Assistance Teams (DMATs):*** Provides stabilizing emergency medical care to communities affected by disaster. DMATs can deploy on the same day they are requested, and are designed to function in austere conditions with little resupply needed for the first 72 hours of operations. These teams include physicians, advanced practice clinicians, nurses, paramedics and non-clinical support staffing and are configured to deploy units of 24, 36, or 48 personnel. During Superstorm Sandy ASPR deployed over 20 DMATs on a rotational basis comprising of 2000+ employees.

- ***International Medical Surgical Teams (IMSURTs*)**: Provides 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. In response to the Haiti Earthquake IMSURTs deployed and performed hundreds of surgical procedures.

- ***Disaster Mortuary Operational Assistance Teams (DMORTs)*:** The teams are structured regionally and can support a community that has experienced a mass-fatality event upon request. 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. Most recently, DMORTs were deployed during the Joplin Tornado. DMORTs also support the National Transportation Safety Board with major transportation incidents that have mass fatalities.

- ***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. Recently, NVRTs have had a critical role in supporting working animals for major national special security events, and disasters.

- **Federal Coordinating Centers (FCCs):** Facilitates patient care through geographically dispersed Patient Reception Areas by transporting medical evacuees from disaster areas to hospitals across the country. There are 1800 hospitals that are part of NDMS network of definitive care facilities.

To support consistent training across NDMS, in 2013, NDMS entered into an agreement with FEMA's Center for Domestic Preparedness (CDP) in Anniston, Alabama. This innovative and cost effective partnership supports fundamental training for NDMS response personnel. Currently, 15 percent of NDMS personnel complete fundamental training annually. As structured, teams are not sent to the training at the same time; rather, an identified group of NDMS personnel from various teams are trained annually. Sending individuals from various teams ensures that every NDMS team has at least one team member who has recently completed fundamentals training and is most familiar with the current equipment supporting response. In addition, when multiple teams are sent to respond to a public health or medical emergency, the cross-training occurring at the fundamental trainings supports better coordination and communication in the field. While participating in the fundamentals training, NDMS personnel train and practice using the equipment that will be available when deployed to support a public health or medical emergency. The training also tests NDMS personnel' skills through comprehensive exercises to test a team's ability to treat people quickly and effectively in unfamiliar environments. NDMS will continue to utilize the training facility and will integrate other partners, including the Medical Reserve Corps, state and local officials, to strengthen response capabilities.

NDMS's recent initiatives and accomplishments include the following:

- Throughout 2014-2015, NDMS has supported efforts to enhance domestic readiness and preparedness for Ebola Viral Disease. NDMS Operational Medicine staff, which includes certified safety professionals, developed and supported the Centers for Disease Control and Prevention (CDC) and US Public Health Service in training their response personnel.

- Throughout 2015, NDMS teams have provided public health and medical support for the following: the State of the Union Address; the United Nations General Assembly; the Peace Officer's Memorial; the Concert for Valor; the Fourth of July Celebration; the Papal Visit to Washington, Philadelphia, and New York; and Hurricane Dolphin in Guam.

- NDMS is completing its pilot year of a "team typing" initiative to enhance its response capabilities by ensuring its assets are flexible and scalable. This process improves ASPR's ability to plan and use teams in an effective and consistent manner, which complements the existing medical infrastructure in the impacted community.

- NVRT teams have consolidated to a one-team configuration to provide a broader approach to the regional concept. This approach has also shown its benefits as allowing for cost effectiveness in its readiness posture.

The Office of Emergency Management's Division of Logistics manages and provides the critical logistical supporting components for NDMS and other HHS public health and medical teams to respond. The Logistics Division ensures that the right equipment is where it is needed to provide an effective response. It is a complex, coordinated effort to rapidly deploy, support the setup, and sustain public health and medical teams with the necessary supplies and equipment in austere environments. Success requires support from The Office of Emergency Management's regional warehouse that can get resources ready and deployed at a moment's notice. The Division of Logistics manages and maintains over $70 million in response material and supplies including: vehicle fleets; medical, lab, pharmacy, and mortuary caches; communication kits; and shelter systems. Subject matter experts provide critical services to support medical cache composition, structure, staging, and other logistical components for public health and medical teams in the field.

The following are examples of some recent Division of Logistics initiatives and accomplishments:

- In support of the Unaccompanied Children and Families Surge Crisis, deployed and rehabilitated tons of medical material and supplies and provided on-the-ground subject matter expertise over a three month period. These efforts enabled clinicians to have critical medical supplies and vaccination materials to rapidly treat several thousand children.

- Led and coordinated the development of the U.S. Inter-Agency Logistics Plan with the Department of Defense (DoD) and USAID to facilitate the successful deployment of the USPHS to Liberia to establish the U.S. Monrovia Medical Unit; and provided critical supplies and materials in support of USPHS team's mobilization, force protection, and redeployment operations.

- Provided subject matter expertise and logistics support to the DoD and CDC in acquiring critical personal protective equipment for screening of Ebola at airports, emergency responders, and research personnel.

- Provided logistics subject matter expertise and technical assistance to several state governments' catastrophic event planning efforts and preparedness exercises. This effort included technical site visits to facilitate the integration of Federal Medical Station assets into local response operations and to enhance national and local preparedness.

- Deployed hundreds of tons of medical material to support both NSSEs as well as natural disasters in 2015 including: the 2015 State of the Union Address, the United Nations General Assembly; the Peace Officer's Memorial; the Concert for Valor; the Fourth of July Celebration; the Papal Visit to Washington, Philadelphia, and New York; and Hurricane Dolphin in Guam

- Deployed several hundreds of tons of medical and logistics material in support of eleven (11) NDMS training events at FEMA's Center for Domestic Preparedness (CDP) in Anniston, Alabama. This enabled NDMS to participate in realistic training with the gear and equipment from HHS response caches which results in increased responder proficiency and efficiency.

- For the Super Typhoon Dolphin Storm, within 6-hours of notification from FEMA to deploy, Logistics was able to quickly assemble, load, convoy, and deploy, via commercial air, mobile medical assets, communications gear, and life sustaining material to Guam to meet with NDMS/DMAT members prior to the storm's impact to the island and territories.

- Deployed IT and Telecommunications equipment in support of the US Public Health Service deployment to provide behavioral health mission support to the Roseburg, OR School Shooting.

The public health and medical response structure continues to innovate to ensure that the right assets are being deployed to the right mission in a fiscally responsible and safe manner. OEM is constantly exploring potential changes to facilitate the deployment of more highly-functional modules that are targeted to deliver a specific type of public health and medical capability. Post Superstorm Sandy, OEM reconfigured caches to smaller components that allow quicker deployment at less cost. Additionally, OEM engaged the CDC Strategic National Stockpile to reconfigure the Federal Medical Station (FMS) assets to move from large, bulky packages to smaller packages that may allow greater use and implementation at lower costs and shorter timeframes.

OEM's Division of Regional and International Coordination also play an important role for NDMS and in all aspects of the preparedness cycle. Regional Emergency Coordinators (REC), led by a Regional Administrator (RA), are located around the country to 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.

Additionally, when the RAs engage in a response mission, they serve as the senior federal public health and medical preparedness and response official in the impacted region. An RA performs essential functions for HHS in several major areas: prevention, mitigation, response, recovery, and agency-wide coordination. These functions directly and indirectly support not only the work of HHS but other federal agencies as well.

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 a dedicated staff, OEM continues to provide surge support when requested, even though there are challenges in years when multiple response events occur.

Funding History

Fiscal Year	*Amount*
FY 2013	$49,708,000
FY 2014	$50,054,000
FY 2015	$50,054,000
FY 2016 Enacted	$49,904,000
FY 2017 PB	$55,054,000

Budget Request

The FY 2017 budget request is $55,054,000 in budget authority, which is +$5,150,000 above the FY 2016 enacted level. The request supports continued NDMS operations and regional emergency coordination to prepare and respond to public health emergencies. Continued funding will be used for medical response assets, including NDMS teams, supplies, and equipment. Lastly, the request strengthens federal response capabilities by investing in additional team trainings and incorporating new stakeholders into existing trainings

At the FY 2017 level, NDMS will increase trainings to ensure 20 percent of existing personnel are trained annually. NDMS's current funding supports a training cycle goal to rotate all 77 teams through the basic training and advanced training components every six years or approximately 15 percent annually. Since FY 2013, when ASPR began its agreement with FEMA's Center for Domestic Preparedness to train NDMS teams at their training center in Anniston, Alabama, 15 percent of NDMS teams have been trained. The FY 2017 funding level is projected to support 20 percent training to NDMS personnel annually. Through management efficiencies, NDMS has been able to realize savings that have been reallocated to finance training to its current level. Most notably, these savings have come from reconfigured logistics packages that are less costly to deploy and restock, while also more nimble and flexible to response needs, and rightsizing the NDMS roster through the removal of employees that were not fully engaged in support of the program.

The request will make significant progress toward establishing a cycle of all staffed trained every three years. Consistent training over a three year cycle will strengthen operations in the field and support a fully trained and knowledgeable NDMS workforce able to augment medical care and support when needed.

Fund also will be used for a pilot to integrate Medical Reserve Corps (MRC) volunteers into NDMS trainings. MRC transferred to ASPR in 2013 under authorities of the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA). Since then ASPR has conducted an assessment to better understand MRC's effectiveness in supporting preparedness, response, and recovery efforts in local communities. Currently, there are almost 970 MRC units across the nation, with about 70% situated within local health departments. ASPR will target members from approximately 45 MRC units (about 5 percent of the MRC network), to integrate into existing trainings (such as the NDMS trainings in Anniston, Alabama). NDMS teams have provided shelter support and other non-clinical/medical services during Federal emergency responses. MRC units have proven to be effective and reliable at performing such support at the local level, and can thereby free NDMS from this responsibility. This will allow NDMS to focus their efforts on the acute care needs of a community.

ASPR National Disaster Medical System - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
1.1 Percent of new NDMS intermittent staff who complete psychological first aid training	FY 2015: 100% new staff trained Target: 100% new staff trained (Target Met)	100% new staff trained	100% new staff trained	Maintain
10 Percent of new NDMS intermittent staff who complete basic and advanced training for deployments.	FY 2016: Result Expected Sep 30, 2016 Target: Execute CDP training for 15% of staff with existing resources (In Progress)	Execute CDP training for 15% of staff with existing resources	Train 20% of all NDMS personnel annually	+5%

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

Budget Summary
(dollars in thousands)

Civilian Volunteer Medical Reserve Corps	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**8,979**	**6,000**	**6,000**	**--**
FTE	6	6	6	6

1/The Medical Reserve Corps (MRC) moved to ASPR from the Office of the Assistant Secretary for Health in FY 2015.

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

Program Description and Accomplishments

Connected communities are more resilient in the face of disasters and emergencies, and volunteers play a critical role in helping communities recover faster and stronger than they were before. The civilian volunteer Medical Reserve Corps (MRC) is a national network of over 200,000 volunteers, organized in almost 1,000 community-based groups that is committed to strengthening public health; reducing vulnerabilities; improving local preparedness, response and recovery capabilities; and building community resilience. MRC units support numerous community public health missions, participate in local and regional exercises across the nation, and respond during emergencies when called upon by state and local response agencies. Due to the community-based nature of the MRC, each unit is unique in what it can provide before, during, and after emergencies and their support to public health missions. MRC units' capabilities vary according to community needs, geographical region, and local investments. MRC is integrated within ASPR's preparedness, response and recovery portfolio and managed by the Office of Emergency Preparedness.

In March 2002, the Office of the Surgeon General within the Office of the Assistant Secretary for Health (OASH) established the 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, the MRC Program formally moved from the OASH to ASPR. During the transition, ASPR supported assessments of local, state, regional and national stakeholders' perceptions and expectations of the MRC.

In 2015, an assessment conducted by the National Association of County and City Health Officials found that stakeholders view MRC units as being effective, important, and reliable; providing valuable services; and enhancing public health, preparedness and emergency response capabilities. Furthermore, an independent review of the MRC response to Superstorm Sandy, performed by HHS's Office of the Inspector General, found similar positive conclusions.

While the MRC has been very successful, respondents also noted some common challenges to address:

1. Resources: Accessing funding is the most significant barrier to effective MRC Units.
2. Unit Capability/Capacity: Increasing awareness of MRC unit capabilities is a critical need.

3. Standardization: Improving standardization, especially regarding emergency response operational areas.
4. Regional Coordination: Supporting local and state MRC leaders through technical assistance and coordination, and strengthening ASPR/OEM's regional footprint through collaboration with other HHS regional partners.

ASPR has utilized the assessment results to strengthen the MRC network, connect MRC units with existing resources, and better target state and local needs before, during, and after public health and medical emergencies. Throughout FY 2016, ASPR will facilitate the implementation and maintenance of local MRC units, and improve their ability to meet local missions. These efforts will pivot the MRC network to be better positioned to support the objectives and priorities of the National Health Security Strategy, including improving community resilience, assisting with medical countermeasure distribution, enhancing situational awareness, and supporting the integration and effectiveness of the public health, healthcare, and emergency management systems. In addition, with the realignment of the MRC into ASPR, OEM is supporting efforts to shift the program toward providing comprehensive public health/emergency medical response capabilities in communities that are fully integrated with local and state medical response as well as with federal assets. Such integrated support better utilizes resources and evolves relationships for a multi-government sector response.

Recent MRC accomplishments include:

- Indiana declared a public health emergency after more than 175 HIV+ cases due to intravenous opioid drug use were reported and confirmed, and many MRC volunteers from twelve local units were activated to assist with response and recovery efforts. Their services included health outreach and education, needle exchange, HIV and Hepatitis testing, counseling, enrollment in Indiana health plans, and vaccinations for Hepatitis A, B and Tetanus.

- Volunteers from the Curry, Linn, Marion, Multnomah, and Washington County Medical Reserve Corps units in Oregon were activated by the state to support behavioral health counseling services in Roseburg, OR as that community recovers from the mass shooting at the Umpqua Community College. These volunteers (from across the state) agreed to travel to Roseburg 1-2 times per week for 2-3 months.

- The Rhode Island Medical Reserve Corps (MRC) was activated after meningitis B cases surfaced at Providence College. Ninety-five MRC volunteers donated over 600 hours of service and vaccinated 3,060 students to prevent a potential public health crisis.

- Hundreds of volunteers from New York City, New Jersey, Washington, D.C., and from all over Pennsylvania responded to provide aid in medical tents for the many thousands of visitors during the 2015 Papal Visits in NYC, Washington, D.C. and Philadelphia.

- Virginia Beach and Western Tidewater Virginia MRC volunteers provided flu shots, blood pressure, cholesterol and glucose checks, smoking cessation, BMI screening, and hygiene kits to 307 homeless people during the Norfolk Project Homeless Connect.

- More than 150 MRC units reported preparedness, response and recovery activities related to Hurricane Sandy. Many units performed sheltering functions such as staffing and/or assisting in the setup of general community, functional or special needs shelters and working at shelters in support of the American Red Cross (ARC). Units also indicated that they provided the community with health education, emergency communications support, and surge staffing to

local hospitals, emergency management agencies, and public health departments. Volunteers in these units provided a total of 36,016 hours in community service, and units within the affected regions reported that they had more volunteers who were ready and willing to assist if needed.

- The MRC program is supporting the planning stages of the public roll-out of an "Active Bystander" training curriculum in conjunction with an upcoming White House-led public health campaign called "Stop the Bleed." Other federal partners include the Department of Homeland Security, Federal Emergency Management Agency, the U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention, the White House National Security Council, and the HHS office of the Assistant Secretary for Preparedness and Response, Office of Policy and Planning, Division of Health System Policy (DHSP). It is anticipated that with training, more members of the public will be ready and able to assist should they be present at mass casualty events or other circumstances in which there are serious injuries or potential loss of life.

- The New York City (NYC) MRC assisted the NYC Department of Health with the response to the recent Legionnaire's Disease outbreak. Clinical MRC volunteers (primarily doctors and nurses): provided medical assessments of residents at a supportive housing building; partnered with DOH staff to visit almost 100 community organizations and sites to provide information/answer questions about legionella; visited 13 senior centers to provide information/answer questions about legionella and to conduct clinical assessments for the senior center attendees; and participated in a health fair in the south Bronx to offer clinical assessments and information.

Funding History

Fiscal Year	*Amount*
FY 2013	$10,672,000
FY 2014[2]	$8,979,000
FY 2015	$8,979,000
FY 2016 Enacted	$6,000,000
FY 2017 PB	$6,000,000

Budget Request

The FY 2017 Budget includes $6,000,000 in budget authority for the civilian volunteer Medical Reserve Corps, which is consistent with the FY 2016 enacted level. This funding will primarily support the following efforts:

- Provide regional coordination and technical assistance to MRC unit leaders to guide the development of the units.
- Identify the key missions/functional areas most often supported by MRC units (i.e. shelter support, mass vaccination, medical countermeasure dispensing, etc.) and developing a system to track, monitor and assess units' ability to support the mission and the extent to which they can assist.
- Provide funding to MRC units to demonstrate their capabilities through a "Challenge Award" program where selected units will need to complete and evaluate a project in their

[2] Reflects the reduction of -$1,693,000 for the FY 2014 Secretary's permissive transfer.

community/region/state that demonstrates success in building resilience, reducing vulnerability, and/or enhancing emergency preparedness, response and recovery capability, and;

- Identify a standardized set of "Mission Ready Packages" that could be used by local and state officials to characterize and type the MRC resources available.

These efforts will promote a new level of consistency throughout the MRC network. ASPR will leverage its existing programs and infrastructure, along with these changes, to yield efficiencies, savings, and a more effective MRC program.

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

Budget Summary
(dollars in thousands)

Hospital Preparedness Program	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**254,555**	**254,555**	**254,555**	**--**
Cooperative Agreements/1 (non-add)	*228,500*	*228,500*	*228,500*	
Program costs/2 (non-add)	*26,055*	*26,055*	*26,055*	
FTE	44	49	49	
These amounts do not include funding for Ebola preparedness and response from the emergency appropriation to the Public Health and Social Services Emergency Fund.				
1/ HPP cooperative agreement awardees are the public health departments in all 50 states, Washington, DC, Chicago, Los Angeles County, New York City, and all U.S. territories and freely-associated states				

Authorizing Legislation:
Authorization ..... Public Health Service Act, as amended by PAHPA and PAHPRA
Allocation Method .....Formula grant/cooperative agreement; direct Federal/intramural; contracts

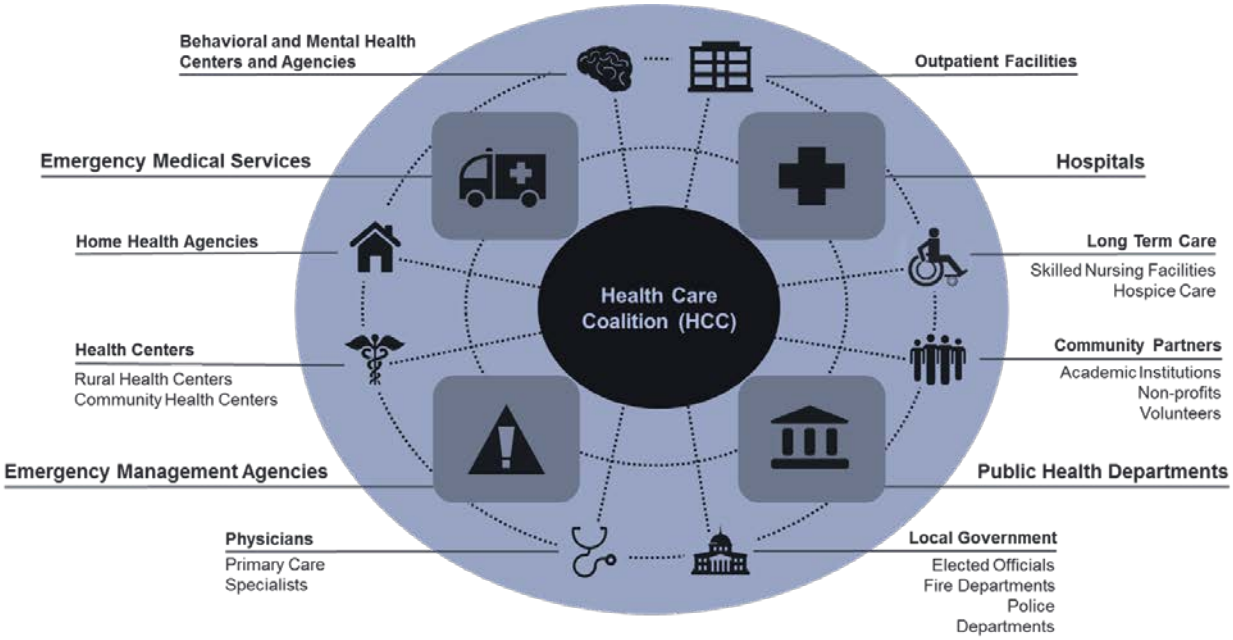
Program Description and Accomplishments

ASPR has a proven track record of responding to requests for assistance from state and local partners. However, more prepared and resilient communities can reduce the need for deploying federal assets, shorten the response and recovery phase, and ultimately reduce the overall human and monetary costs of disasters. The Hospital Preparedness Program (HPP) is critical to the local, state and regional health care preparedness efforts. HPP enables the health care system to save lives during emergencies that exceed the day-to-day capacity of the health and emergency response systems. As a primary source of federal funding for health care system preparedness and response, HPP promotes a sustained national focus to improve patient outcomes, minimize the need for supplemental state and federal resources during emergencies, and enable rapid recovery. The HPP program is managed by the Office of Emergency Management (OEM).

Regional Healthcare Coalitions are Changing the Landscape of Local Preparedness: Saving Lives in Emergencies and Improving Day-to-Day Care
Since 2012, HPP has encouraged its awardees to invest in forming and developing Health Care Coalitions (HCCs). A HCC is a group of health care and public health organizations that work together to leverage resources and address challenges in health care delivery brought on by public health and medical incidents. During emergencies, these regional efforts help each patient receive the right care at the right place at the right time, ultimately saving lives. To do this, HCCs incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. HCCs collaborate to ensure that each member has the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to an emergency. HCCs include a variety of health care and public health organizations: hospitals, emergency medical services, long-term care facilities, dialysis centers, behavioral health, public health departments, and emergency management. Each stakeholder facility/agency must optimize medical surge capacity and resilience planning in order to maximize the potential of the local health care system as a whole to

accommodate disasters. Thus, the HPP cooperative agreement must provide for accountability at both facility/agency level as well as system level performance.

Figure 1. Health Care Coalition Network.



As a multi-agency coordinating body, an HCC assists with mitigation, preparedness, response, and recovery activities related to disaster operations in communities across the nation. HCCs are able to share information on the emerging incident to improve situational awareness and share resources – including healthcare professionals and specialized equipment – when one facility is overwhelmed to provide timely and required levels of care to mitigate the impact of the incident.

HCCs have supported communities' health care systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other health care partners—throughout the nation during past response operations. Successes include responses to: the Amtrak train derailment in 2015; preparations for the papal visit to several U.S. jurisdictions in 2015; the Louisville, Mississippi tornado in April 2014 that wiped out the Winston Medical Center; the Oso, Washington mudslides in March 2014; and many other public health and medical events, including responses to severe weather events and infectious disease outbreaks, that have impacted communities across the nation.

Health care coalitions and their individual health care system members reported in 2014 that they depend on HPP funding for 86 percent of their preparedness funds. These funds allow coalitions and their members to engage in community-level planning, exercises, and trainings for the health care system as well as assistance for and assessment of medical surge planning at the facility and agency level. HPP funding also covers HCC operational costs, such as providing staff to facilitate regional disaster planning efforts, development and implementation of exercises, and promotion and coordination of health care coalition activities with stakeholders.

As of June 30, 2014 (the most recent data available), there were approximately 24,000 health care facilities and community partners participating in 496 HCCs nationwide. This is an increase in HCC

membership of 47 percent since June 2013. The diverse membership of HCCs also contributes to their success in preparing a community to respond to a wide variety of incidents that impact public health. Medical evaluation and treatment of incident victims require coordinated activities that extend beyond hands-on medical care. By building and sustaining HCCs, information can be collected, analyzed, and managed to support rapid patient distribution to appropriate facilities, patient tracking, family support, information coordination, and resource and transportation management. HCCs also disseminate knowledge of the range of injury and illness to inform response and timely requests for additional resources. 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.

Figure 2. HCC Membership Diversity and Participation Rates.

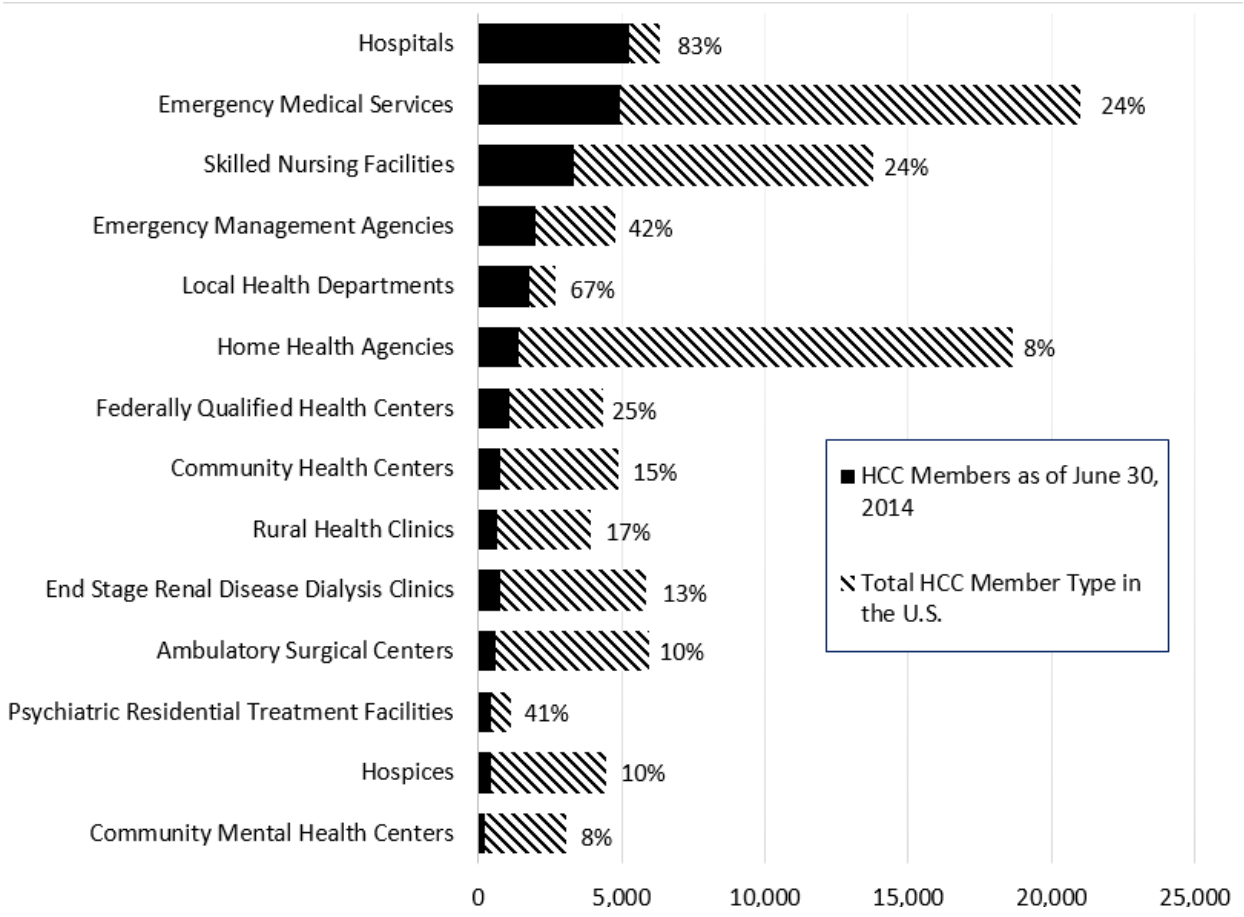


Figure 2 displays the HCC membership diversity and the participation rates by member type. For example, there are currently 5,288 hospitals participating in HCCs, which represents 83 percent of all U.S. hospitals. From 2012-2014, HPP encouraged awardees to emphasize recruitment of hospitals, emergency medical services (EMS) agencies, emergency management agencies, and local health departments. Beginning in 2015, HPP encouraged additional health care system member types.

Investments in coalition development have resulted in improved regional collaboration during emergencies, exercises, collaborative partnerships, and information-sharing that contributed to positive outcomes during local disasters as in the following example.

- **Amtrak Train Derailment, Philadelphia, PA**: In May 2015, en route from Washington DC to NYC, an Amtrak train carrying 238 passengers derailed. Over 200 were injured and eight killed. Fortunately, the Hospital Preparedness Program (HPP), the Pennsylvania Department of Health (DoH), and the regional health care coalition (HCC) prepared local health care systems for events such as this that could cause a surge in patients.

  Even as emergency crews were still on the ground searching for survivors and victims, local health care facilities, EMS, and emergency management agencies, all members of HPP-supported HCCs, were already in action, working together to facilitate a swift, coordinated response. HCCs are an integral part of HPP. The HCC members in Pennsylvania collaborated to ensure that each member of their coalition had the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to public health emergencies, including large scale accidents like the Amtrak train derailment.

  An emergency coordinator on the ground during the Amtrak derailment who is also an HCC leader in Pennsylvania lauded HPP for their regional focus on preparedness and emphasis on the vital systems that help operationalize HCCs. Through HPP funding, the regional HCC created an effective incident management structure that was critical to the health care system response to the Amtrak train derailment. Within a half hour window, HPP-funded systems were able to send out notifications of emergency room capacity to HCC members a full 30 minutes prior to the official city alerts. This enhanced information sharing provided responders real-time communications on vital resources throughout the region. HCC members immediately activated another HPP-funded response platform to track and triage patients, facilitating the proper distribution of patients preventing any single hospital from being overburdened. The operational response of HCC members, along with their systems and training, allowed for an effective response within an organized incident command structure, saving lives, improving care, and increasing accountability.

Health Care System Emergency Preparedness Capability Development

Historically, HPP funding supported the purchase of critical resources including communication systems, volunteer registries, patient tracking, information-sharing tools, and credentialing systems. HPP funding enhanced state and regional health care systems' ability to respond properly to disasters while limiting the need for federal support. A key goal of HPP has been to invest in and increase local capacities to prepare for and respond to events. Preliminary analysis suggests that local health care systems have increased their capacity and decreased reliance on Federal medical assets during disasters, a movement due in large part to past HPP investments. The number of incidents with the potential to impact public health continues to be significant and due to factors such as climate change, are projected to worsen in severity and impact.

The number of incidents across the U.S. with the potential to impact the public's health is significant. For 2014, the Department of Homeland Security (DHS) reported 16,425 National Operations Center (NOC) media notifications. NOC notifications concern threats to homeland security, including those at a local or community level, and include incidents such as large planned events, bomb threats, fires, and oil spills – all of which could have major implications for the health of individuals and communities, and consequently for their healthcare systems. HPP investments enhance local communities' capabilities and ensure they have resources on hand to respond and address incidents as soon as they occur. Given the number of incidents with the potential to impact public health, investments in HPP are critical in mitigating the potential impact one event can have on a community; defusing a small event limits the

potential for it to become widespread. Beyond supporting preparedness and response activities at the local and state level, HPP-funded programs and initiatives have provided assistance to incidents classified under the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (*Stafford Act*), which authorizes the delivery of federal technical, financial, logistical, and other assistance to states and localities during declared major disasters or emergencies. During 2014, the number of Stafford incidents totaled 84. Since HPP's inception in 2002, HPP-funded coalitions, equipment, and systems have engaged in an estimated 1,707 incidents classified under the *Stafford Act*.

Figure 3. Stafford Act Declarations, 2002-2014.

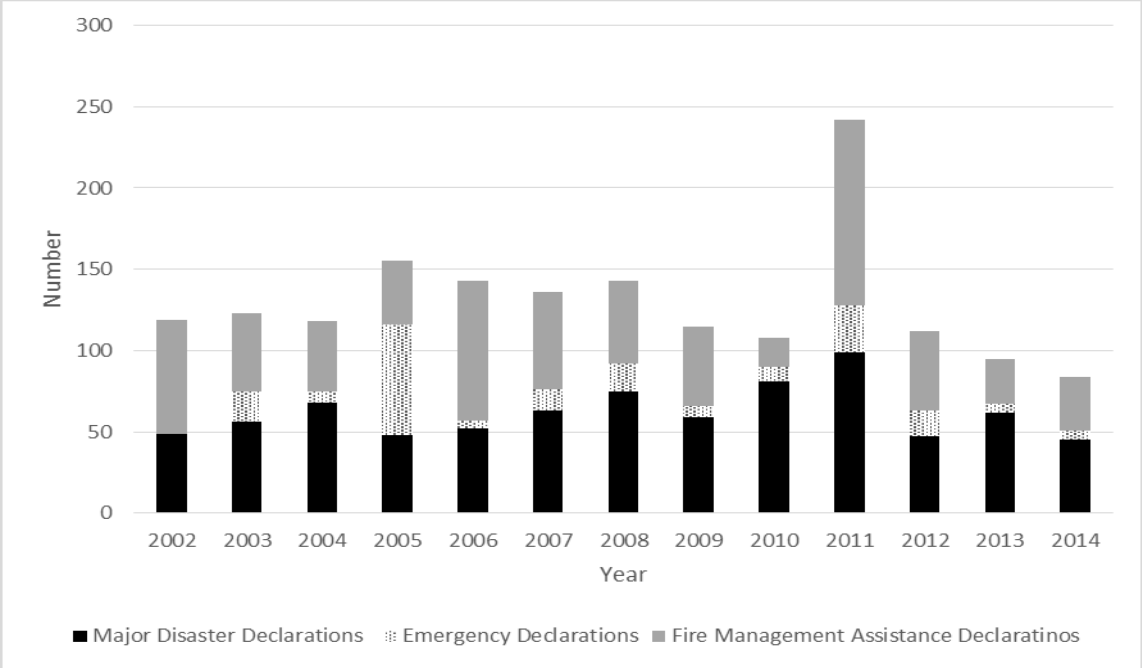


Figure 4. Health Care Preparedness Capabilities.

When HPP's preparedness and response strategy began its focus on HCCs in 2012, awardees were required to meet eight national health care preparedness capabilities. These capabilities are flexible enough to encourage all-hazard planning, including natural disasters, terrorist events, infectious disease outbreaks, or industrial accidents. The capabilities are designed to facilitate and guide joint Emergency Support Function (ESF) 8 preparedness planning and are scalable to maintain effectiveness during every day emergencies as well disasters requiring state and federal declarations. HPP awardees use the health care preparedness capabilities to identify gaps in their preparedness efforts and better target investments to ultimately assure that their communities are safer, more resilient, and better-prepared. These capabilities, detailed in the

Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness[3], are: (1) health care system preparedness, (2) health care system recovery, (3) emergency operations coordination, (4) fatality management, (5) information sharing, (6) medical surge, (7) responder safety and health, and (8) volunteer management.

Impact of Federal Health Care Preparedness Investments

An HPP impact assessment conducted in 2014 revealed that HPP funding is critical to the development and sustainment of health care system capabilities and the specific functions and activities necessary to support them. In large part, this is due to the fact that most jurisdictions do not receive other federal or state support for health care disaster preparedness. In a recent survey, HPP awardees indicated overwhelmingly that HPP support (including funding, guidance, and technical assistance) is critical to developing, implementing, and maintaining health care preparedness capabilities.

- 100 percent agreed or strongly agreed that HPP was critical to Health Care System Preparedness.
- 92 percent agreed or strongly agreed that HPP was critical to Health Care Worker Safety.
- 85 percent agreed or strongly agreed that HPP was critical to Medical Surge.
- 85 percent agreed or strongly agreed that HPP was critical to Information Sharing.
- 74 percent of reported exercises (tabletop, function, and full-scale) that took place at the HCC level were funded by HPP.

Ebola Health Care System Preparedness and Response Accomplishments

Beginning in March of 2014, West Africa experienced the largest Ebola outbreak on record. Unlike many smaller preceding outbreaks of Ebola virus disease, this particular outbreak spread to multiple African countries and caused (as of November 29, 2015) 28,637 suspected, probable, or confirmed human cases[4]. In August 2014, the first American Ebola patient was flown to the U.S. for treatment. Additional patients were medically-evacuated to the U.S. and two returned travelers were diagnosed and treated in Dallas, TX and New York, NY. Two health care workers were also infected in a Dallas hospital. These experiences identified opportunities to improve preparedness for and treatment of suspected and confirmed patients with Ebola. In response, Congress appropriated emergency supplemental funding, in part to ensure that the health care system is adequately prepared to respond to future Ebola patients. In doing so, Congress directed HHS to develop a regional approach to caring for future Ebola patients.

Building upon the state- and jurisdiction-based tiered hospital approach[5] and meeting Congress' regional directive, HPP provided awardees with $194,500,000 of Ebola emergency funding to establish a nationwide, regional treatment network for Ebola and other infectious diseases. This approach balances geographic need, differences in institutional capabilities, and accounts for the potential risk of needing to care for an Ebola patient. While the focus was on preparedness for Ebola, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced. This regional Ebola treatment network consists of:

1) Nine regional Ebola and other special pathogen treatment centers that can be ready within

[3] Healthcare Preparedness Capabilities: National Guidance for Healthcare System Preparedness: http://www.phe.gov/Preparedness/planning/hpp/reports/Documents/capabilities.pdf

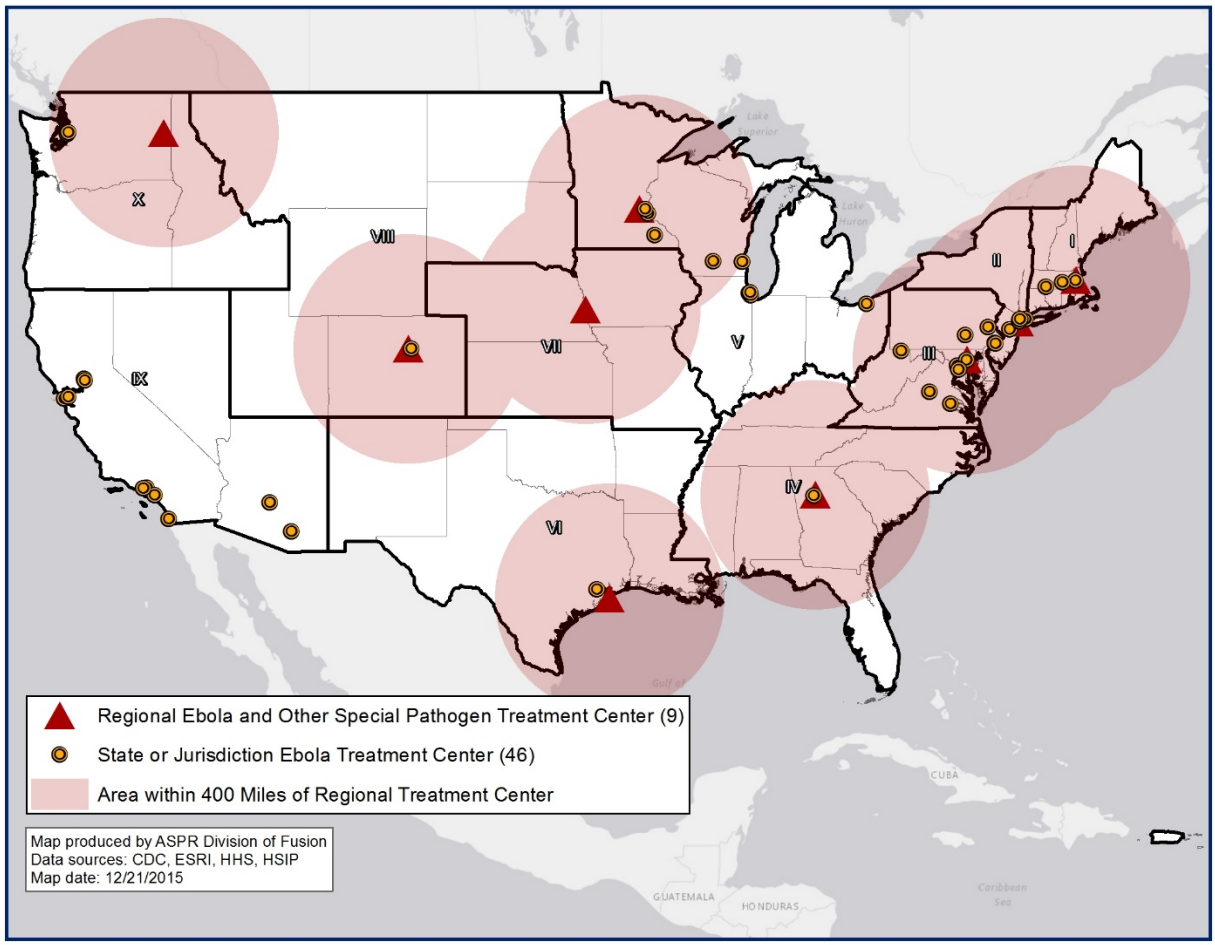
[4] "Ebola Situation Report - 9 December 2015", World Health Organization. http://apps.who.int/ebola/current-situation/ebola-situation-report-9-december-2015.

[5] Interim Guidance for U.S. Hospital Preparedness for Patients under Investigation (PUIs) or with Confirmed Ebola Virus Disease (EVD): A Framework for a Tiered Approach. http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/hospitals.html

a few hours to receive a confirmed Ebola patient from their region, across the U.S. or medically-evacuated from outside of the U.S., as necessary. These hospitals will also have enhanced capacity to care for other highly infectious diseases. [NOTE: As of January 4, 2016, ASPR and the HHS Region IX HPP awardees and their hospital partners continue to make progress toward identifying a regional Ebola and other special pathogen treatment center.]

2) State or jurisdiction Ebola treatment centers (as of February 18, 2015) that can safely care for patients with Ebola in the event of a cluster of Ebola patients that overwhelms the regional Ebola and other special pathogen treatment center. All nine of the regional facilities come from the list of 55 state health official-designated Ebola treatment centers.
3) Assessment hospitals that can safely receive and isolate a person under investigation for Ebola and care for the person until an Ebola diagnosis can be confirmed or ruled out and until discharge or transfer are completed.
4) Frontline health care facilities that can rapidly identify and triage patients with relevant exposure history and signs or symptoms compatible with Ebola and coordinate patient transfer to an Ebola assessment hospital.

Figure 5. Regional Ebola Treatment Network



Lastly, to prepare for and provide safe and successful care of patients with Ebola, HHS awarded $12,000,000 to establish a National Ebola Training and Education Center (NETEC). The NETEC will offer state health departments, regional Ebola and other special pathogen treatment centers, state and jurisdiction based Ebola treatment centers, and assessment hospitals expertise, training, technical assistance peer review, monitoring, and recognition. NETEC is a consortium of the three U.S. health

facilities that safely and successfully treated a confirmed Ebola patient – Emory University in Atlanta, GA; University of Nebraska Medical Center/Nebraska Medicine in Omaha, NE; and the New York City Health and Hospitals Corporation/HHC Bellevue Hospital Center in New York, NY.

It is important to note that the emergency funding for Ebola built on the more than a decade of HPP investments that bolstered health care system preparedness and response at hospitals and other health care providers across the nation. Beginning on April 15, 2014, and prior to the award of supplemental funding, HPP began issuing health care system guidance, checklists, and training documents, offered the flexibility and processes to use cooperative agreement funds to directly address Ebola, and convened national calls and webinars with physicians, nurses, hospital executives, EMS providers, and public health leaders reaching hundreds of thousands of the nation's frontline health workforce to provide updated information about Ebola.

- **New York City Ebola Preparedness and Response:** HPP has provided funding to the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) since 2002. This sustained investment, along with the Ebola emergency supplemental funding, allowed New York City and its partner health facilities and emergency management organizations to successfully respond to one of only a few confirmed patients with Ebola in the U.S.

  Prior to October 23, 2014, when the doctor who had just returned from treating Ebola patients in Guinea tested positive for Ebola at Bellevue Hospital Center, NYC DOHMH had already started activating resources and plans with hospitals, public health laboratories, and other health care entities and first responders to collaboratively prepare. HPP funding enabled the creation of travel history, fever and rash protocols and subsequent trainings on these protocols at New York City Hospitals. These protocols, which had been designed long before the 2014 Ebola outbreak, gave health care workers years of practice implementing strong precautions and identifying patients with emerging infectious diseases, such as Ebola.

  HPP funding also supported the development and maintenance of the Bellevue Hospital Center quarantine and isolation unit and clinical and procedural protocols, guidelines, plans, and other resources. Additionally, HPP funding was utilized in the weeks prior to the arrival of the first Ebola patient to ensure health care responder safety through no-notice first patient drills that test a facility's ability to properly identify, assess, isolate, and treat patients, as appropriate.

  Bellevue staff confirmed the patient to be Ebola-free after he spent 20 days in isolation and discharged him home. In total, over 100 Bellevue staff members ranging from doctors and nurses to waste handlers and administrative employees were involved in his round-the-clock care. Meanwhile, Bellevue staff continued to care for regular patients in its 750-bed hospital, 50-bed intensive care unit, and emergency department, which sees about 300 patients a day.

Improving Preparedness through Evaluation and Research

HPP funds are used by the program's evaluation team to monitor awardee progress, suggest program improvements, conduct research and inform policy including evaluating the performance of HPP awardees in the eight health care preparedness capabilities and health care coalition developmental factors.

In addition, ASPR employs quality improvement strategies 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 regional 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, ASPR/OEM has reduced the number of measures and awardee burden by 80 percent.

Coincident with the focus on coalitions, HPP developed the refined set of program performance measures for 2013 and 2014 to begin establishing a meaningful baseline and a stable set of indicators that will remain consistent and comparable through June 2017 (the end of the current HPP project period). Stable measures will help ensure that HPP can monitor incremental awardee progress over the course of the project period. In FYs 2014 and 2015, HPP developed 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. SHARPER and HPP are already working diligently to assess the current health care preparedness capabilities and program performance measures for the new five-year project period beginning in July 2017 to make any necessary refinements while maintaining consistency to show progress over time.

ASPR is using data from the Centers for Medicare and Medicaid Services (CMS) to examine the effect of disasters on clinical and economic outcomes for both providers and patients and to evaluate trends in the health care system during disasters, such as patient flow patterns. ASPR has teamed with CMS to support their proposed regulation 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.

Technical Resources Assistance Center and Information Exchange (TRACIE)

Beginning in FY 2015, ASPR has been is enhancing and expanding its technical assistance to state and local communities. ASPR 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.

TRACIE provides evidence-based applications, technology, and proven best practices to help our states and communities build enhanced capacity and improve their knowledge and effectiveness. TRACIE develops and disseminates appropriate, action-oriented technical assistance materials through a coordinated system, which includes:

- Consultation with subject matter experts (SMEs);
- Publication of subject matter expert validated resource materials;
- Topic specific collections of resource materials;
- Interactive training materials;
- Access to online training programs and courses;
- Webinars and virtual technical assistance;
- Toolkits, guidance documents, and illustrative examples of promising practices;

- Facilitated, on-line peer to peer engagement and support.

TRACIE launched on September 30, 2015 and has received over 215 requests for technical assistance, near 25,000 visitors to the website (with an average session duration of near five minutes per user), and over 850 members registered in the information exchange. Technical assistance requests range in requestor type (e.g., local, state, regional, tribal, and federal staff, health care associations, etc.) and topics, such as health care coalition development, requests for plan examples and templates, hazard vulnerability assessments, communications/public messaging, crisis standards of care planning, and pediatric-related resources.

TRACIE also provides surge assistance and resources during and after incidents. For example, in response to a possible hurricane in the northeast, TRACIE developed a "Hurricane Resources At Your Fingertips" document within six hours to include applicable hurricane resources and key considerations for various professions/facilities (e.g., public information officers, dialysis centers, emergency managers, public health officials, hospitals, pharmacies, animal care professionals, and long-term care facilities). In addition, TRACIE has a robust cadre of SMEs that are available to provide virtual or on-site support and consultation.

Strengthening Day to Day Systems of Emergency Care

The emergency care system is an essential part of the US healthcare system and serves as the foundation of a well-coordinated health system response to disasters and public health emergencies. Patients depend on the emergency care system 24 hours a day, seven days a week. Emergency department (ED) utilization has been increasing for the last 10 years; Americans made 136 million visits to emergency departments in 2011, accounting for 28% of all acute care visits. The ED represents the intersection between the outpatient and inpatient health system. About half of all hospital admissions, and 82% of unscheduled admissions, originate in the ED. ASPR's Emergency Care Coordination Center (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. The ECCC is focused 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. Central to the work of the ECCC is the notion that an emergency care system that delivers high quality care for day to day emergencies is better able to respond in times of disasters and public health emergencies. As a result, there is substantial synergy between HPP's focus on health care coalition development and the activities of ECCC. The ECCC serves as a functional bridge between many Departmental efforts focused on achieving the triple aim of health care (better care, lower cost, and improved population health) and ASPR's efforts to create a health care system that is more efficient, prepared, responsive and resilient.

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 build systems of care that ensure the best possible outcomes from life and limb threats. Access to health care information creates educated consumers of emergency care, allowing for patients to match their needs to the capabilities of the system. During times of disasters and public health emergencies, situational awareness allows for the efficient triage, transport, and treatment of patients in the safest appropriate level of care. The ECCC works in conjunction with partners to conduct "Post Incident Peer Review of Preparedness Activities" following selected mass casualty incidents to identify what health care preparedness activities most impacted the response.

The ECCC also provides a 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 and Medicaid Services, and the Health Resources and Services Administration) and HPP. The bi-directional link between preparedness and improved day to day emergency care outcomes is a strong catalyst for enhanced healthcare system preparedness and a healthier population. The ECCC also provides administrative support for the federal interagency group, the Council on Emergency Medical Care (CEMC), charged with ensuring the coordination of emergency medical care activities across the federal government.

Recovering from Disasters and Other Public Health Emergencies

Supporting communities as they recover from disasters is critical to ensure communities are able to return to pre-disaster status. ASPR's Division of Recovery works closely with HPP regional partners and HPP coalition members to ensure recovery actions are considered and taken into account as communities plan and prepare for events impacting public health. The 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).

During an emergency or disaster, ASPR's Division of Recovery maintains situational awareness and gathers information about disaster impacts that could affect the recovery of the community or communities. 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 and can occur without an activation of ESF 8 or other response efforts. 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 2015, the Health and Social Services and Recovery Support Function was activated to support recovery from flooding in Texas and Oklahoma. The H&SS RSF remains activated for Hurricane Sandy under an interagency agreement with FEMA. In some disasters, the Division provides technical assistance and informal support without a formal activation.

Protecting Critical Health Care and Public Health Infrastructure

HPP's resources also support other critical efforts to promote public health preparedness and resilience. One such program is the Critical Infrastructure Protection (CIP) program. The CIP program contributes to community resilience by working with businesses to reduce risks to Health Care and Public Health (HPH) Sector critical infrastructure from all hazards, including both physical and cyber threats. Through a public- and private-sector partnership, the program 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 coordinates HHS' sector-specific agency role under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience; and Executive Order 13636, Enhancing Critical Infrastructure Cybersecurity.

In 2015, the CIP program took on a significant role during the Ebola response by coordinating with private sector manufacturers and distributors of personal protective equipment (PPE) to address the critical product shortages that resulted from the response. Leveraging the strength of the Critical Infrastructure Program, ASPR led the interagency in gathering information from the private sector on product availability and assisting PPE suppliers in prioritizing product deliveries to health care facilities with greatest need. Through these efforts, the workgroup was able to assist several hospitals that had previously lacked the PPE they would need to function as domestic Ebola treatment centers. 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 the health care and public health sectors.

Also in FY 2015, ASPR led a comprehensive effort to analyze risks to the HPH sector and develop a multi-year sector specific plan to mitigate those risks. As part of this plan, the program developed a strategy for performing voluntary facility-level risk assessments to assist private sector owners and operators in identifying and mitigating the risks to their facilities. This strategy builds off of existing assessment methodologies and expands them to focus more on issues of growing importance to health care facilities, such as continuity of services during extreme weather events and protection against cyber threats.

In FY 2015 the HPH sector experienced its worst year on record as the target for cyber attacks, leading to the compromise of more than 100 million patient records, even as new vulnerabilities were announced to networked medical devices such as intravenous infusion pumps. In order to assist health care organizations better respond to these threats, ASPR awarded a planning grant to study cybersecurity information needs in the HPH sector and to propose a strategy for filling any identified gaps. In the coming year, ASPR will build of this analysis by providing additional grant funding to an organization to implement the recommendations identified through the planning grant.

The program continues its focus on information sharing by providing classified threat briefings to cleared private sector and state partners; maintaining a secure information sharing portal on the Homeland Security Information Network; and distributing a biweekly partnership newsletter.

Immediately following the November attacks in Paris, ASPR used these information sharing networks to disseminate materials on active shooter preparedness for health care facilities, including new products that the partnership had developed earlier in FY 2015. This information was forwarded by the American Hospital Association and other major national associations to their membership lists, so that thousands of health care organizations nationwide were made aware of the resources available to them to prepare for this emerging threat.

Developing a greater understanding of the threats and vulnerabilities of critical health infrastructure is a major focus of ASPR ’s work in FY 2016. Building on the strategy in its sector specific plan, ASPR is working with its partnership to craft an all-hazards risk assessment specifically for the HPH sector to assist in prioritizing risk mitigation activities. ASPR will continue to engage with industry experts from across the HPH sector, law enforcement, intelligence, among others to modify existing tools to meet sector needs. Also in FY 2016, the program plans to assess national-level health critical infrastructure assets through existing data and pilot site visits to better understand vulnerabilities. ASPR will perform additional analysis of supply chain vulnerabilities to better understand the risk of future product shortages, such as those experienced during the 2014-2015 Ebola response. ASPR will also develop products to assist health care organizations with cybersecurity incident response. Through this and other collaborative work with the private sector, ASPR will continue to contribute to a more secure and resilient HPH sector.

Funding History

Fiscal Year	*Amount*
FY 2013	$358,231,000
FY 2014	$255,060,000
FY 2015	$254,555,000
FY 2016 Enacted	$254,555,000
FY 2017 PB	$254,555,000

Budget Request

The FY 2017 Budget includes $254,555,000 in budget authority for the Hospital Preparedness Program (HPP), which is the same as the FY 2016 enacted budget. Within the total, $228,500,000, level with FY 2016, will be provided through a cooperative agreement funding mechanism to all 62 HPP awardees, which are the public health departments in all 50 states; Washington, DC; Chicago; Los Angeles County; New York City; and all U.S. territories and freely-associated states. Funding also supports programs that directly support the mission of HPP including program evaluation and research, HPP cooperative agreement administration, the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP), the Science Healthcare Preparedness Evaluation and Research (SHARPER) branch, the Technical Resources Assistance Center and Information Exchange (TRACIE), the Emergency Care Coordination Center (ECCC), Critical Infrastructure Protection (CIP), and the Recovery program. Most of these funds (approximately 90 percent) will support cooperative agreements with state, local, and territorial health departments to improve surge capacity and enhance community and health care system preparedness for public health emergencies.

Since 2012, HPP has created a more efficient and effective model for improving national health care system preparedness. Current data as of June 30, 2014, indicate that:

- 67 percent of coalitions have established a formal self-governance structure, including leadership roles;
- 74 percent of coalitions have multi-disciplinary health care organization membership; and,
- 91 percent of coalitions have established geographic boundaries.

HCCs have strengthened communities' responses to public health and medical incidents, mitigating lasting impacts, shortening recovery, and reducing the use of federal assets. As the metrics above demonstrate, HCCs are bringing partners together before, during, and after an incident. The data reveals that, while there is still room to make improvements, the majority of the current 496 health care coalitions nationwide are far enough along in their formation that HPP funding should pivot from supporting their establishment to ensuring their functionality. Beginning in FY 2017, the first year of the new project period (2017-2021), HPP will begin a multiyear initiative focusing on operationalizing HCCs for response.

ASPR Hospital Preparedness Program - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
2.4.2 G Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states with heightened healthcare organization (HCO) engagement in statewide/regional exercises: % of States with heightened HCO engagement in statewide/regional exercises. (Outcome)	FY 2015: Result Expected Dec 30, 2016 Target: 30 % (Pending)	30 %	TBD	N/A
2.4.2.H Improve surge capacity and enhance community and hospital preparedness for public health emergencies through percentage of states with established operational healthcare coalitions: % of States with established operational healthcare coalitions. (Outcome)	FY 2015: Result Expected Dec 31, 2016 Target: Historical Actual, No Target 50.0 (Pending)	50%	TBD	N/A
14 Proportion of coalitions that reported the ability to coordinate and track patient surges and movement during an exercise or event. (Outcome) (Outcome)	N/A	N/A	75.0	N/A
15 Proportion of health care coalitions that use an incident management structure to coordinate and respond (Outcome) (Outcome)	N/A	N/A	55.0	N/A

Hospital Preparedness Program Grant Awards by State

(in whole dollars)

Note: FY 2016 amounts are provided as estimates. HPP will use the same formula in FY 2016 as in FY 2015; however, the risk component of the HPP formula changes annually. A new funding formula will be developed in FY 2017 and allocations will be revised accordingly. The FY 2016 and FY 2017 amounts are provided as estimates.

STATE/TERRITORY	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Alabama	$3,231,541	$3,231,541	$3,231,541	$0
Alaska	$948,583	$948,583	$948,583	$0
Arizona	$3,985,942	$3,985,942	$3,985,942	$0
Arkansas	$2,014,696	$2,014,696	$2,014,696	$0
California	$23,204,454	$23,204,454	$23,204,454	$0
City of Chicago	$2,736,924	$2,736,924	$2,736,924	$0
Colorado	$3,230,913	$3,230,913	$3,230,913	$0
Connecticut	$2,467,952	$2,467,952	$2,467,952	$0
Delaware	$1,061,248	$1,061,248	$1,061,248	$0
District of Columbia	$951,550	$951,550	$951,550	$0
Florida	$11,661,603	$11,661,603	$11,661,603	$0
Georgia	$5,941,199	$5,941,199	$5,941,199	$0
Hawaii	$1,220,804	$1,220,804	$1,220,804	$0
Idaho	$1,217,406	$1,217,406	$1,217,406	$0
Illinois	$8,867,636	$8,867,636	$8,867,636	$0
Indiana	$4,127,659	$4,127,659	$4,127,659	$0
Iowa	$2,091,263	$2,091,263	$2,091,263	$0
Kansas	$2,068,884	$2,068,884	$2,068,884	$0
Kentucky	$2,900,747	$2,900,747	$2,900,747	$0
Los Angeles	$9,197,167	$9,197,167	$9,197,167	$0
Louisiana	$3,137,439	$3,137,439	$3,137,439	$0
Maine	$1,078,955	$1,078,955	$1,078,955	$0
Maryland	$4,916,220	$4,916,220	$4,916,220	$0
Massachusetts	$4,240,648	$4,240,648	$4,240,648	$0
Michigan	$6,086,643	$6,086,643	$6,086,643	$0
Minnesota	$3,520,091	$3,520,091	$3,520,091	$0
Mississippi	$2,174,085	$2,174,085	$2,174,085	$0
Missouri	$3,766,903	$3,766,903	$3,766,903	$0
Montana	$910,977	$910,977	$910,977	$0
Nebraska	$1,376,638	$1,376,638	$1,376,638	$0
Nevada	$1,917,424	$1,917,424	$1,917,424	$0
New Hampshire	$1,104,016	$1,104,016	$1,104,016	$0
New Jersey	$5,835,689	$5,835,689	$5,835,689	$0
New Mexico	$1,507,698	$1,507,698	$1,507,698	$0
New York	$9,617,523	$9,617,523	$9,617,523	$0

STATE/TERRITORY	FY 2015 Actual	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
New York City	$7,928,385	$7,928,385	$7,928,385	$0
North Carolina	$6,144,995	$6,144,995	$6,144,995	$0
North Dakota	$877,391	$877,391	$877,391	$0
Ohio	$7,459,074	$7,459,074	$7,459,074	$0
Oklahoma	$2,602,048	$2,602,048	$2,602,048	$0
Oregon	$2,523,559	$2,523,559	$2,523,559	$0
Pennsylvania	$8,131,994	$8,131,994	$8,131,994	$0
Rhode Island	$969,418	$969,418	$969,418	$0
South Carolina	$3,091,113	$3,091,113	$3,091,113	$0
South Dakota	$858,655	$858,655	$858,655	$0
Tennessee	$4,059,780	$4,059,780	$4,059,780	$0
Texas	$15,821,740	$15,821,740	$15,821,740	$0
Utah	$1,925,825	$1,925,825	$1,925,825	$0
Vermont	$898,240	$898,240	$898,240	$0
Virginia	$6,295,382	$6,295,382	$6,295,382	$0
Washington	$4,220,025	$4,220,025	$4,220,025	$0
West Virginia	$1,380,775	$1,380,775	$1,380,775	$0
Wisconsin	$3,611,886	$3,611,886	$3,611,886	$0
Wyoming	$836,173	$836,173	$836,173	$0
Subtotal, States	$223,955,578	$223,955,578	$223,955,578	$0
American Samoa	$278,128	$278,128	$278,128	$0
Guam	$352,520	$352,520	$352,520	$0
Marshall Islands	$267,111	$267,111	$267,111	$0
Micronesia	$275,479	$275,479	$275,479	$0
Northern Mariana Islands	$270,652	$270,652	$270,652	$0
Palau	$255,101	$255,101	$255,101	$0
Puerto Rico	$2,506,617	$2,506,617	$2,506,617	$0
Virgin Islands (US)	$338,814	$338,814	$338,814	$0
Subtotal, Territories	$4,544,422	$4,544,422	$4,544,422	$0
Total, States/Territories	$228,500,000	$228,500,000	$228,500,000	$0
Total Resources	$228,500,000	$228,500,000	$228,500,000	$0

ASPR Hospital Preparedness Program: Summary of Grant Awards

(estimated amounts in dollars)

	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget
Number of Awards	62	62	62
Average Award (in whole dollars)	$3,685,484	$3,685,484	$3,685,484
Range of Awards (in whole dollars)	$255,101 - $23,204,454	$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)

Biomedical Advanced Research and Development Authority	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	473,000	511,700	511,700	--
Ebola funding (P.L. 113-164) (non-add)	*58,000*	--	--	
Advanced Research and Development (non-add)	*271,000*	*259,700*	*259,700*	--
Combating Antibiotic-Resistant Bacteria (non-add)	*84,000*	*192,000*	*192,000*	--
Operations and Management (non-add)	*60,000*	*60,000*	*60,000*	--
FTE	155	155	155	--

1/These amounts do not include PHSSEF Ebola emergency funding (P.L. 113 – 235).

Authorizing Legislation:

Authorization ..... PAHPRA
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

ASPR works with public and private partners to transition candidates for vaccines, antivirals, diagnostics, and medical devices – known collectively as medical countermeasures (MCMs) – from early development into the advanced and late stages of MCM approval. In the biopharmaceutical industry, all medical products require 8-15 years to develop and reach licensure or approval by the U.S. Food and Drug Administration, and the same is true for MCMs. Continuous, long-term efforts are crucial if the Federal Government is to have products available when needed to save lives and respond to public demand in emergencies. ASPR's cost-efficient and innovative approach to MCM development is stimulating dormant industry sectors and revolutionizing the medical technology needed to protect communities from national health security threats and other public health emergencies. Advanced research and development programs also drive economic growth, supporting thousands of American jobs in medical innovation in across the country. The Pandemic and All Hazards Preparedness Act established the Biomedical Advanced Research and Development Authority (BARDA) within ASPR to carry out this program as well as Project BioShield.

BARDA's approach to advanced research and development has a proven track record of success. This success is built on continuous collaboration with the National institutes of Health, Centers for Disease Control and Prevention, U.S. Food and Drug Administration, and Department of Defense (DoD). Together with the Department of Homeland Security, Department of Veteran Affairs, and U.S. Department of Agriculture, these agencies form the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) and as PHEMCE partners, they set research and development priorities under a five-year strategy and implementation plan. Our advanced research and development decisions also are

guided by the BARDA Strategic Plan 2011-2016 and by the maturity of products in the early research and development pipeline of PHEMCE partner agencies. When feasible, medical products transition from early stage research and development with PHEMCE partners into our advanced research and development portfolio. We strategically support advanced development and acquisition of medical countermeasures that are existing products being repurposed for our needs or new multipurpose products with commercial indications and that meet our needs. This approach increases the sustainability of these medical countermeasures, makes them less dependent on USG support, and provides alternate mechanisms (i.e., vendor management inventory systems) to stockpiling in the Strategic National Stockpile (SNS).

Enhancing Public-Private Partnerships to Face Health Threats

To achieve success BARDA partners – through cost-sharing agreements – with academic, non-government organizations, and private sector companies, including some of the largest names in the biopharmaceutical industry to some of the smallest.[6] In May 2013, BARDA leveraged a procurement tool known as Other Transaction Authority (OTA) provided under the Pandemic and All-Hazards Preparedness Act (PAHPA) to forge a unique partnership with one of the world's largest pharmaceutical companies, GlaxoSmithKline, for the development of new antimicrobial drugs. As partners, GSK and BARDA are using a portfolio approach for the development of new antimicrobial drugs for biothreats, such as plague, tularemia, and multidrug resistant pathogens in community and hospital settings, such as CRE and MRSA. The OTA allows products to move into or out of this advanced development portfolio as warranted based on performance and affords BARDA a voice in the company's decision-making process about which medical countermeasure products should move forward. Currently, two antibiotic candidates are under development in this cost-sharing partnership. BARDA is using this type of partnership for a second Other Transaction Authority with AstraZeneca that started in FY 2015. This new partnership supports Phase 3 clinical studies to evaluate the safety and efficacy of their lead drug candidates against biothreats. Additionally this new Other Transaction agreement enabled BARDA to meet one of the metrics under the President's Combating Antimicrobial-Resistant Bacteria (CARB) action plan ahead of schedule. These partnerships have sparked broader industry interest in developing new antibiotics to treat antibiotic resistant infections and to develop products that are less prone to resistance. This renewed interest can help address the national and global threat of antimicrobial resistance.

To encourage private sector involvement, minimize costs and accelerate results, BARDA has four primary core service assistance programs that support medical countermeasure development for preparedness and response. These core service assistance programs, which are also public-private partnerships, fill gaps in product development and manufacturing by inexperienced MCM developers identified in the *2010 HHS Public Health Emergency Medical Countermeasure Review,* an end-to-end review of the medical countermeasure development process conducted after the 2009 H1N1 pandemic. Also, these core service assistance programs provide public health emergency response as the National Medical Countermeasure Response Infrastructure, formed as part of the 2014-2015 Ebola response.

[6] BARDA consistently exceeds departmental goals for small business contracting.

These core service assistance programs are a huge success for HHS and its PHEMCE partners. Continued funding will be required in FY 2017 to maintain these successful programs.

- *Centers for Innovation and Advanced Development and Manufacturing:* In June 2012, BARDA entered into novel public-private partnerships with industry and academia to establish three Centers for Innovation in Advanced Development and Manufacturing (CIADM); BARDA used one of these Centers in 2013 to produce vaccine in response to the H7N9 avian influenza outbreak in 2013 and utilized another Center in 2015 to develop and manufacture an Ebola monoclonal antibody drug made in mammalian cells. The CIADMs partner with vaccine and biological product manufacturers to meet national demand during public health emergencies especially pandemic influenza. They also are available on a routine basis to assist our industry and federal partners in developing and manufacturing CBRN medical countermeasure products from Phase I through FDA approval. In addition, the CIADMs have workforce development programs to provide formal and applied training in flexible manufacturing and other innovative technologies to future medical countermeasure developers.

- *Fill Finish Manufacturing Network:* BARDA established the network in 2013 to assist medical countermeasure developers with final drug product manufacturing after the *2010 HHS Public Health Emergency Medical Countermeasure Review* identified this preparedness gap. Our Fill Finish Manufacturing Network provides sterile product formulation and filling capabilities for many products including monoclonal antibody (e.g., ZMapp) for use in clinical trials during the Ebola epidemic. The Fill Finish Manufacturing Network is comprised of four domestic contract manufacturing organizations (CMO) with a broad set of capabilities to address every day and emergency needs, such as, filling aseptic syringes and vials. The network holds potential in resolving the need for surge capacity on a day-to-day basis as well. In 2015 the network initiated a pilot program with FDA to address the U.S. drug shortage crisis by performing fill finish manufacturing on two drugs in chronic short supply in the United States.

- *Non-Clinical Studies Network:* Established in 2011, the Non-Clinical Studies Network provides necessary and timely animal studies including recent studies for Ebola vaccine and monoclonal antibody therapeutics. The non-clinical studies network is comprised of 17 laboratories in the United States and the United Kingdom. These organizations now have performed 36 studies in support of BARDA product development, obtaining safety and efficacy data necessary to proceed to clinical studies or to approve products under the FDA Animal Rule, which allows FDA to approve products based on animal research when human clinical trials would be unethical.

  In addition to Ebola, BARDA continues to support through the network the development of animal models, assays (tests), reagents, and studies for such threats as anthrax, smallpox, plague, glanders, chemical agents and acute radiation syndrome. 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 and is using the network to test manufacturers' product candidates in proof of concept studies. Test results are shared with manufacturers and inform decisions about whether to support the development of new MCMs. BARDA also continues to use this network to evaluate the repurposing of already licensed products.

  In FY 2013–2014, this network also supported proof of concept studies to evaluate candidate MCMs and repurposing studies of commercially available products. In FY 2015–2016, BARDA is

conducting utilization studies to provide supplemental data for products in the SNS, repurposing studies for MCMs against chemical threats and continue animal model development studies to support advancement of products currently in BARDA's portfolio based on availability of funds.

- *Clinical Studies Network:* BARDA established the Clinical Studies Network, comprised of five clinical research organizations (CROs), in 2014 to provide clinical study services, including designing clinical protocols and managing clinical trial sites for Ebola medical countermeasures in 2015. The network also can provide surge capacity for the National Institutes of Health's (NIH) clinical study capabilities during public health emergencies. In 2016, BARDA plans to use the Clinical Studies Network to test the immunogenicity of H5N1 pre-pandemic influenza vaccine stored for more than eight years in U.S. pre-pandemic influenza vaccine stockpiles to evaluate their effectiveness and collaborate with the Kingdom of Saudi Arabia to evaluate therapeutic candidates for the treatment of MERS-CoV infections.

Developing Multi-Use Products

BARDA has made significant progress driving innovation to address nationwide shortfalls identified in the *2010 HHS Public Health Emergency Medical Countermeasure Review*. This review led to a strategic transition for HHS from a "one bug, one drug" product paradigm (e.g. anthrax vaccines used for anthrax only) to more sustainable multipurpose product candidates with both biothreat and commercially viable indications for everyday healthcare. As a result, more investments are directed towards product candidates that may be used for treatment of illnesses caused by man-made threats such as plague and tularemia and for treatment of high priority community- and hospital-acquired bacterial infections. BARDA is sponsoring advanced development of the new classes of antibiotics that may be able to treat antibiotic resistant bacteria and it's broad spectrum antimicrobial program aligns with the President's 2014 *National Strategy for Combating Antibiotic-Resistant Bacteria* (CARB), to address the growing antibiotic crisis.

BARDA is also developing a portfolio of products to address burn injuries associated with a nuclear detonation. Many of these products also have the potential to address chemical burns and may find additional commercial everyday healthcare uses, such as for treating diabetic foot ulcers. This portfolio of candidate products addresses the continuum of care that is necessary to treat burn injuries, including field care and definitive care. Several of these thermal burn product candidates were acquired under Project BioShield in FY 2015. Products with these types of additional commercial uses allow the PHEMCE to leverage the commercial market and use vendor-managed inventory to limit the amount of stockpiling necessary. This approach also creates a more sustainable medical countermeasure business model, and dramatically decreases the overall life-cycle management costs associated with these products.

Building a Robust and Formidable MCM Development Pipeline

BARDA in partnership with other federal agencies and industry built a robust and formidable pipeline for advanced research and development of medical countermeasures. These efforts focus on combatting the medical consequences of 13 chemical, biological, radiological and nuclear threats identified by the Department of Homeland Security (DHS). Since 2006, this pipeline has incorporated more than 100

medical countermeasure candidates for CBRN threats. These advanced development programs have developed 16 of these CBRN MCM candidates since 2006 into maturity sufficient for purchase under Project BioShield.

BARDA's advanced research and development programs also have led to FDA licensure or approval of five new products since 2012 using the FDA Animal Rule. BARDA with the FDA and industry have developed new animal models to meet the requirements of this rule as a pathway to approval and these models clarified the approval or licensure requirements for CBRN MCMs. FDA-approved CBRN MCMs, whose development BARDA supported include Raxibacumab® anthrax antitoxin (2012), HBAT® botulinum antitoxin (2013), Anthrasil® (AIG) anthrax polyclonal antitoxin (2015), Neupogen® (2015) to treat hematopoiesis — blood cell damage associated with acute radiation syndrome — and BioThrax® (2015) for post-exposure prophylaxis in individuals suspected of exposure to anthrax.

With these recent FDA approvals, BARDA met the HHS goal of four CBRN medical countermeasures licensed by the FDA by the end of 2015. In addition, one biological license application (BLA) for an anthrax antitoxin was submitted in FY 2015, and two to three more licensure applications for other CBRN MCMs are expected in FY 2016. BARDA expects to purchase 4-6 new medical countermeasures candidates from our advanced research and development programs through Project BioShield by the end of FY 2017. The development pipeline remains poised to continue this trend, transitioning CBRN products from advanced research and development programs to acquisition under Project BioShield always towards FDA approval.

Anthrax: In response to the emphasis the Department of Homeland Security has placed on anthrax as a national security threat, HHS has invested more than $1 billion since 2004 in the advanced development and acquisition of vaccines, antitoxins, and antibiotics. The currently licensed killed whole-organism anthrax vaccine (BioThrax) is approved for use before exposure (General Use Prophylaxis) and widespread use after exposure (Post-Exposure Prophylaxis). Recognizing the need for an anthrax vaccine that is approved for use after exposure and provides greater protection in fewer doses – and therefore faster – than BioThrax, BARDA currently is supporting several enhanced anthrax vaccine candidates and is expanding the domestic manufacturing capacity for anthrax vaccines. Our anthrax vaccine portfolio includes next generation vaccines based on the protective antigen (PA) of B. anthracis. These recombinant PA vaccine candidates use novel bacterial gene expression systems, novel orally-delivered virus vectors, freeze-dried (known as lyophilized) formulations, and adjuvants. Another anthrax vaccine candidate utilizes the killed whole-organism vaccine formulated with an adjuvant to provide greater immunity in fewer doses in a freeze-dried formulation. With support under BARDA's advanced research and development program, the nation will see clinical evaluation of these new vaccine candidates in 2016 and 2017.

In FY 2015, Emergent submitted a Biological License Application (BLA) to FDA for use of BioThrax after exposure before illness begins, known as post-exposure prophylaxis. BARDA sponsored the work necessary to submit the application, building on efforts from NIH and the Department of Defense (DoD). The FDA approved this indication in November 2015; becoming the fifth CBRN MCM supported under PBS to achieve FDA licensure/approval. Additionally, a supplemental BLA submission is expected in FY

2016 for manufacture of BioThrax and their new anthrax vaccine candidates under development in Emergent BioSolutions' new facility. In this new facility, Emergent will have up to a six-fold greater manufacturing capacity than the current facility, which will increase vaccine availability.

The Amerithrax Attacks in 2001 revealed a major gap in preparedness for anthrax: antibiotics alone were not always effective. To bridge that gap, the BARDA anthrax portfolio has included advanced development of three antitoxin products (two monoclonal antibodies and one polyclonal antibody product) to treat people exposed to inhalational anthrax who do not respond to antibiotic treatments. With this support, two anthrax antitoxins – Raxibacumab and Anthrasil - have earned FDA approval. One of these antitoxins (Raxibacumab) was approved by FDA in 2012 to treat people with symptoms of anthrax infection or for prophylaxis and is approved for use in children. Raxibacumab was the first novel product approved under FDA's Animal Efficacy Rule and the first FDA-approved product developed and purchased solely with Project BioShield funding. The second antitoxin, Anthrasil, is a human polyclonal anthrax antitoxin for the treatment of inhalational anthrax, and was approved by FDA in March 2015.

BARDA continues to support late-stage development of another anthrax monoclonal antibody product, Anthim (Obiltoxamimab), that may have greater efficacy, allow for storage as a freeze-dried product at room temperature, and utilize intramuscular administration rather intravenous administration. Elusys submitted a BLA in March 2015 to support an indication for the treatment of inhalational anthrax, and FDA approval may occur in FY 2016. This product was acquired under Project BioShield in early FY2016 with delivery to the SNS in the coming years. These efforts will provide three products to treat individuals with anthrax disease and complete BARDA's goal for providing these critical countermeasures for anthrax.

Smallpox: Smallpox remains a threat of high concern to the international community and the U.S. BARDA's smallpox MCM goal has been to ensure there is adequate vaccine for everyone, including special populations, in the U.S., and that a minimum of two therapeutics will be available to treat persons exposed or infected persons. Since 2006, BARDA has supported the development of smallpox vaccines for immunocompromised persons and several therapeutic antiviral drug candidates with different mechanisms of action. Under Project BioShield, BARDA supported late-stage development, procured, and delivered to the SNS the IMVAMUNE smallpox MVA vaccine for people with HIV or atopic dermatitis and the ST-246 smallpox antiviral drug to treat people with smallpox symptoms. Currently both products may be used post-event under an Emergency Use Authorization from the FDA.

In 2013, Bavarian Nordic (BN) started a large Phase III study to evaluate lot-to-lot consistency and safety of IMVAMUNE with final results pending. In addition, BARDA sponsored a pivotal clinical study to determine whether this vaccine was as effective as the currently licensed vaccine, ACAM2000; study completion is projected for FY 2016. 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 and NIAID. In FY 2018, BN is expected to submit a Biological License Application to the FDA for licensure of a liquid formulation of IMVAMUNE. Additionally, BARDA continues to support development of a freeze-dried formulation of this smallpox MVA vaccine that may afford significantly greater shelf life and lower stockpiling costs. It is expected BN will have sufficient

data to transition to the freeze-dried (lyophilized) product under Project BioShield. In FY 2015, BARDA began the initial procurements of the lyophilized product and will continue this acquisition in FY 2016.

In addition to smallpox vaccines, the USG committed to developing and acquiring two smallpox antivirals with different mechanisms of action to treat symptomatic individuals. 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 – brincidofovir - has demonstrated broad spectrum antiviral activity (efficacy against smallpox and other DNA viruses), which may provide a commercial market to enhance production 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 Advanced Research and Development and Project BioShield programs.

BARDA has worked with both manufacturers and the FDA to develop rabbitpox and *Ectromelia* (mouse pox) animal challenge models to support approval of both products. In FY 2014, the data from the rabbitpox model was shared with the FDA. Both antiviral drug candidates have been evaluated in the rabbitpox model and pivotal studies in support of FDA approval are planned for FY 2016. This collaborative effort is an example of pre-competitive data sharing BARDA drives among industry and government partners to advance the overall field. In FY 2015, BARDA continued to support the development of both smallpox antiviral drug candidates and is working to transition the second antiviral candidate (brincidofovir) to Project BioShield. Due to decreased funding in FY 2015, the second smallpox antiviral was not purchased as planned under Project BioShield. This PBS acquisition will occur in FY 2016 with the available FY2016 PBS funding. These vaccine and antiviral drug efforts over the next 2-3 years will complete BARDA's development and acquisition programs for smallpox countermeasures. Together, these countermeasures will provide for a complete health response to a smallpox incident.

Broad Spectrum Antimicrobials and Combating Antibiotic-Resistant Bacteria Initiative: Antimicrobial resistance poses a growing threat health every day and complicates the ability to respond to public health emergencies. To combat this threat, the United States needs a diverse and vibrant pipeline of antibacterial therapies and preventive measures to ensure that BARDA have a wide array of treatment options for patients. This continuing crisis led to a presidential initiative to support activities outlined in the *National Strategy for Combating Antibiotic-Resistant Bacteria* (CARB). To help stave off a possible catastrophic post-antibiotic era, BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) together are accelerating basic and applied research and development for new antibiotics and other therapeutics to treat infections, even vaccines to protect against some of these diseases, and diagnostics to detect these drug-resistant bacteria.

BARDA is addressing biothreats and antimicrobial resistance simultaneously through a broad-spectrum antimicrobial program. The program is comprised of MCM candidates that would allow our nation to respond to biothreats including anthrax, plague, tularemia, melioidosis, and glanders. BARDA has partnered with seven companies for advanced development of nine antibiotic candidates to treat infections caused by biothreats (i.e., plague) and potentially deadly, multi-drug resistant pathogens acquired in community- and hospital-settings, such as carbapenem-resistant *Enterobacteriaceae* (CRE) and methicillin-resistant *Staphylococcus aureus* (MRSA).

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 (CRE) 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 CRE infections. An additional clinical trial, evaluating plazomicin for complicated urinary tract infections, is planned for initiation in early 2016. The safety data from both trials also supports the biothreat indication of this drug to treat plague and tularemia infections, a cost-efficient approach.

In FY 2012–2015, BARDA expanded the antibacterial portfolio with advanced research and development support for eight candidate small molecule therapies with the potential to address biothreat indications and the broader public health threat of antimicrobial resistance. Two of these candidates address the threats of glanders and melioidosis, for which there are currently no antibiotics in the SNS formulary. Today BARDA has advanced four antimicrobial candidates from the pipeline forward into pivotal Phase III clinical trials. Two of these programs (solithromycin and eravacycline) have achieved their clinical trial endpoints in the first of two Phase III clinical trials and NDA submissions to the FDA are projected in FY 2016. 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 FY 2013, BARDA also advanced the development of pediatric formulations for solithromycin. MCM development for at-risk populations is mandated under PAHPRA. Initial safety testing is completed for adolescents and in FY2015–2016 will expand to include younger pediatric populations. Non-clinical testing in animal models of anthrax and tularemia has provided positive data that the drug is efficacious in treating these infections.

In FY 2015, BARDA invested $91.9 million in development of novel broad spectrum antimicrobial products. Of these funds, $41.9 million was used to exercise options on existing contracts and the Other Transactional Authority was used for a second time to direct the remaining $50 million to a new development portfolio with Astra Zeneca. This FY 2015 agreement met PHEMCE priorities as well as the objectives outlined in the CARB *National Strategy* and supporting *Action Plan*. The *National Strategy* and *Action Plan* call for enhanced opportunities for public-private partnerships to accelerate research on new antibiotics to combat resistant bacteria, requiring BARDA to create at least one additional portfolio partnership with a pharmaceutical or biotechnology company by March 2016 to accelerate development of new antibacterial drugs. The CARB *National Strategy* and *Action Plan* also call for improved international collaboration on antibiotic research and development. To meet this requirement, BARDA will jointly fund the clinical development of one drug candidate within the portfolio with the European Innovative Medicines Institute.

In addition, BARDA and NIAID continue to expand collaboration to advance innovative research on antibiotic resistance. BARDA is developing a plan to launch an "antimicrobial resistance biopharmaceutical accelerator" 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. Presently, BARDA is conducting market research along with NIAID and developing an

acquisition strategy for the accelerator, in accordance with the President's CARB *National Strategy* and *Action Plan*. The FY 2017 funding is necessary to operationalize the antimicrobial resistance biopharmaceutical accelerator. Funds also will be used to invest in biodiagnostic and vaccine platform technologies with the potential to address biothreat pathogens as well as the broader public health concern of antimicrobial-resistant bacteria.

In FY 2016, BARDA will continue to support existing promising candidates and may expand the antibacterial program, based on scientific promise and prioritization. In FY 2016, BARDA's partners are expected to file new drug applications with FDA for two BARDA-sponsored products (eravacycline and solithromycin), the first to be filed with support from BARDA's Broad Spectrum Antimicrobials program. In line with the FY 2016 enacted level of $192 million for advanced development of broad spectrum antimicrobial drugs and CARB, BARDA plans to increase its antibacterial investment in FY 2016 by making two new contract awards to support novel antibacterial candidates. In FY 2016, BARDA also plans to make an initial investment in vaccine platform technologies with the potential to address biothreat pathogens and to address antimicrobial resistance.

In FY 2016, BARDA plans to fund antimicrobial resistance diagnostics development with a focus on diagnostic products that have both biothreat and routine healthcare utility in multiplex formats. This strategy will test capabilities during an antimicrobial resistant biothreat outbreak, since the routine healthcare use will ensure platform availability and user proficiency. BARDA is poised to support the nation in developing new tools, such as rapid point-of-care and laboratory molecular and phenotypic tools, to identify resistant bacteria and to help doctors and patients make informed decisions about effective antibiotic treatment. With NIAID, BARDA will provide funding towards a CARB diagnostic prize to stimulate interest towards innovative and transformative solutions for rapid detection of antibiotic resistant bacteria. BARDA is also interested in improving next generation sequencing platforms critical to understanding antimicrobial resistance so these platforms are appropriate for use in clinical diagnostics laboratories.

Additional FY 2017 funds also will support expansion of the broad spectrum antimicrobial drug pipeline by two-fold, new CARB-related vaccine and diagnostic platform technologies, and initiation of the Antimicrobial Resistance Biopharmaceutical Accelerator in alignment with the CARB *Action Plan* to meet the overall objectives of CARB and BARDA.

Viral Hemorrhagic Fever: Viral Hemorrhagic Fevers (VHF) caused by Ebola Viruses and Marburg Virus are biological threat agents of concern as well as global emerging infectious disease threats. The current outbreak of Ebola in West African countries has highlighted the severity of the disease as well as the extreme challenges in providing adequate medical care, preventing disease transmission, and the early-stage development of the filovirus MCM pipeline. To save lives, the USG launched an immediate, large-scale response in 2014 with a substantial number of MCMs.

To expedite development of MCMs for Ebola in 2014, BARDA pulled early-stage MCM candidates into our new Ebola portfolio and fully engaged industry partners to expedite further advance development of these medical products. Funding will be necessary in FY 2016 and FY 2017 in order to complete the development of several of the most promising vaccine, therapeutic, and diagnostic candidates towards

FDA licensure. We anticipate acquisition of at least one vaccine and two therapeutic candidates under Project BioShield in FY 2017.

BARDA's Ebola efforts in FY 2015 were supported by the FY 2015 Continuing Resolution ($58 million), FY 2015 Ebola emergency appropriation ($157 million), and FY 2015 BARDA advanced research and development annual appropriation ($3 million). By the end of FY2015, BARDA supported development of 12 Ebola MCMs (seven immunotherapeutic and antiviral drug candidates, four vaccine candidates, and one diagnostic candidate).

In 2013 and 2015, BARDA's Broad Agency Announcement solicited proposals for the development of Viral Hemorrhagic Fever MCMs to address the threat of Ebola and Marburg viruses. Our filovirus medical countermeasure advanced development program builds on NIH's and DoD's long-time basic and applied research and development on vaccine, therapeutic and diagnostic product candidates for these viruses and continues development in concert with them and other partners.

Ebola Therapeutics: In late FY 2014, BARDA began support for advanced development of Mapp Biopharmaceutical's monoclonal antibody therapeutic, ZMapp™, produced in tobacco plants to treat Ebola virus infections. This experimental drug was administered initially in 2014 under "compassionate use" to several people infected with the Ebola virus during the 2014 Ebola epidemic in West Africa. In FY 2015, a randomized controlled clinical trial began in West Africa and in the U.S. to evaluate the safety and efficacy of all candidate Ebola therapeutics, including ZMapp. Current efforts are focused on optimizing the manufacturing process, analytical assays for product lot release, developing clinical sample assays, and manufacturing clinical investigational lots of ZMapp for Phase III safety and efficacy clinical studies. NIAID began the Phase III studies in February 2015 in the U.S. and West Africa. BARDA continues to support the development and manufacturing of ZMapp using the Fill Finish Manufacturing Network to make final product for ongoing clinical studies towards FDA licensure. In addition, BARDA partnered with two manufacturers of tobacco-based pharmaceutical products to determine whether other tobacco expression systems could produce higher yields of ZMapp in their proprietary tobacco plant systems. These candidates are under evaluation in non-clinical animal studies supported under our Non-Clinical Studies Network.

BARDA also partnered with two large pharmaceutical companies, Genentech and Regeneron, to produce monoclonal antibody therapeutics in specialized mammalian cells using methods that manufacture greater quantities faster than tobacco-based technology. Both companies' antibody therapeutics showed promise in non-human primate studies undertaken in June 2015 with support from our Non-Clinical Studies Network.

Genentech developed and produced humanized-cell versions of ZMapp monoclonal antibodies under a research agreement with Mapp Biopharmaceuticals. Genentech expressed the antibodies in their specialized CHO mammalian cell line, a proven manufacturing platform for licensed monoclonal antibodies. In July 2015, BARDA issued a task order to the Emergent, as one of our Centers for Innovation and Advanced Development and Manufacturing (CIADM), to manufacture the Genentech Ebola monoclonal antibodies for further evaluation. Emergent will optimize the manufacturing process and scale-up to commercial scale.

Regeneron's monoclonal antibody therapeutic also showed efficacy equivalent to or greater than ZMapp in animal challenge studies. The drug was developed with ZMapp-like antibodies, as well as novel Ebola monoclonal antibodies, that are fully humanized and expressed at high levels in specialized CHO cells. Regeneron's product is slated to begin Phase 1 clinical studies in early 2016 with inclusion into NIAID's clinical trial in West Africa later in 2016. Further, BARDA partnered with BioCryst to support development of a small molecule antiviral drug candidate that has broad spectrum activity against viral hemorrhagic fever viruses. BARDA is supporting manufacturing efforts and non-clinical studies to support NIAID's Phase I clinical studies of this molecule and will support additional Phase 1 and 2 studies in 2016.

Successful development and evaluation of Ebola monoclonal antibodies in mammalian cells may ensure that a more efficient and robust manufacturing platform as compared to tobacco plants may be available to address future outbreaks and the PHEMCE requirement for therapeutic candidates against Ebola. If Ebola MCM products are shown to be safe and efficacious, BARDA may consider purchasing one or more therapeutic candidates in FY 2017 under Project BioShield pending the availability of funds.

Ebola Vaccines: In FY 2015, BARDA awarded contracts for advanced development and manufacturing of four Ebola vaccines: ChAd3 (GSK), rVSVΔG (Newlink/Merck), rVSVN4CT1 (Profectus), and Ad26/MVA (Janssen/Bavarian Nordic). These efforts include manufacturing clinical material, process improvements, scale-up to commercial scale, and development of more thermal stable formulations of the vaccines. Three of the vaccine candidates, the GSK, Newlink/Merck, and Janssen/Bavarian Nordic vaccines, are now in clinical trials in West Africa. The vaccines are being evaluated for safety and efficacy. The Clinical Studies Network and technical and clinical staff supported CDC's clinical study (STRIVE) to evaluate the Merck vaccine in Sierra Leone. BARDA continues to work with CDC to support this clinical study.

Results from a ring vaccination study conducted by the World Health Organization and other partners completed in 2015 in Guinea suggest that the Newlink/Merck vaccine candidate is promising. If shown to be safe and efficacious, one or more of the vaccine candidates may be considered for purchase for small stockpiles under Project BioShield in FY 2017. The Ebola response has highlighted the importance of and need for the core service assistance program that formed the National Medical Countermeasures Response Infrastructure. Based on experience gained in this response, BARDA is poised to respond to MERS-CoV and other emerging and infectious diseases.

Biodiagnostics: Since FY 2013, BARDA has supported development of a biodiagnostic platform technology to detect infection with biothreat pathogens, including laboratory and point of care diagnostics for anthrax, laboratory diagnostics for botulinum neurotoxin, and point-of-care diagnostics for detection of Ebola virus in blood and other bodily fluids. To support development of diagnostics, BARDA is investing in studies to identify host signs of infection (biomarkers) and behavior of these markers during the course of disease. Investigations are ongoing for Filovirus, Anthrax, *B. pseudomallei, B. mall*ei, and *Y. pestis*. One of the anthrax diagnostics should be at a sufficient stage of maturity to transition to Project BioShield in FY 2017. In FY 2016–2017, BARDA will continue to support advancing

the development of existing candidates and expand the portfolio as promising candidates are identified, subject to the availability of funds.

Radiological and Nuclear Threats: This program focuses on developing solutions for all aspects and injuries that may result from a radiological or nuclear event. The two major radiological threats or incidents that are addressed are Improvised Nuclear Devices (IND) and the Radiological Dispersal Devices (RDD). Radiation exposure injuries are complex by themselves, but with a nuclear blast these injuries will be combined with other types of injuries (such as trauma, blast, and thermal burn), and likely will require a multi-pronged approach to treatment amid resource and logistical challenges of a nuclear response. To fill this gap, BARDA has supported advanced research and development for over 35 product candidates since 2007 in collaboration with PHEMCE partners.

While a major challenge facing MCM development for radiological and nuclear threats is that novel candidate products are in early stages of development, over 20 products have transitioned from early development at NIH to advanced development at BARDA. This portfolio includes 11 MCM candidates that target several sub-syndromes of acute radiation syndrome, as well as traumatic injury that could result from IND denotation. In FY 2013, BARDA expanded its portfolio of products to include those for thermal and radiation burns and blood products. To help treat children and meet a PAHPA mandate to develop MCMs for at-risk individuals, BARDA is supporting the development of a pediatric-friendly formulation of Prussian Blue (a drug needed to remove ingested radionuclides).

In September 2013, BARDA repurposed commercially available products, leveraging commercial development efforts and distribution infrastructure to reduce tax payer costs and meet public health emergency needs. BARDA sponsored late-stage development and procurement of two products under Project BioShield: Neupogen made by Amgen and Leukine made by sanofi-aventis. These cytokine products are approved to treat neutropenia, a blood injury resulting from chemotherapeutic treatment of cancer patients. This effort resulted in Neupogen (G-CSF) receiving FDA approval in March 2015 to treat neutropenia resulting from acute exposure to ionizing radiation. Neupogen and Leukine stockpiles are maintained by the manufacturers and rotated through the commercial marketplace. The U.S. Government will have immediate access to the acquired doses when necessary through a vendor-managed inventory process, which will be exercised with the CDC/SNS in 2016. In 2015 FDA reviewed the dosage of Neupogen and determined that the appropriate dosage for the radiation indication required twice as much product as used in the oncology indication. Thus, the number of doses in the stockpile was effectively cut in half. BARDA plans to incrementally purchase more products over several years to restore our previous level of preparedness. Additional FDA approvals for similar generic products from other manufacturers may be available in future years, diversifying the market for cytokines and allowing for greater competition and cost-savings.

In FYs 2016–2017, BARDA will continue to develop promising candidates for acute radiation syndrome, decorporation, and blood products. BARDA anticipates more extensive use of the Non-Clinical Studies Network to continue natural history studies and efficacy assessments and to expand studies that may optimize currently available treatments and supportive care elements to treat acute radiation syndrome.

To address thermal burn injuries from a nuclear blast, BARDA takes a comprehensive approach not only to address the diverse medical needs of burn etiology but also to resolve treatment bottlenecks expected in a mass casualty incident. Work with burn surgeons helps to determine the types of new medical countermeasures needed to treat burn injuries effectively. By supporting MCMs with emergency and daily uses, BARDA may create a more sustainable market with products pre-positioned for care in mass casualty incidents.

BARDA's advanced research and development portfolio includes six candidate products for thermal burns; two are in clinical development. One of the products received a favorable review from the FDA, allowing the product to undergo Phase III studies ahead of schedule. Four of these products – enzymatic debridement therapy (NexoBrid), antimicrobial wound dressing (Silverlon), artificial skin replacement (StratGraft), and autograft cell-sparing therapy (ReCell) - were purchased in FY2015 under Project BioShield as part of a suite of thermal burn therapies and treatments to address the temporal needs for burn patient care and management. This immediately raised the level of our field care preparedness for burns injuries.

Biodosimetry: The amount of radiation an individual absorbs greatly affects the recommended course of treatment. Therefore, since 2010 BARDA has aggressively supported the development of biomarker assays and detection devices to measure the amount of radiation that a person has absorbed. To date, development of 11 biodosimetry device candidates, including biomarkers, assays, and point-of-care or high-throughput diagnostics has been undertaken. In FY 2015, BARDA continued to support five of the most promising candidates from this portfolio. All have shown biomarker feasibility, transitioned to an advanced stage of product development, and have acceptable instrumentation strategies (utilizing existing fielded products where possible). A couple of these products are nearing the end of development. Transitioning the successful candidates to the acquisition phase under Project BioShield is expected in FYs 2016–2018.

Chemical Threats: The lack of antidotes for exposure to chemical threats remains a major gap in 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 provided evidence that the drug, midazolam, could treat seizures associated with exposure to chemical agents, including seizures in children. In September 2013, BARDA awarded a contract under Project BioShield for late-stage development and procurement of midazolam to Meridian Medical Technologies (a Pfizer company). Funding supports ongoing clinical indications for status epilepticus and seizures resulting from exposure to chemical nerve agents in both adults and pediatrics. Midazolam has demonstrated superior efficacy as an anti-convulsive drug to diazepam, the anti-seizure drug currently in the Strategic National Stockpile CHEMPACKs and therefore will replace the diazepam currently in CHEMPACKs as diazepam expires. Midazolam is available at the same cost as diazepam but unlike diazepam, midazolam is available for pediatric populations in an auto-injector format.

To treat chemical burns, BARDA has sponsored development to repurpose a commercially available burn and wound dressing (Silverlon) since September 2013. 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

thermal burns caused by radiation (see above). 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.

BARDA expects to support advanced research and development of several new products to address the threat of chemical agents in FYs 2016–2017, as promising candidates are identified and based on the availability of funds.

Decontamination is also a medical countermeasure, and BARDA has supported studies to determine the most efficient way to remove chemical agents from the skin of exposed individuals. Data collected from demonstrations and clinical studies are being used as the foundation for experiments and additional studies needed to develop scientifically supported guidance for best practices in mass-casualty decontamination. This guidance is expected in FY 2016. Removal of chemical agents is the most effective way to mitigate the short- and long-term effects of exposure to these agents. Further, expansion of the decontamination program occurred in FY 2015 and will inform decontamination procedures under additional operational conditions.

Driving Product Innovation

In addition to the innovation that serves as the foundation for all of BARDA's programs, we pursue innovative programs that have broad implications for all emergency medical countermeasures. In this dynamic portfolio, promising technologies are evaluated and advanced through short-term (one to three years) contracts. Successful technologies may attract further support from other BARDA programs or from private sources. Beginning in FY 2010, BARDA supported eight innovation projects including development of new product sterility assays for influenza and other vaccines; optimization of high-production candidate vaccine virus seed strains for influenza, and establishment of a system for *in vitro* immunity testing with vaccines. These initiatives addressed specific technological gaps that were noted in both the 2010 PHEMCE Review and the President's Council of Advisors on Science and Technology (PCAST) report on Pandemic Influenza Vaccine Production.

BARDA also sponsored technologies that make the development and manufacturing pipeline faster, more efficient, and less expensive using standardized manufacturing platforms and templates. In FY 2012, one of the platform technology projects for vaccine manufacturing progressed from an innovation to an actual vaccine product candidate for anthrax under current development in our anthrax vaccine program. In FY 2012–2014, two new drug delivery technologies including jet injectors were added to the portfolio as other projects completed. BARDA prioritized radiation and nuclear MCM efforts to address specific technological needs and opportunities that may contribute to the success of our mission. In FY 2015, BARDA partnered with FDA to launch a Continuous Manufacturing Innovations initiative to facilitate development and adoption of continuous manufacturing technologies throughout the commercial sector to produce commercial pharmaceutical products and medical countermeasures. This initiative also will incorporate continuous manufacturing transformative technologies into BARDA's CIADMs as a core capability for small molecule drug manufacturing to address public health emergencies and drug shortages. BARDA began support in FY2015 for continuous manufacturing of an influenza antiviral drug candidate that was under development.

Funding History

Fiscal Year	*Amount*
FY 2013[7]	--
FY 2014[8]	$413,494,000
FY 2015	$473,000,000
FY 2016 Enacted	$511,700,000
FY 2017 PB	$511,700,000

Budget Request

The FY 2017 Request for Advanced Research and Development is $511,700,000, which is the same as the FY 2016 Enacted level. The Request supports the advanced development of the highest priority MCMs against all 13 threats identified by DHS and prioritized in the PHEMCE Strategy and Implementation Plan (2014). Specifically, ASPR requests funding for investments in new projects in the following programs, in addition to broad spectrum antimicrobials:

1. Clinical evaluation of next-generation anthrax vaccines;
2. Platform biodiagnostics devices to quantify the level of exposure to biological agents;
3. Existing antiviral drug and vaccine candidates against Ebola and Marburg viruses;
4. New candidate products for addressing the six illnesses resulting from injuries from radiological or nuclear events, including thermal burns; and
5. New antidotes for treatment of chemical agents (for example, mustard gas exposure).

Anthrax ($35 million): BARDA does not anticipate expanding the programs supporting development of rPA-based anthrax vaccines, viral vectored anthrax vaccines, or additional anthrax antitoxins, 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 later in 2015. In addition, BARDA anticipates transitioning at least one new anthrax vaccine and one new anthrax antitoxin to acquisition under Project BioShield in FYs 2016–2017. However, in alignment with the 2010 Medical Countermeasure Review, new starts may only occur if existing programs fail to meet milestones associated with safety or efficacy and are down-selected. New starts also may be limited even at the request level because, as successful programs move through the development pipeline, there is an increased cost associated with Phase II clinical studies, non-clinical studies beyond proof of concept, and scale-up of manufacturing moving toward potential procurement under Project BioShield. Funding provided in FYs 2016–2017 will see the clinical evaluation of existing, next-generation, anthrax vaccines to determine their safety and immunogenicity. If any of the vaccine candidates are shown to be safe and provide advantages of the currently, licensed vaccine, they may transition to acquisition under Project BioShield in FY 2018.

[7] BARDA activities in FY 2013 were supported by Project BioShield Special Reserve Fund balances, which consisted of a $5.6 billion appropriation available over 10 years: FYs 2004 – 2013 (P.L. 108 – 276).

[8] Includes the reduction of -$1,506,434 for the FY 2014 Secretary's Transfer.

Combating Antibiotic-Resistant Bacteria ($192 million): The request includes $107 million to support the CARB initiative, in addition to our BSA program ($85 million) , as a part of a Department-wide budget initiative. The CDC/SNS already has inexpensive antibiotics in the formulary, however, if resistance were to emerge or a resistant organism was used in an incident there would be a need for these novel or improved products. Development of these candidates is not meant to replace existing products but to augment a response in case of resistance. By having products available in hospital formularies with known efficacy against biothreat pathogens, a bridge in our operational response capability would be established to treat the initial wave of patients until mass dispensing of stockpiled antimicrobials could be established. Further, antimicrobial resistance complicates the response to any public health emergency. An influenza pandemic or detonation of a radiological device are examples where patient populations would be generated that are more readily susceptible to infections, increasing the possibility of the spread of drug resistant bacteria.

The broad spectrum antimicrobials program was initiated in 2010 and has grown to a portfolio of nine candidates supported under partnerships with six different pharmaceutical and biotechnology companies. The focus of the program is to develop novel or improved products to address biothreat pathogens while supporting commercial indications; making the products available on the commercial market and decreasing the need for the PHEMCE to stockpile these products. Funding for FY 2017 will continue to support development efforts for existing programs. There is the potential to transition one or more candidates to late-stage development and acquisition under Project BioShield in FY 2017. If this occurs, BARDA may be able to add an additional candidate to complement products already in development or initiated under the CARB initiative. Funds will be necessary to support non-clinical evaluation of candidates against biothreat pathogens and non-clinical, clinical, and manufacturing activities to support commercial indications and potential use of the candidates against biothreat pathogens.

During FY 2017, BARDA will continue to implement the *National Strategy for Combating Antibiotic-Resistant Bacteria* to transition and support new antimicrobials and vaccine and diagnostic platform candidates from early to advanced development for biothreat and public health pathogens, prioritizing those that address the greatest areas of unmet medical need. BARDA plans to utilize our OTA to build innovative public-private partnerships with pharmaceutical and biotech companies that stimulate the antimicrobial drug pipeline. BARDA will continue to invest in novel antibiotic candidates using new mechanisms of action (novel targets or novel chemistries) and improved existing classes of antibiotics with enhanced properties against drug resistance and other properties (i.e., aminoglycosides and other precedented classes). Further, investments will be made in non-traditional approaches including immunotherapies (monoclonal antibodies) targeting common bacterial targets, modulation of the microbiome, and immunomodulators that may down-regulate harmful responses associated with bacterial infections. These therapies may be used in high-risk persons entering long-term hospitalized settings.

BARDA anticipates that at least one award will be for a nontraditional antibacterial therapy (i.e., monoclonal antibody, microbiome modulation, etc.), in alignment with the CARB *National Strategy*. FY 2017 funding will also be used to increase BARDA's investment in AMR vaccines by making at least one

new award. Finally, BARDA anticipates FDA approval of eravacycline and solithromycin in FY 2017, a major milestone for this program.

The FY 2017 President's Budget request for BARDA supports the antimicrobial resistance biopharmaceutical accelerator, in alignment with the CARB *National Strategy* and *Action Plan*. The antimicrobial resistance biopharmaceutical accelerator, to be run in a joint collaboration between NIAID and BARDA, will bring together academic, early stage biotechnology companies, and product developers to rapidly and effectively advance novel and non-traditional antimicrobial therapies, preventative measures, and diagnostics from proof of concept to clinical development. The antimicrobial resistance biopharmaceutical accelerator will utilize OTA to form a flexible and collaborative novel public private partnership. Funds will be used to operationalize the antimicrobial resistance biopharmaceutical incubator within two years and begin work on specific projects.

***Viral Hemorrhagic Fever* (*$50 million*):** The world continues to respond to the Ebola public health emergency in West Africa with only early-stage development of Viral Hemorrhagic Fever MCMs. BARDA has assumed a leadership role in the continued development of vaccines, therapeutics, and diagnostics. Both vaccine and therapeutic candidates are currently being evaluated in clinical trials and additional support is necessary in FY 2017 to continue development of these candidates to address the PHEMCE requirement for countermeasures against viral hemorrhagic fever viruses. This funding level will support one vaccine and one therapeutic candidate as they approach sufficient maturity for potential transition to PBS.

Biodosimetry and Biodiagnostics ($40 million): FYs 2016–2018 will see a transition of biodosimetry devices, both point-of-care and high-throughput clinical lab devices, to acquisition under Project BioShield. Thus, funding under ARD for these programs will decrease in FY 2017, and BARDA will see expansion of the biodiagnostic portfolio; focusing on platform technologies that exist in clinical labs. In FY 2016, 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. BARDA is currently investing in development of anthrax diagnostics (laboratory and point-of-care), botulinum neurotoxin diagnostics (laboratory), and Ebola diagnostics (point-of-care). BARDA is also investing in studies to identify markers of infection and behavior of markers during the time course of disease in preparation for diagnostics development. Investigations are ongoing for filovirus, anthrax, *B. pseudomallei, B. malle*i, and *Y. pestis*. FY 2017 funds will be utilized to continue development of existing programs and provide for new starts if existing candidates are down selected due to failure to meet scientific milestones. BARDA anticipates that one of the anthrax diagnostics will be at a sufficient stage of development to transition to Project BioShield in FY 2017.

Acute Radiation Syndrome ($51 million): In FY 2016, BARDA will continue to support development of promising candidates for acute radiation syndrome, decorporation, and blood products; focusing on developing countermeasures to address the subsyndromes that appear first (hematopoietic then gastro-intestinal). This program anticipates more extensive use of the Non-Clinical Studies Network to continue natural history and efficacy assessments and to expand its use to studies to optimize the use of currently available treatments and supportive care elements to treatment acute radiation

syndrome. These activities would include end-user engagement. A major challenge that still faces radiological and nuclear MCM development is that many of the novel candidate products that could potentially transition to BARDA are in still in early stages of development. Thus, new starts will be limited to programs that have sufficiently progressed to advanced research and development and consideration for BARDA funding. FY 2017 funds will continue to support existing candidates; non-clinical, clinical, and manufacturing activities to support advancement of candidates for possible acquisition under Project BioShield in FY 2018.

Thermal Burns ($20 million): The thermal burn portfolio has progressed significantly, with candidates transitioning to acquisition under BioShield in FYs 2015–2016. Additional candidates are still under development that will address the remaining gaps in continuum of care for burn patients. This includes technologies that prevent the conversion of partial-thickness to full-thickness burns. The funding for FY 2017 is decreased, compared to FYs 2015–2016, based on the transition of programs to acquisition under BioShield and the decreased number of programs to support under advanced research and development. FY 2017 funds will support programs to address the remaining identified gaps and will only be considered for acquisition under BioShield once they have shown the ability to synergize with the existing countermeasures and provide a significant increase in the ability to provide clinical management of burn patients.

Chemical ($30 million): The chemical program currently has a limited number of candidates. Expansion of the existing decontamination program is planned for FYs 2015–2016 and will inform decontamination procedures under additional operational conditions. BARDA will emphasize supporting new candidate products under ARD to address the threat of chemical agents in FYs 2015–2016, as promising candidates are identified. However, there has been a dearth of programs that have transitioned from early-stage development. Given the need to have products available immediately and the limited number of programs progressing through the pipeline, in FYs 2016–2017 BARDA will evaluate already approved products for their efficacy against chemical agents. The President's Budget request for BARDA funds existing programs, programs that may be eligible for transition from PHEMCE partners and evaluation of already approved products for the efficacy to treat individuals exposed to chemical agents. FY 2017 funds will also be used to continue development of animal models to support evaluation of candidate products.

***Non-Clinical Studies Network - Animal Studies ($10 million*)**: BARDA's Non-Clinical Studies Network will 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 Acute Radiation Syndrome sub-syndromes including gastro-intestinal, skin, and lung and chemical agents. BARDA also anticipates that viral hemorrhagic fever models will need to be qualified as new candidate products come into BARDA's pipeline.

Innovation ($24 million): Funds will be used to support the Continuous Manufacturing Innovation initiative started in FY 2015 with FDA to facilitate the development of this transformative technology into pharmaceutical and biotechnology sectors and transfer into the CIADMs for small molecule drug

production. The President's Budget request for BARDA will fund at least two platform technology development projects for emerging infectious diseases that may be used as medical countermeasures. Also funding will ensure the seamless transfer of Continuous Manufacturing technology to least one of the CIADMs to produce a small molecule drug that is also a medical countermeasure.

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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
2.4.13: Increase the number of new Chemical, Biological, Radioactive, and Nuclear threats (CBRN) medical countermeasures under Emergency Use Authority (EUA) or licensed (Outcome)	FY 2015: • On the first component of the goal, BARDA achieved the target because FDA licensed an additional two CBRN MCMs in FY 2015: • Neupogen anti-neutropenia cytokine (Amgen) approved by for ARS treatment indication (March 2015); • AIG anthrax antitoxin (Emergent) approved by FDA for treatment of inhalation anthrax (March 2015). and, • For the EUAs for CBRN, BARDA achieved the target as an additional product (OraSure Ebola rapid diagnostic) was given EUA status by FDA in August 2015. • On the second component of the goal, BARDA previously surpassed the target because FDA has licensed eleven pandemic influenza MCMs cumulative 2010-2015. In addition, two new products were licensed. • Rapivab antiviral drug (BioCryst) for treatment of influenza (December 2014) • Cobas liat PCR system (Roche) for diagnostic detection of influenza A/B was CLIA-waived by FDA (September 2015).	CBRN Licensed=+2; EUA= +5. Pan Flu: Licensed=+2; EUA= +3.	Expected BLA and NDA approvals = 2 new (CBRN) Targets for Pandemic Influenza: Licensed= 1 new EUA.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
	• On the EUA component of the goal, BARDA has achieved the target of three cumulative pandemic influenza MCMs from 2010-2015 given EUA status by FDA. However, there were no additional products given this status in FY 2015. (Target Met)			
2.4.14 Provide technical assistance to medical countermeasure manufacturers through BARDA's core assistance programs in 4 areas. (Output)		For Non-Clinical Studies Network 4 projects; for Centers for Innovation in Advanced Development and Manufacturing 2 projects; for Fill and Finish Network 3 projects; and for Clinical Studies Network 1 project.	Additional new projects: NCSN = 5 new; CIADM = 2 new; FFMN = 2 new; CSN = 2 new	N/A

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Project BioShield

Budget Summary

(dollars in thousands)

Project BioShield	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**255,000**	**510,000**	**350,000**	**-160,000**
FTE	-	-	-	-

Authorizing Legislation:

Authorization ..... PAHPRA

Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

Disease outbreaks, including the recent Ebola epidemic in West Africa, and the increasing threat of chemical, biological, radiological and nuclear (CBRN) acts of terrorism continue to jeopardize national and international health security. Over the last decade, ASPR's commitment to advanced development, enhanced partnerships, and sustained investments made possible under Project BioShield (PBS), lead to 12 new drugs and vaccines — known collectively as medical countermeasures (MCM) – that are critical to prepare for and treat these disease hazards. The advances supported by Project BioShield continue to boost the nation's readiness to respond to the medical consequences of anthrax, botulism, smallpox, radiological and nuclear agents, and chemical threats. The medical countermeasure development pipeline for CBRN threats holds more promise today than ever before. ASPR's Biomedical Advanced Research and Development Authority (BARDA), with its proven track record, is uniquely positioned to make innovative progress in the procurement of future MCMs.

The *Project BioShield Act of 2004* (P.L. 108-276) provided specific authorities and long-term funding for late-stage development and procurement of CBRN MCMs. The law also provided the Federal Government with the power to quickly authorize the use of these experimental MCMs during public health emergencies. Project BioShield authorities were further amended by the *Pandemic and All-Hazards Preparedness Act* (PAHPA) of 2006 and the *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA).* Created by PAHPA, BARDA made unprecedented progress in developing and acquiring products necessary to protect health in CBRN incidents. To minimize lifecycle costs, BARDA pursues advanced development of product candidates, when possible, that also could have commercial uses. For example, products to treat injuries resulting from radiation during a nuclear blast may also help treat cancer patients or burn victims. Project BioShield allows BARDA to purchase promising experimental products for the Strategic National Stockpile that are sufficiently mature for utilization under Emergency Use Authorization issued by the U.S. Food and Drug Administration (FDA). Even after purchase, BARDA continues to support companies and the late-stage development of these product candidates towards FDA approval. Project BioShield funding is also utilized to replenish expiring

CBRN medical countermeasures in the SNS prior to FDA approval (e.g., IMVAMUNE smallpox vaccine) and post-approval in some instances (e.g., Raxibacumab anthrax antitoxin). In the latter case the exact timing of FDA approval, which is uncertain, and budget planning, which occurs several years in advance, required BARDA to purchase anthrax antitoxin to maintain preparedness levels.

From FYs 2004–2013, BARDA obligated $3.4 billion of the original $5.6 billion appropriated to the Special Reserve Fund (SRF) to purchase 12 novel CBRN MCMs under Project BioShield. Over the same period, BARDA used the remaining $2.2 billion in the SRF to establish a robust and formidable development pipeline of more than 85 CBRN MCMs. Since 2013, BARDA has invested new funding that was appropriated annually for Advanced Research and Development (ARD) as authorized under PAHPRA to successfully maintain and expand its development pipeline to more than 90 new and existing CBRN MCM candidates. This robust development pipeline raises the likelihood of success in meeting the diverse health needs of Americans during CBRN disasters.

Developing biopharmaceutical products routinely takes 10 to 15 years for FDA approval and commercial marketing. BARDA's expertise and strategic approach led five products from late-stage development to FDA approval in less than ten years with more to come. In FY 2013, FDA approved two anthrax antitoxin drugs, Raxibacumab® and HBAT® under the Animal Rule. In March 2015, FDA approved another anthrax antitoxin, Anthrasil® to treat inhalational anthrax. Also in March 2015, Filgrastim (Neupogen®) became the first FDA-approved product for treatment of blood illnesses associated with acute radiation syndrome. Neupogen® was previously approved to treat cancer patients undergoing certain types of therapy. Pediatric doses of the drug also are available for acute radiation syndrome. In November 2015, anthrax vaccine absorbed (BioThrax®) was approved by the FDA for a post-exposure prophylaxis (PEP) indication. BioThrax was previously approved for pre-exposure vaccination (GUP) and is now the only licensed anthrax vaccine that can address both pre- and post-exposure.

In the next few years, BARDA expects more companies to seek FDA regulatory approval for CBRN products. In FYs 2015–2016, at least three companies are expected to seek FDA approval of CBRN MCMs purchased through Project BioShield and developed under BARDA's ARD programs. In March 2015, Elusys submitted a Biological License Application (BLA) for their anthrax antitoxin, Anthim®. In addition, Emergent expects to receive a supplemental approval for their new manufacturing facility. Makers of two antimicrobial drugs are expected to submit new drug applications to FDA in 2016. In FYs 2017–2018, BARDA anticipates additional regulatory approval submissions for biodiagnostics, smallpox antivirals, a smallpox vaccine for at-risk individuals, and potentially for more new drugs to treat Acute Radiation Syndrome and exposure to chemical agents.

In FY 2014, BARDA replenished expiring stockpiles of existing anthrax antitoxins for inhalational anthrax and smallpox MVA vaccine for people with weakened immune systems, such as HIV and cancer patients. Our strategy was to maintain our biothreat preparedness levels with existing CBRN MCMs in light of the transition to an annual appropriation structure after the expiration of the Special Reserve Fund at the end of FY 2013.

In FY 2015, BARDA received the same funding level that was provided in FY 2014, $255 million. This funding level supported acquisition of four new and two existing medical countermeasures. The procurements were an enhanced smallpox vaccine for at-risk individuals, four new products to address

burn injuries resulting from a nuclear detonation and maintenance of the USG owned hyper-immune horses that produce the botulism antitoxins. Based on the successful development of CBRN MCMs in ARD programs, HHS will be prepared to acquire at least 4-6 new CBRN medical countermeasures under Project BioShield by the end of FY 2017 (would).

Below are potential CBRN MCM candidates that may be mature enough for consideration for purchase under Project BioShield in FYs 2016–2017.

- A new anthrax antitoxin to complement existing products in the Strategic National Stockpile and complete BARDA's strategy to develop anthrax antitoxins (FY 2016);
- A new smallpox antiviral with a different mechanism of action to the one currently being stockpiled. This will fulfill the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) requirement to have two smallpox antivirals in the stockpile (FY 2016);
- An enhanced smallpox vaccine for at-risk individuals fulfilling the PHEMCE requirement to transition to a more cost effective freeze-dried formulation of this vaccine with longer shelf life (Continue to replace the liquid-frozen formulation with freeze-dried in FY 2016);
- An anthrax vaccine with a new adjuvant that has been shown in clinical studies to provide protective immunity in only two doses (FY 2016);
- A new point-of-care bio dosimetry device to quantify the level of ionizing radiation exposure with additional high-throughput devices to be used in clinical labs (FYs 2017);
- Maintenance and expansion of anti-neutropenia cytokines to treat hematopoietic deficiencies associated with Acute Radiation Syndrome available under vendor management (FY 2016);
- A new biodiagnostic for anthrax and additional devices for other biothreat pathogens (FYs 2017);
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biothreats (FYs 2017); and
- Vaccines, therapeutics, and possibly diagnostics for the treatment of Ebola with the potential for some candidates to address multiple viral hemorrhagic fever viruses (FYs 2017).

In addition, full funding is essential for BARDA to work with sponsors to support Phase IV post-licensure or approval commitments as well as requirements set by FDA for licensing products under the Animal Rule, which uses animal testing when human clinical efficacy trials are considered unethical. These commitments include funding re-labeling activities for products stored in the Strategic National Stockpile to meet FDA labeling requirements as those products become approved or licensed and receive expiration dates.

Under the FY 2016 Omnibus appropriation, BARDA will receive $510 million for Project BioShield. With this funding, BARDA will accommodate high-priority procurements originally planned for FY2015 ($150 million), for new anthrax antitoxins and new smallpox antiviral drugs, which had been planned for FY 2016. Other CBRN MCM procurements ($360 million) that may be procured in FY2016 include new or enhanced vaccines for anthrax and smallpox and diagnostics and drugs for diagnosis and treatment of radiation-related illnesses, respectively.

Funding History

Fiscal Year	*Amount*
FY 2013[9]	--
FY 2014[10]	$254,074,360
FY 2015	$255,000,000
FY 2016 Enacted	$510,000,000
FY 2017 PB	$350,000,000

Budget Request

The FY 2017 Request for Project BioShield is $350,000,000, which is -$160 million below the FY 2016 enacted level. BARDA prioritizes its planned investments to ensure that the highest priority procurements are completed within this lower level of resources.

1. **New antimicrobial drugs to address biothreat pathogens ($135 million, 40,000–60,000 treatment courses):** At least one new antibiotic presently in BARDA's ARD program may be available to purchase under PBS. This antibiotic candidate may be able to replace existing antibiotics in the Strategic National Stockpile that have become obsolete due to antimicrobial drug resistance to one or more biothreats or high-priority public health pathogens. Any products will be maintained under vendor-managed inventory since there are commercial indications that will support this type of stockpiling;

2. **New Acute Radiation Syndrome MCM ($65 million, 5,000–10,000 treatment courses):** FY 2016 and FY 2017 will be used to increase the amount of G- and GM-CSF cytokine products in the SNS formulary to treat neutropenia resulting from exposure to ionizing radiation. A new formulation of G-CSF has been approved for the acute radiation syndrome. Neulasta, manufactured by Amgen, offers a simplified concepts of operations requiring only two administrations over fourteen days versus the current product, Neupogen, that requires daily administration over fourteen days;

3. **New biodiagnostic device and reagents for anthrax ($25 million):** This procurement addresses a major gap for diagnosing a large number of individuals who may have been exposed to anthrax after an incident. The only currently available diagnostic is offered by Laboratory Response Network and does not have the capacity to run the vast number of samples that would need processing after an anthrax incident. The new anthrax diagnostic would leverage existing devices in clinical laboratories (200–300 clinical laboratory platform upgrades to existing instruments and reagents);

4. **New high-throughput biodosimetry diagnostic ($50 million):** These new biodosimetry devices will complement the point-of-care diagnostic supported under BioShield in FY 2016 (100 – 200 units plus reagents). The funds will support late-stage development and acquisition of devices that will be used in clinical labs to verify actual level of exposure to ionizing radiation to better inform clinical care of patients; and,

[9] Project BioShield activities in FY 2013 were supported by Special Reserve Fund balances, which consisted of a $5.6 billion appropriation available over 10 years: FYs 2004 – 2013 (P.L. 108-276).

[10] Includes the reduction of -$925,640 for the FY 2014 Secretary's Transfer.

5. **New Ebola therapeutic and vaccine candidates ($75 million, 5,000–6,000 treatment courses of therapeutics and 150,000–200,000 doses of vaccine):** Funds will also support late-stage development and acquisition of products to partially address the PHEMCE requirement for Ebola. By FY 2017, data sets and manufacturing processes for these candidates are expected to meet PHEMCE product specific requirements, Project BioShield maturity levels, and FDA considerations for accessibility under EUA and thus considered for purchase under Project BioShield. Since the Department of Homeland Security issued a Material Threat Determination for VHF in 2006, the Department prioritized the development, procurement and stockpiling of these MCMs. Early research and development of these MCMs occurred at NIH and have been a key component to BARDA's portfolio since FY 2014, and therefore have been a part of Project BioShield's long-term procurement plans prior to the current outbreak in West Africa. The nature of this requested procurement (i.e., not in direct response to a specific emergency) aligns with the program's overall strategy. Additionally, the remaining PHSSEF Ebola emergency funding supporting a variety of other immediate Ebola-related and other emergency preparedness needs within the Department.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Office of Policy and Planning

Budget Summary

(dollars in thousands)

Office of Policy and Planning	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**14,877**	**14,877**	**14,877**	--
FTE	66	66	66	--

Authorizing Legislation:

FY 2017 Authorization.....PAHPRA

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

Program Description and Accomplishments

ASPR's plays a central role in enhancing national health security through development of coordinated and research-based policies. To accomplish this, ASPR advises the Secretary on policy options and approaches to support, strengthen, and sustain the nation's domestic and international public health and healthcare emergency preparedness and response capabilities. ASPR also 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, response, and recovery activities. ASPR's programs directly support HHS' strategic goals of strengthening healthcare; spurring scientific knowledge and innovation; and advancing the health, safety, and well-being of the American people. The ASPR Office of Policy and Planning (OPP) manages this critical work.

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 *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013* (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 gathered in the aftermath of disasters to promote resilience, health and wellbeing, and better inform response to future disasters. Additionally, OPP manages the National Preparedness and Response

Science Board. 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 quality emergency care, addresses the access and functional needs of at-risk individuals, behavioral health needs of disaster survivors and responders and, 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. OPP also supports U.S. Government efforts to strengthen biosafety and biosecurity and promote outreach and education.

Guiding National Health Security

OPP leads HHS and U.S. Government stakeholders to bolster policy and planning efforts that support the 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 healthcare, public health, human services, behavioral healthcare, and emergency management systems. The NHSS was submitted to Congress in December 2014. OPP leads HHS/ASPR efforts to engage governmental and non-governmental stakeholders to implement the change that is needed to ensure health security. OPP is establishing the National Health Security Coordinating Committees to ensure whole-of-government and cross-sector collaboration on implementation and to develop an annual leadership update to evaluate and report on progress.

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. To meet these objectives OPP leads several efforts, including those in the following areas:

- Review and recommendation of options to ensure the contents of the SNS take into account at-risk populations;
- Update and distribution of best practices on outreach, inclusion and support of individuals with access and functional needs before, during, and following a public health emergency; and
- HHS information distributed during public health emergencies is released and communicated effectively in multiple formats to support the needs of at-risk population.

OPP 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, the HHS Preparedness for Pregnant Women Working Group, the Preparedness Working Group for Healthy People 2020, and the Disaster Human Services Working Group represents ASPR on the Behavioral Health Coordinating Committee. OPP reports on ASPR's implementation and activities for the HHS' Language Access Plan, HHS' Action Plan to Reduce Racial and Ethnic Health Disparities, and the Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities.

Further, OPP implements the HHS Disaster Behavioral Health and Disaster Human Services Concepts of Operations during emergencies and facilitates policy development and service delivery improvement through the creation of tools, guidance, and resources through technical assistance. OPP also convenes federal stakeholders to provide a common operating picture regarding human service 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 and interagency partnerships to integrate health and wellness into national resilience initiatives and projects.

OPP produced a number of resource tools on resilience which are free and available to the public. These include an interactive on-line training entitled *"Building Workforce Resilience through the Practice of Psychological First Aid*," "*Cultural and Linguistic Competency for Disaster Planning and Crisis Response,"* and the publication, "*Disaster Response Guidance for Healthcare Providers: Identifying and Understanding the Healthcare Needs of Individuals Experiencing Homelessness".* OPP also contributed two chapters (available online) to the National Center for Disaster Medicine and Public Health "*Caring for Older Adults in Disasters: A Curriculum for Health Professionals.*"

Providing Global Leadership on Pandemic Influenza and Other Threats

In FY 2017, 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 and to support the implementation of Biological Weapons Convention —in particular, focusing on those with objectives related to the development of frameworks for the international deployment of laboratory samples, medical countermeasures and public health/medical personnel during emergencies.

In addition, OPP will continue to develop, assess, implement, and exercise policies to coordinate HHS-wide response to public health and medical emergencies with a domestic-international interface and to guide HHS international assistance efforts during these events. 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, among others.

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 reported to WHO 87 potential PHEICs and other IHR-obligated notifications. 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. 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, and is currently leading HHS efforts to update the HHS Pandemic Influenza Plan. 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

Recent incidents involving biological select agents and toxins have raised serious safety and security policy issues. OPP intensified and accelerated efforts to strengthen biosafety and biosecurity by examining ways to reinforce policies and practices through policy development and implementation of actions to enhance biosafety and biosecurity. OPP continues to develop and implement policies and conduct outreach related to the mitigation of risks posed by the misuse of life science research. OPP serves as chair of the Interagency Biorisk Management Working Group, which provides federal departments and agencies with a focused forum to coordinate and collaborate on mechanisms to strengthen research laboratory biorisk management. The Working Group also promotes outreach and education programs to inform scientists, biosafety professionals, institutional officials and the public on biorisk management through the Science, Safety, and Security program (http://www.phe.gov/s3/Pages/default.aspx). OPP also supports the Federal Experts Security Advisory Panel and other U.S. Government efforts to enhance biosafety and biosecurity. In addition, OPP supports a range of bilateral and multilateral international engagement efforts (e.g., collaboration with Canadian colleagues to advance biosafety, biosecurity, and pathogen security under the Beyond the Border initiative).

Coordinating Healthcare System 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. Using strategic policy initiatives, OPP encourages healthcare systems to be resilient, sustainable, and prepared. 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, and disaster and public health emergency healthcare preparedness. OPP evaluates policy and makes recommendations to enable health systems to have an appropriate response in alignment with the NHSS' goals, shares information with healthcare system leadership to support decision-making during incidents, and enhances the integration and effectiveness of the public health, healthcare, and emergency management systems. OPP engages in activities that promote wider use of interoperable electronic health records, improve access to emergency/unscheduled acute care, and works with federal partners to align programs in support of these goals. OPP collaborates with stakeholders to advance federal, state and local capacities to respond to disasters and public health emergencies. OPP supports healthcare delivery system reform objectives to improve patient outcomes

and lower costs through a leadership role in enhancing consumer awareness of hospital services and development of unscheduled acute care models.

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, healthcare, and emergency response systems. OPP also works to promote an emergency care system that is patient- and community-centered, integrated into the broader healthcare 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 broad representation from hospital and healthcare systems, behavioral healthcare providers, and human service organizations in order to better leverage expertise and capacity in resource-limited environments. OPP participates in a variety of workgroups and committees that support the coordination and execution of healthcare policies, including those for bystander care and community first-based first aid, long-term care preparedness, healthcare coalitions, private health insurance, acute care, and active shooters.

In response 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 healthcare system, providers, and healthcare workers are prepared to respond to Ebola and other serious communicable diseases. OPP coordinated ASPR and CDC's rapid release of resource materials guidance, training documents, and checklists to help ensure that all elements of the U.S. healthcare system had access to timely and accurate information that ranged from patient receiving and detection, use of personal protective equipment, and waste management and disposal. In continuing support of the aftermath and future preparations for Ebola virus outbreaks, OPP leads the congressionally mandated hospital reimbursement program for uncompensated costs and development of a nation-wide ambulance contract.

Other examples of OPP's continuing support of healthcare systems policy and programmatic issues include the following:

- Laying the foundation to establish a public-private partnership to obtain and share real-time situational awareness of the capacity, capabilities, and stress of healthcare resources throughout the nation;
- HHS emPOWER Map GIS tools and dataset analysis;
- Development of a multi-departmental data enclave to inform disaster research;
- A prescription medication preparedness initiative;
- Enhancement of an EMS health information exchange; and
- Support for community paramedicine mobile integrated healthcare initiatives.

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 the psychologically injured so as to relieve additional demand for services within emergency and hospital systems. In collaboration with CMS, OPP has utilized administrative and claims data to evaluate the impact of prolonged power outages on healthcare delivery, and individuals that rely on electricity-dependent medical equipment and healthcare services. This has been achieved by mapping this data for the purpose of sharing with state and local health department emergency planning and response teams. This tool, the emPOWER Map, is available at http://www.phe.gov/empowermap/Pages/default.aspx.

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 effectively using MCMs.

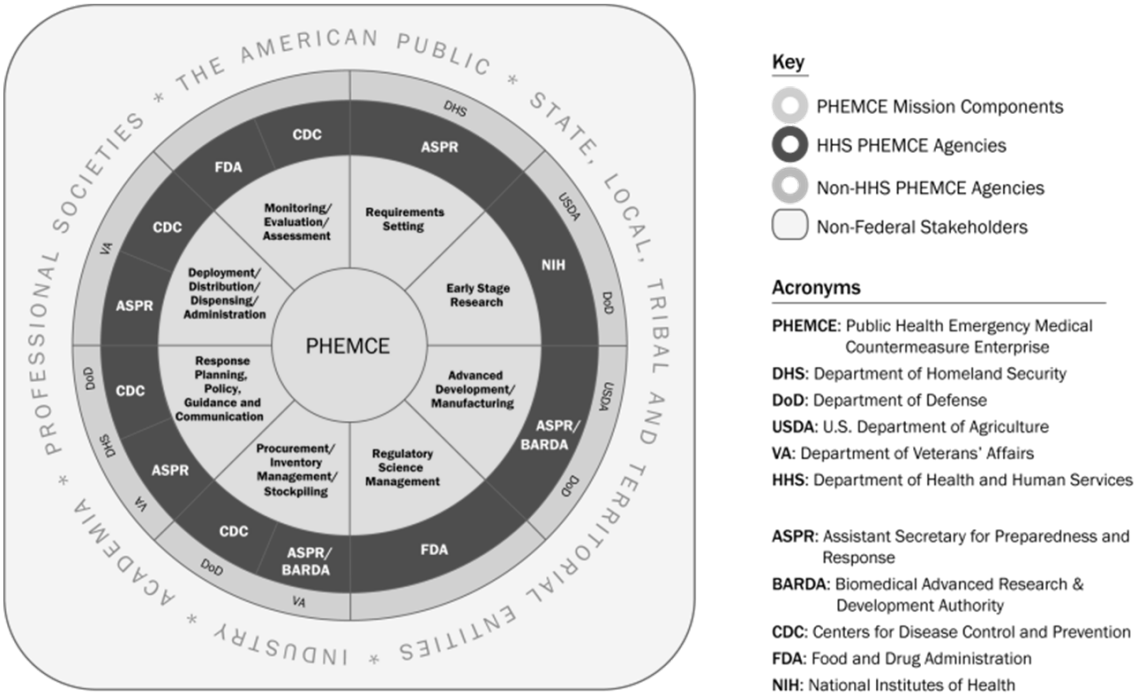
HHS implemented the PHEMCE governance structure in 2006 and revised it in 2011 to support coordination and collaborative decision-making of MCM efforts across federal departments. OPP implemented many of the governance recommendations arising from HHS' 2010 PHEMCE Review and continues to provide the 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. This in turn also helps to inform the development of the PHEMCE Multi-year Budget (MYB) that contributes to the achievement of the Strategy and Implementation goal to "Identify, create, develop, manufacture, and procure critical MCMS." The MYB, which is the five-year budget plan for research, development, procurement, and stockpiling of medical countermeasures, assists PHEMCE leaders to better anticipate, coordinate and understand the interdependencies among agencies. OPP works closely with subject-matter experts across the Federal Government to examine the current and targeted MCM preparedness levels and future resource allocation.

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 also co-leads with CDC the SNS Annual Review, 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) and served as the strategic reviewer to evaluate progress towards goal 3F. 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 managed with accountability. As required by PAHPRA, OPP has led the development of guidance for state and tribal entities to reassign public health personnel during a

public health emergency declared by the HHS Secretary to allow for the most efficient use of available human resources to respond to the emergency. OPP also supports HHS' efforts to establish the Health Resources Priority Allocation System as required by Executive Order to allow health resource contracts to be prioritized by HHS. Following the identification of lessons learned from the H1N1 influenza pandemic, OPP has identified and implemented activities to increase the speed and efficiency with which HHS, states, and local partners can secure, disburse, and manage emergency funds, especially in support of events that the *Stafford Act* does not apply. ASPR also 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. OPP currently is monitoring HHS' administrative preparedness in deploying resources to respond to the Ebola outbreak in West Africa, including emergency funding.

Finally, OPP 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 2013	$15,674,000
FY 2014	$14,877,000
FY 2015	$14,877,000
FY 2016 Enacted	$14,877,000
FY 2017 PB	$14,877,000

Budget Request

The FY 2017 Budget includes $14,877,000 for the Office of Policy and Planning (OPP), which is the same as FY 2016. The Request will support OPP's activities aligned with all six goals in ASPR's Strategic Plan.

In FY 2017, 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 publically in January 2015. Priorities include efforts to: better integrate healthcare 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 access and functional needs of at-risk individuals and behavioral health; build initiatives to exercise, measure, and report the ability to surge during a public health emergency or disaster; and promote solutions to barriers to forming healthcare coalitions. OPP 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 develop and implement policies for responding to public health and medical emergencies with a domestic-international interface and 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, and 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 provide leadership and oversight for the Federal Government's compliance with U.S. obligations under the International Health Regulations, and also will support core capacity development in partner countries under the framework of the IHR (2005) and the Global Health Security Agenda.

OPP will support efforts to strengthen biosafety and biosecurity. OPP participates in 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 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, and assess national preparedness against these needs through the preparedness assessment process and 2017 SNS Annual Review (FY 2020 Plan). PHEMCE-wide priorities established through these efforts will be reflected in both the 2017 PHEMCE Strategy and Implementation Plan (SIP) and in a re-examination of the PHEMCE strategic goals and objectives in preparation for 2018 PHEMCE SIP. OPP will work with the Analytic Decision Support function 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 will help determine the best methods for distributing and dispensing MCMs to the public.

Finally, OPP will contribute to building strong, sustainable, and resilient healthcare systems through policy evaluation and strategic initiatives that align with the NHSS's fourth goal, which is to enhance integration and effectiveness of the public health, healthcare, and emergency management systems. OPP will 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

Measure	Year and Most Recent Result/ Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
1 Establish and coordinate implementation of national strategies for public health and medical preparedness and response (Output)	FY 2015: NHS review completed and delivered to Congress in December 2014, with the 2015 - 2018 NHS Strategy and Implementation Plan. The Public Health Situational Awareness Implementation Plan has been completed and will be published before the end of FY 2015. Target: 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. (Target met) FY 2015: 2014 SNS Annual Review delivered to OMB, the National Security Staff, and Congress in September 2015. 2015 National Preparedness Report published in the spring of 2015, with significant HHS input. Work has commenced on the 2015 SNS Annual Review as well as the 2016 National Preparedness Report. Target: FY 2014 - OPP has published and is now implementing a number of strategy documents, including: The Public Health and Medical Situational Awareness Strategy (May	Continue the process of implementing and evaluating progress for the 2015-2018 NHSS, including the establishment of Strategic Guidance Committee structure and annual report on progress towards NHS.	Publish and implement the 2017 PHEMCE Strategy and Implementation Plan and use the results of the preparedness assessments to scope the re-examination of the PHEMCE strategic goals and objectives in preparation for 2018 PHEMCE SIP.	N/A

Measure	Year and Most Recent Result/ Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
	2014) as required by PAHPRA; ASPR's revised Strategic Plan; and The *National Preparedness Report* released annually by FEMA. OPP has published and is now implementing a number of strategy documents, including: 2010-14 National Health Security (NHS) Review and the 2015-18 NHS Strategy and Implementation Plan; and the National Preparedness Report released annually by FEMA. The 2013 SNS Annual Review Report (FY 2016 Plan) was provided on time to OMB and appropriate Congressional committees (August 2014). FY 2015: OPP has published and is now implementing the 2014 PHEMCE Strategy and Implementation Plan (February 2015). (Target Met) Provided Congress and the White House and publically released the 2015 PHEMCE Strategy and Implementation Plan (December 2015).			
2.4.9 Establish and improve awareness of the ASPR strategy for preparedness and response (Outcome)	FY 2015: Submitted to Congress on time the 2010-2014 National Health Security Review, the 2015-2018 NHSS and Implementation Plan. Also submitted to Congress the Public Health and Medical Situational Awareness	Deliver the Public Health and Medical Situational Awareness Strategy to Congress as required by PAHPRA. Publish the 2010-14 National Health Security Review for the 2009	Continue the process of implementation and evaluating progress for the 2015-2018 NHSS, including the establishment	N/A

Measure	Year and Most Recent Result/ Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
	Strategy. First meeting of Strategic Guidance Committee held in July 2015 and final Charter being reviewed. Working groups meeting to prioritize deliverables for the NHSS Implementation Plan. First meeting of Strategic Guidance Committee held in July 2015 and final Charter being reviewed. Target: Deliver the Public Health and Medical Situational Awareness Strategy to Congress as required by PAHPRA. Publish the 2010-14 National Health Security Review for the 2009 NHSS, the 2015-2018 NHSS and NHSS Implementation Plan. Publish the Public Health and Medical Situational Awareness Implementation Plan. (Target Met)	NHSS, the 2015-2018 NHSS and NHSS Implementation Plan. Publish the Public Health and Medical Situational Awareness Implementation Plan.	of a governance structure. To implement NHSS Strategic Objective 1: Build and Sustain Healthy, Resilient Communities, OPP will conduct stakeholder outreach, education and engagement to integrate the access and functional needs of at-risk individuals, promote disaster behavioral health, and build a culture of resilience by promoting community health resilience.	
12 Create an evidence base of research information gathered in the aftermath of disasters to promote resilience and better inform response to future disasters (Outcome)	FY 2015: OPP established the Hurricane Sandy dataset, which contains administrative claims data from CMS, FEMA, and HUD. OPP issued four Sandy dataset research awards for *ASPR Grants to Support Collaborative Scientific Research Related to Recovery from Hurricane Sandy.* ASPR continued to provide	FY 2016: OPP will maintain the ASPR Hurricane Sandy dataset for internal and grantee Hurricane Sandy related research studies. OPP will continue to provide programmatic oversight for all awards issued in the FYs 2013-2015 ASPR	ASPR Hurricane Sandy Recovery Science grantees will complete Sandy dataset- related research in FY 17. The grantees are expected to share dataset-related	

Measure	Year and Most Recent Result/ Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
	programmatic oversight for all awards issued in the FY 2013 - 2015 ASPR Sandy recovery Science grants program. Target: FY 2015 - OPP established the Hurricane Sandy dataset, which contains administrative claims data from CMS, FEMA, and HUD. (In Progress)	Sandy recovery Science grants program. Support the development of policy and operational frameworks and research infrastructure necessary to build and apply a scientific evidence base for measurements of recovery and resilience through operational programs, including ASPR's BARDA, Fusion, NDMS, and HPP.	research results with federal partners.	

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
Operations

Budget Summary

(dollars in thousands)

ASPR Operations	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	31,305	30,938	30,938	--
FTE	135	135	135	--

Authorizing Legislation:

Authorization ..... PAHPRA

Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

ASPR is committed to exemplary stewardship of public resources, the development of a world class workforce, quality improvement in all aspect of programmatic and management operations, and decisive leadership to ensure the nation's health security. In support of these objectives, 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)

COO administers organizational operations, including management of communications for the public and the media; 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 2017, 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, oversight and mission support to each program office within the Office of the Assistant Secretary for Preparedness and Response (ASPR). As the procuring authority for ASPR, AMCG fosters ASPR's mission through the awarding of contracts, grants, cooperative agreements and Other Transaction Authority agreements for ASPR. AMCG's largest program partner in meeting ASPR's mission is its support of the ASPR Biomedical Advanced Research and Development Authority (BARDA) and the Office of Emergency Management (OEM). AMCG provides functional mission support to include requirements analysis, operations development, consultation and collaboration in the development of the acquisition strategy, acquisition plans, and the tracking of milestones.

ASPR has established an acquisition architecture through the Office of Acquisitions Management, Contracts and Grants that enables responders to obtain the supplies and services as needed to effectively lead the public health and medical response to emergencies under Emergency Support Function-8. Through AMCG's Division of Acquisition Program Support, the implementation of a wide range of program management mechanisms is afforded to the Assistant Secretary, BARDA and OEM directly. This mission support includes the ASPR Acquisition Management System, which provides acquisition oversight, control tools such as "Decision Gate Process," event-driven In-Process Reviews, and Milestone Decision Reviews of applicable acquisitions. AMCG's bandwidth further supports the ASPR through the inclusion of Earned Value Management in accordance with the Federal Acquisition Regulation, auditing, cost and price analysis, and the development and execution of various acquisition-related training programs for the ASPR acquisition community. AMCG's Division of Grants is instrumental in assisting ASPR Office of Policy and Planning in answering the call to build community resilience through its management support of grants awarded by OEM's Hospital Preparedness Program. In this capacity the Division of Grants Management, supports general emergency response, the resolution of A-133 audit findings and grant policy which we promulgate as the Chief Grants Management Officer within ASPR on behalf of the Department.

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 course correcting 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 (PHEMCE), OFPA also has developed budget projections that help inform resource allocation for medical countermeasures. In FY 2015, OFPA coordinated the submission to Congress of the inaugural PHEMCE Multiyear Budget report for FYs 2014 – 2018. The report provided costs estimates for HHS PHEMCE partners at ASPR/BARDA, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration for activities related to the basic and advanced research and development, procurement, regulatory science and stockpiling of medical countermeasures for use against potential chemical, biological, radiological, nuclear and

emerging infectious disease threats. OFPA will continue this coordination role for subsequent Multiyear Budget reports, including those to be submitted in FY 2016 and FY 2017.

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 is activated as Emergency Support Function 8 under the National Response Framework, OFPA integrates with the Emergency Management Group 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. OFPA also coordinates ASPR requests to Congress for emergency supplemental appropriations when needed, including most recently in response to the Ebola epidemic in West Africa.

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 in support of the Department's implementation of Enterprise Risk Management (ERM). This includes promoting a risk aware culture; creating a comprehensive view of risks to drive strategic decisions; and establishing and communicating risk appetite. To this end, OFPA coordinates cross-disciplinary reviews of high-impact, high-visibility programs to identify risks that could impede the completion of the mission and to develop strategies for ensuring effective and efficient operations.

Funding History

Fiscal Year	*Amount*
FY 2013	$31,304,000
FY 2014	$31,305,000
FY 2015	$31,305,000
FY 2016 Enacted	$30,938,000
FY 2017 PB	$30,938,000

Budget Request

The FY 2017 Budget includes $30,938,000 for ASPR's Operations, which is the same as FY 2016. The Request is integral to achieving ASPR's goals and to the success of all of ASPR's activities. The Request supports: salaries for staff in IO, COO, AMCG, and OFPA; rent and service charges; equipment costs; travel; telecommunications; training; and continued implementation of acquisition management innovations, long-term fiscal planning, and 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 of 2013* and other relevant legislation.

ASPR Office of Operations - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
2.4.8 Improve strategic communications effectiveness. (Outcome)	FY 2015: 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) FY 2015: Expanded internal communications and messaging to stimulate organizational synergies. (Target met) Target: FY 2015 - 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) FY 2015: 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. Expanded internal communications and messaging to stimulate organizational synergies.	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.	Ensure strategic communications improvements with additional messaging/info-sharing capabilities during public health emergencies; Streamline organization web systems utilized for mission response; Increase internal communications to expand organizational synergies.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
	Target: 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. (Target Met)			
11 Attract and retain high quality staff ["high quality" defined as subject matter experts with medical countermeasure, response, or other ASPR specific expertise]. (Outcome)	FY 2015: Expanded training curriculums to promote strategic leadership, mentoring, and organizational/mission engagement. (Target met) Target: Expanded training curriculums to promote strategic leadership, mentoring, and organizational/mission engagement. (Target Met) FY 2015: Continue efforts to attract and retain high quality workforce through connections to the public sector, scholastic/ academic arena, as well as industry. Target: Continue efforts to attract and retain high quality workforce through connections to the public sector, scholastic/ academic arena, as well as industry. (In Progress)	Sustain recruitment efforts through an increased presence at industry specific events (attend 5 industry specific events) and public health preparedness and response mission based recruitment fairs.	Retool recruitment program to reach new sectors of quality talent using effective, strategic methods; Continue to expand the organization's leadership training academy-aspiring/emerging leaders, situational leadership, and executive training programs.	N/A

ASSISTANT SECRETARY FOR ADMINISTRATION

Cybersecurity

Budget Summary

(Dollars in Thousands)

StaffDiv name OCIO/Office of Information Security	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	41,125	50,860	50,860	0
FTE	76	123	139	16

Authorizing Legislation:

FY 2017 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 evidenced numerous times recently, as the cyber threats continue to multiply and become more complex, the need for enhanced controls and threat management strategies 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's 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. Based on the trends of these attacks, DHS and FBI have warned that healthcare has become a prime target of cyber criminals and state-supported actors and that healthcare providers' implementation of cybersecurity is lax compared to other sectors, such as the financial sector, making them vulnerable to attacks by hackers searching for Americans' personal medical records and health insurance data.

The Healthcare and Personal Health Sector (HPH) is seeing an increase in attacks because of its shift from paper to digital format, which creates the opportunity for hackers to obtain personal health information (PHI) records.

The 2015 Ponemon Institute Benchmark Study on Privacy and Security of Healthcare Data stated that data breaches could cost the healthcare industry approximately $6 billion. More than 90 percent of the healthcare industry respondents surveyed said they had lost data, and 40 percent had more than five data breaches within a two-year period. PHI is far more valuable to hackers on the black market than credit card numbers because it can be used to build a strong fake identity or even sold to criminals for insurance and billing scams. PHI contains social security numbers, insurance records, birth dates, family details, billing information, transactional history and a detailed medical history. In addition to medical identity theft, there is a serious health risk involved when a medical record is polluted or merged with someone else's medical prescriptions or lab procedures. There also exist serious risks in denying medical care for individuals if their insurance benefits and medical service billings are compromised by malicious attackers.

PHI is not recoverable, nor is the loss of privacy or reputation associated with such a compromise. This threat to the HPH sector is real to HHS, as HHS delivers a diverse set of mission to support the stability of the U.S. healthcare industry and serve the U.S. citizens by providing for effective health and human services and fostering advances in medicine, public health, and social services.

Outside of HHS's initiatives to increase its cybersecurity efforts, the Federal Government has also increased its focus on cybersecurity. The Federal CIO, Tony Scott stated that the entire Federal Government is under constant cyber-attack. In response, the Office of Management and Budget (OMB) launched a 30-day cybersecurity-focused inter-agency "CyberSprint" initiative in June, 2015. These activities demonstrate the level of importance the government is placing on cybersecurity and the scrutiny each Department and Agency is under as a result. OMB's clear expectation as a result of these Cyber Sprint activities is investment in cybersecurity both now and in the future, be that people or technology. OMB's published in July 2015 the initial Cybersecurity Strategy and Implementation Plan (CSIP) for the Federal Civilian Government, which will require HHS to engage in activities to further strengthen its Cybersecurity posture. The appropriate level of resources is critical in order for HHS to be able to comply with CSIP implementation and relevant government-wide initiatives to strengthen Cybersecurity measures. In addition, there exist multiple initiatives being discussed at the President's Management Council (PMC) and Federal CIO Council levels.

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) FY15-18 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 currently comprised of four sub-programs, Computer Security Incident Response Center (CSIRC), Trusted Internet Connection (TIC), Endpoint Security Tools and the 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 2017 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. The HHS CISO

continues to engage each OpDiv CISO and security team via multiple mechanisms, the most notable of which is the CISO Council. The CISO Council is comprised of CISOs and their alternates from each OpDiv and meets, at minimum, once a month to discuss key cybersecurity priorities, develop HHS-wide cybersecurity activities and programs, and communicate cybersecurity developments, issues and risks. Multiple cybersecurity-focused working groups are chartered from the CISO Council. These tend to be capability-specific (i.e., FISMA, policy, continuous diagnostics and mitigation (CDM)) and are made up of subject matter experts from each OpDiv. Each of these venues and activities are designed to ensure collaboration across the Department, foster remediation of risk based on lessons learned and best practices, and put in place stronger mechanisms and controls for facing increased cyber threats.

Trusted Internet Connection:

The Budget invests in engineering and monitoring support costs 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). The Department completed the cutover to TIC in FY 2015, which incorporates 100% of the OpDiv internet circuits into its infrastructure. HHS began migration of OpDiv Virtual Private Network (VPN) and cloud service connections in FY2015. HHS will continue migrating OpDiv VPN and cloud services to the TIC in FY2016 and through FY2017 as OpDiv requirements for this VPN and cloud services connectivity to the TIC are identified.

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 2017, the program will continue to procure 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 2015. 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 accredit a cloud service provider consistent with FedRAMP requirements. In FY 2013, HHS authorized both East/West and GovCloud environments from Amazon Web Services (AWS). In 2014, HHS authorized cloud service offerings from Verizon and Salesforce. In FY 2015, six separate cloud-based Adobe products were accredited by HHS. HHS has three cloud service providers in its queue and continues to work with other cloud service providers whose services support HHS' mission.

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 dollars 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 2013	$37,884,000
FY 2014[11]	$53,417,000
FY 2015	$41,125,000
FY 2016 Enacted	$50,860,000
FY 2017 Request	$50,860,000

Budget Request

The FY 2017 request for the HHS Cyber Security Program is $50,860,000, flat with FY 2016 enacted level and reflects the current landscape in which our adversaries are seeking breach our defenses and extract sensitive information. The protection of the HHS mission that delivers healthcare services to tens of millions of American citizen's remains a priority. Through FY17, HHS is seeking to increase its protections against cyber threats, such as unauthorized access, denial of service, malicious code, and inappropriate usage, insider threat, that pose risks to HHS critical functions, services, and data. Some key initiatives that HHS is undertaking to improve security are focused around improving efficiencies in security tools and deploying enterprise-wise tool solutions to improve HHS's correlation of cyber threat and vulnerability information for better situational awareness and response to actions that could exploit or jeopardize HHS information and to improve protection of HHS assets and endpoints that process and store the information. These efforts include not only purchasing the technology, but building the programs and skilled workforce to ensure these technologies meet HHS objectives to protect its mission and information while also facilitating HHS's compliance against federal mandates and guidelines.

The Budget Request will also 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.

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

	FY 2015	FY 2016 Enacted	FY 2017 Budget	Higher Level +/- FY 2016
CSIRC	$16,000,000	$26,400,000	$18,680,000	-$7,720,000
TIC	$2,600,000	$2,656,000	$2,756,000	+$100,000
Endpoint Security Tools	$4,300,000	$4,300,000	$9,052,800	+$4,752,800
FISMA	$18,225,000	$17,504,000	$20,371,200	+$2,867,200
Total	$41,125,000	$50,860,000	$50,860,000	$0

Computer Security Incident Response Center (CSIRC); and Security Incident Response & Situational Awareness ($18,680,000): The request is a decrease of $7,720,000 to FY 2016 enacted level. The decrease is as a result of the one-time funding of the Enterprise Log Management Tool in FY2016. Ongoing maintenance is included in the FY 2017 Budget and will enable the Department to expand the monitoring and analysis capabilities in order to sustain a very robust capability to defend against computer attacks, and also better detect and respond to cyber threats and incidents. 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 2017 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 2017 request will also allow for the ongoing operations support of CSIRC. OIS continues to partner 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) ($2,756,000): The request is $100,000 above FY 2016 enacted level. The increase in funding from FY 2016 is as a result of annualization of staff support. The FY 2017 request will also allow for the ongoing operations support of TIC.

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). The Department completed the cutover to TIC and 100% of the OpDiv internet circuits into its infrastructure.

Endpoint Protection Security Tools ($9,052,800): The request $4,752,800 above FY 2016 enacted level. The request allow expansion of the endpoint configuration, patching, inventory management and anti-malware capabilities in order to sustain a very robust capability to defend against computer attacks. 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. This FY 2017 Budget request 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 request also includes $3,500,000 for various Departmental Continuous Diagnostic and Monitoring (CDM) licenses previously paid (FY 2014 through FY2016) for by the Department of Homeland Security (DHS) CDM program. The licenses 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. In relation to CDM, 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 ($20,371,200): The request is $2,867,200 above FY 2016 enacted level. The additional resources requested in FY 2017 support the continued 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 including the maintenance costs for an Enterprise eGRC tool. 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 as well as strategic and thought leadership. 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 2016 Enacted Target	FY 2017 Budget Target	+/- FY 2016 Budget Target
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 2015 Target: 95.0% FY 2015 Actual: 94.0%	95.0%	95.0%	Maintain
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 2015 Target: 90.0% FY 2015 Actual: 76.0%	95.0%	95.0%	Increase
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 2015 Target: 95.0% FY 2015 Actual: 82.0%	95.0%	95.0%	Maintain
Boundary protection: What percent of the required TIC 2.0 Capabilities are implemented?	FY 2015 Target: 100.0% FY 2015 Actual 77.0%	100.0%	100.0%	Maintain
FISMA System Inventory Compliance: Percentage of systems with current Security Authorization to Operate (ATO).	FY 2015 Target: 95.0% FY 2015 Actual: 84.0%	95.0%	95.0%	Maintain

Office of Security and Strategic Information

Budget Summary
(Dollars in Thousands)

Office of Security and Strategic Information	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	7,470	7,470	7,470	0
FTE	33	33	33	0

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 analyzing 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, counterintelligence, insider threat, and cyber threat intelligence activities for the Department and these 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 Directorate, Counterintelligence Directorate, and Cyber Threat Intelligence Program within OSSI provide oversight policy guidance and manage the Department's programs for intelligence, counterintelligence, insider threat and Cyber Threat Intelligence 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, and coordination with federal agencies and partners via the Information Sharing Environment, as well as counterintelligence and cybersecurity initiatives. The Intelligence Directorate seeks to provide timely, appropriately-tailored, and relevant intelligence and other strategic (including law enforcement sensitive) information to inform HHS decision-makers and their programs on potential national security threats domestically and abroad. Intelligence/Information is used by HHS to anticipate and warn of emerging threats that may require the Department to adjust policy/programs, achieve global health

security goals, and support national security interests. Critical partners of the Intelligence Directorate include all OPDIVS/STAFFDIVS, the Intelligence Community, law enforcement, and others.

The HHS Directorate of Counterintelligence identifies, counters, mitigates, and deters exploitation of HHS personnel, information, assets, and other equities by foreign intelligence and security services and agents, terrorists, or transnational criminal organizations working under the direction of a foreign entity. HHS Counterintelligence includes, but is not limited to 1) counterintelligence inquiries and preliminary investigations, 2) national security incident investigations, 3) counterintelligence analysis, 4) insider threats detection and mitigation efforts, 5) counterintelligence and insider threat awareness, and 6) technical threat detection and mitigation. These six areas encompass efforts to investigate and resolve counterintelligence and national security allegations, identify and mitigate insider threats, conduct employee security training, sensitize employees to threats overseas, secure Department resources from foreign threats, and analyze foreign threats across the Department.

The Cyber Threat Intelligence Program (CTIP) has the responsibilities to establish implementing guidance, provide oversight and manage the Department's policy for the sharing, safeguarding, and coordinated exchange of cybersecurity intelligence/information and cyber threat intelligence/information related to national or homeland security. CTIP works closely with other federal departments and agencies, including law enforcement organizations and the Intelligence Community, to ensure the protection of both federal critical information and the health care sector. HHS OSSI Cyber Threat Intelligence includes, but is not limited to; assessing, anticipating, and warning of potential Cyber (intelligence, counterintelligence, and cybersecurity) threats to the Department and our national security.

Operational Environment

As the world leader for medical research, medical product and pharmaceutical regulation, the administrator for billions of program dollars supporting health and human services programs domestically and internationally, and the principal repository for personal medical and health related data, HHS is a primary target for physical attacks as well as cyber-attacks; theft of intellectual property, technical data or sensitive information from insider threats; and foreign intelligence services or actors. OSSI established a cadre of intelligence, counterintelligence and cyber threat intelligence professionals, to acquire, synthesize, and report on open source and classified information and assess its usefulness in supporting and furthering HHS missions. OSSI utilizes all-source classified and unclassified information from the Intelligence Community as well as Law Enforcement/Counterintelligence 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, counterintelligence, insider threat and cyber threat intelligence issues, including the sharing and safeguarding of national security information.

Funding History

Fiscal Year	*Amount*
FY 2013	$6,118,000
FY 2014	$6,118,000
FY 2015	$7,470,000
FY 2016 Enacted	$7,470,000
FY 2017 Budget	$7,470,000

Budget Request

The FY 2017 request for OSSI is $7,470,000, flat with the FY 2016 President's Budget request. This budget request will enable OSSI to maintain the operational requirements and responsibilities that have been assigned to OSSI as it relates to Intelligence, Counterintelligence, and Cyber Threat Intelligence. The request will support intelligence, counterintelligence and cyber threat intelligence programs which will result in OSSI fulfilling the numerous requirements in Executive Orders, Presidential Directives and other national security policies and procedures.

The intelligence, and counterintelligence, insider threat and cyber threat intelligence 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: 1) share "actionable" kinetic and cyber threat intelligence for both protection purposes, (i.e., force protection or cybersecurity mitigation), and senior leadership situational awareness; and 2) conduct counterintelligence inquiries and assessments to resolve allegations or suspicious activities by, or on behalf of, foreign entities.

Intelligence Directorate:
The Intelligence Directorate must be able to maintain its capability to provide timely, appropriately-tailored, and relevant intelligence and other strategic (including law enforcement sensitive) information to inform HHS decision-makers and their programs on potential national security threats domestically and abroad. Intelligence/Information is used by HHS to anticipate and warn of emerging threats that may require the department to adjust policy/programs; achieve global health security goals; and support national security interests.

Cyber Threat Intelligence Program:
CTIP must maintain and work closely with other federal departments and agencies, including law enforcement organizations and the intelligence community, to ensure the protection of both federal critical infrastructure, the health care sector and provide deterrence and mitigation strategies from cyber security threats.

System Maintenance/Upgrades:
OSSI must be able to maintain its classified systems and networks to share and receive national security information with the intelligence and law enforcement communities. These classified systems must meet the requirements of the Central Intelligence Agency and the Department of Homeland Security for continued use access by OSSI.

PANDEMIC INFLUENZA

Budget Summary

(dollars in thousands)

Pandemic Influenza	FY 2015 Final	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Budget Authority	**71,915**	**72,000**	**125,009**	**53,009**
ASPR No-year (non-add)	*39,906*	*40,000*	*111,000*	*71,000*
ASPR Annual (non-add)	*28,000*	*27,991*	*10,000*	*-17,991*
Office of Global Affairs Annual (non-add)	*4,009*	*4,009*	*4,009*	--
FTE	5	5	5	5

Authorizing Legislation:

Authorization ..... PAHPRA

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

Program Description and Accomplishments

Human cases of avian influenza in Asia and influenza outbreaks among chicken flocks in the United States continue to raise public concern about emerging infectious diseases. The public outcry over the lack of vaccines, diagnostics, and drugs for the Ebola epidemic in 2014 and for vaccines during the H1N1 influenza pandemic in 2009 demonstrates the immediacy with which American people expect their government to respond and protect public health from new infectious diseases. Influenza and other emerging infectious diseases with pandemic potential continue to mutate, evolve, and infect animals and humans, posing evolving threats to global public health and to the national health security of the United States. To meet public demand, protect health, and save lives in the next pandemic, the Federal Government must take action and maintain momentum to develop new medical countermeasures – vaccines, drugs, diagnostics and devices – so they are available immediately when needed. The Federal Government must also work domestically and internationally to establish and implement the policies, procedures, training, drills, and plans necessary for the nation to be resilient when faced with pandemics.

Strengthening Pandemic Influenza Preparedness

HHS has made significant progress in pandemic preparedness for our nation and with international partners. To identify and resolve barriers to meeting the need for medical countermeasures, HHS conducted an end-to-end review in 2010 of the Department's medical countermeasures enterprise. The resulting report, the *2010 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review,* along with the President's Council of Advisors on Science and Technology's *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* published in August 2010 and the PHEMCE's annual *Public Health Emergency Medical Countermeasure Enterprise Strategy and Implementation Plan*, guide development and procurement of medical products to combat pandemics.

Since 2005, HHS has:

- Developed new influenza vaccines using modern cell- and recombinant-based production technologies to expedite and expand production;
- Advanced the development of high-throughput rapid diagnostics capable of detecting influenza strains in hours rather than days;
- Developed and produced H5N1 and H7N9 vaccine seed strains so they are available to begin producing vaccine quickly;
- Developed and purchased bulk vaccine antigen (the component of vaccine that stimulates the human immune system) and new antigen-sparing adjuvants which can be used in vaccines to stimulate immunity and thus decrease the amount of antigen needed in each vaccine dose for the vaccine to be effective; and,
- Expanded the surge capacity of domestic manufacturing and increased its flexibility to help manufacture pandemic influenza vaccines as quickly as possible.

Also, HHS worked with partners to improve preparedness at the local, state, and international levels, including:

- Improving the technical knowledge and capacity for manufacturing in developing countries;
- Surveillance, research, and international collaboration on policies, plans, and training;
- Risk communication to improve public understanding of the steps individuals, businesses, and organizations can take to protect health from emerging infectious diseases including those with pandemic potential;
- The Food and Drug Administration's clearance of point-of-care clinical diagnostics and the agency's regulatory science base to speed the approval process for new products;
- Development and FDA approval of next-generation portable ventilators to increase availability of ventilators needed for a surge hospitalized patients in a pandemic; and,
- Stockpiling of ventilators and medical supplies, as well as vaccines, adjuvants, and antiviral drugs.

HHS investments have led to innovative technology advancements to meet the need for medical countermeasures as enumerated below:

- ***Cell-based influenza vaccines:*** In November 2012, FDA licensed Novartis' Flucelvax®, the first cell-based influenza vaccine commercially available in the United States, which became available for use for the 2014 influenza season. BARDA partnered with Novartis to build a state-of-the-art, domestic cell-based vaccine manufacturing facility that increased domestic pandemic influenza vaccine capacity by at least two-fold. The International Society for Pharmaceutical Engineering recognized the completed facility as the 2013 Best in Class for Process Innovation. The facility also was awarded Overall Winner for Best Pharmaceutical Facility in 2013 and was fully licensed for production and marketing of its cell-based seasonal influenza vaccine (Flucelvax®) by the FDA in 2014. These achievements marked a milestone toward one of the major vaccine goals in the National Strategy for Pandemic Influenza (2005), 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. Cell-based influenza vaccines were a major component of HHS' H7N9 vaccine response in 2013; the response included rapid vaccine development using new biosynthetic technology, manufacturing, clinical studies, and stockpiling.

Cell-based influenza vaccines have advantages over egg-based vaccines. The raw material supply is more reliable, and cell-based vaccines can be produced faster with scalable technology and more flexible manufacturing scheduling. With cell-based vaccine technology, the nation can produce a higher volume of vaccines in a shorter amount of time than with egg-based vaccine technology. For example, with BARDA support in 2013, Novartis developed and manufactured a cell-based influenza vaccine for H7N9 three to four weeks sooner than the egg-based H1N1 vaccine was produced in 2009. In addition, cell-based influenza vaccines may be more effective than egg-based vaccines because the cell-based vaccines are much closer in genetic and antigenic identity to circulating influenza viruses.

- ***Recombinant Vaccines:*** Recombinant-based influenza vaccines do not depend on the ability of the new influenza virus strain to grow in eggs or cells, or on the availability of eggs. Thus development and manufacturing of recombinant-based influenza vaccines is much faster in an outbreak or pandemic. Recombinant-based influenza vaccines were first developed, manufactured, and clinically tested in HHS' H7N9 vaccine response in 2013, and illustrated the rapidity and flexibility of this technology. In January 2013, FDA licensed Protein Sciences' FluBlØk®, the first recombinant-based vaccine for seasonal influenza licensed in the United States. In 2015, the product indication was extended from persons 18 to 50 year-olds to 18 years and above. BARDA has supported the development of this recombinant-based vaccine since 2009 for seasonal and pandemic influenza.

- ***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 became the first adjuvanted pandemic influenza vaccine licensed in the United States. BARDA has supported advanced development of multiple adjuvants displaying 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 in producing an immunogenic vaccine during our H7N9 vaccine response in 2013. In FY 2014, new support began for advanced development of a fourth pandemic influenza vaccine candidate using an oil-in-water emulsion adjuvant.

- ***Innovation in advanced development and manufacturing:*** In 2012, BARDA established three Centers of Innovation for Advanced Development and Manufacturing (CIADM) to overcome the vaccine manufacturing challenges experienced during the H1N1 pandemic. These Centers can provide advanced development and manufacturing assistance on a routine basis to medical countermeasure developers for CBRN threats. In 2013, one of the Centers (Novartis) developed and manufactured a cell-based pandemic influenza vaccine with adjuvant in response to the 2013 H7N9 avian influenza outbreaks in humans in China. In 2015, the Emergent CIADM initiated development and manufacturing projects for Ebola monoclonal antibody candidates. The CIADMs also will be available to manufacture pandemic influenza vaccine in an emergency, with one CIADM manufacturer able to produce at full capacity already and a second CIADM manufacturer coming online in 2017.

- ***Expedited vaccine availability:*** Under the Influenza Vaccine Manufacturing Improvement initiative led by BARDA since 2010 and in collaboration with academia and industry partners, HHS improved critical steps in the influenza vaccine manufacturing process in order to make influenza vaccines available sooner in a pandemic. Two important aspects of this effort are optimizing candidate vaccine viruses used to produce vaccine so the seed strains have a high-production yield

and developing alternative, novel assays for the potency and sterility of vaccines. Using synthetic biology and novel reverse genetics, influenza candidate vaccine seed strains — including H7N9 seeds — have been made available since 2012 in less than 10 days, compared to weeks using classical methods. Also new sterility assays developed under this initiative have shortened assay time from 14 to 5 days. Lastly, industry partners are evaluating alternative potency assays, such as enzyme-linked immunosorbent assay and mass spectrometric assays.

- ***Expanded domestic influenza vaccine manufacturing surge capacity:*** In 2004–2005, the U.S. was subject to a near-catastrophic failure of a major vaccine producer to manufacture seasonal influenza vaccine. This left the U.S. with a single domestic flu vaccine manufacturer and, therefore, vulnerable to vaccine shortages. To address this problem and ensure the U.S. was prepared for the large-scale production of pandemic influenza vaccine if needed, BARDA supported the retrofitting of domestic manufacturing facilities for two companies and a new set of public-private partnerships to expand U.S. vaccine production capacity. As a result, the vaccine manufacturing production capacity of live, attenuated influenza vaccine doubled, which enabled delivery of vaccine for the 2009 influenza pandemic. In 2012, the retrofitting of another vaccine production facility was completed with BARDA support, allowing for a nearly 50 percent increase in its influenza vaccine manufacturing capacity BARDA's partnership with Novartis led to the establishment and operation of the first cell-based influenza vaccine manufacturing facility resulting in a two-fold increase in domestic pandemic influenza vaccine manufacturing surge capacity. These improvements bring U.S. manufacturing surge capacity for pandemic influenza vaccines closer to the ultimate goal of providing two doses for everyone in the nation (approximately 600 million doses) within four months of pandemic onset.

- ***Providing new influenza antiviral drugs to treat critically ill populations:*** In severe pandemics, hundreds of thousands of people could be hospitalized with influenza. To improve preparedness, protect health and potentially save lives in a pandemic, BARDA supports the advanced development of antiviral drugs for critically-ill persons with influenza. These advanced development projects include influenza antiviral drugs with novel mechanisms of action and that have unique advantages, such as reduced risk of resistance, expanded treatment windows, and co-administration with other influenza antiviral drugs. In 2015, FDA approved Rapivab® (peramivir), which BARDA has supported since 2007, for the single-dose treatment of influenza in hospitalized settings.

- ***Increasing the supply of influenza antiviral drugs for the Strategic National Stockpile:*** HHS has fully met the requirement for federal stockpiling of antiviral drugs for use in a pandemic. The current national inventory of federal stockpiles of influenza antiviral drugs is over 60 million treatment courses. Additionally, a small federal stockpile of peramivir was established during the 2009 H1N1 pandemic to treat critically-ill persons under FDA Emergency Use Authorization.

- ***Simpler point-of-care diagnostics:*** In June 2012, FDA approved the breakthrough product Simplexa, a novel point-of-care diagnostic device and assay for commercial U.S. use to detect influenza and respiratory syncytial viruses. Simplexa uses a molecular biology technology called Polymerase Chain Reaction technology resulting in greater sensitivity than currently marketed diagnostic products and does not require complex sample preparation so the turnaround is faster than with current diagnostic products. The BARDA-supported diagnostic can detect influenza and respiratory syncytial viruses in clinical samples within one hour at the point-of-care, as opposed to the multi-day process required when sending samples to a state lab. Respiratory syncytial virus is the most common virus causing lung and airway infections in children.

- ***Enhancing global pandemic preparedness:*** Diseases do not respect national borders, making global pandemic preparedness fundamental in protecting the global economy as well as U.S. national health security. Led by ASPR and the HHS Office of Global Affairs (OGA), HHS international pandemic influenza programs focus on global health diplomacy. To support these programs, HHS continually coordinates with the White House National Security Council, the Department of State, and other federal departments and agencies, non-governmental organizations, and bilateral and multilateral partners on policy and technical issues surrounding global health security including influenza and countering biological threats. The HHS programs and approach have been so successful that HHS now plays a central leadership role in international influenza preparedness and response with the World Health Organization (WHO), other multi-lateral and international organizations (for example, the Asia-Pacific Economic Cooperation, the Association of Southeast Asian Nations, the Organization of Islamic Cooperation, and the Developing Country Vaccine Manufacturers Network), and with numerous foreign governments, particularly those of developing countries. HHS has leveraged every dollar in USG support with 7- to 24-fold more dollars from developing countries and other sources to build and operate vaccine manufacturing facilities, resulting in a vaccine manufacturing surge capacity of 330 million doses in 2015 in partner countries that made no influenza vaccines in 2005.

  HHS' collaborative efforts have led to significant improvements in global pandemic preparedness, including:

  - New or improved regulatory capacity in five developing countries (Indonesia, Mexico, Vietnam, Serbia, and Thailand) to ensure safety and effectiveness of influenza vaccine manufactured in those countries;
  - Strengthened diplomatic and political support for increasing the sustainable influenza vaccine manufacturing capacity in developing countries, which contributes to the global surge capacity for influenza vaccine manufacturing;
  - Documentation of progress being made in 42 developing countries in the knowledge, skills, and capacities for influenza surveillance, response, and preparedness – HHS supported development, piloting, and use of an evidence-based assessment and evaluation tool to collect longitudinal data in these countries; and
  - Leadership of the 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, the U.S. Department of State, the U.S. Agency for International Development (USAID), and WHO.

  - Strengthened diplomatic and political support for:
    - Increased global surge capacity for influenza vaccine manufacturing through increasing sustainable influenza vaccine manufacturing capacity in developing countries.
    - Ensuring USG policies enable continuous influenza and emerging disease surveillance and public health response worldwide.
    - Developing countries improving self-sustainability to provide surveillance, detection and response for influenza and emerging threats affecting their countries and region. OGA has directly supported efforts to leverage global political will to make global health security and influenza initiatives more sustainable. Examples include: African Vaccine Manufacturer's Initiative, support to Developing Country Vaccine

Manufactuerers Network, HHS/WHO Workshops and trainings, and facilitating support for IHR core capacity development.

- Provided HHS /OGA technical and policy analysis support to:
  - Lead logistical implementation of the USG/HHS donation of H1N1 pandemic influenza vaccine to WHO, in collaboration with ASPR/BARDA, vaccine manufacturers, international transport companies, U.S. Agency for International Development (USAID), Department of State (DOS), and WHO.
  - Other USG departments and agencies, including the DOS, Office of the U.S. Trade Representative, Department of Commerce, and the U.S. Patent and Trademarks Office for international negotiations on WHO's Pandemic Influenza Preparedness Framework for Influenza Virus Sample and Benefits Sharing
  - The National Security Council Staff and White House for policy options for donation of H1N1 pandemic vaccine from the U.S. to WHO, and for funding in response to the H7N9 Flash Appeal for Support for WHO.
  - Ensure policy coherence and program coordination across all HHS OPDIVs and STAFFDIVs engaged in global health security, particularly international influenza activities.
- Promoted global health security efforts and provided leadership for HHS in interactions with the White House, various USG Departments and Agencies, non-governmental organizations, and bilateral and multilateral partners on multiple inter-related policy issues for global health security.

Policy coherence and coordinated programs across all HHS OpDivs and StaffDivs engaged in global health security, particularly around international influenza activities.

Funding History

Fiscal Year	*Amount*
FY 2013[12]	--
FY 2014[13]	$114,606,000
FY 2015	$71,915,000
FY 2016 Enacted	$72,000,000
FY 2017 PB	$125,009,000

Budget Request

The FY 2017 Request for pandemic influenza activities is $125,009,000, which is +$53,009,000 above the FY 2016 enacted level. The Request includes $7 million in annual funding for international policy and diplomacy programs and $118 million for pandemic influenza medical countermeasure programs. Of the $118 million for medical countermeasures, $7 million is as annual ASPR/BARDA funding reserved for advanced research and development of rapid diagnostics. The Request includes $25 million to support the advanced development of a new kind of treatment for influenza: broadly reactive immunotherapeutics, including monoclonal antibodies and immune modulators. The Request also includes $20 million to develop, maintain and conduct clinical studies with the pre-pandemic influenza vaccine stockpile. Finally, ASPR requests $65 million to support the advanced development of vaccine

[12] Pandemic influenza medical countermeasure activities in FY 2013 were supported by balances of prior-year appropriations, including the FY 2006 Pandemic Influenza Supplemental (P.L. 109 – 148) and the FY 2009 Pandemic Influenza Supplemental (P.L. 111 – 32).
[13] Includes the reduction of -$402,926 for the FY 2014 Secretary's Transfer.

candidates that are expected to lead to more effective influenza vaccines, including potential universal influenza vaccines.

Annual Funding Requests for FY 2017 ($14,009,000):

Diagnostics Advanced Development ($7,000,000): Annual funding is requested for the advanced development of rapid and specific multiplexed diagnostic platforms for use in near-patient and point-of-care settings, such as physician's office laboratories or centralized laboratories BARDA also will evaluate the performance of influenza diagnostic tests available in the marketplace to ensure an appropriate quality-of-care and pandemic preparedness level is maintained. These funds also will partially support advanced development of an additional point-of-care or home-use diagnostic platform in FY 2017.

***Office of Policy and Planning International Influenza Activities ($3,000,000*)**: ASPR 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. ASPR also will coordinate international preparedness efforts to address pandemic influenza, emerging infectious diseases, and CBRN threats through the Global Health Security Initiative (G7 countries, Mexico, the European Commission, and WHO) and the Biological Weapons Convention (BWC). ASPR will complete the development and oversee the implementation and exercising of a) policy frameworks to guide the U.S. Government's provision and receipt of international assistance during public health and medical emergencies, and b) policy frameworks to coordinate HHS-wide response to public health and medical emergencies with a domestic-international interface. Furthermore, ASPR will continue to work with domestic and international stakeholders to identify and address legal, regulatory, and logistical barriers to the provision of international assistance, including serving as co-lead for the Global Health Security Agenda (GHSA)'s Medical Countermeasures and Personnel Deployment Action Package (GHSA Action Package Respond – 3). ASPR 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, including collaborations with domestic and international partners to support the development and strengthening of IHR core capacities.

OGA International Influenza Activities ($4,009,000): $4,009,000 is requested in Pandemic Influneza budget authority for the Office of Global Affairs to continue to provide leadership, technical expertise, oversight, policy and program coordination, and global health diplomacy in global health security, including pandemic preparedness and response.

Influenza viruses 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 U.S. The threat of a new pandemic has not decreased despite the 2009 H1N1 influenza pandemic and recent clusters of H7N9 influenza. 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 global health security threats. Areas of work will include expansion of medical, veterinary, and laboratory expertise and capacity abroad; strengthening of emerging disease 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 global health security and 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 2017 ($111 million):

Universal Influenza Vaccine Advanced Development ($65,000,000): BARDA requests $65 million to begin the initial stages of advanced development work for one vaccine candidate that may afford greater effectiveness against a diverse group of influenza virus strains or may serve as a "universal" influenza vaccine candidate affording cross-subtypic immunity. 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. The 2010 – 2011 discoveries of conserved regions on the influenza hemagglutinin protein, which may elicit cross-neutralizing antibodies, has led to the development of these new "universal" influenza vaccine candidates over the past two years. These vaccine candidates termed HA stalk vaccines protect animals challenged with different influenza A virus subtypes (i.e., H1N1, H3N2, H5N1, etc.). Development of one of these HA-stalk vaccine candidates will progress to advanced development in FY 2017. In addition, BARDA initiated one additional project in FY 2015 that supports the advanced development of oral, thermostable, adenovirus-vector influenza HA vaccine that elicits robust antibody and cellular immune responses. Advanced development for these vaccine candidates is more complex and challenging than traditional vaccine development due to the need for new production methods, measures of protection, assays and clinical study designs. The development and potential licensure of more effective, or universal, influenza vaccines will address the omnipresent need for a vaccine that may provide "influenza immunity for life" and transform our pandemic influenza preparedness readiness and response capabilities. The FY 2017 Request for universal influenza vaccine advanced development reflects the strategic transition of vaccine candidates in early development from NIAID to BARDA for advanced development with potentially more effectiveness and universal properties.

Advanced Development of Influenza Immunotherapeutics ($25,000,000): In the last three years, monoclonal antibodies have emerged as a new class of therapeutics for influenza with novel mechanisms of action compared to the current approved antivirals. These human monoclonal antibodies are broadly neutralizing across influenza A Group 1 and Group 2 strains and 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, which is a serious concern for existing small molecule antivirals. These monoclonal antibodies have demonstrated safety in humans and provide an expanded treatment window to allow for treatment later in the course of viral infection. Development of our initial monoclonal antibody candidate began in FY 2015 to meet a significant medical need for the treatment of the severely-ill hospitalized patients with influenza. Together with the planned addition of more immunotherapeutic candidates in FY 2016, this program should ultimately yield the approval of at least one monoclonal antibody immunotherapeutic candidate with broadly neutralizing activity for the treatment of critically-ill influenza patients in hospital settings. BARDA will provide partial funding for the advanced development of existing influenza immunotherapeutic candidates or for one new project in FY 2017 based on the funding requested by offerors. Funding to support existing candidates would also support the validation of the manufacturing process and pivotal Phase III clinical studies. These studies would evaluate the safety and efficacy of that immunotherapeutic monoclonal antibody candidate during an influenza season. If a new influenza immunotherapeutic candidate is added, then funds will support development of a robust and controlled manufacturing process for the new monoclonal antibody candidate and a Phase I clinical study.

Vaccine Stockpiling ($21,000,000): BARDA requests funding to support maintenance and development of the national pre-pandemic vaccine stockpile. Of approximately half of the funding requested, BARDA will support the storage, analytical and stability testing, and maintenance of existing H5N1, H7N9, and other influenza vaccines and adjuvants in the national pre-pandemic influenza vaccine stockpile for pandemic preparedness. This stockpile includes more than 200 million doses of bulk and filled H5N1 vaccine, over 40 million doses of H7N9 vaccine, 125 million doses of bulk and filled adjuvants, and ancillary supplies. These funds are required to maintain these stockpiles, which represent a total investment of more than $1.75 billion by the federal government, and to prepare for emerging pandemic threats. Of the remaining funding, BARDA will support novel influenza strain vaccine developments recommendations from the Pandemic and Seasonal Influenza Risk Management Group and replenish essential stockpiled bulk vaccines. This also serves to maintain the warm-base readiness of this national response capability. CDC, NIH, FDA, BARDA and other federal partners convene at the FRMM regularly to evaluate threats, consider options, and make recommendations related to the national pre-pandemic vaccine stockpile. At the requested level, BARDA will not conduct the needed clinical studies by BARDA's Clinical Study Network to assess prime-boost immunogenicity using vaccines of different clades and adjuvants stored in the stockpile.

Proposed Appropriations 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.

The FY 2017 Budget proposes modification of pandemic appropriations language 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.

ASPR Pandemic Influenza - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 Target +/- FY 2016 Target
2.4.15 Ensure a domestic pandemic influenza vaccine manufacturing surge capacity to produce at least 500 million vaccine doses within 6 months of the onset of an influenza pandemic. (Output)	FY 2016: Result Expected Sep 30, 2016 Target: Increased doses of vaccine to 500 million doses (In Progress)	Increased doses of vaccine to 500 million doses	575 million total doses	N/A

Budget Authority by Object Class

(Dollars in thousands)

	FY 2016 Budget	FY 2017 Budget	FY 2017 +/- FY 2016
Personnel compensation:			
Full-time permanent (11.1)	79,571	81,845	2,275
Other than full-time permanent (11.3)	-	-	-
Other personnel compensation (11.5)	-	-	-
Military personnel (11.7)	6,493	6,588	94
Special personnel services payments (11.8)	-	-	-
Subtotal personnel compensation	**86,064**	**88,433**	**2,369**
Civilian benefits (12.1)	31,662	31,702	39
Military benefits (12.2)	2,799	2,746	(52)
Benefits to former personnel (13.0)	-	-	-
Total Pay Costs	**120,525**	**122,881**	**2,356**
			-
Travel and transportation of persons (21.0)	6,049	5,917	(132)
Transportation of things (22.0)	512	496	(15)
Rental payments to GSA (23.1)	17,439	16,975	(464)
Communication, utilities, and misc. charges (23.3)	991	1,081	90
Printing and reproduction (24.0)	104	101	(3)
Other Contractual Services:			
Advisory and assistance services (25.1)	432,498	416,883	(15,615)
Other services (25.2)	34,669	27,743	(6,926)
Purchase of goods and services from government accounts (25.3)	111,225	108,451	(2,774)
Operation and maintenance of facilities (25.4)	4,045	3,935	(110)
Research and Development Contracts (25.5)	463,335	396,860	(66,475)
Medical care (25.6)	-	-	-
Operation and maintenance of equipment (25.7)	23,722	24,528	806
Subsistence and support of persons (25.8)	570	542	(29)
Subtotal Other Contractual Services	**1,093,063**	**1,007,251**	**(85,812)**
Supplies and materials (26.0)	1,548	1,539	(9)
Equipment (31.0)	537	512	(25)
Land and Structures (32.0)	18	17	(1)
Investments and Loans (33.0)	-	-	-
Grants, subsidies, and contributions (41.0)	315,173	302,656	(12,517)
Interest and dividends (43.0)	-	-	-
Refunds (44.0)	-	-	-
Total Non-Pay Costs	**1,412,434**	**1,308,236**	**(104,197)**
Total Budget Authority by Object Class	**1,532,958**	**1,431,117**	**(101,841)**

Salaries and Expenses

(Dollars in thousands)

	FY 2016 Enacted	FY 2017 Budget	FY 2017 +/- FY 2016
Personnel compensation:			
Full-time permanent (11.1).....	79,570.688	81,845.423	2,275
Other than full-time permanent (11.3).....	-	-	-
Other personnel compensation (11.5).....	-	-	-
Military personnel (11.7).....	6,493.242	6,587.562	94
Special personnel services payments (11.8).....	-	-	-
Subtotal personnel compensation.....	**86,063.930**	**88,432.985**	**2,369**
Civilian benefits (12.1).....	31,662.399	31,701.708	39
Military benefits (12.2).....	2,798.592	2,746.092	(53)
Benefits to former personnel (13.0).....	-	-	-
Total Pay Costs.....	**120,524.921**	**122,880.785**	**2,356**
			-
Travel and transportation of persons (21.0).....	6,049.00	5,926.740	(122)
Transportation of things (22.0).....	511.50	496.200	(15)
Rental payments to Others and GSA (23.2).....	17,438.50	16,862.290	(576)
Communication, utilities, and misc. charges (23.3)....	990.04	1,194.350	204
Printing and reproduction (24.0).....	103.50	100.500	(3)
Other Contractual Services:			
Advisory and assistance services (25.1).....	432,498.00	416,883.060	(15,615)
Other services (25.2).....	34,680.00	27,743.000	(6,937)
Purchase of goods and services from			-
government accounts (25.3).....	111,225.00	108,451.000	(2,774)
Operation and maintenance of facilities (25.4).....	4,005.00	3,885.000	(120)
Research and Development Contracts (25.5).....	463,335.00	396,860.470	(66,475)
Medical care (25.6).....	-	-	-
Operation and maintenance of equipment (25.7).....	23,791.59	24,608.000	816
Subsistence and support of persons (25.8).....	570.00	541.500	(29)
Subtotal Other Contractual Services.....	**1,070,104.59**	**984,972.030**	**(85,133)**
			-
Supplies and materials (26.0).....	1,548.00	1,539.000	(9)
Equipment (31.0).....	497.00	472.150	(25)
Land and Structures (32.0)	18.00	17.100	(1)
Grants, subsidies, and contributions (41.0).....	315,173.00	302,656.350	(12,517)
Total Non-Pay Costs.....	**1,412,433.13**	**1,308,236.71**	**(98,196)**
Total Salary and Expense.....	**1,532,958**	**1,431,117**	**(101,841)**
Direct FTE.....	773	789	16

Detail of Full Time Equivalents (FTE)

	2015 Actual Civilian	2015 Actual Military	2015 Actual Total	2016 Est. Civilian	2016 Est. Military	2016 Est. Total	2017 Est. Civilian	2017 Est. Military	2017 Est. Total
ASPR									
Direct:.....	535	72	607	540	72	612	540	72	612
Reimbursable:.....	--	--	--			--			--
Total:.....	**535**	**72**	**607**	**540**	**72**	**612**	**540**	**72**	**612**
Cyber Security									
Direct:.....	77		77	123		123	139		139
Reimbursable:.....									
Total:.....	**77**	**--**	**77**	**123**	**--**	**123**	**139**	**--**	**139**
Office of Security and Strategic Information									
Direct:.....	19	1	20	31	2	33	31	2	33
Reimbursable:.....	--	--	--	--	--	--	--	--	--
Total:.....	**19**	**1**	**20**	**31**	**2**	**33**	**31**	**2**	**33**
Office of Global Affairs Pandemic Influenza									
Direct:.....	4	1	5	4	1	5	4	1	5
Reimbursable:.....									
Total:.....	**4**	**1**	**5**	**4**	**1**	**5**	**4**	**1**	**5**
OPDIV FTE Total.....	**635**	**74**	**709**	**698**	**75**	**773**	**714**	**75**	**789**

Detail of Positions

	2015 Actual	2016 Base	2017 Budget
Executive level I	0	0	0
Executive level II.....	10	29	29
Executive level III	1	1	1
Executive level IV.....	0	0	0
Executive level V.....	1	1	1
Total - Exec. Level Salaries	**12**	**31**	**31**
ES-6.....	1	1	1
ES-5.....	0	0	0
ES-4.....	0	0	0
ES-3.....	161,460	166,304	171,293
ES-2.....	0	0	0
ES-1.....	0	0	0
Total - ES Salary	**161,461**	**166,305**	**171,294**
GS-15.....	127	151	149
GS-14.....	200	229	233
GS-13.....	116	160	164
GS-12.....	69	81	88
GS-11.....	50	38	41
GS-10.....	1	2	2
GS-9.....	23	27	27
GS-8.....	2	2	2
GS-7.....	16	15	15
GS-6.....	33	20	20
GS-5.....	30	22	22
GS-4.....	14	14	14
GS-3.....	24	8	8
GS-2.....	0	0	0
GS-1.....	0	0	0
Total - GS Salary	**705**	**769**	**785**
Average ES level	ES II	ES II	ES II
Average ES salary.....	133,646	144,731	147,526
Average GS grade.....	52	13	13
Average GS salary.....	129,001	122,289	122,448
Average Special Pay categories	49,383	46,061	46,061

SIGNIFICANT ITEMS FOR INCLUSION IN THE FY 2016 CONGRESSIONAL JUSTIFICATION

SIGNIFICANT ITEM

Committee requests more detailed information in the FY 2017 CJ on how State HPP funding is distributed at the local level. ASPR is encouraged to require States to report how much Federal HPP funding is being allocated to local health departments and what basis or formula each state is using to make such allocations.

RESPONSE

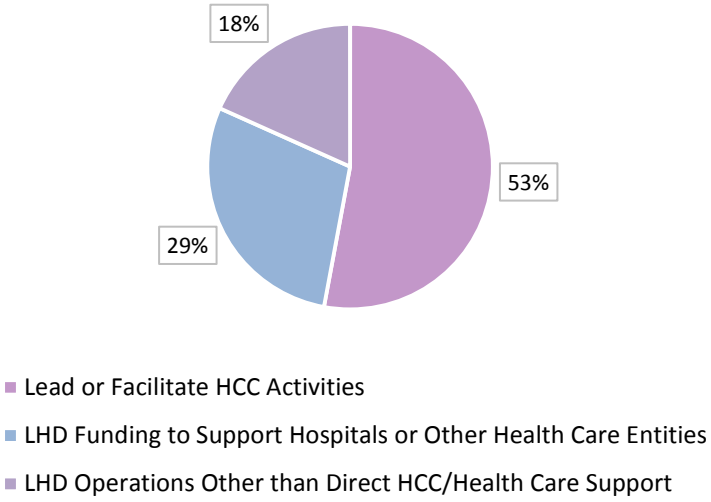
The Hospital Preparedness Program (HPP) annually provides funding through cooperative agreements to the public health departments in all 50 states, the District of Columbia, Chicago, Los Angeles County, New York City, and all U.S. territories and freely-associated states. Through HPP grant guidance, awardees then distribute approximately 75 percent of their annual funding to facilitate development, maintenance, and reinforcement of health care system preparedness capabilities, to build state, local, and regional preparedness, and to support health care entities.

HPP enables the health care system to save lives during emergencies that exceed the day-to-day capacity of the health and emergency response systems. Since 2012, HPP has focused on the formation and support of health care coalitions (HCCs). An HCC is a group of health care and public health organizations, including for example 83 percent of all hospitals and 67 percent of all local health departments (LHDs) in the U.S., which come together, leverage resources, and address challenges in health care delivery brought on by public health and medical incidents. Each stakeholder facility/agency must optimize medical surge capacity and resilience planning in order to maximize the potential of the coalition as a whole to effectively prepare for and respond to disasters. There are approximately 24,000 HCC members across the country in approximately 500 HCCs.

For FY 2015, which corresponds to HPP's current budget period from July 2015 to June 2016, twenty-eight (28) HPP awardees (including the three directly-funded municipalities and the District of Columbia) provide funding to local health departments. This represents a mix of centralized and decentralized state health departments (four of the state awardees have a centralized structure, which means that local health departments are primarily run by state agency employees, 14 of the awardees have a decentralized structure, and the remaining awardees have a shared or mixed structure[14]). In terms of funding, $43,575,319 or 18 percent of HPP's appropriated resources in FY 2015 are going to LHDs. It is important to note that because HPP is focused on the preparing the health care system rather than the public health enterprise, funding provided at the local level is primarily allocated to health care coalitions or health care facilities rather than local health departments. There is variation in the particular activities that LHDs undertake to benefit health care system preparedness and response, but these activities can be broadly sorted into three categories (see figure 1): (1) leading or facilitating health care coalitions; (2) supporting hospitals or other health care entities such as EMS; or (3) other contributions to the LHD's operations specific to preparedness, such as infrastructure planning and training, administrative support functions, or to support the local Medical Reserve Corps unit.

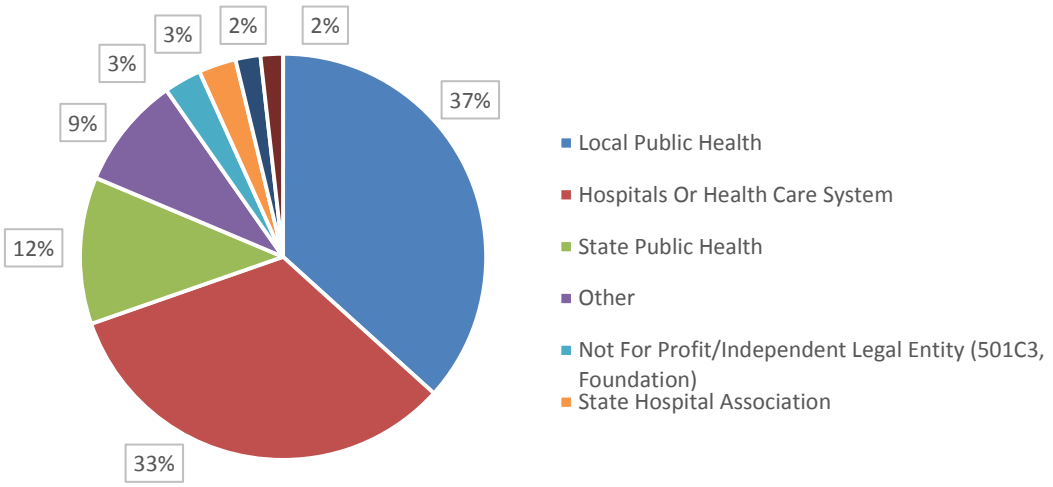
[14] ASTHO Profile of State Public Health, Volume Three, http://www.astho.org/Profile/Volume-Three/, accessed Jan. 6, 2016.

Figure 6. Activity breakdown for local health department funding



Beyond being active members of HCCs, LHDs also play a significant role as leaders of HCCs across the U.S. HCCs can be incorporated as nonprofit organizations or be led by one of its members (e.g., the LHD, a hospital association, or a leading health facility). As seen in figure 2, 37 percent of the approximately 500 HCCs across the U.S. are led by LHDs. The lead organizations of HCCs convene the members, are fiduciary agents, plan and execute HCC-wide drills and exercises, and maintain HCCs in order to enhance the sharing of information and resources, and the movement of patients across a defined geographic region. As a result, local disaster preparedness improves because health facilities within an HCC can share the burden of patients and disaster victims, which prevents any single facility or geographic area from becoming overwhelmed and unable to provide an adequate conventional standard of care.

Figure 7. Type of organization that leads HCCs



For the distribution of appropriated funding, HPP uses a base + population + risk formula derived from section 319C-2 of the Public Health Service Act. Over half of HPP awardees (n = 33) use a formula to further distribute funds to their subawardees (e.g., hospitals, HCCs, and/or LHDs). The most common distribution formula uses a base, adds a population supplement, and then calculates the number of hospital beds available by the entity (county-wide, city-wide, coalition-wide, or facility-wide as appropriate) as a calculation of risk for needing to care for a patient during an emergency or disaster.

The definition of hospital beds available for this calculation varies, but commonly counts emergency department beds, total staffed beds, all organizational beds, or a combination.

HPP awardees that do not use a formula distribution for subawards allocate funding based on state or local initiatives, or provide funding equally to all HCCs or all hospitals in their jurisdiction. Funding to hospitals and other health care facilities is provided either directly by the HPP awardee or via HCCs. When awardees directly fund hospitals, they require that the funding is used for regional level planning and participation in exercises that include other coalition members.

SIGNIFICANT ITEM

Committee directs BARDA and CDC to develop a process to coordinate the ongoing stockpiling of medical countermeasures in order to maintain adequate supplies of approved and purchased countermeasures. The coordination is important as products transition from the advanced research and development phase, where procurement is controlled by BARDA, to approval phase, where procurement responsibility shifts to CDC. The Committee requests an update on this stockpiling coordination process between BARDA and CDC in the FY 2017 budget request. The Committee further expects CDC and BARDA leadership to coordinate on the spend plan for the CDC SNS funds as part of the improved process.

RESPONSE

The Strategic National Stockpile (SNS) Annual Review process 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. Consistent with section 2811 of the PHS Act, the HHS Secretary has implemented a five-year budget planning process across the HHS components of the PHEMCE, including BARDA and the CDC, in order to achieve closer coordination and prioritization of investments in public health emergency preparedness that will be tied to the framework provided by the annual PHEMCE Strategy and Implementation Plan. Given currently existing resources from the federal to the State, Local, Territorial, and Tribal levels and the existing public health infrastructure challenges, the PHEMCE will continue to assess risks and establish and communicate clear priorities, seek multi-use solutions wherever possible, and work to develop innovative MCM development, manufacturing, stockpiling, and fielding alternatives. This budget process is being used to more tightly link investments across NIH, ASPR, CDC, and FDA, including SNS procurement and replacement responsibilities transitioning from BARDA to the CDC. In this way, we project future budget needs within and among agencies as MCM products mature and move across agency boundaries in the development and procurement processes.

SIGNIFICANT ITEM

BARDA is directed to work closely with CDC and NIAID on the government-wide antibiotic resistance activity. The Committee provided support in NIAID and CDC and directs these organizations to jointly work with BARDA on coordinated goals, measureable objectives, and funding plans to spur research and development on AbR, build AbR laboratory capacity in States and best leverage the funds provided support for evidence based public health activities in States on the government wide effort. The Committee requests an update in the FY 2017 budget request on joint BARDA, NIAID and CDC goals and measureable objectives to ensure the best leveraging of the funds provided to CDC and NIAID on this effort.

RESPONSE

ASPR, through its component office BARDA, will collaborate with NIH and CDC to transition new antimicrobial drug and diagnostic candidates from early development into advanced development. Both traditional antibiotics and non-traditional methods including vaccines, microbiomes, and phage therapies will be explored. Additionally NIH and ASPR will invest in a Strategic Accelerator to help facilitate new antibiotic approaches from lab bench into the development pipeline to address antibiotic resistance. Lastly NIH and ASPR are co-sponsoring a prize for the development of new transformative diagnostics to detect rapidly antibiotic-resistant pathogens.