DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2018

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committee

CONTENTS

We are pleased to present the Fiscal Year (FY) 2018 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2018 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 2018 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 before an event 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 disasters strike, ASPR assists state and local governments with public health and medical response, helping communities recover quickly and become healthier and more resilient.

The sudden emergence of infectious diseases that can cause a major impact on health results in an immediate expectation by the public for access to vaccines, diagnostics, and drugs, as was seen during the 2009 H1N1 pandemic and the 2013 Ebola virus epidemic in Africa. The American people expect their government to respond to, and protect public health from, new infectious diseases, however the reality of having these products readily available depends on long-range investment in time and funding for the research and development and procurement of these specialized products. To meet this public demand, protect health, and save lives in the next pandemic or disease epidemic, the federal government must continue to take action and maintain the momentum to develop new medical countermeasures – vaccines, drugs, diagnostics, and devices – so they are available immediately when needed. It must also guide work domestically and internationally to establish and implement the policies, procedures, training, drills, and plans necessary for the needed resiliency to prevent of control these 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 successfully led to novel capability and 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 to combat both long-standing threats and newly emerging ones.

ASPR's advanced research and development program bridges gaps in national preparedness that no other federal agency addresses: 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 2017, is responding to a new variant of that virus now causing morbidity and mortality 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 worked with partners to develop and evaluate MERS-CoV therapeutic candidates in Saudi Arabia. The response to Zika virus in the Western Hemisphere has been equally robust, with the development in record time of diagnostic assays to screen blood supplies, to inform clinical decision-making and to provide public health capability for surveillance. In addition, rapid development of new vaccines has progressed, in the course of a single year, from not a single candidate to a wide variety of vaccine approaches, many of which are now in clinical trials.

The reality of antibiotic-resistant bacteria affects this 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. It recently launched a new Accelerator program for new classes and approaches to treat these resistant bacteria, partnering with other major donors, such as the Wellcome Trust, thus leveraging funding and opportunities to increase the likelihood of breakthroughs.

Since 2006, ASPR has led America's progress in public health emergency response. Hurricane Katrina exposed weaknesses in our efforts for 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 result of these investments has been demonstrated in subsequent events of similar impact, but with much improved outcome, such as the 2012 response to Super Storm Sandy.

The FY 2018 budget request for ASPR is $1.5 billion, which is an increase of $110 million above the FY 2017 Annualized Continuing Resolution level. The request provides:

- $1.0 billion for BARDA, including $512 million for Advanced Research and Development which also includes $192 million for the CARB initiative; and $510 million for Project BioShield procurements of MCMs.
- $207 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
- $227 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
- $80 million for Federal emergency management, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps
- $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. To meet its mission, HHS maintains a vast array of secure information. The Department awards more grants than any other Federal agency, requiring systems in place to keep such financial data secure. Additionally, the Department's systems are utilized across the Federal Government and maintain sensitive data, including personally identifiable information, health records, sensitive biodefense research, and proprietary data. The Budget Justification supports, sustains and enhances the Department's security posture to support a more nimble and flexible operating level. The activities supported in the Budget will 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 Cybersecurity Program is tasked with implementing a comprehensive, enterprise-wide cybersecurity program to protect the critical information with which the Department is entrusted. The FY 2018 budget request for Cybersecurity is $72 million, which is an increase of $21 million above the FY 2017 Annualized CR level. The request will prioritize: Implementing specific cybersecurity capabilities
- Cultivating cybersecurity partnerships in the public and private sectors
- Engaging in HHS-wide security collaboration activities
- Enhancing HHS's security capabilities through current and future programs and projects

The Office of Security and Strategic Information (OSSI) provides strategic all-source 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 Coordination Office (FICO) and Secretary's Senior Intelligence Official, OSSI manages all intelligence, counterintelligence, insider threat, and cyber threat intelligence activities for the Department – all of these programs are resourced with PHSSEF funds. Additionally, OSSI manages the Department's physical security, emergency management, and personnel security services across the Department; and these are resourced by non-PHSSEF funds. The FY2018 budget request also includes $8 million for OSSI, reflecting an increase of $1 million above the FY 2017 Annualized Continuing Resolution level of $7 million. The total increase is due to the realignment of the appropriated budget between OSSI and OCIO (formerly a pass-through) to support OSSI's intelligence, counterintelligence, insider threat and special security programs mission across the Department.

As learned through public health threats such as Ebola and Zika, it is critical for the Department to respond quickly when such threats arise. To enable a swift response to emerging public health threats that have significant potential to affect the health and security of U.S. citizens, the FY 2018 Budget proposes the establishment of a new Federal Emergency Response Fund within the Office of the Secretary. HHS would have Department-wide transfer authority to support the Fund to help bridge the Department's response in situations that exceed the planned scope of emergency preparedness and response programs and activities.

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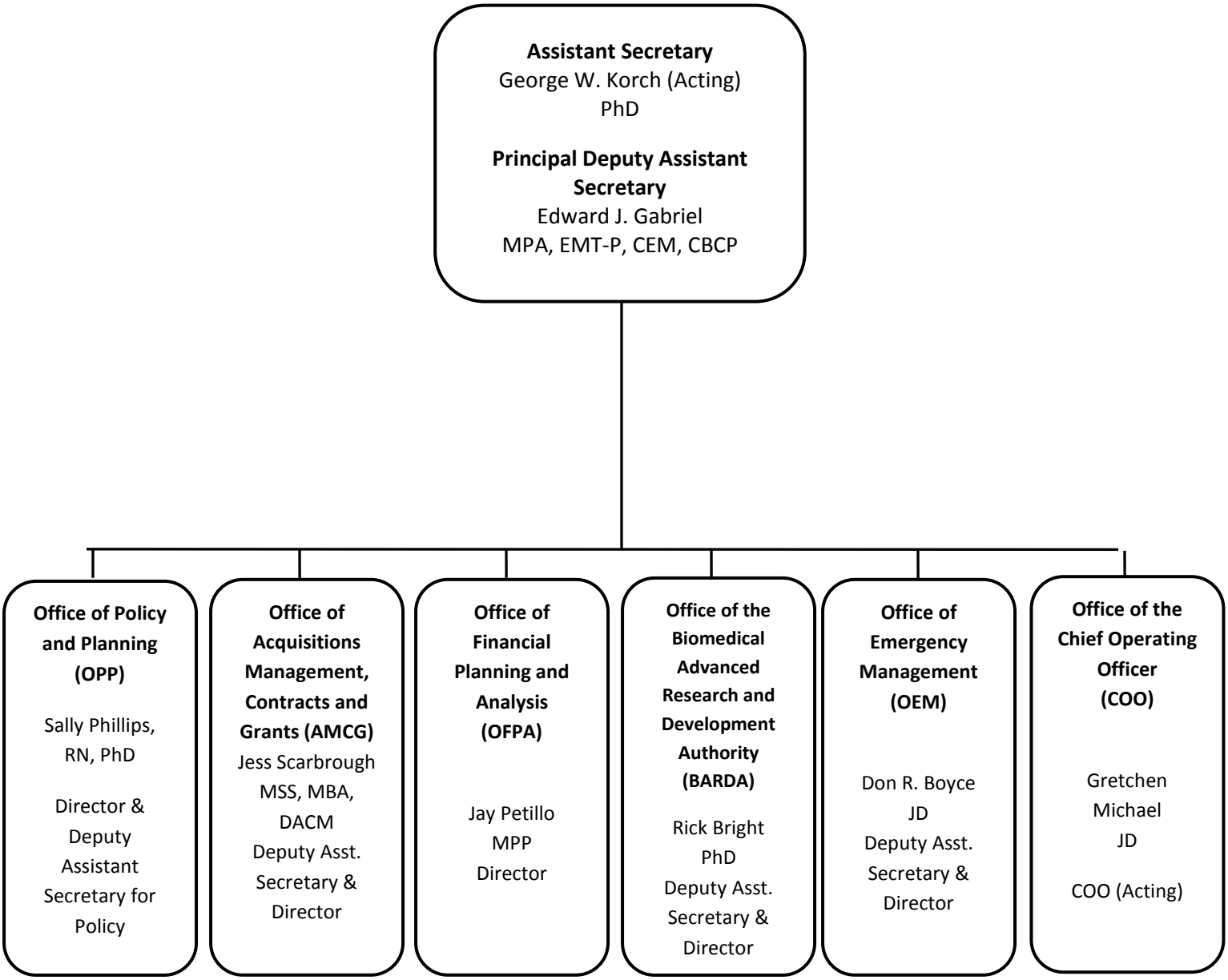
ORGANIZATIONAL CHART

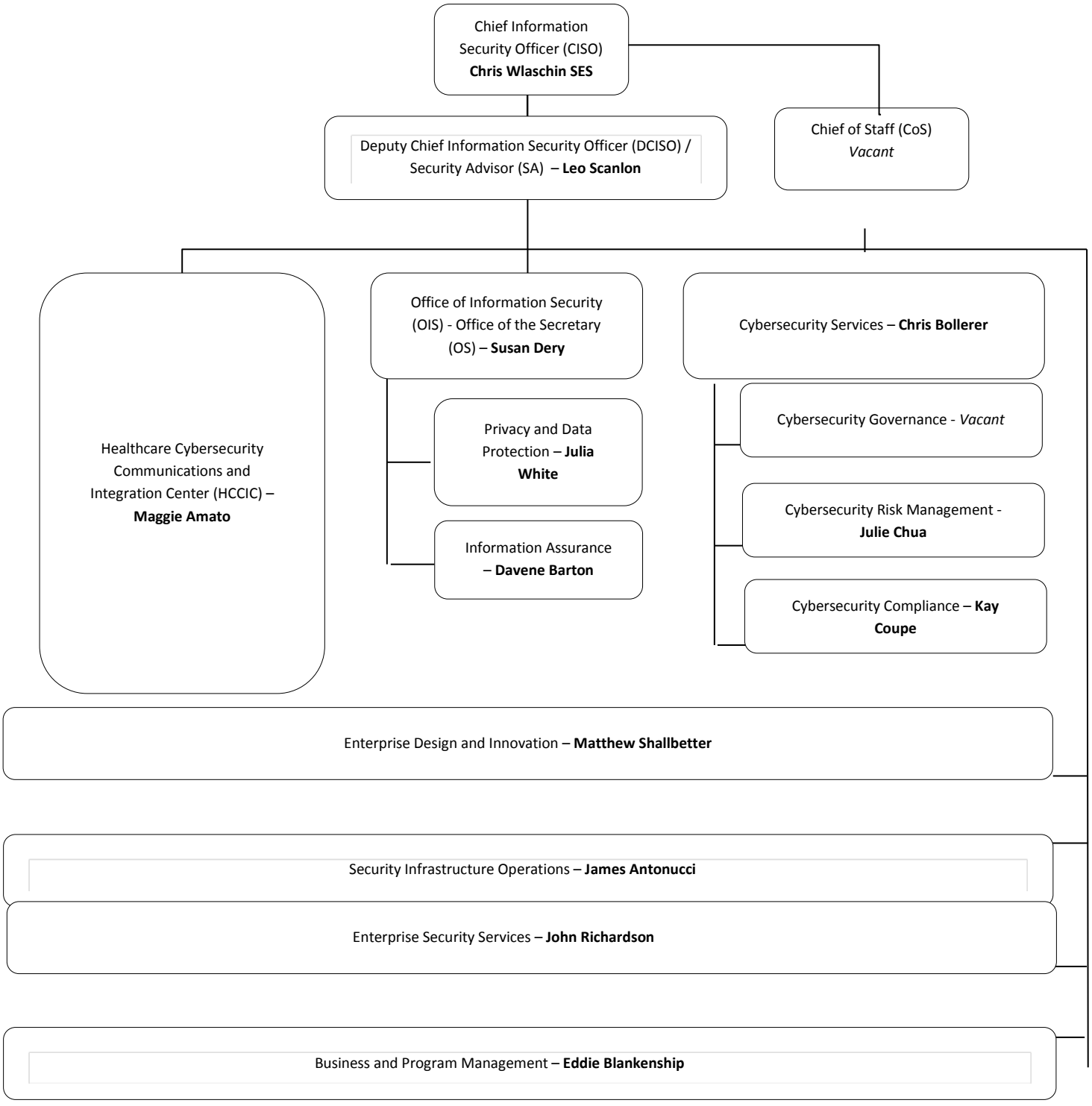
Assistant Secretary for Preparedness and Response

Text version of ASPR Org Chart



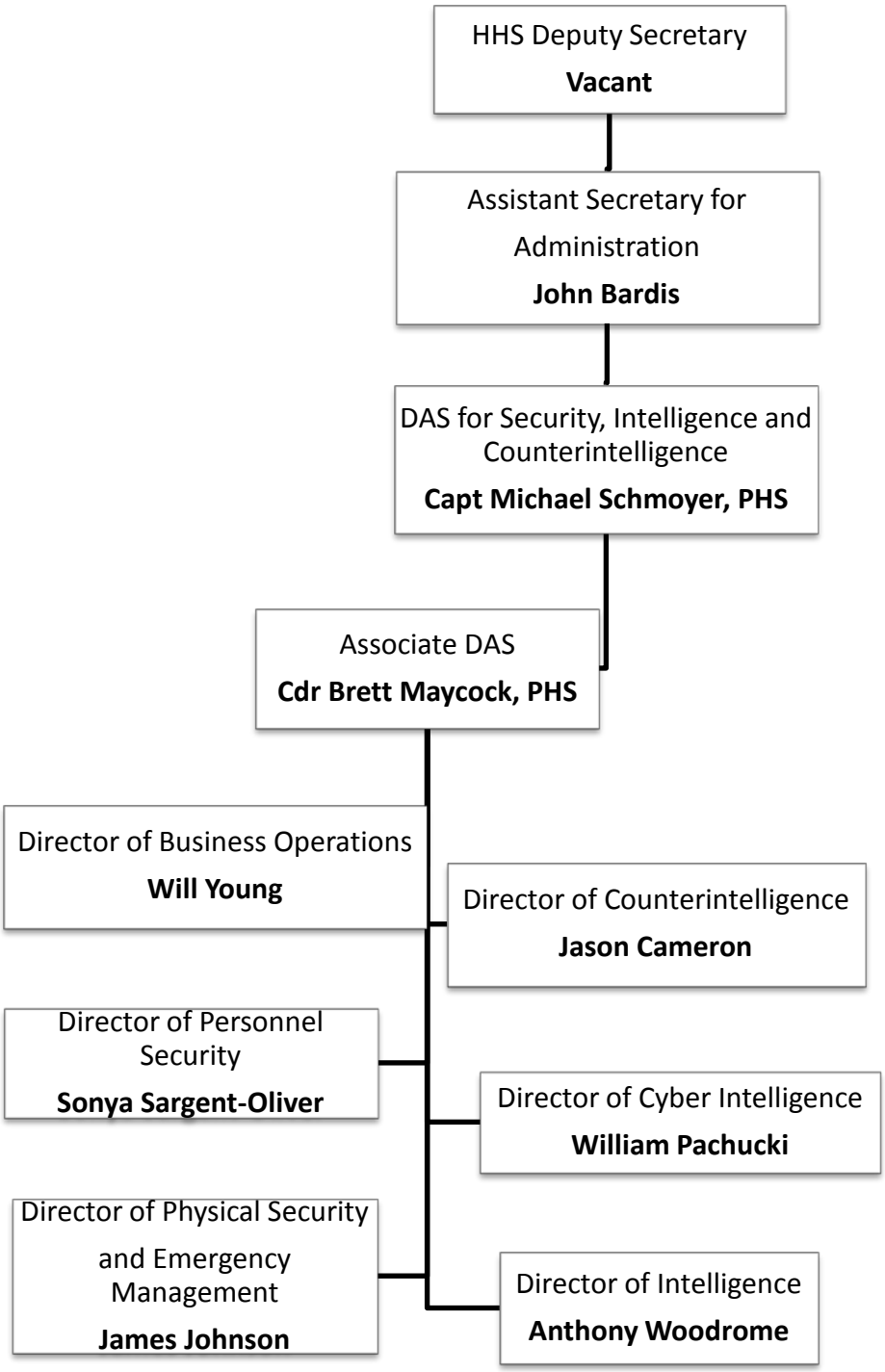
Cybersecurity

Text version of Cybersecurity Org Chart



Office of Security and Strategic Information

Text version OSSI Org Chart



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 per legislative authority 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 and responds to large-scale impacts on regional emergency medical or ancillary support during hurricanes, earthquakes, tsunamis and the like. 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 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. ASPR also coordinates medical countermeasure life cycle management and use through the federal interagency organization known as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

- **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. It also works with other federal partners in leading the way in such diverse areas as biosafety and biosecurity policy, protections for vulnerable populations and cybersecurity impacts on health care systems, and critical infrastructure needs.

- **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. The Budget Justification supports, sustains and enhances the Department's security posture and 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.

Office of Security and Strategic Information:

The Office of Security and Strategic Information (OSSI) provides strategic all-source 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's Federal Intelligence Coordination Office (FICO) and Secretary's Senior Intelligence Official, it manages all intelligence, counterintelligence, insider threat, and cyber threat intelligence activities for the Department – all of these programs are resourced with PHSSEF funds. Additionally, OSSI manages the Department's physical security, emergency management and personnel security services across the Department and these are resourced by non-PHSSEF funds.

Pandemic Influenza:

Pandemic Influenza funding supports HHS's 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 2018 Request for the Public Health and Social Services Emergency Fund (PHSSEF) is $1,662.616 million. The Request represents a program level increase of +$132.572 million relative to the FY 2017 Annualized Continuing Resolution. 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 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 cybersecurity and pandemic influenza activities.

Programmatic Increases (relative to the FY 17 Annualized Continuing Resolution):

- **Pandemic Influenza (+$135 million, $206.863 million total):** The increase in funding will support the sustainment of critical domestic influenza vaccine manufacturing facility infrastructure; ensure pandemic influenza vaccine production requirements; and maintain overall domestic pandemic readiness. The funding level reflects the exhaustion of supplemental influenza balances that have sustained the BARDA influenza program over the last decade.

- **Cybersecurity (+$22.839 million, $72.223 million total):** The funding will support necessary activities to protect the Department's information technology systems. The investment will support the safeguarding of personally identifiable information, commercial propriety data, and scientific research of National importance.

- **Biomedical Advanced Research and Development Authority (+$0.973 million, $511.7 million total):** This funding level supports the advanced development of the highest priority medical countermeasures.

- **Project BioShield (+$0.97 million, $510 million total):** This funding level supports late-stage development and procurement of the highest priority medical countermeasures.

Programmatic Decreases (relative to the FY 17 Annualized Continuing Resolution):

- **Hospital Preparedness Program (-$26.870 million, $227.201 million total):** At this level, funding will support States and localities with the greatest need, prioritizing activities related to hospital and health care coalition planning for emergency management and enhanced community preparedness for public health emergencies.

BUDGET BY STRATEGIC GOAL

(Dollars in Millions)

HHS Strategic Goals and Objectives	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
1.Strengthen Health Care			
1.A Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured			
1.B Improve health care quality and patient safety			
1.C Emphasize primary and preventive care, linked with community prevention services			
1.D Reduce the growth of health care costs while promoting high-value, effective care			
1.E Ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations			
1.F Improve health care and population health through meaningful use of health information technology			
2. Advance Scientific Knowledge and Innovation			
2.A Accelerate the process of scientific discovery to improve health			
2.B Foster and apply innovative solutions to health, public health, and human services challenges			
2.C Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation			
2.D Increase our understanding of what works in public health and human services practice			
2.E Improve laboratory, surveillance, and epidemiology capacity			
3. Advance the Health, Safety and Well-Being of the American People	**1,503.008**	**1,471.825**	**1,581.897**
3.A Promote the safety, well-being, resilience, and healthy development of children and youth			
3.B Promote economic and social well-being for individuals, families, and communities			
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults			
3.D Promote prevention and wellness across the life span			
3.E Reduce the occurrence of infectious diseases	4.009	4.001	4.001
3.F Protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies	1,498.999	1,467.824	1,577.896
4. Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs	**58.330**	**58.219**	**80.719**
4.A Strengthen program integrity and responsible stewardship by reducing improper payments, fighting fraud, and integrating financial, performance, and risk management	14.555	14.555	14.555
4.B Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people	29.220	29.109	51.609
4.C Invest in the HHS workforce to help meet America's health and human services needs	14.555	14.555	14.555
4.D Improve HHS environmental, energy, and economic performance to promote sustainability			
TOTAL PHSSEF Program Level	**1,561.338**	**1,530.044**	**1,662.616**

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND
FY 2018 ALL PURPOSE TABLE

(Dollars in Millions)

Program	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 Annualized CR
Assistant Secretary for Preparedness and Response (ASPR):				
Preparedness and Emergency Operations	24.654	24.607	24.607	--
Office of Emergency Management only (non-add)	*19.654*	*19.617*	*19.617*	--
National Special Security Events (NSSE) (non-add)	*5.000*	*4.990*	*4.990*	--
National Disaster Medical System (NDMS)	49.904	49.809	49.809	--
Hospital Preparedness	254.555	254.071	227.201	-26.870
Hospital Preparedness Program (HPP) Grants (non-add)	*228.500*	*228.500*	*204.500*	*-24.000*
Medical Reserve Corps	6.000	5.989	5.989	--
Biomedical Advanced Research and Development Authority (BARDA)	540.080	510.727	511.700	+0.973
Advanced Research and Development (non-add)	*288.080*	*259.206*	*259.700*	*+0.494*
Combating Antimicrobial Resistance (non-add)	*192.000*	*191.635*	*192.000*	*+0.365*
Operations and Management (non-add)	*60.000*	*59.886*	*60.000*	*+0.114*
Project BioShield	510.000	509.030	510.000	+0.970
Office of Policy and Planning	14.877	14.849	14.849	--
Operations	30.938	30.879	30.879	--
Pandemic Influenza				
No-Year Pandemic Influenza	40.000	39.924	174.924	+135.000
Annual Pandemic Influenza /1	27.991	27.938	27.938	--
Subtotal, Pandemic Influenza	67.991	67.862	202.862	+135.000
Subtotal, ASPR Program Level	**1,498.999**	**1,467.824**	**1,577.896**	**+110.072**
Subtotal, ASPR Budget Authority	***1,498.999***	***1,467.824***	***1,577.896***	***+110.072***
Other Office of the Secretary:				
Pandemic Influenza	4.009	4.001	4.001	--
Annual funding (non-add)	*4.009*	*4.001*	*4.001*	--
Cybersecurity /2	50.860	50.763	72.223	+21.460
Office of Security and Strategic Information (OSSI) /2	7.470	7.456	8.496	+1.040
Subtotal, Other Office of the Secretary	**62.339**	**62.220**	**84.720**	**+22.500**
PHSSEF Total:				
HHS Pandemic Influenza Budget Authority	72.000	71.863	206.863	+135.000
No-Year Pandemic Influenza (non-add)	*40.000*	*39.924*	*174.924*	*+135.000*
Annual Pandemic Influenza (non-add)	*32.000*	*31.939*	*31.939*	--
All Other Budget Authority	1,489.338	1,458.181	1,455.753	-2.428
Total, PHSSEF Program Level	**1,561.338**	**1,530.044**	**1,662.616**	**+132.572**
Total, PHSSEF, Budget Authority	***1,561.338***	***1,530.044***	***1,662.616***	***+132.572***
FTE				
ASPR	612	612	612	--
OGA	5	5	5	--
OSSI	35	40	40	--
Cybersecurity	82	93	123	+30
Total FTE, PHSSEF	**734**	**750**	**780**	**+30**

1/ Includes $3.0 million for Office of Policy and Planning International Influenza Activities

2/ The FY 2018 President's Budget reflects a realignment of $1.040 million between Cybersecurity and OSSI for cyber threat activities.

FY 2018 PROPOSED APPOPRIATIONS LANGUAGE

(Relative to FY 2016 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]*$945,753,000*, of which $511,700,000 shall remain available [through September 30, 2017,] *until expended* 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]*$4,990,000* of the amounts made available to support emergency operations shall remain available through September 30, [2018]*2020: Provided further, That in making awards under section 319C-2 of the PHS Act from funds made available in this paragraph, the Secretary may determine the amounts of such awards without regard to subsection (j)(3)(B) of such section*.

For expenses necessary for procuring security countermeasures (as defined in section 319F–2(c)(1)(B) of the PHS Act), $510,000,000, to remain available until expended*: Provided, That the Secretary may shift up to 10 percent of the funds provided for this purpose and for advanced research and development under section 319L between such purposes*.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic, [$72,000,000]*$206,863,000*; of which [$40,000,000]*$174,924,000* 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.

FY 2018 PROPOSED GENERAL PROVISIONS

(Relative to FY 2016 Enacted)

SEC. 215. (a) The Biomedical Advanced Research and Development Authority ("BARDA") may enter into a contract, for more than one but no more than 10 program years, for purchase of research services or of security countermeasures, as that term is defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. 247d-6b(c)(1)(B)), if—

(1) funds are available and obligated—

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

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

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

(b) A contract entered into under this section—

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

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

SEC. 219. There is hereby established in the Treasury of the United States a fund to be known as the "Federal Emergency Response Fund" (the Fund). Amounts in the Fund shall be available, in addition to any other amount appropriated for such purposes, to carry out titles II, III, and XVII of the PHS Act with respect to domestic preparedness and global health; to prevent, prepare for, or respond to a chemical, biological, radiological, or nuclear threat; to prevent, prepare for, or respond to an emerging infectious disease; and to purchase or lease, and provide for the insurance of, passenger motor vehicles for official use in foreign countries. Amounts in the Fund may only be used for a public health threat or emergency that the Secretary determines has significant potential to occur and potential, on occurrence, to affect national security or the health and security of United States citizens, domestically or internationally. The Secretary may transfer to the Fund in this fiscal year and hereafter such amounts as are necessary from any discretionary amounts (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) appropriated in this and subsequent Acts, provided that no such appropriation is reduced by more than 1 percent. Such transferred amounts shall remain available until expended. When implementing response activities, amounts in the Fund may be transferred to other accounts of the Department of Health and Human Services for the purposes provided in this section. The Committees on Appropriations of the House of Representatives and the Senate shall be notified promptly of the initiation of response activities under this authority and of any transfer made under the authority provided in this section. The Committees on Appropriations of the House of Representatives and the Senate shall receive a report not later than 45 days after the end of each quarter in a fiscal year on the unobligated balances in the Response Fund and all actual obligations incurred for that fiscal year, including obligations by program, project, or activity. The transfer authorities in this section are in addition to any other transfer authority otherwise available to the Department of Health and Human Services. Products purchased using amounts in the Fund may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F-2 of the PHS Act.

APPROPRIATIONS LANGUAGE ANALYSIS

Language Provision	Explanation
For expenses necessary to support activities related to countering potential biological, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies, [$950,958,000] *$945,753,000*, of which $511,700,000 shall remain available [through September 30, 2017,] *until expended* 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	The language provides no-year funding for transitioning CBRN products from advanced research and development to acquisition under Project BioShield.
Provided further, That [$5,000,000] *$4,990,000* of the amounts made available to support emergency operations shall remain available through September 30, [2018.] *2020:*	This language appropriates *$4,990,000* for emergency operations.
Provided further, That in making awards from such funds under section 319C-2 of the PHS Act, the Secretary may determine the amounts of such awards without regard to subsection (j)(3)(B) of such section.	The language allows the HHS Secretary to award state preparedness grants based on risk, ensuring the funds are directed to states with the greatest need.
For expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act), $510,000,000 to remain available until expended[.]*: Provided, That the Secretary may shift up to 10 percent of the funds provided for this purpose and for advanced research and development under section 319L between such purposes.*	This language appropriates $510,000,000 for Project BioShield for procuring security countermeasures. Additionally, it provides permissive authority for the HHS Secretary to transfer up to 10% of the amounts appropriated for BARDA and/or BioShield interchangeably if needed for advanced development or procurement.
For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic [$72,000,000] *$206,863,000*; of which [$40,000,000] *$174,924,000* shall be available until expended for activities including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools;	The language provides funds for preparing for and responding to an influenza pandemic through specific activities.

SEC. 215. (a) The Biomedical Advanced Research and Development Authority ("BARDA") may enter into a contract, for more than one but no more than 10 program years, for purchase of research services or of security countermeasures, as that term is defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. 247d-6b(c)(1)(B)), if— *(1) funds are available and obligated—* *(A) for the full period of the contract or for the first fiscal year in which the contract is in effect; and* *(B) for the estimated costs associated with a necessary termination of the contract; and* *(2) the Secretary determines that a multi-year contract will serve the best interests of the Federal Government by encouraging full and open competition or promoting economy in administration, performance, and operation of BARDA's programs.* *(b) A contract entered into under this section—* *(1) shall include a termination clause as described by subsection (c) of section 3903 of title 41, United States Code; and* *(2) shall be subject to the congressional notice requirement stated in subsection (d) of such section.*	The language provides permissive authority for BARDA to enter into a contract for no more than ten program years for purchase of research services or of security countermeasures, provided that: funds are available to execute the contract; the Secretary determines a multi-year contract will serve the best interests of the Federal Government; and, the contract includes a termination clause and is subject to a congressional notice requirement.

SEC. 219. There is hereby established in the Treasury a fund to be known as the "Federal Emergency Response Fund" (the "Fund"). Amounts in the Fund shall be available, in addition to any other amount appropriated for such purposes, to carry out titles II, III, and XVII of the PHS Act, and domestic preparedness activities and global health; to prevent, prepare for, or respond to a chemical, biological, radiological, or nuclear threat; or to prevent, prepare for, or respond to an emerging infectious disease; and may be used to purchase or lease, and provide for the insurance of, passenger motor vehicles for official use in foreign countries. Amounts in the Fund may only be used for such threats or emergencies that the Secretary determines have significant potential to occur and potential, on occurrence, to affect national security or the health and security of United States citizens, domestically or internationally. The Secretary may transfer to the Fund in this fiscal year and hereafter such amounts as are necessary from any discretionary amounts (pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985) appropriated in this and subsequent Acts, provided that no such appropriation is reduced by more than 1 percent. Such transferred amounts shall remain available until expended. When implementing response activities, amounts in the Fund may be transferred to other accounts of the Department of Health and Human Services for the purposes provided in this subsection. The Committees on Appropriations of the House of Representatives and the Senate shall be notified promptly of the initiation of response activities under this authority and of any transfer made under the authority provided in this section. The Committees on Appropriations of the House of Representatives and the Senate shall receive a report not later than 45 days after the end of each quarter in a fiscal year on the unobligated balances in the Response Fund and all actual obligations incurred for that fiscal year, including obligations by program, project, or activity. The transfer authorities in this section are in addition to any other transfer authority otherwise available to the Department of Health and Human Services. Products purchased using amounts in the Fund may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F-2 of the PHS Act.	This language provides the Secretary with the authority to transfer up to one percent of any discretionary appropriation account within HHS to a newly established “Federal Emergency Response Fund” for emergency response and recovery purposes. The notification requirements would allow transfers to be executed quickly once the emergency arose. Amounts in the “Fund” could only be used for such threats or emergencies that the Secretary determines have significant potential to occur and potential, on occurrence, to affect national security or the health and security of United States citizens, domestically or internationally.

OVERVIEW OF PERFORMANCE

Office of the Assistant Secretary for Preparedness and Response's (ASPR) Mission
ASPR makes decisions that protect life and health while limiting death and injury. As a dynamic, responsive organization that continually improves, ASPR focuses resources where there is greatest need. ASPR takes an organization wide approach to performance management and also is actively engaged in the Department of Health and Human Services (HHS) Enterprise Risk Management (ERM) program.

ASPR's mission is to lead the country in preparing for, responding to, and recovering from adverse health effects of emergencies and disasters by supporting our communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security. As a principal adviser to the Secretary of HHS, ASPR coordinates direction related to public health preparedness as well as federal responses to emergencies and threats of all kinds, including threats to national security.

Priority Setting and Strategic Planning
The needs of American citizens and communities are central to setting and revising ASPR's priorities. To do this, ASPR uses data, rigorous evaluations, research findings, and stakeholder feedback. Priorities are adjusted to contribute to new national goals while continuing to focus on expanding operational capabilities for emergency response, developing, procuring and testing medical countermeasures, and funding evaluation and research.

ASPR's strategic plan includes six core goals. These goals form a framework for the development of streamlined performance management processes. ASPR contributed to the HHS's 2014-2018 Strategic Plan, mostly to Goal 3, Objective F: which is to protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies. ASPR also contributed to other key performance reports, such as HHS's Annual Performance Plan and Report as well as HHS's Strategic Reviews.

Aligning ASPR's Performance with National Priorities
During times of change, performance management helps realign priorities. For example, by revisiting each performance outcome and goal, ASPR is adding, removing, and refining measures and targets to be sure that ASPR's approach is data-driven, evidence-based, and actionable. Also, ASPR programs are testing new performance measures to be sure that ASPR is providing accurate and meaningful information to its stakeholders. Over time, such strategies support the development of standards and benchmarks. This helps ASPR to gauge effectiveness and continually improve.

Examples of Key Accomplishments
When disaster strikes, ASPR's Office of Emergency Management (OEM) supports communities with critical services to protect public health and promote resilience and faster recovery. When requested by a state, local, tribe, territory or federal agency, OEM's National Disaster Medical System (NDMS) provides essential medical and emergency management services with advanced equipment and subject matter expertise. NDMS response teams include clinical providers and emergency medical service professionals, such as physicians, nurses, paramedics, and other support staff, including information technology specialists.

ASPR's NDMS program is testing new performance measures so that innovations to the response structure are accurately captured and reported in a timely way. For example, workforce training data for those deployed during emergencies is being collected and analyzed. As of April 2017, 100 percent of new NDMS intermittent staff hired during 2017 already have completed Psychological First Aid training. This training provides an evidence-informed approach for assisting children, adolescents, adults, and families after disasters or terrorist attacks.

ASPR's Biomedical Advanced Research and Development Authority (BARDA) reports performance data in ASPR's budgets, including the number of new countermeasures for Chemical, Biological, Radiological, and Nuclear threats under FDA's Emergency Use Authority and also the technical assistance provided by BARDA to medical countermeasure manufacturers. These measures provide some of the data BARDA uses to support their evidence-based approach to working with public and private partners to transition candidates for vaccines, antivirals, diagnostics, and devices.

Performance Management Challenges

Influenza provides a snapshot into the performance management challenges faced by a federal agency with ASPR's complex mission. Because changes, including natural mutations, are taking place quickly, it can be a challenge to adjust performance measures so that the most useful performance data are reported with consistency over several years. The stability that allows analysis of trends and comparisons can be challenging to maintain during times of rapid change. In such a situation, there is an inherent potential to derail the relevance of performance metrics that become less relevant or even obsolete. To address this challenge, what is measured is actively revisited and improved over time. For example, measures are being considered as data from Asia, including information about influenza outbreaks among chicken flocks, are raising concerns. Although the virus has not gained sustained human to human transmissibility and remains within China, H7N9 avian influenza has spread. This ever-changing pathology and epidemiology impacts the development of vaccines and antiviral drugs to ensure their efficacy and safety.

The Potential Impact of Resource Changes

The FY 2018 budget request for the Hospital Preparedness Program (HPP) shows a decrease of $26,869,000 below the FY 2017 Annualized Continuing Resolution level. Within the HPP total, $204,500,000 will be provided for cooperative agreements to states and high risk political subdivisions. This amount is a $24,000,000 decrease below the FY 2017 annualized Continuing Resolution level. The FY2018 HPP funds support cooperative agreement administration, performance evaluation and oversight, as well as other programs that directly support the mission of HPP. As part of its HPP proposals in the FY 2018 budget request, HPP will do the following, based on legislative authority: (1) continue to expand the consideration of risk; (2) increase innovation; and (3) continue to evaluate and refine the performance measures reported in budgets. Unfortunately, ASPR cannot adequately predict what the loss of HPP funds, either through reduction or elimination, will mean for any jurisdiction, hospital, or other health care service delivery entity across the Country. However, coordination activities carried out by Health Care Coalitions (HCC) previously funded through HPP sub-awards may no longer occur in those jurisdictions where funding is reduced or eliminated.

AMOUNTS AVAILABLE FOR OBLIGATION

(In Dollars)

Detail	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Annual Appropriation	466,258,000	465,372,400	461,002,000
Recissions			
Sequester Order			
Transfers	25,852,744		
Subtotal, Adjusted Annual Appropriation	**492,110,744**	**465,372,400**	**461,002,000**
Multi-Year Appropriation	516,700,000	515,717,300	516,690,000
Supplemental (PL 114-223)	245,000,000		
Recissions			
Sequester Order			
Transfers	2,526,996		
Subtotal, Multi-Year Appropriation	**764,226,996**	**515,717,300**	**516,690,000**
No-Year Appropriation	550,000,000	548,954,450	684,924,000
Recissions			
Sequester Order			
Transfers	22,563,000	23,723,000	
Subtotal, No-Year Appropriation	**572,563,000**	**572,677,450**	**684,924,000**
Total, Adjusted Budget Authority	**1,828,900,740**	**1,553,767,150**	**1,662,616,000**
Unobligated balance, start of year	311,513,426	70,436,864	
Unobligated balance, end of year	70,436,864		
Total obligations	**1,797,000,000**		

SUMMARY OF CHANGES

(Dollars in Millions)

FY 2017 Annualized CR	
Total estimated budget authority	1,530.044
FY 2018 President's Budget	
Total estimated budget authority	1,662.616
Net Change	132.572

	FY 2018 PB FTE	FY 2018 PB BA	FY 2018 +/- FY 2017 FTE	FY 2018 +/- FY 2017 BA
Increases:				
Assistant Secretary for Preparedness and Response				
Biomedical Advanced Research and Development Authority	155	511.700	--	0.973
Project BioShield	0	510.000	--	0.970
Pandemic Influenza				
No-Year Pandemic Influenza	0	174.924	--	135.000
Cybersecurity	123	72.223	30	21.460
Office of Security and Strategic Information	40	8.496	--	1.040
Total Increases	318	1277.343	30	159.442
Decreases:				
Assistant Secretary for Preparedness and Response				
Hospital Preparedness Program	49	227.201	--	-26.870
Total Decreases	49	227.201	--	-26.870
Net Change				132.572

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Millions)

Activity	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Bioterrorism and Emergency Preparedness	1,489,338	1,458,181	1,455,753
Pandemic Influenza	72,000	71,863	206,863
Total Budget Authority	**1,561,338**	**1,530,044**	**1,662,616**

AUTHORIZING LEGISLATION

(Dollars in Millions)

Details	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Pandemic and All-Hazards Preparedness Reauthorization Act 2013 (PAHPRA)	1,561,338	1,530,044	1,662,616

APPROPRIATIONS HISTORY

(Dollars in Thousands)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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)
Subtotal	2,300.831	2,343.827	2,121.758	10,660.795
FY 2010				
Appropriation	2,678.569	2,100.659	2,621.154	3,770.694
Supplemental Appropriation (PL 111-212)				220.000
Recission (PL 111-226)				(6.630)
Subtotal	2,678.569	2,100.659	2,621.154	3,984.064
FY 2011				
Appropriation	1,041.694		1,050.795	674.828
Supplemental Appropriation (ARRA)		50.000	50.000	50.000
Subtotal	1,041.694	50.000	1,100.795	724.828
FY 2012				
Appropriation	595.023	543.114	574.452	596.452
Recission (PL 111-226)				(1.076)
Subtotal	595.023	543.114	574.452	595.376
FY 2013				
Appropriation	642.262			584.205
Transfer to CDC				(1.919)
Transfer to OMHA				(0.629)
Supplemental Appropriation		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				(0.250)
Sequester				(38.343)
Subtotal	642.262	800.000	800.000	738.064
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
Subtotal	-	-	1,389.813	1,966.069
FY 2016				
Appropriation	1,939.981	1,171.523	1,227.277	1,532.958
Supplemental Appropriation (PL 114-223)				245.000
Transfer to BARDA				28.380
Subtotal	1,939.981	1,171.523	1,227.277	1,806.338
FY 2017				
Appropriation	1,431.117	1,631.258	1,517.958	1,517.958
FY 2018				
Estimate	1,662.616			

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

SUMMARY OF REQUEST

Budget Summary
(Dollars in Thousands)

ASPR	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Program Level	**1,498,999**	**1,467,824**	**1,577,896**	**110,072**
Budget Authority (non-add)	*1,470,619*	1,467,824	1,577,896	110,072
Other Sources (non-add) /2	*28,380*	-	-	-
FTE	**612**	**612**	**612**	**-**

1/ Totals include ASPR's Pandemic Influenza funding.
2/ Reflects the increase of +$28,379,740 for the FY 2016 Secretary's permissive transfer.

The Fiscal Year (FY) 2018 Budget Request for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is $1,577,896,000. The request is an increase of +$110,073,000 above the FY 2017 Annualized Continuing Resolution level.

America has made great strides in public health emergency management since 9/11 and Hurricane Katrina. Since its establishment, ASPR has led 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.

BARDA in partnership with 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). These advanced development programs have supported 21 products under Project BioShield; 14 of these products have been procured for the Strategic National Stockpile.

ASPR has also led our nation's progress in public health emergency response. Hurricane Katrina exposed major gaps in emergency management and response. Congress established ASPR after Hurricane Katrina, and addressing these weaknesses has been one of ASPR's most important parts of its mission. 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.

Additionally, ASPR continues to dedicate efforts and resources towards the Ebola and Zika viruses. For FY 2018, work will continue on evaluating both vaccine and therapeutic medical countermeasure candidates for viral hemorrhagic fever viruses. These current medical countermeasures target Ebola-Zaire. Funding will also support biodosimetry and biodiagnostics. ASPR is currently investing in development of anthrax and Ebola diagnostics. Support for both Clinical and Non-clinical studies networks will also continue. These networks were heavily utilized during the Zika outbreak to collect samples to aid and accelerate the development of Zika diagnostic tests. ASPR will continue efforts in providing technical assistance to local, state, regional, tribal, territorial, and federal staff, health care associations, and other stakeholders, including surge assistance and resources during and after incidents through the Technical Resources Assistance Center and Information Exchange (TRACIE). In response to

the Zika virus outbreak, TRACIE brought together subject matter experts from around the country to develop "Zika: Resources at Your Fingertips," a valuable tool for health care systems preparedness planners. ASPR also will continue to prepare for, and provide safe and successful care of patients with, Ebola through the National Ebola Training and Education Center (NETEC), a collaborative effort with CDC. The NETEC offers expertise, training, technical assistance, peer review, monitoring, and recognition.

ASPR's goals for FY 2018 are to sustain its mission and achieve new successes in public health emergency management. The FY 2018 budget proposes funding increases for pandemic influenza and BARDA, which will contribute significantly to advances in public health emergency management.

Other Increases above the FY 2017 Annualized Continuing Resolution Level:

- Pandemic Influenza: The budget requests $202,862,000, which is +$135,000,000 above the FY 2017 Annualized CR level. This budget increase reflects the exhaustion of supplemental influenza balances that have sustained the BARDA influenza program over the last decade. Funds are needed to sustain critical domestic influenza vaccine manufacturing facility infrastructure; ensure pandemic influenza vaccine production requirements; and maintain overall domestic pandemic readiness. The Request includes $3 million in annual funding for international policy and diplomacy programs and $199.86 million for pandemic influenza medical countermeasure programs.
- Biomedical Advanced Research and Development Authority (BARDA): The budget request for Advanced Research and Development is $511,700,000, which is +$973,000 above the FY 2017 Annualized CR 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 (2016).
- Project BioShield: The budget request for Project BioShield is $510,000,000, which is +$970,000 above the FY 2017 Annualized CR level. The Request will continue the development and procurement of Ebola vaccines, therapeutics, next-generation anthrax vaccines and new procurements of antibacterial drugs and chemical agent medical countermeasures. It will also support new intravenous formulations of currently stockpile smallpox antiviral drugs for use in special populations or those who are severely ill.

Decreases below the FY 2017 Annualized Continuing Resolution Budget Level:

- Hospital Preparedness Program (HPP): The budget requests $227,202,000 for the HPP, which is a decrease of $26,869,000 below the FY 2017 Annualized CR level. Within the total, $204,500,000 will be provided for HPP cooperative agreements with states and high risk political subdivisions. This amount is a $24,000,000 decrease below the FY 2017 Annualized CR level. The remaining funds support cooperative agreement administration and performance evaluation and oversight, as well as other programs at ASPR that directly support the mission of HPP including the Technical Resources Assistance Center and Information Exchange (TRACIE), the Emergency Care Coordination Center (ECCC), Critical Infrastructure Protection (CIP), and the Division of Recovery. The decrease in funds will impact the management and oversight functions to administer HPP, the HPP cooperative agreement awardees, and each of the supporting programs.

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

PREPAREDNESS AND EMERGENCY OPERATIONS

Budget Summary
(Dollars in Thousands)

ASPR Preparedness and Emergency Operations	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority	24,654	24,607	24,607	--
National Special Security Events/Public Health Emergencies (non-add)	*5,000*	*4,990*	*4,990*	*-10*
FTE	86	86	86	--

Authorizing Legislation:
Authorization ..... Public Health Service Act
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. Peacetime activities include 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 has a vital role in fulfilling the U.S. Department of Health and Human Services' (HHS) responsibilities for responding to, recovering from, and mitigating, the lasting impacts of public health and medical emergencies. HHS is the coordinator and primary Federal agency responsible for Public Health and Medical Emergency Support Function #8 (ESF#8) of the National Response Framework and the Health and Social Services Recovery Core Capability of the National Disaster Recovery Framework; and serves as the Lead Federal Agency when designated by the Secretary 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) covers the full spectrum of emergency management responsibilities. OEM's programs work together to advance state and local health care system preparedness and emergency response capabilities to maintain resilience in the face of disasters. OEM's programs are integral to ensuring state and local entities can prepare and plan for, respond to, and recover from public health and medical incidences. OEM is comprised of ten divisions that work together to assist communities in building and maintaining resilience in the face of disasters. The divisions are:

1. Planning – coordinates the Department's all-hazards operational planning in coordination with federal partners to support the ASPR's mission in leading the Federal ESF#8 response.

2. Regional and International Coordination – provides critical collaboration and timely coordination before, during, and after, national and global public health incidents
3. 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.
4. 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.
5. Fusion – captures, analyzes, and interprets information before, during, and after an emergency to ensure decision-makers receive timely and updated situational analysis and information.
6. Operations – leads deployments and exercises, and provides informed situational awareness and information management for the Department for all emergencies and events, both domestic and international through the Secretary's Operation Center.
7. 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.
8. National Disaster Medical System – augments the nation's medical response capability.
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's 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 and the Deepwater Horizon oil spill in 2010. In FY 2016 and FY 2017, OEM was the lead federal agency for the Flint Water Contamination Crisis; coordinated assets for the major flooding in Louisiana and Texas; established a Unified Coordination Group in Puerto Rico for Zika Virus response; and provided key information to North Carolina during Hurricane Matthew. In addition, OEM supports a number of planned annual events including: the President's State of the Union Address; the Peace Officer's Memorial, Independence Day celebrations in Washington, D.C.; as well as Democratic and Republican National Conventions, Presidential Inaugurations, and Presidential addresses to Congress. 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) to ensure it was able to meet its responsibilities to provide for the health and medical needs of children and families coming to the United States across the southern 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 the life threatening crisis. The command and control structure for this emergency included DHS Customs and Border Protection's (CBP), the 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, 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 was significantly engaged in both the Zika and Ebola outbreaks, where it played critical roles in compiling and providing daily information to the White House on behalf of the federal government response

during the emerging and sustained crisis, highlighting Interagency and state and local collaboration. OEM also deployed NDMS staff to work in CDC's Operations Center as subject matter experts during the Ebola response. Additionally, OEM coordinated and facilitated direct support to the U.S. Agency for International Development (USAID) Mission and to USPHS officers deployed to Africa during the Ebola response. 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 health care system review of domestic Ebola preparedness and response plans. These plans outline how the federal government, states, and health care 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 Council, as well as directly to the President. OEM supports 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 $200 million to enhance the medical capability of the national health care footprint to prepare for outbreaks such as Ebola. OEM sponsored, coordinated, and oversaw the development of the *Report of the Independent Panel on the U.S. Department of Health and Human Services (HHS) Ebola Response* for the HHS Secretary and the White House. The report was also given wide distribution to public health and medical professionals. The development of the report included research into public and internal documents; interviews with hundreds of individuals inside and outside of government; careful deliberations; and extensive review of the findings and recommendations with government officials and other stakeholders. OEM also developed the Ebola Lessons Learned Review Internal Report & Improvement Plan which describes the challenges HHS faced during its domestic and international responses to West Africa Ebola outbreak. The plan also outlines key priorities and improvement actions to enhance HHS's ability to effectively prepare for, prevent, and respond to, future urgent public health threats.

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. 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's 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's 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.

In FY 2017, OEM's Division of Planning completed an ASPR Threat and Hazard Identification and Risk Assessment Methodology and Process (THIRA) to assess the vulnerability of people, property, the environment; and OEM's operations from potential threats and hazards, including natural and man-made disasters. The results of the THIRA found that there would be significant requirements of OEM's assets, including ESF#8 response assets and preparedness functions, for the highest threats of hurricanes, emerging infectious diseases outbreaks, and human pandemic. The THIRA enables OEM to understand the exact requirements for each of these potential hazards and to plan accordingly. OEM is incorporating results from the THIRA, as well as consideration of state, local, and territorial capabilities obtained through state and regional collaborations, to ensure new threats and risks are addressed going forward. Considerations have already been incorporated into OEM's incident command structure as well as preparedness initiatives at the state and local level through regional partners. The THIRA also determined the logistical response resources required to support state, local, tribal, and territorial (SLTT) entities during catastrophic and moderate events. The results validated the need for ASPR to continue to stockpile critical material at current levels at a high state of readiness to facilitate patient care by the NDMS and other Public Health and Medical response teams to support gaps identified by SLTT.

OEM's Division of Planning developed 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 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 incident. These annexes address HHS's 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 conducts a plan validation exercises on each All-Hazards Plan annex. OEM uses this process to capture corrective actions and adjust annexes, as needed, to enhance planning considerations.

OEM's Division of Planning also collaborates with federal partners in the development of interagency plans. The Planning Division coordinates the HHS input to the Strategic National Risk Assessment, National Response Framework, ESF#8 Annex, and Federal Interagency Operations Plan. The Planning Division also co-led, with FEMA, the development of the Biological Incident Annex and participated in the development of the Power Outage Incident Annex, Food and Agriculture Incident Annex, Nuclear Radiation Incident Annex, and Federal Evacuation Incident Annex. In addition to these plans for catastrophic incidents, the Planning Division supports a number of crisis events by developing National Support Plans for consequence management and Crisis Action Plans for Ebola, Zika, H7N9, and MERS-CoV.

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's 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 drafts and refines the required overarching policy and planning documents to scope and define the HHS unified COOP and COG Programs.

Annually, OEM integrates the COOP programs of separate HHS components into an overarching HHS COOP Program. Most recently in FY 2016 and 2017, this integration continued and allowed HHS to implement a comprehensive continuity program while eliminating redundancies, creating efficiencies in information sharing and situational awareness, and addressing gaps in a cost-effective manner. OEM also has the primary responsibility for HHS's implementation of several key regulations, primarily Presidential Policy Directive (PPD) 40 and White

House Office of Science and Technology Policy/Office of Management and Budget (OSTP/OMB) Directive D-16-1. PPD-40, referred to as the National Continuity Policy, provides guidance to all executive branch agencies to ensure a comprehensive and integrated national continuity program that enhances the integrity of the Nation's national security posture and enables a more rapid and effective response to and recovery from a catastrophic emergency. D-16-1 establishes the minimum continuity communications requirements for all executive branch agencies. ASPR serves as the HHS lead for building and implementing the HHS continuity program and for ensuring that all communication capabilities HHS must possess at headquarters and alternate locations are available and functional in support of continuity of operations activities. As a result of OEM's leadership, HHS has maintained a 100% compliance rate for ten straight quarterly testing cycles in a row - tops among interagency participants. OEM also increased HHS's emergency communications capabilities, including the management and implementation of Government Emergency Telecommunications Service and 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.

Similarly, and on an annual basis, OEM developed and facilitated several continuity-focused test, training, and exercise events to strengthen and assess the HHS COOP program. Most recently in June 2015 and May 2016, OEM participated in the White House's annual continuity exercise and interagency evaluation. Working and planning with the interagency and all other HHS Operating and Staff Division senior leaders, the HHS COOP program achieved the highest possible scores from the Department of Homeland Security's Federal Emergency Management Agency (FEMA) during the evaluation. In May 2016, OEM hosted a tabletop exercise for HHS principals and other senior leadership that focused on reviewing initial decisions before and after the detonation of a device of unknown magnitude impacting HHS headquarters location and verifying expectations of the Secretary and Deputy Secretary for Operating and Staff Division leadership following an incident impacting HHS headquarters locations. Likewise, OEM continued its work with other parts of HHS on policy and plan development, continuity facility managements, training and exercises, and efforts to improve devolution and reconstitution capabilities for the Department.

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, in order 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, Community Analyst, and social media analytics. These tools allow the division to monitor emerging threats with public health and medical impacts as well as the status of healthcare infrastructure and system resources. 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.

Recent examples of how Fusion provides this kind of situational awareness are reflected in the products produced during the 2017 Inauguration. The GeoHEALTH Platform was used to integrate data from multiple Federal agencies including the US Secret Service and DHS with ASPR data on medical personnel and resource locations. GeoHEALTH was used to create and share several mapping products for this event, some of which were live maps that were used in real time for decision making. Fusion Analytics was used during Hurricane Matthew in October 2016 for dashboard display of patient encounter information as recorded by electronic medical record (EMR) kits used at several OEM staffed field medical stations. Fusion's daily social media reports captured data about main themes of conversation regarding the hurricane, specific information on hospitals, injuries, illness and shelters and any other information relevant to ASPR's public health and medical mission and were provided to leadership and field personnel. Fusion maps and social media reports were also shared with local/state and interagency partners.

Fusion collaborated in real time with local/state public health partners for several events in 2016 and 2017. During Hurricane Matthew, Fusion provided a de-identified data share of electronic medical record (EMR) data for patient encounters in the field to Florida Department of Health (FL DOH). Using an existing data sharing agreement, Fusion quickly re-tested the capability with FL DOH as Hurricane Matthew was approaching. When ASPR Disaster Medical Assistance Team (DMAT) teams were deployed to provide medical support at Holmes Regional Medical Center in Melbourne, FL, Fusion was able to provide an automated EMR data share (updated every 15 minutes) directly to FL DOH's surveillance system ESSENCE-FL. The ASPR DMAT mission was referenced in the "FL ESF-8 Epi Surveillance Hurricane Matthew" report, as was an ASPR DMAT EMR patient encounter data table. Additionally, FL DOH shared their full Epi Surveillance report for Matthew with ASPR. During the 2017 Inauguration, Fusion worked closely with DC Homeland Security Emergency Management Agency's (HSEMA) Washington Regional Threat Assessment Center (WRTAC). Using information obtained from WRTAC on protest/demonstration events, Fusion used open source to enhance this information and worked with GIS to create maps that provided leadership with situational awareness of potentially violent protests in proximity of ASPR deployed personnel and resources.

Over the last year, Fusion continued to enhance its ability to provide key demographic information for communities impacted by disasters through its GIS-based Community Analyst tool. Information from this tool is provided to relevant stakeholders to inform situational awareness about the community profile, particularly indicators of community vulnerability. Enhancements include a more streamlined reporting capability, reducing the time needed to create demographic reports, as well as additional age ranges (<5) and language data.

During OEM's response to the Flint, MI, Water Crisis, the Fusion GIS team organized and led a GIS working group that included representatives from several Federal agencies (HHS, EPA, FEMA) as well as state and local GIS representatives. GeoHEALTH was used to integrate and share data among this group and helped provide a common operating picture. The Fusion Data & Analytics team provided a twice per week social media report that summarized information discovered in open/social media in the following categories: HHS/Federal Government Related, Response Issues, Local Government Issues and Broader Issues. During OEM's response to Zika, Fusion GIS organized and led a similar GIS working group and provided on-site support to the Zika Unified Coordination Group (UCG) in Puerto Rico.

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 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 matter 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.

HHS also uses National Special Security Event (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.

In FY 2016 OEM convened the first ESF#8 Senior Leader advisory council to identify and coordinate all related public health and medical assets and issues prior to an incident. This initiative has enabled OEM to have broad coordination with all interagency partners in a centralized format, and to improve preparedness functions at the federal level. Specifically, agencies that had never participated in the preparedness phase for ESF#8 were brought together by OEM to confirm available public health and medical assets in the event of a large scale response requiring federal assistance.

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.

OEM has captured significant lessons learned from involvement in National Exercises, Trainings and Responses. Corrective Actions and Lessons Learned from these events include:

- The broad recognition that tactics, techniques, processes and procedures for responding at the tactical, operational and strategic level are not robust and well documented. This resulted in a renewed effort to create Concept of Operations at all levels to document and standardize our actions

- Identified and tracked corrective actions which led to the formalization of various policies and procedures, including the development and finalization of the Emergency Management Group (EMG) Concept of Operations (CONOPS), Disaster Medical Assistance Team (DMAT) CONOPS and National Special Security Events CONOPS.
- The corrective actions process is used for training events, the resulting feedback from training participants and observers led to a standard Program of Instruction format and the development of an instructor training curriculum. This standardization has improved training ensuring response staff is knowledgeable to respond effectively within the HHS framework when deployed.
- Updated Training, Exercises, and Lessons Learned (TELL) Corrective Action Program (CAP) policies and procedures in support of the Emergency Management Program (EMAP) Accreditation process through the development of a TELL CAP , standard operating procedure, the maintaining of detailed records for CAP working group meetings, and the implementation of system upgrades within the CAP Management Tool.
- Deployed as members of the IRCT to provide in-person evaluation support at NSSEs such as the 2016 Republican National Convention (RNC) expanding the lessons learned data collection from responder only to an outside perspective.
- Overall, corrective actions implemented in FY16 focused on standardization and documentation significantly enhancing OEM preparedness.
- Led the design, planning and coordination for HHS participation in 14 major exercises including:
    - Planning and coordinating ESF#8 participation in The "Cascadia Rising" exercise with the States of Washington, Oregon, and Idaho which focused on the public health and medical issues surrounding a Cascadia subduction zone earthquake. In addition to the national level exercise the HHS exercise team conducted two ramp up events designed to prepare HHS and our ESF#8 partner organizations for participation in Cascadia Rising.
    - Continuation of 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. As an example, Nimble Challenge exercises in FY 2016 addressed the most challenging aspects of medical countermeasure distribution, and managing critical scarce resources in a catastrophic event.
    - Expanded the Nimble Challenge no-notice exercise series with the addition of the Nimble Response no-notice exercise series. These no-notice exercises examine the second and third order effects of decisions made during a Nimble Challenge exercise and allow participants to operationalize those decisions.
    - Continued the Noble Lifesaver series of exercises designed to increase preparedness to conduct patient evacuation and movement. Conducted two Noble Lifesaver Patient Movement exercises in Washington and Oregon.
    - Conducted a major mission rehearsal exercise in preparation for ESF#8 support to the RNC. This exercise, conducted in Cleveland, Ohio, allowed public health and medical organizations, emergency services and emergency management agencies to walk through their plans to support the RNC identifying and de-conflicting gaps in planning and response capabilities.
    - Continued our exercise planning in support of the 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.
    - Support to NSCS 2016 Senior Level Transition Exercises designed to demonstrate how domestic incident management authorities and doctrine may be applied during response to a major disaster, illustrating both the key issues facing federal decision-makers and the relevant statutes, policies, doctrine, and plans

- Development and delivery of four OEM Plans validation exercises 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 its role as the HHS lead for exercises, the Exercise Team supported the design, development and conduct of two international exercises involving eight different countries in support of the Global Health Security Initiative Ministerial exercise and the joint USA/Korea Able Response exercise designed to enhance both countries' biological response capabilities. During the Able Response exercise, more than 140 Republic of Korea and United States officials participated from over 40 agencies.
- Conducted multiple Federal Coordinating Center exercises focused on the collaboration between HHS and DoD for patient movement.
- The TELL Exercise Team also supported the FEMA National Exercise Division in the design, development and conduct of the 2016 Capstone Exercise. The Capstone Exercise was a complex event to test information sharing between federal agencies, Continuity of Operations Plans, and the US Government response to a nuclear detonation in Washington, D.C.

Funding History

Fiscal Year	*Amount*
FY 2014[1]	$28,029,000
FY 2015	$24,789,000
FY 2016 Final	$24,654,000
FY 2017 Annualized CR	$24,607,000
FY 2018 President's Budget	$24,607,000

Budget Request

The FY 2018 Budget includes $24,607,000 in budget authority for Preparedness and Emergency Operations activities. This request is consistent with the FY 2017 annualized CR level. The request supports OEM's ability to immediately respond to a public health emergency or medical incident.

The FY 2018 request includes $4,990,000 in three-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)

ASPR National Disaster Medical System	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority	49,904	49,809	49,809	--
FTE	**115**	**115**	**115**	**--**

Authorizing Legislation:
Authorization ..... Public Health Service Act
Allocation Method ..... Direct Federal/intramural, contracts

Program Description and Accomplishments

When disaster strikes, the Office of the Assistant Secretary for Preparedness and Response (ASPR) Office of Emergency Management (OEM) is called upon to support communities with critical medical services to protect public health and help communities recover faster. OEM's National Disaster Medical System (NDMS), logistics capabilities, and Regional Emergency Coordinators (RECs) are unique assets positioned and authorized to deliver essential medical and emergency management services with advanced equipment and subject matter expertise when requested by a state, local, tribe, territory or Federal agency.

In FY 2017 NDMS is incorporating results from the Threat and Hazard Identification and Risk Assessment (THIRA), as well as consideration of state, local, tribal, and territorial (SLTT) governments. NDMS' mission is to augment communities with medical services after a disaster or public health emergency; and to support the Department of Defense and Veterans Administration (VA) in cases of a surge in military casualties that could overwhelm their medical systems. Since its establishment in 1987, NDMS has responded to over 300 domestic incidents to support communities in need and two international incidents. NDMS provides assistance to communities impacted by public health and medical emergencies due to natural and/or man-made incidents. For each incident, NDMS deploys trained medical teams to provide medical services and/or augment health and medical facilities in impacted communities.

NDMS's is supported by a workforce of more than 5,000 intermittent federal employees organized into 73 teams. NDMS teams include clinical providers and emergency medical service professionals, including physicians, nurses, paramedics, and other support staff such as logisticians and information technology specialists. NDMS is capable of providing medical, veterinary, and mortuary response; patient movement support; definitive care; and behavioral health support. NDMS Team employees are permanent excepted–service federal employees utilized on episodic intermittent basis acting under official orders. Team employees receive protection under the Uniformed Services Employment and Reemployment Rights Act (USERRA), Federal Tort Claims Act (FTCA) and Workers' Compensation under the Federal Employees' Compensation Act (FECA), and are compensated, traveled and billeted based on Civil Service classifications and standards associated with a public health emergency or a designated and properly rated National Security Special Event (NSSE). In FY 2017 NDMS instituted medical and fitness standards to ensure its personnel deploy in an increased health and safety posture that does not obstruct its ability to conduct the mission of the Department.

NDMS teams include:

- ***Disaster Medical Assistance Teams (DMAT):*** The DMAT is responsible for providing medical care and support during public health and medical emergencies such as natural and technological disasters, acts of terrorism, disease outbreaks, and special events including NSSEs and responsible for providing stabilizing emergency medical care to the affected communities. DMATs are designed to respond to all-hazards situations and function in a self-sufficient manner 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 a 7-person task force (TF), 14-person TF, and a 35-person team that are capable of deploying within eight hours of notification. During Superstorm Sandy ASPR deployed over 20 DMATs on a rotational basis comprising of 2000+ employees.

- ***Trauma Critical Care Teams (TCCT):*** The TCCT is responsible for providing trauma and critical care support during public health emergencies and special events including NSSEs by providing a deployable advance unit, augmentation to existing medical facilities, or establish a stand-alone field hospital. The TCCTs are configured to deploy as 7-person TF, 28-Person TF, and a 48 person team. The TCCTs are staffed heavily with board certified and practicing surgical and trauma professionals.

- ***Disaster Mortuary Operational Assistance Teams (DMORT):*** The DMORT provides services for the management of fatalities resulting from natural and/or man-made disasters. These services include providing support to the local medical staff with jurisdictional and/or legal authority (e.g. Medical Examiner, Coroner) during a mass fatality incident by obtaining post-mortem data from the decedent's remains as well as ante-mortem data and medical and/or dental records of victims from their next of kin or other responsible parties, to aid in the identification of the victims; and to do this with 100% accuracy and the utmost respect, dignity, compassion, and confidentiality. DMORTs also support the National Transportation Safety Board with major transportation incidents that have mass fatalities. The DMORT is modular and can deploy only those sections required to support a particular mission requirement. The modular structures consist of DMORT Fatality Management Assessment Team and DMORT 12-Hour Morgue Operations Team. Upon deployment, these modular teams can be augmented and expanded, or contracted depending on the specific needs of the incident. Organizationally, the DMORTs are regionally assigned in each of the ten HHS Regions.

- ***National Veterinary Response Teams (NVRT*)**: The NVRT deliver disaster medical care for large and small animals during large scale disaster responses. In addition, the team provides support, upon request, to federal service animals during designated NSSEs. NVRTs are primarily composed of veterinarians and animal health technicians to facilitate the stabilization of animal populations affected by a disaster and serve a critical role in supporting working animals for NSSEs. The NVRT is a single national team with regional support capability for a more rapid deployment.

- ***Victim Identification Center Team (VIC):*** The VIC is responsible for providing support to local authorities during a mass fatality and/or mass casualty incident by collecting ante-mortem data and serving as liaison to victim families or other responsible parties in support of the DMORT, DMAT, and/or the TCCT. When activated, VIC deploys as a single, unified team as single resource elements in a subject matter expert role.

NDMS continues to provide individual and team training to all team members based on individual roles and team mission requirements. NDMS currently trains thirty percent of its workforce per annum on a rotating basis. In previous years NDMS has trained team members without the total team concept; however, in FY 2017 the training model changed to include entire teams attending training. This approach not only ensures total familiarity of mission and equipment but increases team building. For fundamental training, NDMS selects staff from various teams to attend each fundamental training event ensuring each team has staff that are trained and familiar with current equipment and also understand current policies and procedures. NDMS will continue to utilize all methods to conduct training and will continue to integrate other federal entities including the Medical Reserve Corps, Public Health Service Officers, and SLTT and territorial officials, to strengthen response capabilities.

Deployment of NDMS teams require support from multiple Divisions within OEM once the NDMS and Operations Director determine which team or teams will deploy and the order in which teams respond to an event. The decision considers the request from the state, time to get a team onsite, and which teams are on-call for the period of the event. The Division of Logistics provides the logistical resources inclusive of medical equipment and supplies, communications equipment, pharmaceuticals and wrap around services. The initial resource package allows NDMS to conduct patient care for 72 hours with minimum disruption. Once the teams are fully engaged in the mission, approximately ten hours upon arrival, the resupply process is established per documented procedures. The Division of Operations conducts operational oversight from the time of activation through return to home station. Operational oversight includes personnel accountability and mission assignments. Without the consolidated effort of the Divisions, NDMS would not be successful in accomplishing its multifaceted mission.

NDMS's recent initiatives and accomplishments include the following:

- Throughout FYs 2016 and 2017, NDMS teams provided public health and medical support for the following: Hurricane Matthew, the Louisiana flood, the 45th Presidential Inauguration, the State of the Union Address; the United Nations General Assembly; and the Peace Officer's Memorial, and ongoing operations in Puerto Rico for the federal Zika response.

- Beginning in FY 2016, NDMS provided state and local emergency responders a low-cost training resource utilizing mobile training assets and logisticians. These mobile training assets train hundreds of NDMS and state and local emergency responders.

Division of Logistics

In FY 2017, OEM completed an ASPR Threat and Hazard Identification and Risk Assessment Methodology and Process (THIRA) to assess the vulnerability of people, property, the environment, and OEM's operations from potential threats and hazards including natural and man-made disasters. The results of the THIRA found that there would be significant requirements of OEM's assets, including NDMS teams and logistics equipment, for the highest threats of hurricanes, emerging infectious diseases, and human pandemic outbreaks. The THIRA enabled OEM to understand the exact requirements for each of these potential hazards and plan accordingly. NDMS is incorporating results from the THIRA, as well as consideration of state, local, and territorial capabilities obtained through state and regional collaborations, to ensure new threats and risks are addressed going forward. Considerations have already been incorporated into NDMS's training curriculum and mission constructs. The THIRA also determined the logistical response resources required to support state, local and tribal territories during catastrophic and moderate events. The results validated the need for ASPR to continue to stockpile critical material at current levels at a high state of readiness to facilitate patient care by NDMS and other Public Health and Medical response teams to support gaps identified by state, local and tribal territories.

The OEM's Division of Logistics manages and provides the critical logistical supporting components for NDMS and other HHS public health and medical teams to respond to public health emergencies. When NDMS teams are deployed, the supplies they will need to support the mission are also deployed with the team. The Division of Logistics 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 catastrophic environments. Staff located and operating in regionally-based warehouses maintain strategically positioned medical material and deploy resources at a moment's notice. By supporting a regional footprint and maintaining assets in various geographic locations, OEM is prepared for disasters, no matter where they occur within SLTTs. The Division of Logistics manages and maintains over $70 million in response material and supplies including: vehicle fleets; medical, laboratory, 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 to include ancillary planning and technical support to SLTT governments on how to integrate federal logistics resources into the local response.

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

- The Division deployed, sustained, and reset hundreds of tons of medical material and resources to support both NSSEs as well as natural disasters such as the historic 2016 Louisiana flood response; multiple states for Hurricane Matthew response; Zika Unified Coordination Group in Puerto Rico; Flint, Michigan Water Crisis United Coordination Group; 2016 State of the Union Address; Peace Officer's Memorial; fifteen regional and local NDMS training events; Democratic and Republican National Conventions; 2017 Presidential Inauguration; 2017 Joint Session of Congress Address; Fourth of July Celebration on the National Mall; and United Nations General Assembly.

- Continued support and participation in the above events highlight the critical need for medical logistics resources to save lives, but also highlights the need to modernize medical equipment, communications, personal protective equipment to ensure that NDMS and other public health and medical response teams have the best equipment, supplies, and resources to protect themselves, communicate effectively, and save lives. To ensure efficiency with the modernization, the Division must leverage state of the art technology, e.g. barcoding systems, that interface emergency management systems to enhance interoperability and transparency while reducing error and cost. Leveraging new technology will create efficiency, reduce redundancy, and reduce the potential for medication and medical supply errors being introduced in deployable caches. Modernization will be balanced with currently available resources; with current static funding levels, the Division will seek trade-space between the need to modernize critical equipment while sustaining current operational tempo and activities.

The Division continues to collaborate with the private sector, SLTT governments and inter-agency federal partners to implement best supply chain management practices to enhance national preparedness and response with a focus on continuous improvement of successful patient outcomes. During the past several years, the Division has completed a national regionalization initiative that standardized and centralized response resources for NDMS teams for efficiency and effectiveness; established inter-agency agreements with federal partners to gain efficiencies in warehousing, procurement activities, and use common resources to reduce redundancy; re-engineered medical caches to be scalable and mobile; and lastly, OEM's Emergency Prescription Program (EPAP) was re-established and awarded with an increased medication formulary resulting in a 93% cost avoidance compared to the previous contract. EPAP is a vital national rapid response capability used during disasters by SLTT governments to get life sustaining chronic care medications for disaster victims and evacuees. EPAP has provided life sustaining medications to thousands of disaster victims via real time payment at community pharmacies and in doing so preventing additional stress to the disaster affected healthcare systems particularly at Emergency Departments (ED). The listed initiatives and associated cost savings valued at well over $3 million, demonstrates the Division's innovation, tenacity, and resilience in sustaining critical medical logistics activities with the complexity of static funding levels despite rising inflationary cost.

Division of Regional and International Coordination

OEM's Division of Regional and International Coordination also plays 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 in each of the 10 HHS regions to build and maintain relationships with SLTT officials and health care representatives. These regions are the ten HHS regions. These established 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 2014	$50,054,000
FY 2015	$50,054,000
FY 2016 Final	$49,904,000
FY 2017 Annualized CR	$49,809,000
FY 2018 President's Budget	$49,809,000

Budget Request

The FY 2018 budget request is $49,809,000 in budget authority, which is the same as the FY 2017 annualized CR level. The request supports continued NDMS operations, logistics support, and regional emergency coordination, to prepare and respond to public health emergencies and disasters. Continued funding will be required for medical response assets, including NDMS teams, supplies, and equipment.

Funding in FY 2018 will be used to maintain trainings to ensure personnel are trained annually. NDMS's current funding supports the training cycle goal to rotate the 73 teams through the basic training and advanced training components every three years or approximately 30 percent of the total workforce annually. NDMS will strive to continue to meet operational requirements; however, with operational and sustainment costs increasing, NDMS may reduce training back to FY 2015 levels. In addition, the training structure supported with current resources does not allow for team training or offer opportunities to enhance NDMS partnership requirements. 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. NDMS may implement further efficiencies to trainings, capabilities, and requirements to ensure the system remains prepared for all disasters while meeting the evolving administrative and operating costs. NDMS will continue to review internal operations, programs, and initiatives in FY 2018 to prioritize the highest-priority/critical activities to support NDMS in meeting the mission of the Department.

In addition, the Division of Logistics will continue to replenish and maintain medical, communications and pharmaceutical caches at a high state of readiness; however, in FY 2018 and future fiscal years, Logistics will be challenged to support cache readiness and lifecycle replacement of critical technology. The current inventory of logistics equipment for NDMS and other personnel to utilize are critical to OEM's capability to support a response requesting resources. It is fundamental for OEM to establish a comprehensive lifecycle management program for deployable cache equipment and consumable products, as the majority of the equipment was transferred in 2007, when NDMS was realigned from FEMA to ASPR, with only four years of replacement and sustainment funding. Several of the major components of the caches will reach their expiry and inadequate functionality by the end of FY 2019. The faster than normal inflationary rate for medical materials and pharmaceuticals has added a new cost barrier for the routine sustainment of deployable medical caches. For example, 100% of the cache respiratory ventilators are beyond the timeframe for lifecycle replacement and ventilator failure rates among the caches are as high as 50% requiring more repairs and increase gaps in deployable resources The target is 50% lifecycle

replacement of cache ventilators (75 ventilators and ancillary consumable supplies) by FY 2019. The ventilator is one example of many cache equipment sets that requires immediate replacement to maintain not only cache deployment readiness for an effective response to a disaster but maintain a standard of care consistent with current medical practices. The NDMS medical caches are designed to provide a healthcare response team medical capability to provide treatment to a board range of medical conditions seen in a disaster not available from the Strategic National Stockpile. Furthermore, the deployable OEM medical caches are designed for the federal medical response teams and provide full operational requirements (tents, generators, beds, etc.) to establish a base of operation to effectively treat victims of a disaster.

ASPR National Disaster Medical System - Outputs and Outcomes Table

Measure		Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
1.1	**Maintain the percent of new NDMS intermittent staff that complete psychological first aid training (Output)**	FY 2016: 100% Target: 100% (Target Met)	100%	100%	Maintain
1.2	**Adjust the percent of new NDMS intermittent staff who complete both basic and advanced deployment training (Output)**	FY 2016: 25.0% Target: 15.0% (Target Exceeded)	20.0%	10.0%	-10%

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

CIVILIAN VOLUNTEER MEDICAL RESERVE CORPS

Budget Summary
(Dollars in Thousands)

ASPR Civilian Volunteer Medical Reserve Corps	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority	**6,000**	**5,989**	**5,989**	**--**
FTE	**6**	**6**	**6**	**6**

Authorizing Legislation:
Authorization ..... Public Health Service Act
Allocation Method ..... Direct Federal/intramural, contracts

Program Description and Accomplishments

The civilian volunteer Medical Reserve Corps (MRC) is a national network of over 200,000 volunteers, organized in almost 1,000 local community-based units. These units are committed to strengthening public health, reducing vulnerabilities, improving local preparedness, response and recovery capabilities, and building community resilience. MRC units have supported numerous community public health missions, participated in local and regional exercises across the Nation, and responded during emergencies when called upon by Local and State response agencies. Due to the community-based nature of MRC, each unit provides a unique set of capabilities before, during, and after emergencies, how it supports and during public health missions. MRC units' capabilities can vary according to community needs, geographical region and local investments,, among other factors.

MRC units are very active in their communities, as evidenced by their 18,019 activity reports in FY 2015 that show more than 172,000 MRC participants contributed over 400,000 hours of volunteer service. These activities have had significant local impact: 306 activities/responses to local emergencies, 8,560 activities where MRC members strengthened the local public health system, 4,141 activities that served a vulnerable population, 5,918 activities that supported non-emergency community events, 11,963 activities that developed or strengthened the MRC unit, 8,457 activities that improved community preparedness or resilience, and 6,869 activities that trained or exercised MRC members to improve unit or community response capability and capacity.

Recent MRC accomplishments include:

- In early 2016, MRC units began planning for a potential public health response to Zika. Since then, many units have reported activities in support of Zika virus education, outreach, prevention, and collaboration with community and other partners.
    - Puerto Rico MRC volunteers have provided near-daily community education and outreach in local municipalities across the island since February 2016.
    - Florida MRC volunteers assisted with Zika epidemiological surveillance and active case finding. They participated in Zika-related preparedness training and local tabletop exercises, and conducted door-to-door outreach, including providing community members with mosquito repellant, Zika prevention information, and (with the home occupant's permission) a vector control assessment and demonstration about the elimination of potential mosquito breeding situations on the property. Some MRC units engaged the community by distributing Zika educational materials at local businesses and community events.
    - Texas MRC units participated in Community Assessment for Public Health Emergency Response (CASPER) surveys to collect information and provide education on the Zika virus.

- There was severe flooding in several states, and MRC were on hand to assist with shelters and other needed support.
    - The nurses and administrative volunteers of Pee Dee MRC, based out of South Carolina, served as team members on mobile vaccination units to provide tetanus vaccinations in response to heavy and flash flooding in the State. The State's Department of Health and Environmental Control sent the units to multiple community and disaster recovery centers around the region to ensure that people had access.
    - MRC volunteers from several units in Texas supported shelters and resource distribution centers, staffed phone banks and crisis hotlines, and coordinated with partners from public health, emergency management and local Voluntary Organizations Active in Disaster (VOAD). Of special note, the newly formed Brazos County Veterinary MRC was able to provide care for companion animals at shelters as well as field care for large animals that were left alone for extended periods.
    - The Calcasieu MRC, Acadiana MRC, Baton Rouge Area Volunteer Health Corps MRC, and New Orleans MRC units actively engaged in activities related to the heavy rain and flooding in Louisiana. They partnered with local stakeholders to accept, log, and distribute donations, and worked with their local VOAD to complete intake assessments for flood victims. Additionally, MRC nurses, mental health providers, and non-medical/support volunteers assisted at shelters in Lafayette and Baton Rouge.
- The New York City MRC was activated to staff a three day Point of Dispensing (POD) for nearly 400 individuals that were potentially exposed to H7N2 influenza, after adopting a pet from a shelter with infected cats. During the PODs, individuals were swabbed and offered Tamiflu and a flu shot, if needed. Fourteen MRC volunteers provided 97 hours of service.
- The New Orleans MRC in Louisiana was supporting a Mardi Gras first aid station with local emergency responders when a car drove into a crowd three blocks away. Approximately, a dozen people were injured in the incident and MRC volunteers were able to quickly respond and provide first aid until EMS arrived.
- Tulsa County MRC, based in Oklahoma, activated volunteers to provide administrative support for a mumps POD. The health department confirmed eight cases linked to the ongoing mumps response in Arkansas, and the POD allowed for the screening and vaccination of 500 potential cases.
- The Region 2 North, Monroe County, Livingston County, Wayne County, Washtenaw County, and CCS Bay Region MRC units in Michigan had 25 volunteers respond to the Flint, MI Water Crisis by participating at a Volunteer Reception Center. Volunteers provided assistance with credentialing, water filtration kit assembly, registration, and orientation.
- The Colorado Acupuncture MRC was requested by the State's Public Health Department for a behavioral health response to provide care to survivors and responders at a Colorado Springs field clinic after the mass shooting at Planned Parenthood. Sixteen MRC volunteers provided more than 300 hours of service.
- MRC volunteers across the nation were trained and now provide education on the use of Naloxone in recognition of the significant increase in drug overdoses due to the opioid crisis in across the nation.

Funding History

Fiscal Year	*Amount*
FY 2014	$8,979,000
FY 2015	$8,979,000
FY 2016 Final	$6,000,000
FY 2017 Annualized CR	$5,989,000
FY 2018 President's Budget	$5,989,000

Budget Request

The FY 2018 Budget includes $5,989,000 for the civilian volunteer Medical Reserve Corps, which is level to the FY 2017 Annualized CR. This funding will primarily support the following efforts:

- Provide overarching support, regional coordination and technical assistance to MRC unit leaders to guide the development of the units.
- Identify the key missions and/or functional areas most often supported by MRC units (i.e. shelter support, mass vaccination, medical countermeasure dispensing) and develop a system to track, monitor and assess units' ability to support the mission and the extent to which they can assist.
- 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)

ASPR Hospital Preparedness Program	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority /1	**254,555**	**254,071**	**227,201**	**-26,870**
Cooperative Agreements /2 (non-add)	*228,500*	*228,500*	*204,500*	*-24,000*
Program Costs /3 (non-add)	*26,055*	*26,055*	*22,701*	*-3,354*
FTE	**44**	**49**	**49**	**--**

1/ These amounts do not include funding for Ebola preparedness and response from the emergency appropriation to the Public Health and Social Services Emergency Fund.
2/ The Public Health Service (PHS) Act determines HPP cooperative agreement eligibility as the 50 states, Washington, DC, three high-risk political subdivisions, and all U.S. territories and freely-associated states. HPP does not directly fund hospitals.
3/ Other costs include: HPP cooperative agreement administration, evaluation, and performance management, the Emergency Care Coordination Center (ECCC), Critical Infrastructure Protection (CIP), the Technical Resources Assistance Center and Information Exchange (TRACIE), and the Division of Recovery.

Authorizing Legislation:
Authorization ..... Public Health Service Act
Allocation Method ..... Formula grant/cooperative agreement; direct Federal/intramural; contracts

Program Description and Accomplishments

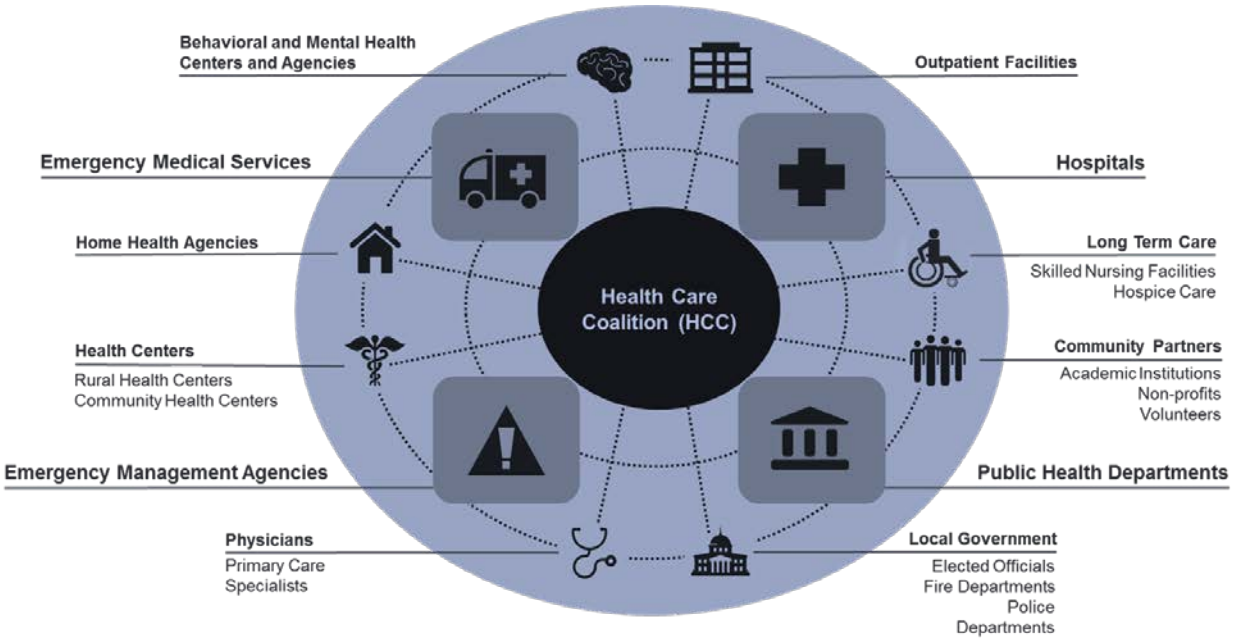
The Hospital Preparedness Program (HPP) is critical to the local, state and regional health care preparedness and response efforts. HPP enables the health care system to save lives during emergencies that exceed the day-to-day capacity of the health and emergency response systems. As the only source 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.

Health Care Coalitions Help Each Patient Receive the Right Care at the Right Place at the Right Time during Emergencies
Since 2012, HPP has encouraged its awardees, the public health departments in all 50 states, U.S. territories, Washington, DC, Chicago, Los Angeles County, New York City, and all freely-associated states, to invest in forming and developing health care coalitions (HCCs). HCCs are groups of individual health care and response organizations (e.g., hospitals, EMS, emergency management organizations, public health agencies, etc.) in a defined geographic location that play a critical role in developing health care delivery system preparedness and response capabilities. HCCs serve as multiagency coordination groups that support and integrate with Emergency Support Function #8 (ESF #8, public health and medical services) activities in the context of incident command system (ICS) responsibilities. HCCs coordinate activities among health care organizations and other stakeholders in their communities; these entities comprise HCC members that actively contribute to HCC strategic planning, operational planning and response, information sharing, and resource coordination and management. As a result, HCCs collaborate to ensure each member has what it needs to respond to emergencies and planned events, including medical equipment and supplies, real-time information, communication systems, and educated and trained health care personnel. The ability to share information in an emerging incident, improves situational awareness and use of resources – including health care professionals and specialized equipment – when one facility is overwhelmed to

provide timely and required levels of care mitigate the impact of the incident on the facilities themselves, as well as existing and potential patients or event casualties.

To do this, HCCs incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. HCCs include core members, such as hospitals, emergency medical services (EMS), emergency management organizations, and public health agencies, as well as additional HCC members that all collaborate to prepare, plan, and respond to emergencies. Figure 1 below displays the ideal and varied network approach that HCCs offer to 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.

Figure 1. Health Care Coalition Network. Text version of Figure 1



HCCs serve as a public-private partnership. As stated in the *National Response Framework*:

> "…private sector organizations contribute to response efforts through partnerships with each level of government….During an incident, key private sector partners should have a direct link to emergency managers and, in some cases, be involved in the decision making process….Private sector entities can assist in delivering the response core capabilities by collaborating with emergency management personnel before an incident occurs to determine what assistance may be necessary and how they can support local emergency management organizations during response operations….".

HCCs 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 for emergencies with the potential to cause a medical surge, HCC- and individual health care facility-level exercises, and trainings for health care workers. HCCs have supported communities' health care systems throughout the nation during past response operations.

HCCs are pivotal to ensuring that the nation's health care system is ready to respond to many kinds of events and infectious disease outbreaks. Recent examples include preparations for the Republican National Convention in northeast Ohio, response to the Ft. Lauderdale airport shooting, and the Hurricane Matthew response in Georgia, and many other public health and medical events.

Republican National Convention Preparations, Northeast Ohio – An estimated 50,000 visitors congregated in Cleveland for the Republican National Convention (RNC) in July 2016. The Northeast Ohio Regional Health Care Coalition (HCC), a network of hospitals, EMS, public health departments, and emergency management services, proved critical to coordinating the city's year-long medical preparations for the convention. The HCC connected with cities that had previously hosted conventions to incorporate lessons-learned, while also reaching out to 27 hospitals and specialty medical facilities across Ohio and neighboring states to prepare medical surge support. Before and during the Convention, the HCC coordinated closely with HHS and the Secret Service and led information management efforts, surveying health care facilities daily to ensure inventories of specialized equipment, contact information, blood inventories, and hospital bed availability were up-to-date. "Without the Northeast Ohio Regional HCC, there would have not been a centralized body to coordinate all of the different players and information sources involved with the Convention," noted an HCC member. "When you stop and contemplate what could happen if your city all of a sudden needed to care for 20,000 people, you recognize the importance of an HCC."

Ft. Lauderdale Shooting Response – When a shooter opened fire on January 6, 2017 in at the Fort Lauderdale - Hollywood International Airport, killing five people and injuring many more, the Broward County HCC was ready to respond. The HCC and the airport have been close partners since 2007, performing multiple disaster drills together every year. Thanks to years of exercising together, the HCC and airport have formalized plans placing representatives at both the airport's Emergency Operations Center (EOC) and in local hospitals, greatly enhancing information sharing during a response. This shared coordination enabled effective, real-time communication between health care responders, transit authorities, and law enforcement as the incident unfolded. Within seven minutes of shots being fired, the HCC EOC liaison at the airport was coordinating patient distribution with first responders on the scene while providing real-time updates to local hospitals and HCC members. As a result, local hospitals were able to suspend scheduled surgeries and accommodate over 50 incoming patients. One HCC member reflected that, "…the response felt like an organized symphony. Without our HCC, we would not have had the established relationships or communication channels that enabled us to efficiently transport and treat so many unexpected patients and, ultimately, save lives."

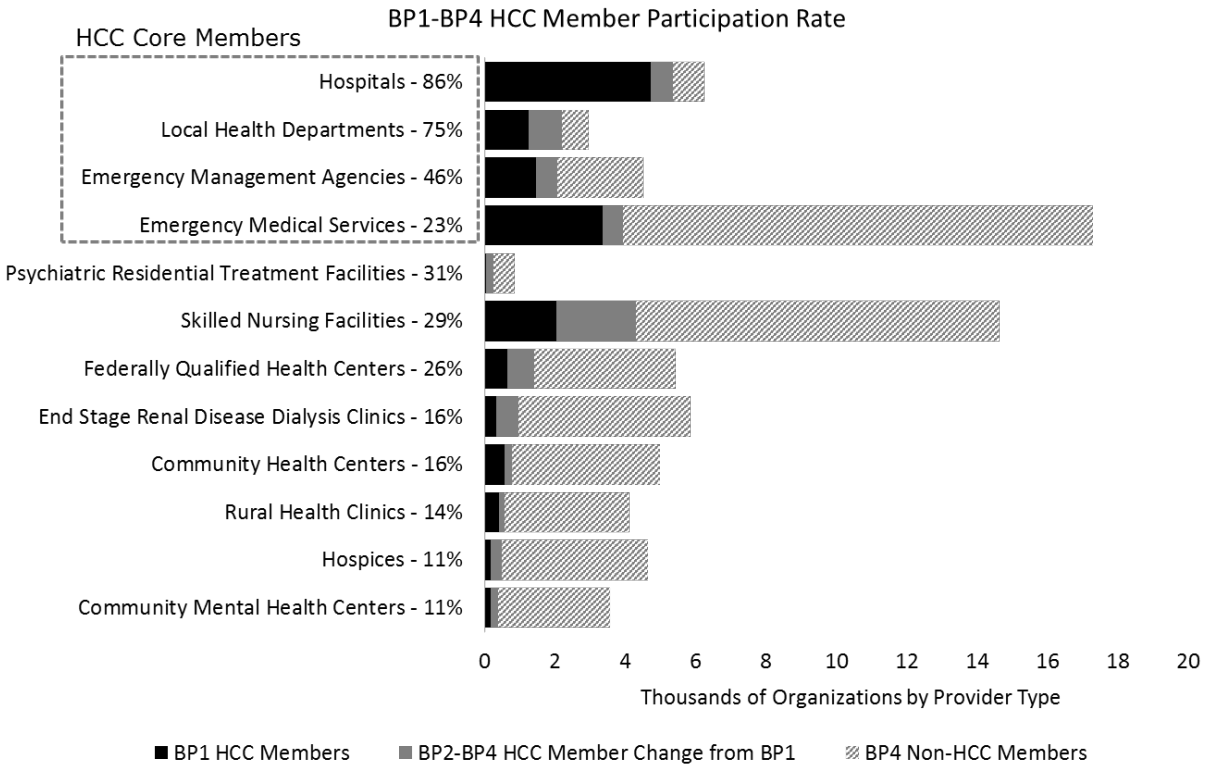
Hurricane Matthew Response in Georgia – As Hurricane Matthew barreled towards Georgia, local HCC members knew what to do. The HCC had a strong coastal evacuation plan developed based on lessons learned through years of HPP-funded exercises, as well as numerous agreements with health care and other partners essential for moving patients across Georgia. These formalized, cross-functional partnerships enabled shared understanding of staffing, capacity, and resource availability before and during the response. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 patients – some just out of surgery – without any loss of life. The HCC turned to its strong partnerships, including law enforcement, to ensure all patients were relocated around the state using appropriate transportation, which included using helicopters from neighboring states to evacuate the most critical patients to safety. One HCC member shared that, "HPP enables critical partnerships to be formed and tested before a disaster. By exercising and planning together, our HCC ensured that everyone knew their role during the response. We would not have successfully evacuated over a thousand patients – some in extremely vulnerable condition – in 24 hours without our HCC and HPP."

As of June 30, 2016 (the most recent data available), over 28,055 health care facilities and community organizations were participating in 476 HCCs nationwide. This is an increase in HCC membership of 85 percent since the project period began in July 2012. The diverse membership of HCCs also contributes to their success in preparing a community to respond to a wide variety of incidents that impact the public's 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 below displays the HCC membership diversity and the participation rates by member type. For example, there are currently 5,370 hospitals participating in HCCs, which represents 86 percent of all U.S. hospitals.

Figure 2. HCC Membership Diversity and Participation Rates, June 2016.

Text version of Figure 2



Health Care System Emergency Preparedness and Response: Capacity and Capability

The number of incidents across the U.S. with the potential to impact the public's health is significant. HPP-funded programs and initiatives provide assistance to incidents at the local and state level, as well as those 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.

Historically, HPP funding invested in and increasing local *capacity* to prepare for and respond to events through the purchase of critical resources including communication systems, volunteer registries, patient tracking, information-sharing tools, and credentialing systems. As a result, local health care systems increased their capacity and decreased reliance on federal medical assets during disasters.

Current HPP investments not only focus on health care organization *capacity*, but also enhance the health care systems' *capability* to ensure that a region can prepare and respond to emergency situations as soon as they occur. In late 2016, HPP refined the health care preparedness and response capabilities that describe what the health care delivery system, including HCCs, hospitals, and emergency

Figure 3. 2017-2022 Health Care Preparedness and Response Capabilities.

medical services (EMS), have to do to effectively prepare for and respond to emergencies that impact the public's health. The *2017-2022 Health Care Preparedness and Response Capabilities*[2] outlines the high-level objectives that the nation's health care delivery system should undertake to prepare for, respond to, and recover from emergencies. These capabilities illustrate the range of preparedness and response activities that, if conducted, represent the ideal state of readiness in the United States. They support and cascade from guidance documented in the *National Response Framework*, *National Preparedness Goal*, and the *National Health Security Strategy* to build community health resilience and integrate health care organizations, emergency management organizations, and public health agencies.

The new, streamlined capabilities were developed with significant input from health care, public health, and emergency management stakeholders. Additionally, ASPR incorporated lessons learned from previous responses to emergencies and extensive stakeholder engagement into the revised capabilities. Stakeholder feedback included a Capability Needs Assessment in 2015, which involved surveys and facilitated discussions with state public health department awardees, HCCs, and other stakeholders, to obtain their reactions to the capability content, structure, level of detail, and suggested areas for revision. ASPR also solicited and considered input from more than 50 national associations whose members have an interest in emergency preparedness and response. Finally, ASPR facilitated discussions at emergency preparedness and response conferences, solicited public feedback on ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) website, and consulted preparedness and response and health care subject matter experts. ASPR also conducted a thorough review of relevant preparedness and response literature and researched recent past events to inform the revision process.

These capabilities are flexible enough to encourage all-hazard planning, including for natural disasters, terrorist events, infectious disease outbreaks, or industrial accidents, and to address all populations:

Exercising for Preparedness – Pediatric Safety and Planning – Children have special needs that must be incorporated into emergency preparedness and response efforts and in order to adequately protect them. The Arizona Pediatric Disaster Coalition recognized the need to prioritize pediatric patients and involve the education system in preparedness efforts. In December 2015, a joint exercise, funded in part through the Arizona's HPP cooperative agreement, evaluated how schools and hospitals interact in the wake of an emergency.

The exercise took a medical surge exercise model and tailored the design to include schools and unaccompanied and injured minors. Health care workers, school administrators, and teachers participated along with law enforcement, emergency medical services, and other emergency response personnel to comprehensively test a response centered on children. Within this revised model, health care and education partners ran through a myriad of difficult scenarios, including how best to handle multiple minors separated from guardians, obtaining consent to care for minors, and family reunification.

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 April 13, 2016, which marks the end of updated case counts after the World Health Organization terminated the Public Health Emergency of International Concern) 28,616 suspected, probable, or confirmed human cases.[3] In response, Congress appropriated emergency supplemental funding, in part to ensure that the U.S. health care system is adequately prepared to respond to future Ebola outbreaks. In doing so, Congress directed HHS to develop a regional approach to caring for future Ebola patients.

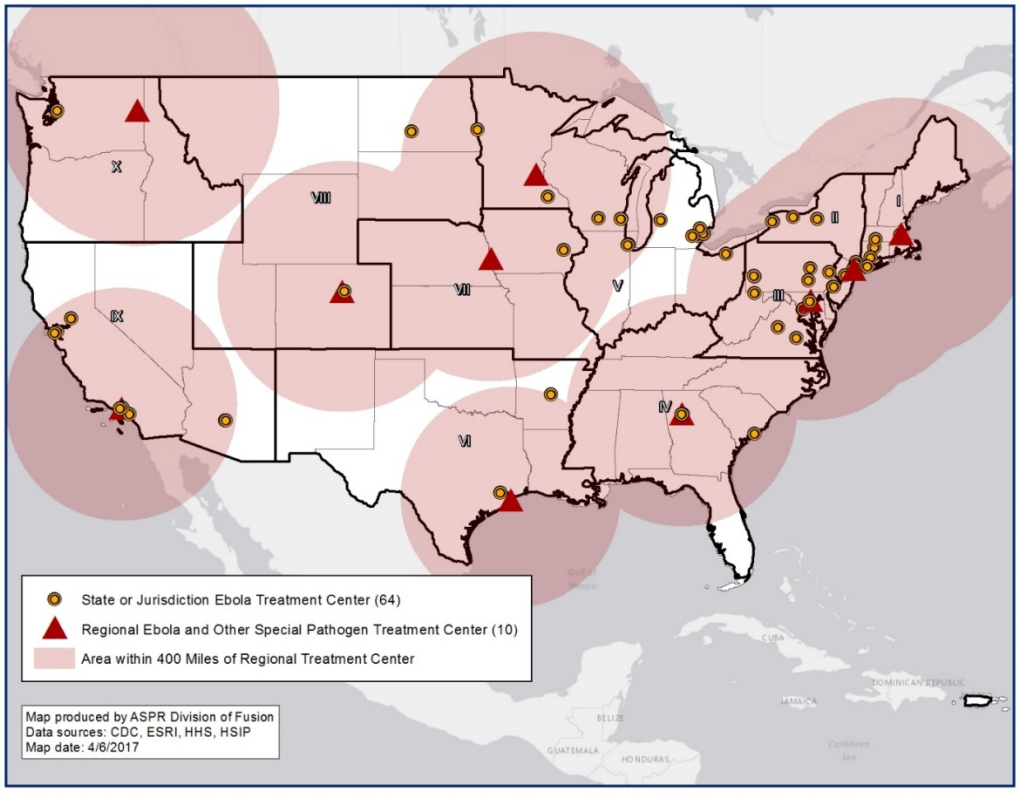
[2] *2017-2022 Health Care Preparedness and Response Capabilities,* https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capablities.pdf

[3] 2014 Ebola Outbreak in West Africa - Case Counts, Centers for Disease Control and Prevention. http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html. Accessed May 3, 2017.

Building upon the state- and jurisdiction-based tiered hospital approach[4] and meeting Congress' regional directive, HPP provided awardees with Ebola emergency supplemental funding to establish a nationwide, regional treatment network for Ebola and other infectious diseases. This approach balanced geographic need, differences in institutional capabilities, and accounted 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 (figure 4) consists of:

1) Ten regional Ebola and other special pathogen treatment centers that can be ready within 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.
2) State or jurisdiction Ebola treatment centers (64 as of April 2017) 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.
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 4. Regional Ebola Treatment Network



Additionally, to prepare for and provide safe and successful care of patients with Ebola, HHS (a collaboration between ASPR and CDC) awarded funding to establish a National Ebola Training and Education Center (NETEC). The NETEC offers state health departments, regional Ebola and other special pathogen treatment centers, state and

[4] 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

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, Georgia; University of Nebraska Medical Center/Nebraska Medicine (UNMC) in Omaha, Nebraska; and the New York City Health and Hospitals Corporation/HHC Bellevue Hospital Center in New York, New York.

Lastly, through the domestic Ebola response, HHS found that there was a significant gap in quarantine capacity in the U.S. health care delivery system. The U.S. lacked adequate space to monitor individuals coming to the U.S. who may have been exposed to Ebola patients from the impacted regions. To close this gap, HPP awarded nearly $20,000,000 to UNMC for a Training, Simulation, and Quarantine Center. This center provides simulated clinical training to federal responders (the National Disaster Medical Response System and the U.S. PHS Commissioned Corps) and now has the capacity to quarantine up to 20 individuals simultaneously, if necessary, on the UNMC campus.

Improving Preparedness through Evaluation and Research

The Science Healthcare Preparedness Evaluation and Research (SHARPER) branch serves as the evaluation team for HPP. SHARPER monitors awardee progress on performance measures, suggests program improvements, conducts research and informs program policy. In addition, ASPR employs quality improvement strategies to streamline business processes and reduce unnecessary burden on HPP awardees.

For FY 2017, SHARPER developed new performance measures (PMs) to align to the core concepts of the health care preparedness and response capabilities and the FY 2017 funding opportunity announcement to allow for the opportunity to evaluate program performance and track program progress of HPP awardees. The new PMs will enable better communication of program results to elected officials and policymakers, as well as various internal and external stakeholders, and will inform continuous program improvement.

For FY 2017 there are 28 measures (of which 6 apply only to select territories and all freely-associated states). These measures allow HPP to objectively track trends in engagement, coordination, communication, patient care, and continuous learning. Half of the performance measures are exercise-based, which will reduce the reporting burden on awardees, improve collection of actionable data, and permit data validation. HPP performance measure guidance is now available[5]. Awardees will report PMs data in September 2018 and HPP will issue results in December 2018.

To measure HPP performance, a variety of measures were developed at the input-, activity-, output-, or outcome-level. While the HPP PMs have historically focused on program activities and outputs, the new PMs further target output and outcome measures to address the information needs of various stakeholders. At a high-level, HPP stakeholders can be organized into three groups based on their information needs—national-, program-, and implementation-level. For example, at the national-level, Congress, HHS, and ASPR leadership, and other national stakeholders may be most interested in the preparedness of the nation's health care delivery system; at the program-level, HPP is interested in program effectiveness, appropriate use of funds, and identifying trends to continually improve the nation's preparedness; and, at the implementation-level, awardees, HCCs, and individual health care organizations may be most interested in how prepared they are to respond to events in their communities.

Figure 5. TRACIE Topic Collection Categories

[5] *2017-2022 Hospital Preparedness Program: Performance Measures Implementation Guidance,* https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hpp-pmi-guidance-2017.pdf

Technical Resources Assistance Center and Information Exchange (TRACIE)

Beginning in FY 2015, ASPR has been enhancing and expanding its technical assistance to state and local communities. ASPR is committed to expeditiously providing technical assistance to help communities connect with the right resources and experts – whether improving the preparedness of 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 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 SME-validated resource materials;
- Topic-specific collections of resource materials (Figure 5 shows the six categories that house our 64 Topic Collections);
- Access to online plans, templates, and trainings;
- Newsletter, *The Exchange*, featuring lessons learned from practitioners in the field;
- Webinars and virtual technical assistance (e.g., Health Care Coalition Involvement in Mass Gatherings and Cybersecurity and Health Care Facilities Roundtable);
- Facilitated, on-line peer-to-peer engagement and support through the Information Exchange; and
- Toolkits, guidance documents, fact sheets, and illustrative examples of promising practices (e.g., CMS Emergency Preparedness Rule Resource at Your Fingertips and HIPAA and Disasters: What Emergency Professionals Need to Know).

Figure 6. TRACIE Infographic

TRACIE launched on September 30, 2015 and has provided technical assistance to local, state, regional, tribal, and federal staff, health care associations, and other stakeholders on a variety of 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. Figure 6 provides an infographica snapshot of TRACIE statistics such as the number of visitors to the TRACIE website, number of technical assistance requests received, number of members in our Information Exchange, and subscribers to the TRACIE listserv.

TRACIE also provides surge assistance and resources during and after incidents. For example, in response to recent activations of the Emergency Prescription Assistance Program (EPAP), TRACIE developed Fact Sheets on the use of EPAP In response to the Zika virus outbreak, TRACIE brought together SMEs from across the country to develop Zika: Resources at Your Fingertips which includes considerations for health care system preparedness planners. In response to the Orlando nightclub shooting, TRACIE developed a resource guide for Florida and Orlando that included Post-Mass Shooting program and resource offerings for public health and health care needs of the community. This resource guide was also used following the Oakland Warehouse Fire and was formally published as the Disaster Behavioral Health Resources at Your Fingertips.

Text version of Figure 6

Strengthening Day to Day Systems of Emergency Care

The emergency care system is an essential part of the US health care 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 steadily increasing with over 130 million patient visits to emergency departments in 2013, the ED is a critical interface between inpatient and outpatient care. ED visits account for 28% of all acute care visits, 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.

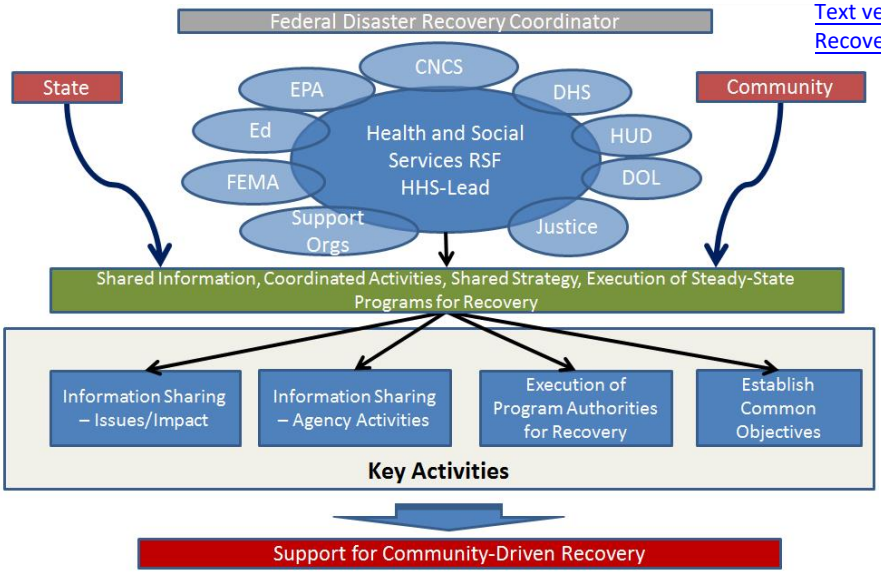
Current ECCC initiatives include improving situational awareness for patients, pre-hospital providers, and emergency managers by improving transparency around the acute care capabilities of hospitals; understanding how acute unscheduled care is managed across different types of providers (primary care, 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 & 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 health care 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

Natural, technological, acts of terrorism, and public health emergencies are often inevitable for communities and regions nationwide. Critical to how the community will persevere and endure the consequences of emergencies and disasters is their capacity to recover. ASPR's Division of Recovery works closely with HPP regional partners and HPP coalition members to build and enhance their pre-disaster and post-disaster recovery knowledge, skills, and networks. A key facet of building recovery capabilities is to follow the policy and doctrinal guidance under the National Disaster Recovery Framework (NDRF) through the Health and Social Services Recovery Support Function (H&SS RSF). Derived from years of lessons learned after major disasters, the NDRF identifies HHS as the coordinating agency for the Health and Social Services (H&SS) Recovery Support Function (RSF). The ASPR Division of Recovery is the lead for coordinating HHS's resources and activities with other federal departments and agencies to support communities' recovery from emergencies and disasters.

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.



[Text version of Federal Disaster Recovery Diagram]

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 with respect to a widespread drought). The Division of Recovery also played an integral role in providing subject matter expertise and technical assistance to support recovery-related initiatives following the Flint water crisis of 2016. Activation of the H&SS RSF capabilities can require deployment to the impacted areas and can occur with or 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 deficits and priorities, develop a recovery support strategy, and coordinate federal health and social services recovery efforts.

In FY 2016, HPP resources supported the development of critical capabilities of HPP coalition members to reach to different healthcare and non-healthcare entities, in doing so the Division of Recovery actively sought out perspectives, experiences and challenges to disaster recovery planning from constituents nationwide. This approach was facilitated through prior relationships established with representative organizations (e.g. ASTHO, NACCHO, NACHC) whereby members of their constituency had the opportunity to provide perspectives and feedback over time. These resources have been effective in building recovery capabilities at the state and local levels because they are built on relationships that have developed over years. Integral to these relationships is the consistent delivery of value-add outcomes and outputs like state plans that have incorporated health and social services recovery -- a clear indicator of increased capacity to lead and manage post-disaster recovery.

In FY2016, HPP resources also enabled the development of the first-ever Health and Social Services Recovery-focused training for the FEMA Emergency Management Institute (EMI) distance learning platform. This project filled a gap repeatedly echoed by HPP regional partners that there was a significant lack of health and social services-specific recovery training resources.

In FY 2016, the Division of Recovery led the activation of the Health and Social Services and Recovery Support Function twice to support recovery from flooding in Louisiana (DR 4263, DR 4277). In addition, the H&SS RSF was activated to support mission scoping activities following the landfall of Hurricane Matthew and the subsequent riverine flooding in North Carolina. In other emergencies, the Division has provided technical assistance and informal support without a formal activation, such as the Flint water crisis and also for the behavioral health resource support requests at Umpqua Community College in Roseburg, OR, following the mass violence incident.

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 Healthcare and public health systems of the U.S. rely on a complex network of staff, supplies, systems, and space to provide care. Americans rely on that critical infrastructure every day. The CIP program enhances the security and resilience of the Nation's Healthcare and Public Health (HPH) critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. Our partners work together to mitigate risk from all hazards, including physical and cyber threats. 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 during steady-state and response. The program coordinates HHS's Sector-Specific Agency role under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience; and Executive Order 13636, Enhancing Critical Infrastructure Cybersecurity.

The Healthcare and Public Health Sector-Specific Plan, developed in FY 2015, identifies several priorities to enhance the Partnership and mitigate risks across the Sector: developing a Sector-wide risk assessment tool; working together to mitigate risks to cyber systems and supply chain; assessing and improving effectiveness of current Partnership communication; enhancing engagement of existing and new partners; and clarifying response and recovery actions among partners.

In FY 2016, CIP began development of a risk assessment tool specific to the needs of the HPH Sector, leveraging the experience of government and private sector partners. The tool assists private sector owners and operators in identifying and mitigating the risks to their facilities and compiles data across coalitions for assessment and planning purposes. This tool expands upon existing risk methodologies 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. This tool may be a resource for facilities identified in CMS's Proposed Rule, "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" who may not historically have been required to implement risk assessment methodologies. In FY 2017, CIP is piloting the tool with coalitions and health care systems and refining the user interface. In FY 2018, CIP will coordinate efforts of the DHS National Protection and Programs Directorate to assess HPH Sector assets, such as the regional Ebola and other special pathogen treatment centers, to utilize our new tool and other Department of Homeland Security (DHS) tools and analyses. The Healthcare and Public Health Sector Risk Assessment Tool will be released for public use in FY18 and efforts will continue to assess its utility, improve the user interface, and tie results to mitigation resources where applicable.

In FY 2016, the HPH Sector continued to be a target for cyber-attacks with 80 percent of health care providers noting that they had encountered at least one significant cybersecurity incident in 2016.[6] Beginning in FY 2015, ASPR awarded a planning grant to assist health care organizations better respond to these threats. The awardee, Harris Health System, studied the cybersecurity information needs in the HPH sector and proposed a strategy for filling identified gaps. The study showed that fewer than 20 percent of health care facilities obtain threat information from Information-Sharing and Analysis Organizations (ISAOs), which are the primary structures promoted by Executive Order 13691 to facilitate private sector cybersecurity information sharing. Often the reason health care facilities do not engage with ISAOs is because they are unable to afford membership. In FY 2017, ASPR awarded a cooperative agreement to the National Healthcare Information-Sharing and Analysis Center (NH-ISAC) to implement several of the recommendations identified through the planning grant and assist smaller and medium sized healthcare organizations in obtaining the useful analysis and awareness products developed by ISAOs. In FY 2017, CIP and private sector partners participated in the development National Cyber Incident Response Plan, as required by PPD-41, "United States Cyber Incident Coordination," and will look to exercise the Plan during participation in CyberStorm VI in FY 2018.

[6] 2016 HIMSS Cybersecurity Survey, available at http://www.himss.org/hitsecurity?utm_source=carousel&utm_medium=banner_ad&utm_content=survey&utm_campaign=cybersecurity

In December 2015, the Cybersecurity Information Sharing Act (CISA) (Pub.L. No. 114-113, Div. N) was enacted. The Act recognizes the unique challenges facing cybersecurity in the health care system and included specific provisions on HPH Sector preparedness reporting, HHS incident response, and information-sharing protocols. The Act called for a Healthcare Industry Cybersecurity Task Force; and in FY 2016, CIP established the Task Force and continues to manage it. The Task Force has developed recommendations on challenges and barriers in the Sector and how to achieve near real-time sharing of actionable threat information at no cost to businesses. Its first report to Congress is expected in Spring 2017. FY2018 activities for enhancing cybersecurity will include the expansion of the Partnership's Cybersecurity Working Group to implement CISA's tasking for HHS, in partnership with the private sector, to develop a common set of voluntary cybersecurity guidelines that are practical, relevant, and implementable by healthcare stakeholders of every size and resource level.

During the Ebola response in FY 2015, the CIP program took on a significant role by coordinating with private sector manufacturers and distributors of personal protective equipment (PPE) to address the critical product shortages that resulted from the response. Recognizing that supply chain challenges continue to affect health systems preparedness and response, CIP funded a project to map the ecosystem of the health care supply chain and identify areas where CIP could be impactful in combating those challenges. At the same time, Zika infections continued to spread across South America and the Caribbean, threatening to spread to North America. In FY 2016, the CIP program leveraged analysis done on the supply chain to identify priority products to monitor. With a mosquito-borne disease without treatment or vaccine, insect repellent and tools to aid in public health response, such as mosquito traps, became a focus of the program. CIP coordinated across Departments and Agencies to ensure that the most effective traps, which are in short supply, were available for state purchase and not constrained by federal purchasing demands. In FY 2017, CIP continues its coordinating role across the government and private sector through the activities of its Government and Private Sector Coordinating Councils to monitor demand and potential disruptions; deconflict and prioritize government activities, improve transparency, and unify federal messages to enhance communication with the private sector. CIP is also working with DHS' Regional Resilience Assessment Program team to assess supply chain challenges for healthcare facilities in New York City and, in FY18, will utilize that analysis to direct future activities in supply chain management.

Developing a greater understanding of the threats and vulnerabilities of critical health infrastructure and leveraging resources from across the government to enhance resilience in the HPH Sector continue to be major goals of CIP's work in FY 2017. In FY 2018, the Partnership will perform a review of our list of U.S. HPH sector critical infrastructure and begin work on the next Sector Specific Plan 2019-2023. CIP will continue to engage with industry experts from across the HPH sector, law enforcement, intelligence, among others to enhance activities to prepare for, respond to, and recover from natural hazards, manmade threats and continue to contribute to a more secure and resilient HPH sector.

Funding History

Fiscal Year	*Amount*
FY 2014	$255,060,000
FY 2015	$254,555,000
FY 2016 Final	$254,555,000
FY 2017 Annualized CR	$254,071,000
FY 2018 President's Budget	$227,201,000

Budget Request

The FY 2018 Budget requests $227,201,000 for the Hospital Preparedness Program (HPP), which is a decrease of $26,870,000 below the FY 2017 annualized CR level. Within the total, $204,500,000 will be provided for the HPP cooperative agreements to states and high risk political subdivisions. This amount is a $24,000,000 decrease below the FY 2017 annualized CR level. The remaining funds support cooperative agreement administration and performance evaluation and oversight, as well as other programs at ASPR that directly support the mission of HPP

including the Technical Resources Assistance Center and Information Exchange (TRACIE), the Emergency Care Coordination Center (ECCC), Critical Infrastructure Protection (CIP), and the Division of Recovery. Decreased funds will impact the management and oversight functions to administer HPP, the HPP cooperative agreement awardees, and each of the supporting programs. (each component of the appropriation will be reduced by 11 percent or more).

The U.S. health care delivery system has made tremendous strides since September 11, 2001 to heighten its state of readiness and save lives when disaster strikes. That preparedness is due in large part to the investments the federal government has made through **HPP**. Through HPP, ASPR has overseen an **investment of nearly $5.8 billion in the preparedness and response** efforts of the nation's health care delivery system from 2002-2017.[7] This investment is less than 1 percent of the $2.4 trillion average annual U.S. health care expenditures from 2002-2015[8]. Thus, while significant federal investment has been made and leveraged by the private sector, preparing an entire multi-trillion dollar private health care system to be ready to work collaboratively for medical surge events takes innovation and continued diligence to close the gaps that remain in U.S. health care delivery system readiness.

As the federal government, we must make the health and safety of Americans the driving force behind all that we do. As the only 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. HPP funding also enables ASPR to convene partnerships within the U.S. health care system to focus on preparedness and response; and to maintain relationships at the state, local, and private health care system levels. The HCCs and the relationships across the health care and public health systems are critical for ASPR to accomplish its mission during responses to large-scale public health and medical emergencies.

In order to deliver the needed change to protect Americans from disasters that impact people's health, ASPR proposes to ameliorate gaps and streamline HPP as part of its FY 2018 budget request. The innovations and improvements outlined below will drive strategic advancements in health care delivery system readiness and leverage private sector ideas and best practices to enhance government efficiency and accountability:

1. **Define the Target Market** – focus HPP's investments in states and jurisdictions facing the greatest risk. For the health care system, risk takes many forms: risk of terrorism, risk of infectious disease, risk to infrastructure and economy, and risk of natural disasters. Different from public health, the private health care system risk is further complicated by the variety of health care organizations that must be ready to respond – from large academic medical centers to long-term care facilities to urgent care centers – as well as the sheer volume of patients and health care workers who must remain healthy and safe in times of crisis.
   HPP intends to create a lean, effective program by targeting federal funding to those states and jurisdictions at greatest risk. HPP has incorporated risk into its funding distribution formula since FY 2014. However, in FY 2018, HPP proposes to improve its risk determination by using evidence- and science-based tools to more clearly define risk, as well as limit awards to only those states and jurisdictions with the highest risk.

   Determining Risk: For FY 2018, HPP will continue to incorporate FEMA's State Homeland Security Program (SHSP) risk score[9,10] in its funding distribution formula. The FEMA SHSP is a comprehensive assessment of risk to jurisdictions for security incidents. It also includes a population index, which can help to determine risk for infectious disease outbreaks.

[7] For FY 2017, ASPR includes the annualized CR funding amount for the HPP cooperative agreements.
[8] Health Spending Explorer, Kaiser Family Foundation: http://www.healthsystemtracker.org/interactive/health-spending-explorer/?display=U.S.%2520%2524%2520Billions&service=. Accessed April 14, 2017.
[9] Department of Homeland Security (DHS), FY 2016 Homeland Security Grant Program. https://www.fema.gov/media-library-data/1467836973305-76b1650140531d2fab3f08e67f755572/FY_2016_HSGP_Fact_Sheet.pdf
[10] DHS Risk Lexicon, 2010 Edition. https://www.dhs.gov/xlibrary/assets/dhs-risk-lexicon-2010.pdf

Public health and medical risk must consider other factors that result in medical surge incidents, namely natural disasters. HPP's formula distribution from 2014-2017 captured risk for hurricanes, tornadoes, and earthquakes. Better targeting this risk must be part of the program moving forward. New for FY 2018, HPP proposes to improve the natural disaster risk score calculation used for the funding formula distribution by introducing more advanced methodologies and a historical hazard incidence to better understand the consequence of these disasters on people's health. Twenty years of natural hazard incidence data from the National Oceanic and Atmospheric Administration (NOAA)[11,12,13], the Advanced National Seismic System (ANSS)[14], and the National Interagency Coordination Center (NICC)[15] will be used to determine each HPP awardee's natural hazard rating. Further, hazard impact will be measured as the total number of affected people plus the total number of deaths, as reported in the Centre for Research on the Epidemiology of Disasters (CRED) Emergency Events Database (EM-DAT)[16]. Earthquakes, floods, flash floods, ice storms, hurricanes and tropical storms, tornadoes, and wildfires cause 99 percent of the total impact of natural disasters in the U.S.

Using these two risk scores and population for its FY 2018 funding formula distribution, HPP proposes to limit awards to only those states and jurisdictions with the highest risk. Inevitably, this means that there will be some states that see increases based on this new calculation of risk, some see major decreases, and still other awardees will no longer receive HPP cooperative agreement funding in FY 2018 (see state-by-state funding table for more information). Unfortunately, ASPR cannot adequately predict what the loss of HPP funds, either through reduction or elimination, will mean for each jurisdiction, hospital, or any other health care service delivery entity across the U.S. However, coordination activities carried out by HCCs previously funded through HPP subawards may no longer occur in those jurisdictions where funding is eliminated due to the fact that HCCs get approximately 90 percent of their preparedness and response resources through HPP.

With these two risk scores for its FY 2018 funding formula distribution, HPP proposes to award funds to states and jurisdictions with the highest overall risk score; therefore, not all current awardees will receive funds in FY 2018.

2. **Innovate through Competition** – competition breeds excellence and innovation. Injecting competition to determine HPP's awardees will permit HHS to finance the best ideas to improve the nation's health security.

   For FY 2018, ASPR proposes to allow for state- and jurisdiction-level competition for HPP funds by allowing state and directly-funded cities governmental public health departments, academic medical centers, and state and local hospital associations to apply to serve as the awardee for their jurisdiction. Under this proposal, each funded state, directly-funded city, or territory will still only receive one award; however, this proposal will create competition within each state or jurisdiction for the award. This proposal will allow HPP to fund those entities that present the most innovative approaches to health care delivery system readiness.

   Additionally, many of the current public health department awardees subcontract their HPP award to a state hospital association or other health care entity to carry out health care preparedness and response activities. In doing so, the public health department takes an average of 21% of the HPP award off the top for direct costs (i.e. personnel, fringe, and travel), in addition to indirect costs, for overseeing their award and subcontracts.

[11] Storm Events Database, NOAA. https://www.ncdc.noaa.gov/stormevents/.
[12] Best Track Data (HURDAT2), National Hurricane Center (NHC). http://www.nhc.noaa.gov/data/#hurdat.
[13] Historical Hurricane Tracks, NHC, NOAA. https://coast.noaa.gov/hurricanes/.
[14] Comprehensive Earthquake Catalog (ComCat), ANSS. https://earthquake.usgs.gov/earthquakes/search/.
[15] National Report of Wildland Fires and Acres Burned by State, NICC. http://www.nifc.gov/fireInfo/fireInfo_statistics.html.
[16] EM-DAT, CRED. http://www.emdat.be/.

A second benefit to introducing competition is the potential it has to address the misalignment between HPP's *health care mission* and its current awardees' *public health mission*. Many of HPP's governmental public health department awardees work well with their private sector health care delivery system counterparts to enhance preparedness and response, while others struggle to work collaboratively with the private health care system that they also regulate. Through this proposal, private health care entities or hospital associations that have the organizational capacity and initiative to lead sector-wide preparedness and response activities would also be able to compete for HPP funds for their state or jurisdiction, not just health departments.

3. **Accelerate Results through Accountability** – excellent performance should be rewarded and poor performance corrected. Government programs must be agile to identify, address, and resolve problems to remain good stewards of American tax dollars.

   In FY 2018, HPP proposes to use its resources as smartly as possible by answering the questions: what works, for whom, and under what conditions; are awardees implementing programs at the state and jurisdiction level effectively; and how can HPP improve health care system preparedness and response nationwide to produce better results? HPP will use performance measures (PMs) discussed above to evaluate and analyze funding impact. The new PMs allow HPP to objectively track trends in coordination, communication, patient care and continuous learning and improvement. The PMs are predominantly exercise-based or may be met through preparing and/or responding to real-world events. Others measure effectiveness and timeliness on achieving certain outcomes, such as distributing funds to the health care delivery system quickly and efficiently[17].
   HPP has the authority to withhold funding from awardees for failure to achieve certain programmatic benchmarks and performance metrics in the immediately succeeding fiscal year following a failure. However, the drafting of the authority does not allow HPP to operationalize this authority simply due to the timing of end of year performance data collection and the distribution of subsequent awards. To address this, HPP proposes to:

   - Provide technical assistance to low performing awardees to take corrective actions;
   - Allow funds to be withhold up two years following a failure, and;
   - Increase the percentage of funds that may be withheld from 10 to 20 percent for each initial failure with an additional 10 percent for each continued failure in subsequent years.

   HPP will re-compete the funding withheld from any entity that fails to achieve performance benchmarks and will give preference to alternative entities within the states or jurisdictions where the failures occur to ensure that funding is still targeting those areas at greatest risk.
   Additionally, HPP proposes to re-compete the funding withheld among existing awardees.

   Through these proposals, HPP will strive to take the readiness of the U.S. health care delivery system from acceptable to world class.

[17] See HPP Performance Measure 2: Number of calendar days from start of budget period for awardees to execute subawards with each HCC. https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hpp-pmi-guidance-2017.pdf

ASPR Hospital Preparedness Program - Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
14 Increase the proportion of coalitions that reported the ability to coordinate and track patient surges and movement during an exercise or event (Intermediate Outcome)	FY 2016: 40.5 % Target: 40.5 % (Baseline)	75.0 %	75.0 %	Maintain
15 Increase the proportion of health care coalitions that use an incident management structure to coordinate and respond (Intermediate Outcome)	FY 2016: 54.0 % Target: 54.0 % (Baseline)	55.0 %	55.0 %	Maintain

NOTE: HPP currently has a five-year project period. Each program year within that period goes from July through June. Final performance data from awardees is transmitted 90 days after the close of the project year (in October). As such, HPP performance information provided here follows that timeline. In addition, HPP's new project period begins in FY 2017. New performance measures are established for this new project period.

ASPR Hospital Preparedness Program – Grant Awards by State

State, *Locality, Territory*	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Alabama	$3,231,541	$3,316,320	$4,478,616	+1,162,296
Alaska	$948,583	$951,914	$1,219,930	+268,016
Arizona	$3,985,942	$3,930,938	$0	-3,930,938
Arkansas	$2,014,696	$2,002,932	$2,585,053	+582,121
California	$23,204,454	$23,397,482	$20,175,928	-3,221,554
City of Chicago	$2,736,924	$2,736,056	$2,048,099	-687,957
Colorado	$3,230,913	$3,119,392	$0	-3,119,392
Connecticut	$2,467,952	$2,330,641	$0	-2,330,641
Delaware	$1,061,248	$1,049,193	$0	-1,049,193
District of Columbia	$951,550	$944,353	$1,814,895	+870,542
Florida	$11,661,603	$11,822,752	$12,767,567	+944,815
Georgia	$5,941,199	$5,973,258	$6,732,448	+759,190
Hawaii	$1,220,804	$1,261,124	$0	-1,261,124
Idaho	$1,217,406	$1,247,694	$0	-1,247,694
Illinois	$8,867,636	$8,772,659	$7,990,729	-781,930
Indiana	$4,127,659	$3,934,926	$4,735,094	+800,168
Iowa	$2,091,263	$2,130,401	$2,616,125	+485,724
Kansas	$2,068,884	$2,117,146	$2,348,757	+231,611
Kentucky	$2,900,747	$2,759,985	$3,970,833	+1,21,0848
Los Angeles	$9,197,167	$9,263,958	$6,729,769	-2,534,189
Louisiana	$3,137,439	$2,895,985	$4,412,533	+1,516,548
Maine	$1,078,955	$1,065,567	$1,512,008	+446,441
Maryland	$4,916,220	$4,864,700	$4,240,380	-624,320
Massachusetts	$4,240,648	$4,315,709	$3,684,602	-631,107
Michigan	$6,086,643	$6,157,587	$4,221,454	-1,936,133
Minnesota	$3,520,091	$3,518,356	$2,716,950	-801,406
Mississippi	$2,174,085	$2,176,032	$2,861,356	+685,324
Missouri	$3,766,903	$3,676,990	$5,186,585	+1,509,595
Montana	$910,977	$920,601	$0	-920,601
Nebraska	$1,376,638	$1,373,309	$0	-1,373,309
Nevada	$1,917,424	$1,911,347	$0	-1,911,347
New Hampshire	$1,104,016	$1,089,878	$0	-1,089,878
New Jersey	$5,835,689	$5,633,732	$5,098,344	-535,388
New Mexico	$1,507,698	$1,527,031	$0	-1,527,031
New York	$9,617,523	$9,639,512	$16,693,113	+7,053,601
New York City	$7,928,385	$7,941,327	$13,455,551	+5,514,224
North Carolina	$6,144,995	$6,112,501	$7,562,187	+1,449,686

State, *Locality, Territory*	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
North Dakota	$877,391	$879,429	$0	-879,429
Ohio	$7,459,074	$7,450,278	$6,202,189	-1,248,089
Oklahoma	$2,602,048	$2,602,493	$2,758,110	+155,617
Oregon	$2,523,559	$2,577,424	$0	-2,577,424
Pennsylvania	$8,131,994	$8,093,898	$7,851,839	-242,059
Rhode Island	$969,418	$940,547	$0	-940,547
South Carolina	$3,091,113	$3,117,650	$3,929,521	+811,871
South Dakota	$858,655	$848,108	$1,128,320	+280,212
Tennessee	$4,059,780	$4,040,788	$3,659,664	-381,124
Texas	$15,821,740	$16,176,634	$15,435,244	-741,390
Utah	$1,925,825	$2,271,467	$0	-2,271,467
Vermont	$898,240	$780,333	$0	-780,333
Virginia	$6,295,382	$6,075,317	$6,743,291	+667,974
Washington	$4,220,025	$4,279,234	$0	-4,279,234
West Virginia	$1,380,775	$1,405,606	$1,578,846	+173,240
Wisconsin	$3,611,886	$3,634,631	$0	-3,634,631
Wyoming	$836,173	$837,538	$0	-837,538
American Samoa	$278,128	$278,422	$0	-278,422
Guam	$352,520	$374,754	$0	-374,754
Marshall Islands	$267,111	$268,005	$0	-268,005
Micronesia	$275,479	$276,806	$0	-276,806
Northern Mariana Islands	$270,652	$270,356	$0	-270,356
Palau	$255,101	$255,373	$0	-255,373
Puerto Rico	$2,506,617	$2,576,010	$2,854,070	+2,780,60
Virgin Islands	$338,814	$305,611	$0	-305,611
Total States/Territories	$228,500,000	$228,500,000	$204,500,000	-24,000,000

ASPR Hospital Preparedness Program – Summary of Grant Awards

	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Number of Awards	62	62	36
Average Award (in whole dollars)	$3,685,484	$3,685,484	$5,666,667
Range of Awards (in whole dollars)	$255,373 - $23,405,491	$255,373 - $23,397,482	$1,128,220 - $20,175,928

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Budget Summary
(Dollars in Thousands)

ASPR Biomedical Advanced Research and Development Authority	FY 2016 Final /2	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority	**540,080**	**510,727**	**511,700**	**973**
Advanced Research and Development (non-add)	*288,080*	*259,206*	*259,700*	*494*
Combating Antibiotic-Resistant Bacteria (non-add)	*192,000*	*191,635*	*192,000*	*365*
Operations and Management (non-add)	*60,000*	*59,886*	*60,000*	*114*
FTE	**155**	**155**	**155**	**--**

1/ These amounts do not include PHSSEF Ebola emergency funding (P.L. 113 – 235) or PHSSEF Zika supplemental funding (P.L. 114-223).
2/ Reflects the increase of +$28,379,740 for the FY 2016 Secretary's permissive transfer.

Authorizing Legislation:

Authorization ..... Public Health Service Act
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

BARDA 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. BARDA'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 across the country. In 2006, Public Health Service Act, as amended by PAHPA, established the Biomedical Advanced Research and Development Authority (BARDA) within ASPR to carry out this program in close coordination with 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 (NIH), Centers for Disease Control and Prevention (CDC), 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 Countermeasures Enterprise (PHEMCE)—and, as PHEMCE partners, set research and development priorities under a five-year strategy and implementation plan, currently the 2016 PHEMCE Strategy and Implementation

Plan[18]. BARDA's advanced research and development decisions also are guided by its Strategic Plan 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 BARDA's advanced research and development portfolio. BARDA also strategically supports advanced development and acquisition of medical countermeasures that are existing products being repurposed to meet medical countermeasure needs or new multipurpose products with commercial indications that meet public needs. This approach increases the sustainability of these medical countermeasures, makes them less dependent on federal government support, and provides alternate mechanisms (e.g., 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 and some of the smallest.[19] In May 2013, BARDA leveraged a procurement tool known as Other Transaction Authority (OTA), provided under the Pandemic and All-Hazards Preparedness Act (PAHPA), of 2013 to forge a unique partnership with one of the world's largest pharmaceutical companies, GlaxoSmithKline, for the development of new antibacterial drugs. As partners, GSK and BARDA used 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 carbapenem-resistant Enterobacteriaceae (CRE) and Methicillin-resistant *Staphylococcus aureus* (MRSA). The OTA also 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, three antibiotic candidates are under development in this cost-sharing partnership. BARDA used this type of partnership for a second OTA agreement with AstraZeneca that started in FY 2015. This partnership supports Phase 3 clinical studies to evaluate the safety and efficacy of their lead drug candidates against biothreats. Additionally, this new agreement enables BARDA to meet one of the metrics under the *National Action Plan for Combating Antimicrobial-Resistant Bacteria* ahead of schedule. These partnerships spark broader industry interest in developing new antibiotics to treat antibiotic resistant infections and developing products that are less prone to resistance. This renewed interest helps address the national and global threat of antimicrobial resistance. In FY 2016, BARDA awarded two additional OTA partnerships to Hoffman-La Roche and The Medicines Company for the development of novel antibacterial drugs and diagnostics.

In July 2016, BARDA established the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X). CARB-X is a novel public private partnership aimed at promoting innovation in antibacterial drug, vaccine, and diagnostic development. CARB-X is a collaboration between NIH's National Institute of Allergy and Infectious Diseases (NIAID), BARDA, Boston University, and four life science Accelerators, the Wellcome Trust, AMR Center, California Life Science Institute, and MassBio, which aims to identify, build, and manage a portfolio of innovative antibacterial MCMs.

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. As a outcome of the *2010 HHS Public Health Emergency Medical*

[18] https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx
[19] BARDA consistently exceeds departmental goals for small business contracting.

Countermeasure Review[20]*, (2010 PHEMCE Review)* an end-to-end review of the medical countermeasure development process conducted after the 2009 H1N1 influenza pandemic, these core service assistance programs, which are also public-private partnerships, fill gaps in product development and manufacturing by inexperienced MCM developers. Also, these core service assistance programs provide public health emergency response capabilities as part of the National Medical Countermeasure Response Infrastructure, formed during the 2014–2015 Ebola response. These core service assistance programs have been a huge success for HHS and its PHEMCE partners. The FY 2018 Budget will 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 may partner with vaccine and biological product manufacturers to meet national demand during public health emergencies, especially for pandemic influenza. They also are available on a routine basis to assist our industry and federal partners in developing and manufacturing chemical, biological, radiological or nuclear (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. Each CIADM has completed, or is nearing completion of, facilities and is focusing on establishing additional domestic influenza vaccine capacity, and refining its core services to support advanced research and development of products to address CBRN threats.

- *Fill Finish Manufacturing Network (FFMN):* 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. BARDA's Fill Finish Manufacturing Network (FFMN) provides sterile product formulation and filling capabilities for many products, including monoclonal antibody (e.g., ZMapp) for use in clinical trials during the Ebola outbreak. The FFMN was originally comprised of four domestic contract manufacturing organizations (CMOs) with a broad set of capabilities to address every day and emergency needs, such as filling aseptic syringes and vials. In September 2016, two additional contractors with specific live virus products experience were added to supplement the FFMN Program. The network holds the potential to resolve 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 funding the technical transfer of fill finish manufacturing activities for sterile injectable product on the FDA's official drug shortage list, which includes products in 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, Zika animal models to identify potential surrogates of immune response needed to support licensure of vaccine candidates, and monoclonal antibody therapeutics. The Non-Clinical Studies Network is comprised of 23 laboratories in the United States and Europe. To date, these organizations have performed over 55 studies in support of BARDA product development, developing safety and

[20] https://www.phe.gov/Preparedness/mcm/phemce/Pages/review-2010.aspx

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. It 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 medical products, such as in FY 2013–2014 when the network was utilized for proof of concept studies. In FY 2015–2016, BARDA conducted utilization studies to provide supplemental data for products in the SNS, repurposing studies for MCMs against chemical threats, and animal model development studies to support advancement of products currently in BARDA's portfolio.

In 2016-2017, BARDA continued to expand its network to include specialized capabilities in animal model development, analytical services and toxicology services, in order to enhance support and development of MCMs and/or reagents and assays for regulatory acceptance in the U.S.

- *Clinical Studies Network (CSN):* BARDA established the Clinical Studies Network (CSN), comprised of five clinical research organizations, in 2014 to provide clinical study services in support of BARDA*'s* mission and to provide surge capacity for the NIH's clinical study capabilities during public health emergencies. Since its inception, the CSN has engaged in six clinical research projects, including emergency response support activities during the 2014–2015 Ebola outbreak in West Africa where the CSN supported the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) vaccine study in Sierra Leone, and during the 2016 Zika outbreak where the CSN collected clinical samples to aid and accelerate development of Zika diagnostic tests.

Developing Multi-Use Products

BARDA has made significant progress driving innovation to address nationwide shortfalls identified in the *2010 PHEMCE 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 weaponized 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. Its broad spectrum antimicrobial program aligns with the 2014 *National Strategy for Combating Antibiotic-Resistant Bacteria*[21] to address the growing antibiotic crisis.

[21] https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

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. These products include a silver impregnated bandage, enzymatic debridement technologies, artificial skin substitutes, and autograft sparing technologies. 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. In FY 2017–2018, BARDA will expand the use of these products to include special populations (e.g., pediatrics).

Building a Robust and Formidable MCM Development Pipeline

BARDA, in partnership with 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). These advanced development programs have supported 21 products under Project BioShield; 14 of these products have been procured for the SNS.

BARDA's advanced research and development programs also have led to FDA licensure or approval of six 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), ANTHIM® (obiltoxaximab) anthrax antitoxin(2016), 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. BARDA expects to purchase three to five 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 and 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 anthrax vaccines, antitoxins, and antibiotics. The currently licensed, cell filtrate, 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 potential 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. BARDA's 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 nasally-delivered virus vectors, freeze-dried (known as lyophilized) formulations, and adjuvants.

Another anthrax vaccine candidate utilizes the subunit vaccine derived from culture supernatant formulated with an adjuvant to provide greater immunity in fewer doses. With support under BARDA's advanced research and development program, clinical evaluation of these new vaccine candidates will occur in 2017 and 2018.

In FY 2015, Emergent BioSolutions 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, making this the fifth CBRN MCM supported under Project BioShield to achieve FDA approval and/or licensure. Additionally, a supplemental BLA submission was approved in June of 2016 for manufacture of BioThrax and 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.

The Amerithrax (or Anthrax Investigation) 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, three anthrax antitoxins – Raxibacumab,® ANTHIM® (Obiltoxamimab), 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; pediatric dosing was also approved. The third, ANTHIM® (Obiltoxamimab), a monoclonal antibody based product, was approved in March 2016.

BARDA continues to support late-stage development of ANTHIM® (Obiltoxamimab), to support work that may allow for storage as a freeze-dried product at room temperature, which would help reduce sustainment costs for the product. In summary, BARDA has developed three products to treat individuals with anthrax disease, which completes BARDA's goal of providing these critical countermeasures for anthrax.

In FY 2016, BARDA awarded a contract under Project Bioshield to Emergent BioSolutions for the development of Nuthrax,® a next-generation anthrax vaccine that combines the Anthrax Vaccine Adsorbed (AVA) vaccine with the CpG 7909 adjuvant. This candidate vaccine has a number of advantages over the licensed AVA vaccine. It induces potential protective immunity more rapidly and with fewer doses. This reduces the total sustainment costs and will allow the CDC to stockpile less antibiotics, as the immunity from the vaccine is established more rapidly, reducing the need for prolonged antibiotic therapy. BARDA anticipates the delivery of Nuthrax® to the SNS in FY 2019.

Smallpox: Smallpox remains a threat of high concern to the U.S. and the international community. 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 therapeutic agents would be available to treat persons exposed or infected with smallpox. 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 the late-stage development of, procurement, and delivery to the SNS of 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 3 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. That study completed enrollment in 1QCY2017. 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 bulk drug substance to prepare for conversion to the lyophilized form in FY 2019.

In addition to smallpox vaccines, the United States Government (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. It would also allow for treatment options if patients were contraindicated to receive either antiviral. BARDA is supporting the development of ST-246, which transitioned in development from NIH to BARDA in 2008. ST-246 has been stockpiled for emergency use and the manufacturer is projected to file a New Drug Application with the FDA in FY 2017. The development of a second smallpox antiviral drug remains a high priority for advanced research and development and eventual procurement. Together, the presence of both a vaccine and antiviral drug for smallpox helps provide for a more complete public health response to a smallpox incident.

Broad Spectrum Antimicrobials and Combating Antibiotic-Resistant Bacteria Initiative: Antimicrobial resistance poses a growing public health threat 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 there is a wide array of treatment options for patients. This continuing crisis led to an initiative to support activities outlined in the *National Strategy for Combating Antibiotic-Resistant Bacteria*. To help stave off a possible catastrophic post-antibiotic era, BARDA and NIAID are accelerating basic and applied research and development for new antibiotics and other therapeutics to treat infections, including 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 nine companies for advanced development of multiple broad spectrum antibiotic candidates to treat infections caused by biothreats (e.g., plague) and potentially deadly, multi-drug resistant pathogens acquired in community- and hospital-settings, such as CRE and MRSA. BARDA has advanced six candidates into Phase 3 clinical development and is projecting its first product approved by the FDA in FY 2017.

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 has completed a Phase 3 clinical trial for complicated urinary tract infection, and hit its primary endpoint to demonstrate non-inferiority against the standard of care. The product was also evaluated as a treatment for CRE in a clinical trial. The product was able to provide a clear survival benefit in patients when compared to the standard of care for CRE infections. Achaogen and BARDA are sharing the costs of this clinical trial to evaluate the efficacy of plazomicin for CRE infections. 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 2015, BARDA invested $92 million in development of novel broad spectrum antimicrobial products. Of these funds, $42 million was used to exercise options on existing contracts and the OTA 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 noted above*.

In FY 2016, BARDA supported existing promising candidates and expanded the antibacterial program, based on scientific promise and prioritization. In line with the FY 2016 enacted level of $192 million for advanced development of broad spectrum antimicrobial drugs and CARB, BARDA awarded two new OTA portfolio partnerships to support novel antibacterial candidates and diagnostics. These partnerships, with Hoffman La Roche and The Medicines Company supported multiple antibiotic and diagnostic candidates. In FY 2018, BARDA plans to make an initial investment in vaccine platform technologies with the potential to address biothreat pathogens and antimicrobial resistance. Platform technologies represent a vaccine vector backbone that will allow for different antigens from different organism/pathogens to be incorporated into the vector to develop vaccines against the organism/pathogen. This is often referred to as “plug and play” technologies.

Starting in FY 2015, BARDA funded antimicrobial resistance diagnostics development with a focus on diagnostic products that have both biothreat and routine healthcare utility in multiplex formats. This strategy ensured testing capabilities were available during an antimicrobial resistant biothreat outbreak, since the routine healthcare use ensured platform placements 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. In FY 2016, NIAID with BARDA initiated the Antimicrobial Resistance Diagnostic Challenge to stimulate interest towards innovative and transformative solutions for rapid detection of antibiotic resistant bacteria. Ten semifinalists were announced in FY 2017 for the first step in this competition. In FY 2016, BARDA also invested in improving next generation sequencing platforms which were critical to understanding antimicrobial resistance. BARDA continues funding this improvement in platforms so they are appropriate for use in clinical diagnostics laboratories.

Since 2010, BARDA has support many of the candidates that are in late stage development, Phase 2 and Phase 3 clinical evaluation. Evaluation of the upstream pipeline of candidates revealed a dearth of candidates that could potentially transition. To address the absence of a robust pipeline, BARDA and NIAID established CARB-X; mentioned above. The goal of CARB-X is to develop two antibiotic candidates into Phase 1 clinical testing over the five years of the program. The creation of CARB-X was a goal of the *National Action Plan for Combating Antimicrobial-Resistant Bacteria*. BARDA accomplished the goal of initiating CARB-X two years ahead of schedule. In March 2017, CARB-X announced the first set of companies that are to be supported by CARB-X. All products address pathogens on the World Health Organization (WHO) or CDC bacterial threat list. Three companies are developing completely novel

classes of antibiotics and four companies are developing novel non-antibiotic approaches to treating drug resistant bacterial infections. More CARB-X partnerships will be announced in 2017.

The FY 2018 Budget will support expansion of the broad spectrum antimicrobial drug pipeline, new CARB-related diagnostic platform technologies, and continued support of CARB-X in alignment with the *National Strategy for Combating Antibiotic-Resistant Bacteria*[22] 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 outbreak of Ebola in West African countries 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 its new Ebola portfolio and fully engaged industry partners to expedite further advance development of these medical products. Funds will be used in FY 2017 and FY 2018 to complete the development of several of the most promising vaccine, therapeutic, and diagnostic candidates towards FDA licensure as well as expand the scope of the program to include MCM development to address Ebola-Sudan and Marburg viruses. BARDA is projecting acquisition of at least one vaccine and two therapeutic candidates under Project BioShield in FY 2017.

Our filovirus MCM 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.

All current BARDA-supported VHF MCMs target Ebola Zaire. For FY 2018, BARDA is anticipating significant investments in Ebola-Sudan and Marburg virus medical countermeasures. Several candidates are in development, and current investments in existing vaccine or therapeutic platforms could be leveraged to develop MCMs for these threat agents.

Ebola Therapeutics: In late FY 2014, BARDA supported the 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 FDA's expanded access (or "compassionate use") regimen to several people infected with the Ebola virus 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 3 safety and efficacy clinical studies. NIAID began the Phase 3 studies in February 2015 in the U.S. and West Africa. BARDA supported the transition of ZMapp to a conventional eukaryotic cell based expression system. Further, in FY 2016, the FDA approved an Expanded Access Protocol for ZMapp, in the US and the three west African countries impacted by the 2014/2015 outbreak. BARDA has worked closely with the company to implement this expanded access protocol to have the ability to collect clinical data in the three affected West African countries and at certain medical centers in the United States, if the outbreak were to reemerge. BARDA also made advanced research and development investments in a candidate Ebola

[22] https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf

monoclonal antibody therapy that is being developed by Regeneron Pharmaceuticals. 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 supported manufacturing efforts and non-clinical studies to support NIAID's Phase 1 clinical studies of this molecule and supported additional Phase 1 and 2 studies in 2016. BARDA will award a contract under Project BioShield for the late-stage development and procurement of an Ebola therapeutic in FY 2017.

In FY 2018, BARDA is planning on initiating programs to develop MCMs, particularly therapeutics, to address Marburg virus. These programs will help BARDA develop MCMs for a threat agent for which we currently have no MCMs.

Ebola Vaccines: In FY 2015, BARDA awarded contracts for advanced development and manufacturing of four monovalent Ebola Zaire vaccine candidates: ChAd3 (GSK), rVSVΔG (Newlink/Merck), rVSVN4CT1 (Profectus), and Ad26/MVA (Janssen/Bavarian Nordic). These projects specifically funded manufacturing of clinical trial material, process improvements, and scale-up of the manufacturing processes to commercial scale in support of an international effort by product sponsors, governments, and non-government organizations to accelerate vaccine development activities to address the 2014 West African Ebola outbreak. As a result, two of the four vaccine candidates have completed Phase 2 and Phase 3 clinical trials with one vaccine candidate, Newlink/Merck's rVSVΔG, demonstrating potential clinical efficacy during a ring vaccination trial conducted by the WHO and other partners in Guinea. BARDA also supported the CDC-sponsored Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE). BARDA is projecting that one or two candidates may be considered for purchase and stockpiling under Project BioShield in FY 2017. Unfortunately, the licensing and stockpiling of a monovalent vaccine against Ebola-Zaire addresses only part of the federal government's filovirus requirement. For FY 2018 and beyond, there will be a need for continued development of vaccines for Ebola-Sudan and Marburg virus. Several of the vaccine platforms developed under BARDA during the 2014 Ebola outbreak can be leveraged to support the development of vaccines for Ebola-Sudan and Marburg.

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 anthrax, *B. pseudomallei, B. mallei*, and *Y. pestis*. One of the anthrax diagnostics should be at a sufficient stage of maturity to transition to Project BioShield in FY 2018. BARDA will continue to support advanced development of existing candidates and expand this portfolio for the foreseeable future 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).

BARDA has 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 three products under Project BioShield: Neupogen and Neulasta (FY2013-current) made by Amgen; and, Leukine (FY2013-current) 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) and Neulasta (pegylated-G-CSF) receiving FDA approval in March 2015 and November 2015, respectively, to treat neutropenia resulting from acute exposure to ionizing radiation. Neupogen, Neulasta, and Leukine stockpiles are maintained by the manufacturers and rotated through the commercial marketplace. The USG will have immediate access to the acquired doses when necessary through a VMI process, which was exercised with the 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 its 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 has continued to develop promising candidates for acute radiation syndrome, decorporation agents, and blood products. This has involved 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 four candidate products for thermal burns; all are in various stages of clinical evaluation and development. In addition, two products are focused on mitigating the consequences of injuries from nuclear fallout like cutaneous radiation injuries (CRI). One of the products received a favorable review from the FDA, allowing the product to undergo Phase 3 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 FY 2015 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 field care preparedness for burns injuries. In FY

2017, BARDA anticipates providing additional funding under the current Project BioShield contracts to support clinical studies in pediatric patients; further addressing the PAHPA mandate to develop MCMs for at-risk individuals.

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, BARDA has supported the development of 11 biodosimetry device candidates, including biomarkers, assays, and point-of-care or high-throughput diagnostics. In FY 2016, 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). In FY 2016, two of these products transitioned to the acquisition phase under Project BioShield. In FY 2017, BARDA expects to transition up to two more candidates to Project BioShield.

Chemical Threats: The lack of antidotes for exposure to chemical threats remains a major gap in emergency 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 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 SNS 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.

Decontamination is also a medical countermeasure, 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 was published in 2016 under the Primary Response Incident Scene Management system (PRISM). 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 informed decontamination procedures under additional operational conditions.

To treat chemical burns, BARDA sponsored development to repurpose a commercially available burn and wound dressing (Silverlon) since September 2013. If approved, this product would be the first ever medical product 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's Chemical MCM program has adopted a strategy of treating the injury caused by these agents, as opposed to treating the agent itself. This strategy involved identifying products with routine clinical used for other types of injury and repurposing them for chemical agents. Under BARDA's advanced research and development program, it is anticipating several new programs in FY18, based upon the availability of funds.

BARDA's current example of a repurposing program is the program with the University of Colorado examining the efficacy of Alteplase for the treatment of lung injury caused by the inhalation of mustard gas, a threat for which there are no current MCMs. Altephlase is currently FDA-approved for the treatment of acute ischemic stroke. To date, animal model data appears promising, and BARDA is working towards further developing the product to be ready for late-stage development.

Driving Product Innovation

In addition to the innovation that serves as the foundation for all of BARDA's programs, BARDA pursues 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 *Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza*[23].

Funding History

Fiscal Year	*Amount*
FY 2014[24]	$413,494,000
FY 2015	$473,000,000
FY 2016 Final[25]	$540,079,740
FY 2017 Annualized CR	$510,727,000
FY 2018 President's Budget	$511,700,000

Budget Request

The FY 2018 Request for Advanced Research and Development is $511,700,000, which is +$0.973 million above the FY 2017 Annualized CR 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 (2016). Specifically, ASPR requests funding for investments in new projects in the following programs, in addition to broad spectrum antimicrobials:

1. Development of new antiviral drug and vaccine candidates against Ebola-Sudan and Marburg viruses;
2. New antidotes for treatment of chemical agents (for example, mustard gas exposure and chlorine gas);
3. Platform biodiagnostics devices to confirm infection with biological agents;

[23] https://www.broadinstitute.org/files/sections/about/PCAST/2010%20pcast-influenza-vaccinology.pdf
[24] Reflects the reduction of -$1,506,434 for the FY 2014 Secretary's permissive transfer.
[25] Reflects the increase of +$28,379,740 for the FY 2016 Secretary's permissive transfer.

4. New candidate products for addressing the pathologies resulting from radiological or nuclear events, including thermal burns; and
5. Novel antibacterial drugs, diagnostics, and vaccines.

Anthrax ($20 million): Funding provided in FY 2018 will support the clinical evaluation of potential intranasally-administered, single dose anthrax vaccine, to determine its safety and immunogenicity. 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. BARDA obtained licensure of anthrax vaccine absorbed (BioThrax®) for post-exposure prophylaxis, in 2015. In addition, BARDA transitioned a next-generation anthrax vaccine to acquisition under Project BioShield in FY 2016. These vaccines would have to be transformative in their operational advantages or cost to warrant the additional investment to bring them to licensure.

Smallpox ($15 million): The National Academy of Medicine has made the recommendation that the federal government should develop two antiviral drugs for the treatment of smallpox infection. The Academy recommends that these antivirals possess distinct mechanisms of action. In FY 2011, BARDA supported the late-stage development and procurement of tecovirimat (ST-246) under Project Bioshield. That program successfully reached pre-EUA status and delivered two million treatment courses to the SNS. A New Drug Application is projected to be filed with the FDA in 2017. Funding in FY 2018 will support the development of a second antiviral candidate against smallpox. This would include studies to evaluate efficacy in animal models, manufacturing, and human safety testing.

Combating Antibiotic-Resistant Bacteria ($192 million): The request includes $107 million to support the CARB initiative that includes the CARB accelerator, CARB-X, and $85 million to support BARDA's Broad Spectrum Antimicrobials (BSA) program. CARB activities primarily support the broader public health concern of antimicrobial resistance. The BSA program also addresses antimicrobial resistance but the products must also have the potential to be used against biothreat pathogens. The SNS 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 novel or improved products. Development of broad spectrum antimicrobial candidates is meant to augment a medical 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 FY 2018 request for BARDA supports CARB-X and the advanced development of broad spectrum antimicrobials including vaccines, diagnostics, and novel antibiotic treatments for both complicated and uncomplicated infections. Funds will be used to sustain and expand the scope and scale of investments being made by CARB-X and to graduate programs out of CARB-X in FY 2018. CARB-X will build a portfolio of therapeutics, vaccines, and diagnostics in FY 2017, and will look to expand the number of companies and technology types it is working with to promote innovation in antibacterial product development. Later and more advanced stage product development activities are planned in FY 2018 to support investments made to bring critically needed products to market to address and

combat life-threatening infections for the general public. These include a focused target on gram-negative and complicated, multi-drug resistant bacterial infections in line with the CARB National Strategy.

***Viral Hemorrhagic Fever* (*$30 million*):** As a result of the 2014 Ebola outbreak, BARDA has assumed a leadership role in the continued development of vaccines, therapeutics, and diagnostics for viral hemorrhagic fever viruses. Several candidate vaccines and therapeutics are now positioned to transition to Project BioShield in FY 2017. Both vaccine and therapeutic candidates are currently being evaluated in clinical trials and additional support is necessary in FY 2018 to continue development of these candidates to address the PHEMCE requirement for MCMs against viral hemorrhagic fever viruses. These current MCMs target Ebola-Zaire. There remains an outstanding requirement to develop MCMs for Ebola-Sudan or Marburg viruses. The FY 2018 funding level will support one vaccine and one therapeutic candidate as they approach sufficient maturity for potential transition to Project BioShield.

Biodosimetry and Biodiagnostics ($50 million): By FY 2018, BARDA will see a transition of biodosimetry devices, in both point-of-care and high-throughput clinical lab devices, to acquisition under Project BioShield. This represents a significant accomplishment, leveraging previous investments made under ARD targeting the critically unmet need for devices that can determine an individual's level of absorbed radiation.

Thus, funding under ARD for the biodosimetry programs will decrease and funding efforts will support expansion of the biodiagnostic and antimicrobial resistance diagnostics portfolios. In FY 2018, BARDA will continue ongoing investments in development of anthrax diagnostics (laboratory and point-of-care), and Ebola diagnostics (point-of-care). BARDA will also invest 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 anthrax, *B. pseudomallei, B. mallei*, and *Y. pestis*.

Acute Radiation Syndrome ($60 million): In FY 2017, the Radiological and Nuclear Threats program undertook comprehensive efforts, utilizing the Non-Clinical Studies Network, to develop models that would facilitate greater understanding of the molecular mechanisms of injury that underlie the pathologies that are observed following radiation exposure. Specifically, there are common molecular pathways that could be targeted to prevent the coagulopathy and vascular leak that is induced from radiation exposure. These studies would allow selected therapies that are marketed, or in development, to be repurposed for radiation injury, representing a significant cost savings for the USG. 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 for acute radiation syndrome. FY 2018 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 2019.

Thermal Burns ($25 million): The thermal burn portfolio has progressed significantly, with four candidates transitioning to acquisition under Project BioShield. Further, additional studies are planned for FY 2017 that will evaluate MCMs that transitioned to Project Bioshield in FY 2015 in pediatric clinical studies. Additional candidates are still under development that will address the remaining gaps in the continuum of care for burn patients. This includes technologies that prevent the conversion of partial-thickness to full-thickness burns. FY 2018 funds will support additional

clinical trials for products supported previously under PBS. BARDA is mandated to develop MCMs for "at-risk" populations and the funds will support clinical trials in pediatric populations to support expansion of the label indication.

Chemical ($50 million): BARDA's Chemical MCM program is currently initiating a new strategy that involves addressing the injury of chemical agent exposure and not the agent itself. This strategy will allow BARDA to repurpose candidate drugs that are being used for routine clinical use as countermeasures for chemical agents. In FY 2018, new candidate products will be supported under ARD to address the threat of chemical agents, as several promising candidates have been identified. Given the need to have products available immediately and the limited number of programs progressing through the pipeline, products approved for other indications will be evaluated for their efficacy against chemical agents. FY 2018 funds will be used to continue development of animal models to support evaluation of candidate products. BARDA anticipates the transition of a chemical MCM to Project BioShield in FY 2018–2019.

***Non-Clinical Studies Network - Animal Studies ($10 million*)**: The 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 Rule. Further work is critical in evaluating MCM candidates' efficacy for ARS sub-syndromes including gastro-intestinal, skin, and lung and chemical agents. Viral hemorrhagic fever models also will need to be qualified as new candidate products come into BARDA's pipeline.

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 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
2.4.13a Increase the number of new licensed Chemical, Biological, Radiological, and Nuclear threats medical countermeasures (Intermediate Outcome)	FY 2016: 3.0 Target: 3.0 (Target Met)	3.0	3.0	Maintain
2.4.13b Increase the number of new countermeasures for Chemical, Biological, Radiological, and Nuclear threats under Emergency Use Authority (Intermediate Outcome)	FY 2016: 3.0 Target: 3.0 (Target Met)	3.0	3.0	Maintain
2.4.14a Increase the technical assistance provided by BARDA to medical countermeasure manufacturers (Intermediate Outcome)	FY 2016: 21.0 Target: 21.0 (Target Met)	11.0	11.0	Maintain

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

PROJECT BIOSHIELD

Budget Summary
(Dollars in Thousands)

ASPR Project BioShield	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority	510,000	509,030	510,000	970
FTE	-	-	-	-

Authorizing Legislation:

Authorization ..... Public Health Service Act
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

Disease outbreaks, including the recent Ebola outbreak 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, BARDA's commitment to advanced development, enhanced partnerships, and sustained investments made possible under Project BioShield (PBS), has led to the support of 21 products that are critical to prepare for and treat these disease hazards including but not limited to any acts of terrorism and biological emergencies, man-made or naturally-occurring. Fourteen of these products have been delivered to the Strategic National Stockpile (SNS) with the remaining products to be delivered in FYs 2017 and 2018. 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. The *Pandemic and All-Hazards Preparedness Act* (PAHPA) of 2006 and the *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)* amended further the Project BioShield authorities in the Public Health Service Act. 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 SNS 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 through 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 and to address the needs of at risk populations.

Developing biopharmaceutical products routinely takes 8 to 15 years for FDA approval and commercial marketing. BARDA's expertise and strategic approach led six products from late-stage development to FDA approval in less than 10 years with more to come. In FY 2013, FDA approved two antitoxin drugs, Raxibacumab® for the treatment of inhalational anthrax and HBAT® for the treatment of botulism, under the FDA's 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 (ARS). Neupogen® was previously approved to treat cancer patients undergoing certain types of therapy. Pediatric doses of the drug also are available for ARS. In November 2015, anthrax vaccine absorbed (BioThrax®) was approved by the FDA for a post-exposure prophylaxis (PEP) indication. BioThrax was previously approved for use as General Use Prophylaxis and is now the only licensed anthrax vaccine that can address both pre- and post-exposure. In 2016, FDA approved ANTHIM® (obiltoxaximab), a monoclonal antibody, for the treatment of inhalational anthrax.

In the next few years, BARDA expects more companies to seek FDA regulatory approval for CBRN products. In FYs 2018–2019, at least three companies are expected to seek FDA approval of CBRN MCMs purchased through Project BioShield and developed under BARDA's ARD programs. BARDA is anticipating that the first BARDA supported antibiotic will receive FDA approval in FY 2017. Makers of two additional antimicrobial drugs are anticipating FDA approval in FY 2018. In FYs 2017–2018, BARDA anticipates additional regulatory approval submissions for biodiagnostics, smallpox antivirals, a smallpox vaccine for at-risk individuals, Ebola vaccines or therapeutics, biodosimetry, and potentially for more new drugs to treat Acute Radiation Syndrome (ARS) and exposure to chemical agents.

In FYs 2014–2016, 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. This strategy was to maintain our biothreat preparedness levels with existing CBRN MCMs in light of the transition to an annual appropriation structure after the exhaustion of funds from the SRF at the end of FY 2013. In FY 2017, BARDA also is replenishing stockpiles of the licensed anthrax vaccine to ensure the U.S. maintains the appropriate preparedness posture against anthrax and paves way to bridge to the next generation of anthrax medical countermeasures.

In FY 2016, Congress appropriated $510 million for Project BioShield. That funding level supported acquisition of three new, and replenishment of three existing, medical countermeasures. The new procurements were the next-generation anthrax vaccine which elicits potential protective immunity in

two doses versus three with the current vaccine, and two biodosimetry devices which can measure the amount of ionizing radiation an individual has been exposed to in order to triage patients and determine who should receive medical countermeasures (e.g. cytokine therapy). FY 2016 funds were also used to support initial efforts to replenish expiring heptavalent botulism antitoxin; the only botulism antitoxin product currently approved by the FDA. The funds were used to convert the stored, hyperimmune, horse plasma into an intermediate bulk that will provide additional shelf-life as an intermediate and for quicker conversion to final product if needed. Two cytokines were also added to the SNS under existing contracts with Amgen and Sanofi, Neulasta and Leukine, respectively. Neulasta was added to the SNS based on the ease of use; once weekly dosing as opposed to daily dosing for Neupogen. Leukine was added to increase the percentage of this product for the cytokine formulary. Neupogen and Neulasta are approved by the FDA for the acute radiation syndrome (ARS) indication, and Leukine is expected to be approved in 2018.

Based on the successful development of CBRN MCMs in ARD programs, HHS will be prepared to acquire four to six new CBRN medical countermeasures under Project BioShield by the end of FY 2018. Below are potential CBRN MCM candidates that may be mature enough for consideration for purchase under Project BioShield in FYs 2017–2018.

- Late-stage development and procurement of Ebola vaccines and therapeutics to prevent and treat infections by Ebola-Zaire virus. These products will require sustained investment in both FY 2017 and FY 2018.
- In FY 2016, BARDA supported the late stage development and procurement of a next-generation anthrax vaccine that will lower the number of required doses to elicit potential protective immunity. This will decrease the overall life cycle management cost to stockpile this vaccine. BARDA is working together with SNS to replace the existing anthrax vaccine stockpile with this next generation product. This necessitates sustained investment in this program to make the necessary procurements to replace and sustain the anthrax vaccine stockpile (FY 2018).
- Medical Countermeasure to mitigate or reverse the lung injury that occurs with the inhalation of vesicating agents like mustard gas (FY 2018).
- Medical Countermeasures that can mitigate or reverse the neurological injury that occurs from nerve agent induced seizures that are refractory to currently stockpiled treatments (FY 2018).
- Expansion of utility of an artificial skin substitute to include pediatric populations. Such a skin substitute would reduce or eliminate the need for skin grafting in burn patients (FY 2018).
- Late-stage development and procurement of an intravenous formulation of a smallpox antiviral drug. Such a formulation would be used to treat those who were severely ill and pediatric populations unable to swallow medication (FY 2018).
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biological threats (FY 2018).
- Maintenance of anti-neutropenia cytokines to treat hematopoietic deficiencies associated with ARS available under vendor management (FY 2018).
- Maintenance of midazolam as a therapy to treat nerve agent induced seizures (FY 2018).

Funding History

Fiscal Year	*Amount*
FY 2014[26]	$254,074,360
FY 2015	$255,000,000
FY 2016 Final	$510,000,000
FY 2017 Annualized CR	$509,030,000
FY 2018 President's Budget	$510,000,000

Budget Request

The FY 2018 Request for Project BioShield is $510,000,000, which is +$0.970 million above the FY 2017 Annualized CR level. This funding level will continue development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines and new procurements of new antibacterial drugs and chemical agent medical countermeasures. It will also support new intravenous formulations of currently stockpiled smallpox antiviral drugs for use in special populations or those who are severely ill. Project BioShield funds support both late-stage development activities and initial procurement of the product. Late-stage activities include: Phase 3 clinical studies; pivotal non-clinical studies; and validation of the manufacturing process, all costly activities. Thus, the funding amounts listed below reflect the cost of procurement as well as late-stage development activities and the cost cannot be divided by the number of treatment courses to determine a cost per treatment course or dose. At the requested level, the following six procurements which reflect the highest priority countermeasures for FY 2018 will be funded:

1. **New antimicrobial drugs to address biothreat pathogens ($60 million, ~10,000 treatment courses):** At least one new antibiotic presently in the ARD program may be available to purchase under Project BioShield. This antibiotic candidate may be able to replace existing antibiotics in the SNS 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. **Sustain development and procurement of Ebola-Zaire vaccines and therapeutics ($127 million, ~50,000 vaccine doses, 500 treatment courses).** The funding provided in FY 2017 supported the late-stage development and procurement of multiple Ebola-Zaire virus medical countermeasures, including vaccines and therapeutics. To sustain the pace of development and meet ASPR's MCM preparedness requirements against Ebola, additional funding in FY 2018 is needed to continue procurement for those products. The PBS funding in FY 2017 provided for the initial procurement and the funding in FY 2018 will allow for additional procurements to increase our preparedness and move closer to the PHEMCE requirements.

3. **Sustain development and procurement of next-generation anthrax vaccine ($128 million, 3-4 million vaccine doses).** In FY 2016, a Project BioShield contract was awarded to Emergent BioSolutions for the development of NuThrax, a next-generation anthrax vaccine that elicits protective immunity in two doses instead of three when compared with the current licensed AVA vaccine**.** In FY 2018, Project BioShield funds will continue procurement of Nuthrax to replace the

[26] Includes the reduction of -$925,640 for the FY 2014 Secretary's permissive transfer.

currently stockpiled anthrax vaccine. This funding is critical to the maintenance of the federal government's preparedness posture against anthrax.

4. **Chemical Medical Countermeasures for vesicant induced lung injury ($50 million, 1,000 doses).** There are currently no medical countermeasures for the treatment of injury following exposure to vesicating agents, like mustard gas. Funds will support the late stage development and procurement of a drug that mitigates or reverses the lung injury that occurs upon inhalation of mustard gas.

5. **Chemical Medical Countermeasure for nerve agent induced seizures ($25 million, 1,000 doses).** At present, diazepam is stockpiled for the treatment of nerve agent induced seizures. In FY 2013, the late-stage development and procurement of midazolam for the treatment of nerve agent induced seizures was initiated because of its improved characteristics, as compared to diazepam. Regardless, some individuals' seizures will not be able to be treated with these therapies and they may endure severe neurological injury, particularly if the seizures occur in a prolonged fashion without medical intervention. Funds will procure a therapeutic that has been shown to minimize the neurological injury in animal models when combined with midazolam.

6. **Late stage development and procurement of an intravenous formulation of a smallpox antiviral drug ($40 million, 150,000 treatment courses).** In FY 2011, a Project BioShield contract was awarded to SIGA Technologies for the late-stage development and procurement of a smallpox antiviral drug, tecovirimat. This contract has successfully delivered two million treatment courses of tecovirimat to the SNS. FDA approval of tecovirimat is anticipated for FY 2018. Funds will be used for an award of a follow-on Project BioShield contract to support the late stage development and procurement of an intravenous formulation of tecovirimat. An intravenous formulation would allow for the treatment of severely ill individuals and pediatric patients unable to swallow medication.

7. **Smallpox oral antiviral drug milestone payment ($50 million, SIGA Technologies**). In 2011, a Project BioShield contract was awarded to SIGA Technologies for the late stage development and procurement of two million treatment courses of their oral (capsules) smallpox antiviral drug, tecovirimat, for delivery to the SNS. SIGA anticipates submission of their new drug application to support the treatment of smallpox in 2017. As part of the original award, a milestone was incorporated to encourage the company to seek eight year expiry. In doing so, this would significantly decrease the recurring costs of procurement upon expiry of product stored in the SNS. The company has data to support eight year expiry and, if approved by the FDA, the company will receive a one-time payment of $50 million.

8. **Cytokines to treat hematopoietic injury resulting from exposure to ionizing radiation ($5 million, extend VMI storage)**. In FY 2013, task orders for delivery of Neupogen and Leukine under Project BioShield were awarded to Amgen and Sanofi, respectively. In FY 2016, cytokine products were purchased under task orders awarded to Amgen for Neulasta and Sanofi for additional Leukine. Neupogen and Neulasta have been approved by the Food and Drug Administration for the Acute Radiation Syndrome (ARS) indication and also have approvals for the treatment of cancer patients. Leukine has a commercial market for treatment of cancer patients and can be used under Emergency Use Authorization for ARS treatment. BARDA anticipates Sanofi will submit their supplemental New Drug Application supporting the ARS indication to the FDA in 2017. The funding in FY 2018 will extend the vendor managed inventory (VMI) storage of all three products

by an additional five years. VMI storage provides a significant costs savings to the government since the product is rotated through the commercial marketplace and replenishment costs are not incurred.

9. **Burn product, expanding the potential use to pediatric populations ($25 million)**. In FY 2015, four Project BioShield contracts were awarded to address burn injuries resulting from the thermal flux of a nuclear detonation. These products have the potential to improve the outcome for burn patients under everyday care. The products address the continuum of care for burn patients to include field dressing, improved debridement of burn injuries, cell-based skin substitute, and donor site sparing technology. In FY 2017, clinical trials were conducted in pediatric populations for two of these products to expand their potential use beyond adults and address a mandate under PAHPA to address at-risk populations. In FY 2018, funds will support a pediatric clinical trial for the cell-based skin-substitute product (Stratagraft).

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

OFFICE OF POLICY AND PLANNING

Budget Summary
(Dollars in Thousands)

ASPR Office of Policy and Planning	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Budget Authority	**14,877**	**14,849**	**14,849**	**--**
FTE	**66**	**66**	**66**	**--**

Authorizing Legislation:

Authorization ..... Public Health Service Act
Allocation Method ..... Formula Grants/Cooperative Agreements, Direct Federal/Intramural, Contracts

Program Description

The Office of Policy and Planning (OPP) leads disaster policy development and coordination across HHS Department and develops policies that guide the operational functions of ASPR programs, including the Office of Emergency Management (OEM) and the Biomedical Advanced Research and Development Authority (BARDA). OPP also leads policy coordination for preparedness and response across federal, state, and local governments, the private sector, academia, and international partners. The budget justification below describes OPP's critical activities to enhance the security of the American people and demonstrates OPP's leadership in four areas: strategic planning, policy development, research and evaluation, and leverage partnerships.

Strategic Planning

OPP leads strategic planning efforts for public health emergency preparedness, response, and recovery. The National Health Security Strategy (NHSS) and Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) are examples of nationally recognized OPP-led activities that set the strategic direction for a wide range of partners who must effectively collaborate to prepare and respond to public health emergencies.

The National Health Security Strategy and Implementation Plan is the Nation's comprehensive strategy for protecting people's health during public health emergencies and disasters, as required by Congress. It integrates national security, homeland security, and health security sectors. Through its leadership in developing strategy, OPP builds health resilience against threats in every community and enhances the infrastructure needed to prevent, withstand, and recover from public health emergencies and disasters. OPP leads planning efforts across federal, state, local, tribal, and territorial (SLTT) government, non-governmental, and private sector partners to develop and implement a unified strategy that helps HHS and

our partners prioritize critical actions for protecting health security. OPP also leads the NHSS's Evaluation of Progress, as required by Congress, to demonstrate progress and areas needing additional attention.

The PHEMCE protects the health of Americans from natural disasters, emerging infectious diseases, and intentional threats from chemical, biological, radiological, and nuclear (CBRN) agents by ensuring the nation's capacity to develop and deploy medical countermeasures (MCMs). The PHEMCE sets priorities for MCMs such as vaccines, antibiotics, and devices to protect against these national security threats. In leading the interagency PHEMCE, OPP provides guidance to several U.S. Department of Health and Human Services (HHS) agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), as well as interdepartmental partners including the Departments of Homeland Security (DHS), the Department of Defense (DoD), the Department of Veterans Affairs, and the Department of Agriculture. Annually, OPP leads the review and development of the PHEMCE Strategy and Implementation Plan (SIP), as required annually by Congress, to inform decisions about basic and advanced research, development and acquisition, stockpiling, and the policies needed for effective distribution, dispensing and administration of MCMs during emergencies.

Policy Development

Building on the national strategies outlined above, OPP leads policy development that directly impacts national preparedness and response capabilities and ensures the nation is prepared to effectively respond to and recover from public health emergencies and disasters. Examples of critical OPP policy development and coordination include:

- Setting MCM requirements by identifying the number and characteristics of MCMs and aligning HHS investments for research and development, acquisition, stockpiling, and deployment of MCMs based on sound scientific, medical, and policy principles. In the past five years, OPP established MCM requirements that set the direction of $4 billion in the multiyear budget for investments across the PHEMCE, OPP also supports BARDA and CDC contracts for 40 stockpiled MCMs and aligns MCM research, development, and procurements for BARDA, NIH, CDC, and FDA.
- Creating flexibility for how MCMs are used in certain emergency circumstances where they would not normally be allowable. OPP leads the coordination of Emergency Use Authorization (EUA) policy; and provides guidance to the Secretary of HHS on the declaration and determination of EUAs. EUAs are issued by FDA and authorization requires determination of a health risk to national security by the Secretaries of HHS, DHS, or DoD. The EUAs for Ebola virus disease diagnostics led to the deployment of DoD diagnostic systems in West Africa that were instrumental to the success of HHS's Ebola response.
- Providing liability protections to strengthen incentives for the entire MCM enterprise, including industry, to participate in developing and manufacturing MCMs and health care workers to administer life-saving MCM treatments. OPP's policy coordination for ASPR supports issuance of Public Readiness and Emergency Preparedness (PREP) Act declarations of immunity from liability (except for willful misconduct) to entities and individuals that develop, manufacture, test, distribute, administer, and use MCMs. In 2016 and 2017, OPP led policy coordination for PREP Act declarations on Zika virus vaccines and Ebola virus disease vaccines and therapeutics. These liability protections enabled commitments by manufacturers to develop vaccines and therapeutics to conduct necessary clinical trials in the United States and West Africa in the fight against the Ebola virus. OPP recently helped to facilitate initiation of NIH- and BARDA-sponsored clinical trials for Zika virus vaccines. The initial results of clinical trials move the nation closer to effective vaccines.

- In 2017, OPP also led PREP Act and EUA activities strengthening the nation's preparedness against nerve agent attacks by facilitating development, manufacturing, procurement, and use of nerve agent antidotes. These flexible authorities prevent the depletion of federal and local MCM stockpiles during an emergency.
- Ensuring the necessary balance of laboratory safety and security with the economic benefits of a robust life sciences research enterprise. OPP coordinates three major biosafety and biosecurity efforts across HHS: 1) a framework to standardize biosafety in HHS laboratories for CDC, NIH and the FDA; 2) a departmental-level review process for high-risk research; and 3) metrics for the review of dual-use research of concern. OPP also leads a public-private transparency initiative to provide a portal for scientists, laboratory staff, policy makers, and the public to locate federal and non-federal resources on biorisk management. In 2016-2017, OPP trained scientists and biosafety officers in three workshops on biosafety and biosecurity practices.
- Increasing health care system preparedness and enhancing day-to-day emergency and trauma care. OPP leads policy development through the Emergency Care Coordination Center to advance emergency and trauma care system design, improve the value and quality of emergency care, and coordinate emergency medical care activities across the federal government. During 2016, OPP partnered with the Centers for Medicare & Medicaid Services (CMS) to finalize a rule that established national emergency preparedness requirements for health care facilities.
- Optimizing patient health outcomes by enhancing both health care and human services delivery during disasters. OPP identifies promising practices across HHS-funded human services programs. In addition, OPP leads several working groups to address the needs of pregnant women and children, as well as address behavioral health issues during disasters. In 2016, OPP led the development of a behavioral health concept of operations plan to address the behavioral health and stress-related needs of responders and disaster survivors; and developed a resource on stress management for pregnant women during the Zika virus disease outbreak that health care providers used with patients. OPP also partnered with HHS's Office of Minority Health to produce a culturally-appropriate, Spanish-language version of the document.
- Leading U.S. domestic partners and coordinating the assessment of potential public health emergencies of international concern (PHEIC) that legally require reporting to the World Health Organization (WHO) under the International Health Regulations (IHR). Lead 23 federal departments and agencies to standardize IHR-related reporting procedures. Since 2007, the U.S. Government notified WHO of 97 public health incidents of concern, with 17 notifications in 2016-2017 alone, including multiple Zika virus cases and multiple infections with novel influenza viruses.

Research and Evaluation

OPP-led evaluations save lives by improving policy effectiveness and resource allocation. OPP research identifies promising practices and builds the evidence base for effective preparedness, response, and recovery. Through evaluation, OPP identifies areas for improvement upon which to focus strategic planning and policy development activities. Examples of OPP's research and evaluation outcomes include:

- The Strategic National Stockpile (SNS) Annual Review, which determines appropriate acquisition levels, guides future SNS procurements, and maximizes resource allocations. OPP co-leads with CDC the annual review of SNS essential drugs and medical supplies. An OPP-led preparedness assessment resulted in the reallocation of $64 million in MCM intravenous assets to better position the SNS to save lives during public health emergencies. In 2016, recommendations were also

adopted to reallocate SNS resources to enhance preparedness for at-risk populations, including children.

- Disaster research, evaluation, and improvement planning ensures that we learn from emergency responses and improve. OPP leads research and evaluation projects after major emergencies. For example, OPP-administered supplemental funds for research grants provided to ASPR after Superstorm Sandy which were critical to understanding how communities, states, and the regions recover most quickly. OPP also leads efforts to evaluate and apply lessons learned from the 2014-2016 Ebola outbreak. Results from these efforts are currently being incorporated into policy and operations to improve decision-making, preparedness, and response for future events. Critical outcomes of recent research, evaluation, and improvement planning activities led by OPP include:
    - OPP-administered Hurricane Sandy research grants resulted in over 20 scientific publications; data sharing agreements providing access to critical databases; critical trainings and decision-making tools; and identification of key unmet access and functional needs of at-risk populations in that disaster.
    - OPP implemented the January 2017 Progress Report on the Ebola Response Improvement Plan that included 32 corrective actions to ensure HHS-wide improvement. OPP's evaluations provide a pathway for strengthening planning and response to future outbreaks of emerging infectious diseases. To date, 17 recommended actions are complete or nearing completion and 15 are actively being addressed.
    - To protect U.S. citizens from health threats outside our borders, OPP leads assessments of international public health emergencies (including HHS responses to H7N9 influenza, Middle Eastern Respiratory Syndrome Coronavirus, the West Africa Ebola outbreak, and the recent Zika epidemic). For example, in 2015-2016 at the onset of the Zika epidemic in the Americas, OPP led efforts to acquire Zika virus samples from foreign countries that enabled critical work on diagnostic assays and vaccine development. The same process was used to obtain H7N9 samples from China to begin development of an U.S. vaccine in response to the influenza outbreak in 2017.
    - In 2016, OPP led the U.S. government's effort to conduct the Joint External Evaluation (JEE), a comprehensive assessment of capacities to detect, prevent, and respond to public health emergencies that resulted in identification of 40 areas for improvement.
    - OPP's analysis of BARDA investments to develop a burn countermeasure product found the product also benefits routine burn treatment. The initial investment of $24 million is projected to provide improved patient outcomes for routine burn care within a few years of launching in the U.S. market. The study affirms the economic value of such investments for both emergencies and day-to-day, routine health care.

Leverage Partnerships

OPP's strategic planning, policy development, and evaluation efforts provide our partners a strong foundation for effective responses to public health emergencies and disasters. OPP serves as a leader and convener across federal partners, private healthcare organizations, the pharmaceutical industry, international partners, and others to ensure support for preparedness, response, and recovery activities. This leverages resources, both public and private. Examples of OPP-led efforts to engage partners and leverage resources are:

- Coordinating HHS-wide decision making during public health emergencies and disasters, sharing situational awareness updates, and informing and advising the HHS Secretary regarding policy issues by convening the Disaster Leadership Group (DLG). OPP leads the DLG, which is composed of senior

leaders from across HHS. During 2016, DLG activations included those for the Flint water crisis, Zika virus epidemic, and Louisiana floods. The Flint DLG focused on four priorities to support the community: immediate access to safe water, long-term safety of the water supply, immediate health needs, and mitigating and monitoring the long-term effects of lead exposure. Additionally, the Zika DLG continues to meet regularly as the 2017 mosquito season arrives.

- Convening a DLG for H7N9 influenza due to the evolving epidemiology of the virus in China and the lack of a vaccine. OPP is leading the DLG to begin pre-pandemic planning for prevention and response actions should it reach the US.
- Enhancing response partners ability to save lives by providing near real-time data and mapping products of at-risk populations that may be adversely impacted by a disaster. In partnership with CMS and OEM, OPP led the HHS emPOWER initiative that provides three national capabilities. The capabilities include a de-identified public map, de-identified emergency planning datasets, and a restricted dataset that a public health official can request to conduct outreach in an emergency. Community partners have used these tools to advance their ability to anticipate, plan for, and respond to the needs of more than 3.8 million at-risk individuals that live independently as well as rely upon 17 types of life-saving electricity-dependent medical equipment, such as ventilators and electric wheelchairs, and oxygen tank, dialysis and home health care services. As of 2016, more than 40,000 organizations, including local healthcare, first responders, and utilities, have used the public HHS emPOWER Map to plan and respond to emergencies across the nation. During 2016 and in anticipation of Hurricane Matthew and Gatlinburg, Tennessee wild fires, public health and emergency management officials partnered to conduct nearly 35,000 outreach calls as well as health and wellness outreach visits to at-risk individuals.
- Helping to ensure that patients have access to vital prescription medication before, during, and after a disaster. OPP leads the Prescription Medication Preparedness Initiative (PMPI), a public-private partnership with pharmacies. During 2016, OPP's PMPI partnered with private sector pharmacies to direct messages to millions of patients at potential risk in advance of the Louisiana floods, Hurricane Matthew, and Winter Storm Jonas. Customer notifications prior to Winter Storm Jonas resulted in a nine percent increase in the number of patients who refilled prescriptions in advance of the storm.
- Providing strategic advice and recommendations to the HHS Secretary, OPP leads the coordination, management, and operational services for the National Preparedness and Response Science Board (NPRSB) and the National Advisory Committee for Children and Disasters (NACCD). These advisory committees assemble nationally renowned experts to advise the HHS Secretary and provide a public forum in which partners and the public can voice their concerns and provide input. The NPRSB and NACCD met 18 times in 2016 and through spring 2017, held 6 public meetings, and issued reports with 22 recommendations to the HHS Secretary on issues such as getting youth engaged in preparedness and MCM readiness.
- Ensuring the needs of at-risk individuals are met during public health emergencies by developing culturally and linguistically appropriate policies and plans. OPP also provides expertise to partners in all major public health emergencies, including real-time technical assistance to address the access and functional needs of at-risk individuals and behavioral health needs of disaster survivors and responders to promote individual and community health and resilience. During 2016, OPP convened a workshop to collect lessons learned and promising practices from home and community-based services providers impacted by Hurricane Sandy that can be used to save lives during future emergencies. The workshop included more than 90 participants representing more than 20 state and local organizations providing an opportunity for providers to share innovations and promising practices to foster resilience and recovery for at-risk individuals with access and functional needs. During 2016-2017, OPP developed and released a report that tracked HHS

progress in integrating the needs of children across all disaster and public health emergency preparedness, response, and recovery activities.

- Leading strategic partnerships with other nations, intergovernmental organizations, and public and private stakeholders to promote efforts to strengthen preparedness and response capacities for public health emergencies with a domestic/international interface. OPP serves 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), to prepare for CBRN threats and diseases with pandemic potential. OPP also leads HHS's implementation of the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza, as well as health security actions under the Biological Weapons Convention. OPP leads development and implementation of domestic and multilateral frameworks for international event response coordination, emergency communication, and the rapid cross-border mobilization of medical countermeasures, health care personnel, and biospecimens during public health emergencies. OPP has implemented these frameworks to guide HHS responses to H7N9 influenza, Middle Eastern Respiratory Syndrome Coronavirus, the West Africa Ebola outbreak, and the recent Zika epidemic, among others. In addition, OPP also leads ASPR engagement with the WHO to ensure that the reform of the *WHO Health Emergency Programme* is aligned with, and informed by U.S. public health emergency preparedness and response strategies.

Funding History

Fiscal Year	***Amount***
FY 2014	$14,877,000
FY 2015	$14,877,000
FY 2016 Final	$14,877,000
FY 2017 Annualized CR	$14,849,000
FY 2018 President's Budget	$14,849,000

Budget Request:

The FY 2018 funding request for ASPR's Office of Policy and Planning (OPP) is $14,849,000, which is level funding to the FY 2017 Annualized CR.

To set the strategic direction for public health emergency preparedness, in FY 2018, OPP will continue to lead the development and delivery of all Congressionally mandated strategic planning products including the NHSS, NHSS Implementation Plan, and the PHEMCE Strategic and Implementation Plan.

OPP will continue to be responsive in meeting new strategic goals and objectives set forth by both ASPR and HHS leadership. The Office will conduct evaluations as required by Congress, including NHSS Evaluation of Progress, and the Strategic National Stockpile Annual Review.

OPP's policy priorities for FY 2018 include efforts to better integrate healthcare organizations into coalitions; enhance state and local coordination; integrate disaster behavioral health into preparedness, response and recovery activities; identify and disseminate best practices on community resilience, including planning tools that address the access and functional needs of at-risk individuals; build initiatives to exercise, measure, and report the ability for the health care system to surge during a public health emergency or disaster; strengthen biosafety and biosecurity practices; work with international partners to

protect U.S. citizens from global threats, and maintain compliance with U.S. obligations under the International Health Regulations.

In FY 2018, OPP will continue to lead engagement efforts across SLTT government, non-governmental, and private sector partners, to develop policies and resources that are responsive to their needs. OPP will continue to receive input from the public and non-federal partners by leading federal advisory committees, such as the National Preparedness and Response Science Board (NPRSB), and the National Advisory Committee for Children and Disasters (NACCD). OPP will also lead the DLG to coordinate departmental decision making, share situational awareness updates, and inform and advise the HHS Secretary on responses to public health emergencies and disasters.

Key Outputs and Outcomes Table
ASPR Program: Office of Policy and Planning (OPP)

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
1 Establish and coordinate implementation of national and international strategies for public health and medical preparedness and response (Output)	FY 2016: Target Met Led development of five requirements documents, four for improvised nuclear devices and one for Zika MCMs, to ensure alignment of HHS programs. Led policy coordination for PREP Act liability protections that enabled commitments by manufacturers to develop vaccines and therapeutics and conduct clinical trials. Provided policy guidance to the HHS Secretary on emergency use authorizations for Ebola virus disease diagnostics. Led development of a healthcare providers' resource on promoting stress management for	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.	Develop the updated NHSS and Implementation Plan. Develop and submit PHEMCE annual SIP. Implement NPRSB and NACCD recommendations of priorities into implementation. Develop policies for (1) professional medical or public health personnel, and manage offers of assistance, from foreign countries; and (2) MCMs, and manage offers of assistance, from foreign countries. Develop NAPAPI influenza virus sample sharing manual.	

	pregnant women during the Zika virus outbreak. Led the development of a behavioral health concept of operations for disaster survivors and responders. Led review of lessons learned and promising practices from community-based providers impacted by Hurricane Sandy. Coordinated 17 IHR notifications to WHO in 2016-2017. Led evaluations to enhance SNS; adopted recommendations to ensure integration of at-risk populations. Managed 15 meetings of the NPRSB and NACCD, including 4 public meetings, and issued a final report with 10 recommendations to the HHS Secretary.		Integrate the Emerging Infectious Disease Threat Risk Assessment Tool into the GHSI Early Alerting and Reporting situational assessment process and establish schedule for reports that include actions for senior officials.	
2.4.9 Establish and improve awareness of the ASPR strategy for preparedness and response (Intermediate Outcome)	FY16: Target Met Monitored implementation of the *National Health Security Strategy (NHSS) and Implementation Plan 2015-2018* and promulgated information on social media (OPP reached 17,840 people via Facebook and 9,179 target impression via Twitter with 38,800 Q&A 114th Congress Twitter followers). Worked to make local health departments aware of the NHSS guidance and	Continue the process of implementation and evaluating progress for the 2015-2018 NHSS, including the establishment of a governance structure. To implement NHSS Strategic Objective 1: Build and Sustain Healthy,	Increase by 10 percent strategic partner outreach, education and engagement around OPP policy products over FY17 baseline. Conduct at least two, in-person Federal Advisory Committee meetings on relevant topics, stakeholder engagement workshops, and Working Group or public sessions as	

	found that approximately 47% of preparedness coordinators feel that their work is influenced by the NHSS. OPP DLG activations in 2016 included the Flint water crisis, Zika virus epidemic, Louisiana floods. HHS emPOWER Map, which provides de-identified data on populations reliant on life-saving electricity-dependent medical equipment and health care services, was used by LHD and first responders to inform disaster response. OPP's PMPI partnership with private sector pharmacies notified patients to refill prescription in advance of notice events (e.g., hurricanes). Led efforts for rapid importation of Zika virus samples from foreign countries, enabling the validation of critical diagnostic assays and development of a vaccine candidate in the U.S. In 2017, the same process was used to acquire H7N9 samples from China to development an influenza vaccine. Engaged scientific community by leading three workshops to train scientists and biosafety	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.	needed. Ensure that at least 85 percent of IHR-required notifications to WHO are within 72 hours of initial reporting to a federal agency. Develop and disseminate a training toolkit and conduct train-the-trainer events with CDC, DOD, and USAID. Develop a dissemination and implementation plan for the updated Disaster Human Services Concept of Operations through engagement with state-level providers to ensure planning for continuity of care during public health emergencies and disasters.	

	officers in laboratory security practices for dangerous pathogens.			
12 Expand an evidence base of scientific information about disasters	2016: Target Exceeded Administered supplemental funds for research grants provided to ASPR after Superstorm Sandy to evaluate recovery in communities, states, and the regions. The grants resulted in over twenty scientific publications; data sharing agreements providing access to critical databases; critical trainings and decision-making tools; and identification of key unmet access and functional needs of at-risk populations in that disaster. Led the evaluation and applied lessons learned from the 2014-2016 Ebola epidemic, produced the January 2017 Progress Report on the Ebola Response Improvement Plan with corrective actions to ensure HHS-wide improvement; the corrective actions are complete or in progress. Led 23 federal government agencies in a comprehensive assessment of capacities to detect, prevent, and respond to public health emergencies which resulted in a report outlining the strength of our systems and areas for improvement. OPP is leading the development	ASPR Hurricane Sandy Recovery Science grantees will complete Sandy dataset- related research during FY17. The grantees are expected to share dataset-related research results with federal partners.	Develop the PHEMCE annual review of the contents of the strategic national stockpile. Develop the NHSS Evaluation of Progress to meet the statutory requirement. Initiate response improvement plans for public health emergencies. Develop a 2016-2017 Report of the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group: Update on Departmental Activities. Develop the updated HHS Disaster Human Services Concept of Operations approved by the ASPR that incorporates current evidence-based best practice. Evaluate and analyze promising practices for implementation of the 2016 Disaster Behavioral Health Concept of Operations to assess percentage of state-level providers influenced by CONOP. Publish a progress	

	an action plan to address areas identified for improvement. Led the evaluation of BARDA's investment in an emergency burn countermeasure, which affirms the economic value of such investments for both the emergency response and day-to-day, routine health care. Recent publications reflect advancements in the research evidence-base for emergency and trauma care system design and include: increasing value in emergency care; patterns in access and use of emergency and trauma care services; assessing national preparedness for mass casualty incidents; and defining geographic units to describe total population health. OPP manages the ASPR Hurricane Sandy dataset for research studies on topics including population health impacts, disruption to health facilities and housing, and predictive analytics.		report on the Joint External Evaluation "action plans" to address 40 identified improvements from the FY 2016 evaluation.	

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

OPERATIONS

Budget Summary
(Dollars in Thousands)

ASPR Operations	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Budget Authority	**30,938**	**30,879**	**30,879**	**--**
FTE	**135**	**135**	**135**	**--**

Authorizing Legislation:

Authorization ..... Public Health Service Act
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, identifying and mitigating risk in all aspects 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 for Preparedness and Response's unique role as the principal advisor to the Secretary on all matters related to public health emergency as well as 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)

The Office of the Chief Operating Officer leads the management services which enable ASPR to carry out its mission. COO oversees communications with the public and the media; human capital management and workforce development; technology management and information security; facility operations and administration; emergency response and routine travel; legislative affairs; records management; and executive secretariat. COO continually seeks to improve business operations for maximum return on investment, strengthen ASPR's human capital and communications practices, provide innovative technology solutions, and create a more nimble and flexible organization. COO also will leverage innovative communication tools and technologies—including social networking and crowd-source

media—to enhance community connectedness and empower individuals to take action before, during, and after 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 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. AMCG partners with ASPR's largest programs, Biomedical Advanced Research and Development Authority (BARDA) and the Office of Emergency Management (OEM), in pursuit of ASPR's mission. 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 AMCG 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 (ESF) #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. 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 entire ASPR acquisition community. AMCG's Division of Grants is instrumental in assisting ASPR's Office of Policy and Planning (OPP) 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 is promulgated as the Chief Grants Management Office within ASPR. AMCG uses Other Transaction Authorities (OTAs) to enable ASPR to partner with multiple companies, such as consortiums, as well as support a portfolio of multiple products.

The Office of Financial Planning and Analysis (OFPA)

OFPA assures that ASPR's financial resources are aligned to its strategic priorities and conducts annual planning under a multi-year strategy, measuring financial 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 assure efficient expenditures. 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 cost estimates for HHS PHEMCE partners at 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 2017 and FY 2018.

OFPA also oversees emergency administration and finance operations that provide Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (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 ESF#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 outbreak 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 2014	$31,305,000
FY 2015	$31,305,000
FY 2016 Final	$30,938,000
FY 2017 Annualized CR	$30,879,000
FY 2018 President's Budget	$30,879,000

Budget Request

The FY 2018 Budget includes $30,879,000 for ASPR's Operations, which is level with the FY 2017 Annualized CR. 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, enterprise risk management 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 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
2.4.8 Improve strategic communications effectiveness. (Outcome)	FY 2016: Target Met Increased internal communication to expand organizational synergies. Demonstrated expansion of communications including messaging/information sharing capabilities during public health emergencies. Expanded social media. Streamlined organization's web systems utilized for mission response.	Streamline internal communication to support organizational synergies and efficiencies. Continue to assure strategic communications improvements with additional messaging/info-sharing capabilities during public health emergencies. Streamline organizational web systems utilized for mission response.	Drive modern design and integrate functionality of public facing web and social media platforms to improve external communications for emergency preparedness and response. Coordinate and integrate communications with partners to maximize reach of consistent, credible messaging and to leverage info-sharing capabilities during public health emergencies. Maintain resilient access to ASPR web systems for mission response.	N/A
11a Ensure deployment of emergency response personnel, consistent with mission timing requirements/objectives (Intermediate Outcome)	FY 2017: Result Expected Feb 27, 2018 Target: 80.0 % (Pending)	80.0 %	TBD	N/A

ASSISTANT SECRETARY FOR ADMINISTRATION

CYBERSECURITY

Budget Summary
(Dollars in Thousands)

Office of the Chief Information Officer - Office of Information Security	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Budget Authority[1]	**49,820**	**49,723**	**72,223**	**22,403**
FTE	**82**	**93**	**123**	**30**

1/ The FY 2018 Request reflects a realignment of $1.040 million between Cybersecurity and OSSI for cyber threat activities.

Authorizing Legislation:

FY 2018 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.

HHS is the repository for information on bio-defense, development of pharmaceuticals, and medical information for one hundred million Americans, among a great deal of other sensitive information. As a result, HHS information is a target for cyber criminals seeking economic gain, as well as nation states who might seek in general to compromise the security of government information and gain economic, military, or political advantage.

The Cybersecurity Program is tasked with implementing a comprehensive, enterprise-wide cybersecurity program to protect the critical information with which the Department is entrusted. To accomplish this, HHS provides and engages in:

- Implementing specific cybersecurity capabilities
- Cultivating cybersecurity partnerships in the public and private sectors
- Engaging in HHS-wide security collaboration activities
- And enhancing HHS' security capabilities through current and future programs and projects

As cyber threats continue to multiply and become more complex, the need for enhanced controls and threat management strategies will continue to amplify. The evolving cyber threat landscape coupled with the rapid proliferation of information assets, the increased mobility of the HHS workforce, and the need to derive value and intelligence from information assets have forced HHS to redefine its approach for managing and protecting information assets. A mature cybersecurity workforce – equipped with the appropriate training, education, and skill sets – is vital to managing the evolving threats to these information assets and adequately implementing the controls necessary for protecting information

assets. Although OCIO has the capacity to drive secure resolutions to many of these challenges, ongoing stakeholder engagement is a 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.

HHS is continually increasing its protections against cyber threats, such as unauthorized access, denial of service, malicious code, and inappropriate usage, and insider threat, all which pose risks to HHS critical functions, services, and data.

- In fiscal year (FY) 2016, HHS managed 9,047 cybersecurity incidents
- In the first half of FY 2017, HHS has conducted 2,185 vulnerability scans that prevented 32,776 cybersecurity vulnerabilities from being exploited
- In March 2017 alone HHS investigated 5,226 cybersecurity incidents of spam, 450 of which were malicious and, gone unchecked, could have compromised HHS data
- Cybersecurity, privacy and end-of-life legacy systems consume 70% of HHS' IT budget and have been identified as the top three IT challenges HHS faces in the next year.

Some key initiatives that HHS is undertaking to improve security are focused around improving efficiencies in security tools and deploying enterprise-wise tool solutions. These enterprise-wide tool solutions work 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 of federal mandates and guidelines.

The HHS cybersecurity program and the capabilities it supports are directly derived from 66 cybersecurity mandates and legislation with which HHS must comply. In FY17 – and moving forward – HHS identified 13 critical cybersecurity functions HHS must provide derived from these federal mandates. In addition to these 13 critical cybersecurity functions, HHS identified eight additional capabilities required to sustain a secure organization and support legislative mandates. These 21 critical functions and supportive initiatives take the shape of four sub-programs – Computer Security Incident Response Center (CSIRC), Trusted Internet Connection (TIC), Enterprise Security Tools, and the Federal Information Security Modernization Act (FISMA) Program Management.

Computer Security Incident Response Center

The mission of the Computer Security Incident Response Center (CSIRC) is to maintain cyber security operational readiness and assurance that strengthens the security and resilience of HHT IT systems, networks, and critical infrastructure from cyber events and incidents. The HHS CSIRC leads the coordination of operational cybersecurity situational awareness Department-wide and partners with the HHS Operating Divisions (OpDivs) to proactively manage cyber risk to HHS IT resources from cyber-attack. In short, CSIRC is HHS' nerve center for identifying threats, sharing threat information and coordinating appropriate response. The CSIRC maintains, enhances, and leverages extensive Department-wide security tools and capabilities across the Department in coordination with individual OpDivs. The CSIRC provides five key services in support of HHS – incident response and security monitoring; cyber investigations and research; maintenance of the Healthcare Threat Operations Center to coordinate information across HHS, the Department of Veterans Affairs and the Defense Health

Agency; leadership of the Cyber Threat Information (CTI) capability, focusing on cyber intelligence research, analysis and coordination; and maintenance of a secure network infrastructure. Continued expansion of the CSIRC and cybersecurity operations across the Department will continue through FY 2018 and will enable the CSIRC 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.

Trusted Internet Connection:

The Trusted Internet Connection (TIC) program aims to improve the Federal Government's security posture through the consolidation of external telecommunication connections and establishing a set of baseline security capabilities through enhanced monitoring and situational awareness of all external network connections. This program improves HHS' security posture and incident response capability through reduction and consolidation of external connections while providing enhanced monitoring and situational awareness of external network connections. The Budget invests in engineering and monitoring support costs of the TIC, which will enable the Department to meet its obligations specified in the DHS TIC and Einstein service level agreements. Building upon design work completed in FY 2011, the four physical TIC locations (Bethesda, Maryland; Ashburn, Virginia; Atlanta, Georgia; 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 FY 2015. HHS will continue migrating OpDiv VPN and cloud services to the TIC through FY 2018, as OpDiv requirements for this VPN and cloud services connectivity to the TIC are identified.

Enterprise Security Tools

The HHS Cybersecurity Program supports a range of tools, including security information and event management (SIEM) capabilities, intrusion detection systems (IDS), packet capture, firewalls, and network taps to monitor, analyze and protect network traffic. 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 2018, the program will continue to procure enterprise wide licenses for digital investigation technology to be deployed across all OpDivs, procure 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 capabilities, firewalls, web proxies, and security analytics.

Federal Information Security Management Act Program Management

The HHS Cybersecurity Program supports Federal Information Security Management Act (FISMA) responsibilities to manage risk to the HHS enterprise through a portfolio of programs and capabilities:

- **Information Security Governance** establishes dynamic information security policies, standards and guidance, while improving adoption of best practices, providing training to employees and ensuring recruiting and retention of cybersecurity expertise.

- **Information Security Risk Management** evaluates Department-wide vulnerabilities and threats to the entire organization, to support effective risk management decisions. This includes implementation of DHS Continuous Diagnostics and Mitigation (CDM) program, and the FedRAMP authorization program.

- **Information Security Compliance** manages all FISMA-focused reporting and oversight initiatives for the Department, in order to assure accurate interpretation of requirements, documentation of information, status of IT systems and related information, and HHS and OMB reporting while also providing oversight of security across the Department.

- **Enterprise Privacy** provides HHS-wide privacy governance and advisory support, reduces exposure to privacy risks and ensures that risks are mitigated, develops privacy policy and offers training, and provides privacy incident management support for the department.

- **Office of the Secretary Security Services** provides privacy and data protection, incident management, information assurance, and workforce development services to the Office of the Secretary (OS) and OS Staff Divisions.

- **HHS Cybersecurity Program Strategy, Engagement, and Resource Management** develops and implements HHS Cybersecurity program strategy, ensuring mission and organizational goal-alignment; leads internal and external engagement planning and execution to support the mission; leads organizational and capability maturity and assessment efforts, supporting alignment with the National Institute of Standards and Technology (NIST)'s Cybersecurity Framework and long-term maturity and risk-reduction; leads organizational resource management, controls, and related executive reporting to connect execution with strategy and support decision-making.

Funding History

Fiscal Year	*Amount*
FY 2014[1]	$52,377,000
FY 2015	$40,085,000
FY 2016 Final	$49,820,000
FY 2017 Annualized CR	$49,723,000
FY 2018 President's Budget[2]	$72,223,000

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

[2] The FY 2018 Request reflects a realignment of $1.040 million between Cybersecurity and OSSI for cyber threat activities.

Budget Request

The HHS Cybersecurity Program is mandated, in whole or in part, by 66 federal mandates, chief among them FISMA which requires each Department and Agency to implement a comprehensive cybersecurity program. Based on these requirements, HHS must protect the vital health information with which it is entrusted, respond to existing and emerging cybersecurity threats, and continue to enhance the program to ensure HHS has the capability and capacity to respond to new and emerging requirements, technologies and threats. It remains critical that HHS continue to operate a robust program to meet today's cybersecurity needs while ensuring HHS has the ability to meet the needs of an ever-changing threat landscape.

The FY 2018 request for the HHS Cyber Security Program is $72,223,000, a programmatic increase of $22,403,000 and is reflective of a $1,040,000 realignment of funds between OCIO and OSSI. The increase will support, sustain and enhance the Department's security posture 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 citizens remains a priority. HHS is seeking to increase its protections against cyber threats, such as unauthorized access, denial of service, malicious code, and inappropriate usage, insider threats 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' 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' compliance against federal mandates and guidelines.

The Budget 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 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; and support security engineering and fund a suite of Enterprise Security Tools, which will be required to comply with recent guidance requiring the automated reporting of the security continuous monitoring of all HHS and OpDiv IT systems and networks.

	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 Budget +/- FY 2017 CR
CSIRC	$8,932,000	$9,690,000	$18,230,000	+$8,540,000
TIC	$2,000,000	$2,100,000	$2,100,000	+$0
Enterprise Security Tools	$19,933,000	$16,072,400	$23,955,00	+$7,882,600
FISMA	$18,955,000	$21,957,600	$27,938,000	+$5,980,400
Total	$49,820,000	$49,820,000	$72,223,000	$22,403,000

1/ The FY 2018 Request reflects a realignment of $1.040 million between Cybersecurity and OSSI for cyber threat activities.

Computer Security Incident Response Center (CSIRC); and Security Incident Response & Situational Awareness ($18,230,000): The request is $8,540,000 above the FY 2017 Annualized CR level and will support the continued creation and expansion of the Fusion Center. The Fusion Center – also called the Healthcare Cybersecurity Communications and Integration Center (HCCIC) - will be a central location for information sharing across HHS and Federal Government partners, and it will provide data and tools to aid in fusion efforts to support threat analysis efforts for the healthcare sector. This will be implemented through enhancing enterprise capabilities to support operational cyber threat intelligence and be a focal point for responding to CISA Title I requirements, combining Department operational cyber threat information with internal and external information and intelligence, supporting correlation analysis and sharing this information with privacy and federal sector stakeholders to reduce risk and enable risk-based decision making.

Also included in the request is ongoing maintenance, which will enable the Department to maintain the monitoring and analysis capabilities in order to sustain a 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 provided cybersecurity situational awareness across the entire enterprise. It has also addressed 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 2018 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). 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. 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.

Trusted Internet Connection (TIC) ($2,100,000): The request is flat to the FY 2017 Annualized CR and will 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.

Enterprise Security Tools ($23,955,000): The request is $7,882,600 above FY 2017 Annualized CR level. Of the request, $2,482,000 will allow expansion of the malware blocking and incident response capabilities across the Department. The enhancements improve capabilities to the enterprise, an incident response readiness assessment, and a retainer for all major infrastructures and the CSIRC while allowing OpDivs to quickly engage expert-level incident response resources in the event of a significant cybersecurity incident. 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 request 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 2018 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 $5,400,000 for various Departmental Continuous Diagnostic and Mitigation (CDM) licenses previously paid (FY 2014 through FY2017) for by the Department of Homeland Security (DHS) CDM program, but which must now be acquired through PHSSEF Cybersecurity funds. 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 ($27,938,000): The request is $5,980,400 above FY 2017 Annualized CR level. The additional resources requested in FY 2018 will provide for the on-going maintenance support Enterprise eGRC tool. The tool allows for the automated reporting of security performance measures to the Department of Homeland Security. Funds will also enable the more effective implementation of security weakness remediation in response to recommendations and findings made in connection with the audits and evaluations, including the Department's annual financial statement audits 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 2017 Target	FY 2018 Target	FY 2018 Target +/- FY 2017 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 2016 Actual: 77.0%*	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 2016 Actual: 98.0%	95.0%	95.0%	Maintain
Vulnerability management:	FY 2016 Actual: 94.0%	95.0%	95.0%	Maintain
Boundary protection: What percent of the required TIC 2.0 Capabilities are implemented?	FY 2016 Actual 80.8%	100.0%	100.0%	Maintain
FISMA System Inventory Compliance: Percentage of systems with current Security Authorization to Operate (ATO).	FY 2016 Actual: 95.0%	95.0%	95.0%	Maintain

* For Hardware Asset Management and Software Asset Management (formerly the Configuration Management metric above), the lowest performing metric applicable to the Cybersecurity Capability was used to determine the Agency's internal target.

ASSISTANT SECRETARY FOR ADMINISTRATION

OFFICE OF SECURITY AND STRATEGIC INFORMATION

Budget Summary
(Dollars in Thousands)

Office of Security and Strategic Information	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Budget Authority	7,470	7,456	8,496	1,040
FTE	35	40	40	5

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) and the Director of National Intelligence (DNI) as the Department's Federal Intelligence Coordinating Office (FICO). In this capacity, OSSI is the HHS point of contact with the Intelligence Community (IC) and is responsible for coordination with the IC and with intelligence support to senior policy makers and consumers of intelligence across the Department. Additionally, OSSI is responsible for safeguarding classified national security information across the Department and the appropriate sharing of intelligence, homeland security and law enforcement information externally and internally within HHS among the Operating and Staff Divisions. OSSI integrates and synthesizes intelligence and all-source information on public health, terrorism, national security, weapons of mass destruction, and homeland security to support HHS missions to 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 provides strategic all-source 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. As HHS' FICO, it manages all intelligence, counterintelligence, insider threat, and cyber threat intelligence activities for

the Department. All of these programs are resourced with PHSSEF funds. In addition, OSSI manages the Department's physical security, emergency management and personnel security services across the Department; these are resourced by non-PHSSEF funds.

The Intelligence Directorate, Counterintelligence Directorate, Cyber Threat Intelligence Program and Special Security Program within OSSI provide oversight, policy guidance and manage the Department's programs for intelligence, counterintelligence, insider threat, cyber threat intelligence and the safeguarding of classified information, facilities and equipment 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, insider threat awareness, and inquiries and direct engagement and coordination with federal agencies and partners.

The Intelligence Directorate seeks to provide timely, appropriately tailored, and relevant intelligence and other strategic all-source (including law enforcement sensitive) information to inform HHS decision-makers and their programs on potential national and homeland security threats domestically and abroad. Intelligence 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 homeland security agencies, and other federal or state partners.

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. HHS Counterintelligence activities include, but are 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 Counterintelligence Directorate is responsible for implementing a Department-wide Counterintelligence program and ensuring the tracking and screening of foreign nationals in compliance with DNI and White House requirements.

The Cyber Threat Intelligence Program (CTIP) has the responsibility to establish implementing guidance, provide oversight and manage the Department's policy for the sharing, safeguarding, and coordinate 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 and homeland security organizations and the Intelligence Community, to ensure the protection of internal federal critical information and the external health care and food and drug sectors. 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.

The Special Security Program (SSP) has the responsibility to safeguard national security information, facilities and equipment, including communications security across the Department. The SSP develops and implements classified information and intelligence security policies, programs, and procedures

consistent with mission requirements across HHS. SSP manages resources, personnel programs and implementation of all collateral and Sensitive Compartmented Information (SCI) and SCI Facilities (SCIF) associated security policies, programs, and initiatives associated activities and training related to information and facility security. SSP coordinates and works in concert with existing intelligence, counterintelligence, and cyber threats intelligence functions to develop and review policies and procedures pertaining to all aspects of the national and classified information, facilities and equipment programs.

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, cyber threat intelligence and special security professionals, in order to acquire, synthesize, analyze and report on open source and classified information and to assess its usefulness in supporting and furthering the HHS mission. OSSI utilizes all-source classified and unclassified information from the Intelligence Community as well as Law Enforcement, Homeland Security, Counterintelligence Community, and other stakeholder organizations to provide a comprehensive national or homeland security assessment to HHS senior leadership and others across the Department. In addition, OSSI represents HHS on a number of external committees and councils responsible for interagency coordination on security threats, intelligence, counterintelligence, insider threats 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 Final	$7,470,000
FY 2017 Annualized CR	$7,456,000
FY 2018 President's Budget	$8,496,000

Budget Request

The FY2018 request for OSSI is $8.496M, which is reflective of a realignment of $1.040 million from Cybersecurity to OSSI. OSSI's budget has remained steady since 2015. The FY 2018 total increase is due to the realignment of the appropriated budget between OSSI and OCIO (formerly a pass-through) to support OSSI's intelligence, counterintelligence, insider threat and special security programs mission across the Department.

OSSI and OCIO Realignment

The FY 2018 budget for OSSI includes a $1.040 million increase due to the realignment of the appropriated budget between OSSI and OCIO. Historically, these funds have been used to support 5 FTE within OSSI; these FTE are now reflected in both OSSI's budget and FTE total.

In 2012, an arrangement was made between the two offices to transfer funds as a pass-through rather than fund directly. These funding streams, and the activities funded by this pass-through, have evolved and require this change to align both the appropriated costs as well as the activities funding under the Services and Supply Fund. Realigning the appropriation directly to OSSI allows OSSI to continue to support the cyber security services provided directly to the Secretary, Deputy Secretary, and all the Operating and Staff Divisions within the Department. The cyber threat intelligence program managed by OSSI enables a nation-wide Departmental response capability that provides senior leadership with public health, 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 protection, mitigation, and senior leadership situational awareness; and 2) to conduct counterintelligence inquiries, investigations and assessments to resolve allegations or suspicious activities by, or on behalf of, foreign intelligence or criminal entities.

OSSI will continue to partner with the Office of the Chief Information Officer (OCIO) to increase operational awareness and information disseminated to Operating and Staff Divisions. OSSI 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 other Departmental 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 such as those related to the Ebola epidemic, Zika virus and Polio vaccination programs; and support national security interests. To continue to support these efforts, OSSI is seeking funds to support an increase of one additional FTE in FY 2018.

Cyber Threat Intelligence Program (CTIP):

The continuing cyber threats to the Department's vital systems and information and those to the Public Health sector, including ransomware, make cyber threat intelligence critical to preventing and mitigating these incidents. The CTIP's ability to maintain relationships and work closely with other Federal departments and agencies, including law enforcement organizations and the Intelligence Community, will ensure the protection of both federal critical infrastructure, the health care sector and provide deterrence and mitigation strategies from cyber security threats.

Mission Support/ Inflationary Increase

OSSI must be able to continue to integrate national and homeland security information and collaborate with the intelligence and law enforcement communities in order to synthesize information to support

the Department's evolving Public Heath missions. In FY 2016, OSSI provided support to all of the Secretary's priority items, including the Ebola epidemic, the Zika virus, and the Unaccompanied Children program. The Assistant Secretary for Preparedness and Response, the Office of the Chief Information Security Officer, the Office of the Inspector General, the Office of Global Affairs, the Administration for Children and Families, the Food and Drug Administration, National Institutes of Health, and the Centers for Medicare & Medicaid are just some of the customers that OSSI supports with intelligence, law enforcement and homeland security information and its intelligence, cyber, insider threat, counterintelligence and special security programs. To meet these needs, OSSI requires mission support personnel to effectively continue its national, homeland security and classified programs. OSSI's Business Operations Directorate provides human resource, logistics, IT, property, travel, time and attendance and other daily mission support to OSSI employees and programs critical to its continued operations. To support this effort, OSSI is requesting an increase of one additional (1) FTE. Likewise, OSSI is requesting a three percent (3%) increase in support for inflation. This will account for rent and utility increases and the replacement of aging equipment and required additional systems in order to support the Department's growing requirements for classified and unclassified programs.

PANDEMIC INFLUENZA

Budget Summary
(Dollars in Thousands)

Pandemic Influenza	FY 2016 Enacted	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017 CR
Budget Authority	**72,000**	**71,863**	**206,863**	**+ 135,000**
ASPR No-year (non-add)	*40,000*	*39,924*	*174,924*	*+135,000*
ASPR Annual (non-add)	*27,991*	*27,938*	*27,938*	-
Office of Global Affairs Annual (non-add)	*4,009*	*4,001*	*4,001*	-
FTE	5	5	5	-

Authorizing Legislation:

Authorization.....Public Health Service Act

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 an influenza pandemic. The public outcry over the lack of vaccines, diagnostics, and drugs for the Ebola outbreak and for vaccines during the H1N1 influenza pandemic in 2009 demonstrates the immediacy with which Americans expect their government to respond and protect the public 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 our national health security. During the winter of 2016-2017, China experienced the largest epidemic of Avian Influenza (H7N9) on record since its emergence in 2013. The virus has diversified into a new genetic lineage (Yangtze River), prompting WHO to recommend development of a new vaccine. Some viruses in this new lineage have become highly pathogenic for poultry. The virus has not gained sustained transmissibility in people and remains within China, but the related H5N1 avian influenza has spread to bordering countries in several instances since early 2003 raising concerns among public health authorities. Furthermore, some Yangtze Lineage H7N9 viruses have shown markers of resistance to licensed antiviral drugs eliminating the main specific therapeutic option for severely ill patients. To protect public 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 and 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. HHS conducted an end-to-end review in 2010 of the Department's medical countermeasures enterprise to identify and resolve barriers to faster, more coordinated medical countermeasure development. The resulting report, the *2010 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review*, along with two other reports, 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 annual *PHEMCE Strategy and Implementation Plan*, guide development and procurement of medical products to combat pandemics.

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 that will allow vaccine production to begin quickly when the need arises;
- Developed and purchased H5N1 and H7N9 bulk vaccine antigen (the component of vaccine that stimulates the human immune system);
- Developed and acquired 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;
- Expanded the surge capacity of domestic manufacturing while increasing its flexibility to help manufacture pandemic influenza vaccines as quickly as possible; and
- Conducted clinical trials that provide the necessary evidence base to use stockpiled and newly manufactured adjuvanted H5N1 and H7N9 vaccines without delays in response to an emerging pandemic, if needed.

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

- Improved 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;
- Food and Drug Administration's (FDA) clearance of point-of-care clinical diagnostics and strengthening the agency's regulatory science capability to speed the approval process for new products;
- Development and FDA approval of next-generation portable ventilators designed to increase access and availability to the ventilators needed for a surge in hospitalized patients during a pandemic; and
- Increased stockpiling of vaccines, ventilators and medical supplies, including adjuvants and antiviral drugs.

HHS investments have led to innovative technologic advancements which meet the need for medical countermeasures, as enumerated as follows:

Cell-based influenza vaccines: In November 2012, FDA licensed Novartis' Flucelvax®, the first cell-based influenza vaccine commercially available in the United States, which was available for use during the 2013-2014 influenza season and subsequent influenza seasons. 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 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.

Recombinant Vaccines: Since 2009, BARDA has supported the development of recombinant-based vaccine for seasonal and pandemic influenza. Development and manufacturing of recombinant-based influenza vaccines is much faster in an outbreak or pandemic than cell or egg-based vaccines because they 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, recombinant-based influenza vaccines were first developed, manufactured, and clinically tested in HHS's H7N9 vaccine response during 2013, which illustrated the rapidity and flexibility of this technology. In January 2013, FDA licensed Protein Sciences' FluBlok®, the first recombinant-based vaccine for seasonal influenza licensed in the United States. In 2015, the product indication was extended from persons between the ages of 18 and 50 to people age 18 years and above. FluBlok® subsequently received an additional approval for a recombinant Quadrivalent Influenza Virus Vaccine in the winter of 2016.

Expanding vaccine capacity through the use of adjuvants: BARDA supports advanced development of multiple adjuvants to achieve dose sparing of antigen, 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 HHS's H7N9 vaccine response in 2013. During November 2013, FDA licensed the first adjuvanted pandemic influenza vaccine in the United States, GlaxoSmithKline's Q-PAN H5N1 pandemic vaccine with AS03 adjuvant, which BARDA has supported since 2007. Q-PAN was subsequently licensed for pediatric patients in September 2016. In November 2015, FDA approved Fluad®, the first seasonal influenza vaccine containing an adjuvant. Fluad® is a trivalent vaccine for the prevention of seasonal influenza in people 65 years of age and older. Ongoing clinical studies will further delineate the clinical benefits in this population. The Clinical Studies Network (CSN) also launched BARDA's first sponsored trial, the BARDA *Ready in Times of Emergency* (BRITE) study, evaluating safety and immune responses of H5N1 pre-pandemic influenza vaccines and adjuvants that have been stored in the national stockpile for up to 10 years. The results of this study are expected to inform future decisions on the length of time pre-pandemic influenza vaccines and adjuvants are safe to store in the National Pre-Pandemic Influenza Vaccine Stockpile in order to help protect the US population. Importantly, the CSN has helped to further strengthen inter-agency collaboration and cooperation via field operations support of CDC's Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE) study and via active engagement with US Government partners, including the National Institutes of Health (NIH), FDA, CDC, and Department of Defense (DoD) on creation of the USG Zika vaccine development roadmap. The CSN plans in 2018 to conduct additional clinical studies linked to BARDA's areas of investment, including: testing of a new, H7 influenza vaccine produced using

recombinant technology and matched to the strain recently isolated in Asia; heterologous prime boost studies of different influenza vaccines in the National Pre-Pandemic Influenza Vaccine Stockpile; and studies of an anthrax vaccine for an elderly population. In conjunction with partner programs in the National MCM Response Infrastructure, these activities will increase BARDA's readiness to respond to biothreats and public health emergencies.

Innovation in 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 may partner with vaccine and biological product manufacturers to meet national demand during public health emergencies, especially for pandemic influenza. They also are available on a routine basis to assist our industry and federal partners in developing and manufacturing chemical, biological, radiological or nuclear (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. Each CIADM has completed or is nearing completion of facilities and is focusing on establishing influenza capacity and refining core services to provide cGMP manufacturing capacity and capability including but not limited to cell culture and protein purification for vaccines and potential therapeutic production.

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 that the seed strains have a high-production yield and developing alternative, novel assays for the potency and sterility of vaccines. Since 2012, use of synthetic biology and novel reverse genetics has allowed influenza candidate vaccine seed strains — including H7N9 seeds — to be available in less than 10 days, compared to weeks using classical methods. 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 working 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 that 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 that served 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 H1N1 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. This resulted 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 six months of pandemic declaration.

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 during 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. These medications have unique benefits, 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 during an influenza 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 for administration to critically-ill persons under FDA Emergency Use Authorization.

Simpler point-of-care diagnostics In June of 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. The Simplexa test was the first of its kind. It is a rapid multiplexed test, faster than other diagnostic products that required complex and time-consuming sample preparation. Today, both the Cepheid and Roche tests are also CLIA-waived, along with others in the development pipeline. BARDA continues to fund projects supporting new technologies, including antiviral drug resistance tests, that can improve the capability to recognize and more effectively treat influenza infections early, prevent influenza-associated hospitalizations, and reduce antibiotic use for respiratory illness. BARDA is investing in development of Point of Need (PON) influenza diagnostics that are more sensitive and specific than current influenza tests and that will also inform pandemic response. BARDA is also improving the ease of use of next generation sequencing systems for use in subtyping influenza samples to aid in identification of novel influenza strain emergence. The goal is to drive home use diagnostics to empower patients and prevent transmission of disease.

Enhancing global pandemic preparedness: The health security of the United States is intimately linked to the health security of the global community. Diseases do not respect national borders, making global pandemic preparedness fundamental in protecting the health and wellbeing of the U.S. population. Led by ASPR and the HHS Office of Global Affairs (OGA), HHS international pandemic influenza policies and programs focus on strengthening preparedness and response for diseases with pandemic potential that can affect the US. To support these activities, 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, emerging infectious diseases of pandemic potential and other biological threats that can spread to our borders. 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). 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.

The concrete accomplishments from the HHS/OS International Pandemic Influenza funds have substantially contributed to USG global health diplomacy in countries that are a priority for U.S. foreign policy goals. Accomplishments include, but are not limited to:

- New procedures for WHO to recommend and facilitate emergency use authorization of medical countermeasures donated by developed countries or provided by manufacturers during public health emergencies in countries around the world to save lives and/or slow disease spread globally;
- 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;
- Documentation of progress being made in more than 50 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; preparedness in these countries will lessen the need for US support during emergencies, thus making sure assets are available to protect the US population;
- Leadership of the logistical implementation of the U.S. donation of H1N1 pandemic influenza vaccine to WHO, the response to the MERS-CoV, Ebola, and H7N9 Flash Appeal for support to WHO, in collaboration with partners in HHS, vaccine manufacturers, international transport companies, the U.S. Department of State, and the U.S. Agency for International Development (USAID); and
- Development of new frameworks for sharing of non-influenza biospecimens to accelerate development of diagnostics and medical countermeasures. Through this process, the US was rapidly able to obtain samples from foreign countries to expedite the development of Zika and H7N9 diagnostics and vaccine.

- Strengthened infrastructure 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, making other countries less dependent on US vaccine donations;
    - 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 Manufacturers Network, HHS/WHO Workshops and trainings, and facilitating support for IHR core capacity development; and
    - Establishing and updating national pandemic influenza plans in Africa and other vulnerable regions to support the prioritization of influenza at the national level.

- 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.
  - Leading policy coordination for key international treaties, agreements, and arrangements including implementation of the World Health Organization Pandemic Influenza Preparedness Framework (PIP-FW) and the Nagoya Protocol; and
  - The development of model tools and documents (e.g., model material transfer agreement, model benefit sharing agreements, model legislation) that could be used by Member States during public health emergencies.

Funding History

Fiscal Year	*Amount*
FY2014[1]	$114,606,000
FY 2015	$71,915,000
FY 2016 Final	$72,000,000
FY 2017 Annualized CR	$71,863,000
FY 2018 President's Budget	$206,863,000

[1] Pandemic influenza medical countermeasure activities in FY 2014 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).

Budget Request

The FY 2018 Request for pandemic influenza activities is $206,863,000, which is +$135,000,000 above the FY 2017 Annualized Continuing Resolution. This budget increase reflects the exhaustion of supplemental influenza balances that have sustained the BARDA influenza program over the last decade. Funds are needed to sustain critical domestic influenza vaccine manufacturing facility infrastructure, ensure pandemic influenza vaccines and therapeutics can be produced when needed, and maintain overall domestic pandemic readiness. The Request includes $7 million in annual funding for international policy and diplomacy programs and $199.86 million for pandemic influenza medical countermeasure programs. The medical countermeasures budget will support activities to maintain the significant pandemic preparedness and response capabilities that have been developed over the last decade to meet requirements, while also supporting technologies to improve, and ultimately transform, our approach to pandemic readiness and response. Of the $199.86 million for medical countermeasures, $24.94 million is annual funding and $174.92 million is no-year funding to pay sustainment costs and continue the advanced research and development of improved vaccines, immunotherapeutics, and rapid diagnostics. The Request includes $108.8 million to support domestic egg and cell-based pandemic vaccine manufacturing capacity needed for pandemic response, and $30 million for advanced development of therapeutics, including monoclonal antibodies and immune modulators for the severely ill. The request also includes $19 million required to maintain and monitor pre-pandemic influenza vaccine and adjuvant stockpiles. These stockpiles protect against influenza viruses with pandemic potential and also support clinical studies to optimize the utility of these vaccines. With the ultimate goal of in-home diagnostics, BARDA requests $5.94 million to

advance two candidates towards point of need potential. Finally, BARDA requests $36.12 million to support the advanced development of vaccine candidates and platform technologies that are expected to lead to rapid and effective pandemic influenza vaccines, with potential to protect against all influenza strains.

Annual Funding Requests for FY 2018 ($31,939,000):

Vaccine Stockpiling ($19,000,000): BARDA requests $19 million to support maintenance, development, and testing of the national pre-pandemic influenza vaccine stockpile. This funding will sustain our significant pre-pandemic influenza vaccine stockpile investment by monitoring current stockpiles of bulk adjuvant and vaccine antigens (essential vaccine components) to ensure coverage of influenza viruses with pandemic potential. BARDA will continue ongoing acquisitions for the maintenance and replenishment of vaccines and adjuvants to achieve pandemic preparedness goals. BARDA will support clinical studies to test safety, immunogenicity, tolerability, and/or efficacy of stockpiled vaccines.

***Office of Policy and Planning International Influenza Activities ($3,000,000*)**: To protect the health security of the United States from global threats, ASPR will continue to lead HHS's implementation of the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza with Canada and Mexico and the cross-border health security actions 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 coordinate HHS-wide response to public health and medical emergencies with a domestic-international interface, and b) 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, addressing legal, regulatory, and logistical barriers to deploying and receiving biospecimens, medical personnel and medical countermeasures. 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 (IHR), including collaborations with domestic and international partners to support the development and strengthening of IHR core capacities, including evaluation of those capacities through the IHR Joint External Evaluation.

Diagnostics and Respiratory Protection Device Advanced Development ($5,944,000): Funding would be utilized for investment in two diagnostic programs for the advanced development of rapid and specific diagnostic platforms for use in near-patient and point-of-need settings, such as physician's offices and pharmacies, with the goal of moving toward fast, real-time notification of infection at the point of need in-home.

OGA International Influenza Activities ($4,001,000): $4,001,000 is requested in Pandemic Influenza 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.

OGA provides strategic international health coordination and policy coherence for the Department and within the US Government interagency process. OGA synthesizes, integrates, and translates policy, science, and diplomacy issues and challenges into priorities and actionable steps by HHS, and for the many global partners with whom we work. On behalf of the Secretary, OGA manages key relationships with almost 200 Ministries of Health across the globe, and with key multilateral and international institutions involved in global health security (e.g. World Health Organization (WHO), the Association of Southeast Asian Nations, Organization of Islamic Cooperation, etc.) and with numerous foreign governments (including through partnerships in the G7 and G20), particularly developing countries. To that end, OGA is the critical interface among international influenza science/programs, foreign policy, diplomacy and security. A key objective for OGA is to enhance U.S. diplomatic and political efforts to increase effectiveness and efficiency of our international pandemic preparedness activities in the development of new global partnerships to bolster global health security efforts. Having this structure in place is a pre-requisite for coordinating internationally for a pandemic or public health emergency of international concern. This is based on our experience and lessons learned during H5N1 outbreaks, the 2009 H1N1 pandemic, and the recent H7N9 outbreaks.

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 (2005) 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 2018 ($174,924,000):

***Facilities and Infrastructure Readiness ($108,800,000)*:** Funds will sustain domestic influenza egg and cell-based vaccine manufacturing infrastructure necessary to maintain our baseline capability to meet our pandemic vaccine production requirements. Funding is requested for the following purposes: 1) sustain domestic manufacturing and fill-finish capacity for cell based vaccines, including production of pre-pandemic vaccine and adjuvant, at the Holly Springs, NC facility; and 2) renew the dynamic egg-supply contract that ensures adequate supply for the Sanofi Pasteur Swiftwater manufacturing facility. A year round, secure supply of eggs addresses what would otherwise be a critical vulnerability in our ability to quickly manufacture pandemic vaccine. This effort has allowed BARDA to reach to previous targeted goals of 500 million (FY2016) and 575 million bulk antigen vaccine doses (FY2017) and will allow BARDA to reach the targeted goal of 600 million bulk antigen vaccine doses (FY2018) as noted in the performance metric 2.4.15a.

Universal Influenza Vaccine Advanced Development ($36,124,000): Funds will support the strategic transition of vaccine candidates in early development from NIAID and industry partners to BARDA for advanced development with potentially more effectiveness and characteristics of reactive universal influenza vaccines that provide broad spectrum protection. Additionally, funds will support the mission to continue advanced development work for at least one platform technology to rapidly produce a vaccine candidate that may afford faster and more effective protection against a diverse group of influenza virus strains. This endeavor could provide transformative momentum to our pandemic preparedness and response posture.

Advanced Development of Influenza Therapeutics ($30,000,000): Effective treatments for those who are severely ill with influenza are a critical component of pandemic preparedness and response, with significant benefit for use in annual influenza epidemics. Despite this persistent need, there are no approved influenza antiviral drugs indicated for use in severely ill and hospitalized patients in the US. In FY 2015, BARDA expanded its strategy to develop therapies for use in this patient population. In particular, monoclonal antibodies have emerged as a new class of therapeutics for influenza with novel mechanisms of action compared to the current approved antivirals. These monoclonal antibodies are broadly neutralizing across all influenza A viruses and inhibit viral replication by binding to highly-conserved regions of the virus. 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 drugs, such as oseltamivir (Tamiflu®). 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. Currently, BARDA supports one novel influenza immunotherapeutic. Together with the planned addition of at least one more immunotherapeutic candidate in FY 2017, this program should ultimately yield the approval of at least one monoclonal antibody immunotherapeutic candidate for the treatment of critically-ill influenza patients in hospital settings. BARDA will utilize Other Transactional Agreement (OTA) awards to advance product development of therapeutics.

ASPR Pandemic Influenza: Outputs and Outcomes Table

Measure	Year and Most Recent Result Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 Target +/-FY 2017 Target
2.4.15a Assure that domestic pandemic influenza vaccine manufacturing surge capacity produces desired number of vaccine doses within six months of influenza pandemic declaration (Intermediate Outcome)	FY 2016: 500.0 million doses Target: 500.0 million doses (Baseline)	575.0 million doses	600.0 million doses	+25 million doses

OGA Pandemic Influenza: Grants and Program Data Chart

Grants

Grants (whole dollars)	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Number of Awards	1	1	1
Average Award	$1,519,514	$2,000,000	$2,000,000
Range of Awards	$1,519,514	$2,000,000	$2,000,000

Program Data Chart

Activity	FY 2016 Final	FY 2017 Annualized CR	FY 2018 President's Budget
Contracts	$292,139	$376,000	$376,000
Grants/Cooperative Agreements	$1,519,514	$2,000,000	$2,000,000
Inter-Agency Agreements (IAAs)	$182,000	$293,000	$277,000
Operating Costs	$1,697,971	$1,332,000	$1,348,000
Total	**$3,691,624**	**$4,001,000**	**$4,001,000**

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Millions)

Public Health and Social Services Emergency Fund	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Personnel compensation:			
Full-time permanent (11.1)	95.865	100.587	4.722
Other than full-time permanent (11.3)	-	-	-
Other personnel compensation (11.5)	0.050	0.056	0.006
Military personnel (11.7)	6.618	6.948	0.329
Special personnel services payments (11.8)	-	-	-
Subtotal, Personnel Compensation	**102.534**	**107.591**	5.057
Civilian benefits (12.1)	36.797	38.634	1.836
Military benefits (12.2)	2.757	2.894	0.137
Benefits to former personnel (13.0)	-	-	-
Subtotal, Pay Costs	**142.088**	**149.119**	**7.031**
Travel and transportation of persons (21.0)	6.354	6.652	0.298
Transportation of things (22.0)	0.501	0.526	0.025
Rental payments to GSA (23.1)	18.860	19.844	0.984
Communication, utilities, and misc. charges (23.3)	1.269	1.326	0.058
Printing and reproduction (24.0)	0.102	0.107	0.005
Other Contractual Services:			
Advisory and assistance services (25.1)	468.589	515.083	46.494
Other services (25.2)	30.270	31.833	1.563
Purchase of goods and services from government accounts (25.3)	108.831	114.214	5.383
Operation and maintenance of facilities (25.4)	3.965	4.172	0.207
Research and Development Contracts (25.5)	396.861	470.795	73.934
Medical care (25.6)	-	-	-
Operation and maintenance of equipment (25.7)	45.002	68.448	23.446
Subsistence and support of persons (25.8)	0.542	0.569	0.027
Subtotal, Other Contractual Services	**1,054.060**	**1,205.113**	**151.054**
Supplies and materials (26.0)	1.621	1.703	0.082
Equipment (31.0)	0.517	0.553	0.036
Land and Structures (32.0)	0.017	0.018	0.001
Investments and Loans (33.0)	-	-	-
Grants, subsidies, and contributions (41.0)	304.656	277.656	(27.000)
Interest and dividends (43.0)	-	-	-
Refunds (44.0)	-	-	-
Subtotal, Non-Pay Costs	**1,387.956**	**1,513.497**	**125.541**
Total, Budget Authority by Object Class	**1,530.044**	**1,662.616**	**132.572**

SALARIES AND EXPENSES

(Dollars in Millions)

Public Health and Social Services Emergency Fund	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 +/- FY 2017
Personnel compensation:			
Full-time permanent (11.1)	95.865	104.679	8.814
Other than full-time permanent (11.3)	-	-	-
Other personnel compensation (11.5)	0.050	0.056	0.006
Military personnel (11.7)	6.618	6.947	0.329
Special personnel services payments (11.8)	-	-	-
Subtotal personnel compensation	**102.533**	**111.682**	**9.149**
Civilian benefits (12.1)	36.797	38.634	1.836
Military benefits (12.2)	2.757	2.894	0.137
Benefits to former personnel (13.0)	-	-	-
Total Pay Costs	**39.554**	**41.528**	**1.973**
Travel and transportation of persons (21.0)	6.354	6.652	0.298
Transportation of things (22.0)	0.501	0.526	0.025
Rental payments to GSA (23.1)	18.860	19.844	0.984
Rental payments to Others (23.2)	-	-	-
Communication, utilities, and misc. charges (23.3)	1.269	1.324	0.056
Printing and reproduction (24.0)	0.102	0.107	0.005
Other Contractual Services:			
Advisory and assistance services (25.1)	468.589	515.083	46.494
Other services (25.2)	30.270	31.823	1.552
Purchase of goods and services from government accounts (25.3)	108.831	114.243	5.412
Operation and maintenance of facilities (25.4)	3.965	4.162	0.197
Research and Development Contracts (25.5)	396.573	466.703	70.130
Medical care (25.6)	-	-	-
Operation and maintenance of equipment (25.7)	45.002	68.447	23.446
Subsistence and support of persons (25.8)	0.542	0.569	0.027
Subtotal Other Contractual Services	**1,053.772**	**1,201.030**	**147.258**
Supplies and materials (26.0)	1.909	1.696	(0.213)
Equipment (31.0)	0.517	0.553	0.036
Land and Structures (32.0)	0.017	0.018	0.001
Grants, subsidies, and contributions (41.0)	304.656	277.656	(27.000)
Total Non-Pay Costs	**307.099**	**279.923**	**(27.176)**
Total Salary and Expense	**1,530.044**	**1,662.616**	**132.572**
Direct FTE	750	780	30

DETAIL OF FULL TIME EQUIVALENTS (FTE)

	2016 Actual Civilian	2016 Actual Military	2016 Actual Total	2017 Est. Civilian	2017 Est. Military	2017 Est. Total	2018 Est. Civilian	2018 Est. Military	2018 Est. Total
ASPR									
Direct:	540	72	612	540	72	612	540	72	612
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	**540**	**72**	**612**	**540**	**72**	**612**	**540**	**72**	**612**
Cyber Security									
Direct:	82	--	82	93	--	93	123	--	123
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	**82**	**--**	**82**	**93**	**--**	**93**	**123**	**--**	**123**
Office of Security and Strategic Information									
Direct:	33	2	35	38	2	40	38	2	40
Reimbursable:	--	--	--	--	--	--	--	--	--
Total:	**33**	**2**	**35**	**38**	**2**	**40**	**38**	**2**	**40**
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**
PHSSEF FTE Total	**659**	**75**	**734**	**675**	**75**	**750**	**705**	**75**	**780**

DETAIL OF POSITIONS

Public Health and Social Services Emergency Fund	2016 Actual	2017 Annualized CR	2018 President's Budget
Executive level I	10	10	10
Executive level II.....	3	3	3
Executive level III	0	0	0
Executive level IV.....	1	1	1
Executive level V.....	0	0	0
Total - Exec. Level Salaries	**14**	**14**	**14**
ES-6.....	106,797	109,467	109,467
ES-5.....	171,618	173,352	176,732
ES-4.....			
ES-3.....			
ES-2.....			
ES-1.....			
Total - ES Salary	**278,415**	**282,819**	**286,199**
GS-15.....	141	140	140
GS-14.....	157	155	173
GS-13.....	92	101	106
GS-12.....	79	81	86
GS-11.....	90	92	91
GS-10.....	3	3	3
GS-9.....	34	34	37
GS-8.....	1	1	1
GS-7.....	61	61	61
GS-6.....	0	0	0
GS-5.....	0	0	0
GS-4.....	0	0	0
GS-3.....	0	0	0
GS-2.....	0	0	0
GS-1.....	0	0	0
Total - GS Salary	**658**	**668**	**698**
Average ES level	ES-3	ES-3	ES-3
Average ES salary.....	106,797	134,290	135,297
Average GS grade.....	13	13	13
Average GS salary.....	103,255	107,827	114,367
Average Special Pay categories	92,121	92,121	92,121

SIGNIFICANT ITEMS FOR INCLUSION IN THE FY 2018 CONGRESSIONAL JUSTIFICATION

SIGNIFICANT ITEM

The Committee commends BARDA for supporting advanced development efforts of industry to develop vaccines, diagnostics, drugs, and therapeutics to minimize the serious threats of infectious disease and urges BARDA to continue to invest in the development of countermeasures for infectious diseases through the CARB initiative and the Emerging Infectious Disease program. (S. Report 114-274)

RESPONSE

Through its Antibacterial Program, BARDA has partnered with nine drug companies to establish a diverse portfolio of twelve antibacterial drugs with the potential to address both 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 limited antibiotics in the US Strategic National Stockpile. The first BARDA-supported antibiotic is projected to be FDA approved in 2017; and we anticipate additional approvals in 2018. BARDA has also leveraged a procurement tool known as Other Transaction Authority (OTA) provided under the Pandemic and All-Hazards Preparedness Act (PAHPA) to enter into public-private partnerships. BARDA has created unique business arrangements with four large pharmaceutical companies that are each pursuing a portfolio-based approach for the research and development of new antibacterial products. These partnerships have in turn sparked broader industry interest in developing new antibiotics to treat antibiotic resistant infections.

In addressing Emerging Infectious Diseases, currently BARDA supports the manufacturing of three Ebola therapeutics candidates in addition to ZMapp, which was used to treat patients in West Africa. BARDA continues to support the late stage development of these candidates toward consideration for FDA approval. Further, BARDA is supporting the clinical use of ZMapp in West Africa and US sites under FDA approved protocols to prepare for potential future outbreaks. BARDA is projecting acquisition of at least one monovalent vaccine and two therapeutic candidates for Ebola-Zaire under Project BioShield in FY 2017. It is the intent that several of the vaccine platforms developed with BARDA funding during the 2014 Ebola outbreak will be leveraged to support the development of vaccines for Ebola-Sudan and Marburg viruses.

BARDA has responded to Zika virus outbreaks in the Western hemisphere with a portfolio approach, including vaccines, diagnostics and protecting the blood supply through testing and pathogen reduction technologies. BARDA is supporting the development of four vaccine candidates using multiple different vaccine platforms to increase the probability of success in quickly making available a safe and effective vaccine. In 2016, BARDA rapidly responded to the need for Zika diagnostic development by acquiring convalescent serum from people exposed to the Zika virus and made this serum available for diagnostic developers to use in test development and validation. BARDA also provided funding and technical support to four companies to develop antibody detection tests, and two companies to develop tests to screen the blood supply. BARDA's Diagnostics and Medical Devices Division is exploring options to build capabilities for specimen acquisition, test development and manufacturing that can be utilized for more rapid response to emerging diseases.

As a supporting advanced development core service, BARDA established the Non-Clinical Studies Network, a network of 23 laboratories that provide necessary and timely animal studies that includes studies for Ebola vaccines and therapeutics, Zika vaccines, and monoclonal antibody therapeutics for various targets. These organizations have performed over 55 studies in support of BARDA product development, obtaining safety and efficacy data necessary to support the development of clinical studies or product approval . In FY 2017, the Non-Clinical Studies Network will focus on development of viral hemorrhagic fever models to support vaccine development for Ebola-Zaire, Ebola-Sudan and Marburg viruses.

SIGNIFICANT ITEM

The Committee is aware of BARDA's investigation into blood platelet-derived medical countermeasures as a hemostatic agent, and urges BARDA to expand its research to address the opportunities that cell stabilization of blood platelet provides, including radiation exposure remediation, acute burn healing, drug delivery, hemorrhagic fevers, and diagnostic imaging. (S. Report 114-274)

RESPONSE

The Radiological and Nuclear Threats program focuses on developing solutions for all aspects and injuries that may result from a radiological or nuclear event. Under this program, BARDA supports the development of multiple blood products to include a lyophilized platelet derived hemostatic product, spray-dried plasma and pathogen reduction technology for Red Blood Cells and Platelets. BARDA supports the development of Thrombosomes®, a lyophilized human platelet-derived hemostatic agent manufactured by Cellphire. Due to stabilization of the platelets, it is anticipated Thrombosomes® will have a shelf life of 36 months compared to 5 days for platelets. Under the BARDA contract, Cellphire is pursuing indications for mitigation of excessive bleeding and injury from acute radiation syndrome. Cellphire has successfully completed an exploratory investigational new drug clinical study and is currently in discussion with the FDA to initiate a clinical trial in bleeding patients. In non-clinical models, Cellphire demonstrated safety in a deep vein thrombosis model and improved hemorrhage scores in an acute radiation model and coronary artery bypass model. Although the current BARDA program does not address application to thermal burns or hemorrhagic fever, the company is investigating these indications.

In developing medical countermeasures (MCMs) to mitigate burn injuries, BARDA has developed extensive knowledge in working with burn care specialists. A product under clinical investigation supported by BARDA under the Burn program includes application of patient's own (autologous) platelet-rich plasma (PRP) to treat burn wounds. The study will investigate if PRP application prevented or slowed the conversion of indeterminate (partial thickness) burns to full-thickness then requiring surgical intervention. This clinical study has completed recruitment and BARDA anticipates a discussion with the FDA to confirm a regulatory path in 2017.

SIGNIFICANT ITEM

The Committee directs ASPR to provide a report in the fiscal year 2018 budget request on the current and on-going efforts to improve the logistics of burn patient triage and transfer in the event of a mass casualty event**.** The Committee understands the ability to maximize efficiency and effectiveness of triage and that subsequent care would be critical to the management of an overwhelming surge in burn patient volume and intensity. Specifically, the report should note the on-going and planned research from across HHS related to treatment and systems capability like the development of a network platform for reporting immediate and surge burn bed availability to match patient acuity or critical providers into the network. (H. Report 144-699)

RESPONSE

Any large burn event, such as a large structure fire, chemical accident, or nuclear detonation, may result in hundreds or thousands of burn patients. During such events, the delivery of optimal burn care to affected patients requires specialized equipment and experienced personnel. In 2008, of the roughly 5,000 U.S. emergency departments (ED), 128 were dedicated burn centers with the resources and expertise needed to treat burn patients.[27] Each year, burn injuries lead to over 500,000 ED visits and about 50,000 hospital admissions.[28] About half of admissions for burn injuries are to the 128 burn centers,[29] but almost a quarter of patients who would benefit from burn care are admitted to hospitals without the resources and expertise needed to provide optimum care.[30] These burn-related injuries result in approximately 4,000 deaths annually.[31]

Within an hour, a quarter of Americans have access to burn centers by ground ambulance, and 54 percent have access by air ambulance. Within two hours, these figures rise to 46.3% and 79.0% by ground or air ambulance, respectively. Burn centers are highly concentrated within the northeast U.S.; the lowest proportion of the population has ready access in the southern U.S. [32] Although best practices for triage or transfer to burn centers exists,[33] many patients are treated outside of the burn system because of limited access to burn care. As in trauma, systems of care can be constructed so burn centers and non-burn center hospitals coordinate care to ensure patients who are severely burned are treated in the appropriate setting.[34]

ASPR, through the Technical Resources, Assistance Center, and Information Exchange (TRACIE) partnered with the American Burn Association to conduct national drills focused on assessing hospital burn bed capacity. ASPR has a current contract in place to develop an inventory of the emergency care

[27] Burn care facilities: United States. American Burn Association Web site. http://www.ameriburn.org. Access verified April 11 2017.

[28] American College of Surgeons, Committee on Trauma, American Burn Association. Chapter 14: Guidelines for the Operation of Burn Centers. Resources for Optimal Care of the Injured Patient. Chicago, IL: American College of Surgeons; 2006.

[29] American Burn Association. Burn Incidence and Treatment in the United States: 2015. 2015; http://www.ameriburn.org/resources_factsheet.php. Accessed December 9, 2015.

[30] Zonies D, Mack C, Kramer B, Rivara F, Klein M. Verified centers, nonverified centers, or other facilities: a national analysis of burn patient treatment location. *Journal of the American College of Surgeons.* 2010;210(3):299-305.

[31] American Burn Association. Burn Incidence and Treatment in the United States: 2015. 2015; http://www.ameriburn.org/resources_factsheet.php. Accessed December 9, 2015.

[32] Klein MB, Kramer CB, Nelson J, Rivara FP, Gibran NS, Concannon T. Geographic access to burn center hospitals. *JAMA.* 2009;302(16):1774-1781.

[33] http://www.ameriburn.org/BurnCenterReferralCriteria.pdf

[34] ACS-COT. *Resources for Optimal Care of the Injured Patient: 2006* Chicago, IL: American College of Surgeons; 2006.

capabilities of the health care system. During the first year of this award, the contractor will conduct stakeholder sessions to determine the minimal set of data elements to include in the national inventory of EDs, trauma centers, and burn centers (including pediatrics) and then develop an easily interpretable interface that is appropriate for patients, EMS, and others to determine their capabilities.

SIGNIFICANT ITEM

BARDA is directed to work closely with CDC and NIAID on the government-wide antibiotic resistance activity. The Committee requests an update in the fiscal year 2018 budget request on the joint BARDA, NIAID, and CDC goals and measurable objectives to ensure the best leveraging of the funds provided to CDC and NIAID for this effort. (H. Report 122-699)

RESPONSE

BARDA has worked closely with NIAID and CDC to ensure that antibacterial research and development activities and funding actions are coordinated among all agencies. Representatives from BARDA, CDC and NIAID participate as voting members of the interagency Antimicrobial Resistance Integrated Program Team that supports and coordinates United States Government (USG) efforts on antibiotic resistance. Members from CDC and NIAID also participate in all BARDA program reviews to evaluation progress on BARDA's antibacterial development projects prior to approval.

In July of 2016, BARDA and NIAID established the Combatting Antibiotic Resistant Bacteria Accelerator (CARB-X), a novel public private partnership aimed at promoting pre-clinical innovation in antibacterial drug, vaccine, devices and diagnostic development to enhance national security. CARB-X is a collaboration among Boston University, BARDA, NIAID, and the Wellcome Trust and brings together three life science accelerators (AMR Center, California Life Science Institute, and MassBio) with the aim to identify, build, and manage a portfolio of innovative antibacterial medical countermeasures. CARB-X held the *Powered by CARB-X* Launch Event in March 2017 to announce the first set of companies to receive CARB-X support which also included an announcement by Wellcome Trust that the charitable organization would contribute $155 million over five years to the partnership. The initial portfolio includes 11 new products, three of which are entirely new classes of antibiotics and four companies are pursuing alternatives, non-antibiotic based technologies to treat drug resistant bacterial infections. In 2017/2018, CARB-X will add additional candidates to the portfolio.

BARDA and NIAID collaborated in FY 2016 to establish the Antimicrobial Resistance Diagnostic Challenge, a federal prize competition that will award up to a total of $20 million in prizes for innovative rapid, point-of-need diagnostic tests to combat the emergence and spread of drug resistant bacteria. In March 2017, ten semifinalists were selected from among 74 submissions for their concepts for a diagnostic based on a technical and programmatic evaluation and will each receive $50,000 to develop their concepts into prototypes.

SIGNIFICANT ITEM

The Committee requests a detailed summary from ASPR in its fiscal year 2018 CJ about the level of unspent pandemic influenza supplemental balances. The summary should include an analysis of how funds have been spent over the previous 3 fiscal years and how any remaining funds will be allocated. (S. Report 114-274)

RESPONSE

BARDA Pandemic Influenza 4-Year Obligation Record from No-year Supplemental Balances					
(Dollars in millions)					
	FY 2014	**FY 2015**	**FY 2016**	**FY 2017**	
	Obligations	**Obligations**	**Obligations**	**Obligations**	
ASPR Activities:	**Supp Balances (X-Year)**	**Supp Balances (X-Year)**	**Supp Balances (X-Year)**	**Supp Balances (X-Year)**	**Total**
Therapeutic Advanced Development	32.643	132.861	7.679	20.000	193.183
Vaccine Stockpiling, Storage, and Stability Testing	14.775	38.548	8.244	82.000	143.567
Respirators and Ventilators	13.820	0.350	0.000	0.175	14.345
Universal Influenza plus Cell- and Recombinant-based Vaccine Advanced Development	190.575	113.265	3.320	35.211	342.371
Diagnostics Advanced Development	13.169	0.000	0.000	0.000	13.169
Facilities and Infrastructure	42.372	0.000	0.000	60.100	102.472
Total	**307.354**	**285.024**	**19.243**	**197.486**	**809.107**

Over the period between FY 2014 – FY 2017, ASPR has obligated a total of $809.107 million from no-year pandemic influenza (PI) supplemental balances. Due to obligations in FY 2017 to support the stockpiling of new H7N9 vaccines, the Department currently has approximately $4 million in remaining no-year pandemic influenza supplemental balances. These remaining balances are expected to be obligated in FY 2017 to support ongoing pandemic preparedness activities across the Department. Thus, all projected FY 2018 pandemic influenza funding needs will require newly appropriated funds.

Therapeutic Advanced Development ($193.183 million FY 2014-FY 2017)– As part of its mission, BARDA is charged with developing and making available new influenza antiviral drugs to treat critically ill populations during severe influenza pandemics. In these instances, hundreds of thousands of people are estimated to become severely ill and hospitalized with influenza. To improve preparedness, protect health, and potentially save lives during a pandemic, BARDA supports the advanced development of antiviral drugs for those who are severely ill, a critical unmet medical need.

Candidate/Status	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Therapeutic/Drug	2 New Contracts	2 New Contracts	1 modification	1 New Contract/2 New OTA portfolio	3 Existing Products Advancing to Clinical Trials
Advanced R&D	1 IAA	1 IAA		1 IAA	

Vaccine Stockpiling, Storage, and Stability Testing ($143.567 million FY 2014-FY 2017)– In fulfillment of requirements set forth in the *National Strategy for Pandemic Influenza (2005)*[35], BARDA develops and maintains the National Pre-Pandemic Influenza Vaccine Stockpile (NPVS). This effort has improved sustainment goals by ongoing monitoring of current stockpile vaccine antigens and adjuvant material to ensure coverage of currently circulating H5N1 and H7N9 influenza viruses with pandemic potential. BARDA has developed a nimble and responsive stockpile program and has developed a robust testing program to monitor the potency, safety, and efficacy of vaccine in the pre-pandemic stockpile.

Target Achievement	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Stockpile Contract	Maintenance of ongoing stockpile contracts	Maintenance of ongoing stockpile contracts	Maintenance of ongoing stockpile contracts	Maintenance of ongoing stockpile contracts/procurement of H7N9 vaccine	Maintenance of ongoing stockpile contracts
Clinical Study	1 New clinical study	Ongoing clinical studies	Completion of clinical study	2 New clinical studies	Ongoing clinical studies

Respirators and Ventilators ($14.345 million FY 2014-FY 2017) – During influenza pandemics, supplies of respirators to protect the wearers from inhaling influenza viruses are likely to be highly constrained. BARDA seeks to develop reusable, easy-to-fit, and cost-effective respirators that would be critical to protect frontline healthcare workers in an influenza pandemic. Ventilators are important life saving devices for those who are unable to breathe on their own. BARDA supports the development of ventilators that are easy-to-use in all age groups (including neonates), mobile and readily accessible in point of care and hospitals.

Candidate/Status	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Respirators	N/A	N/A	N/A	1 potential new respirator	Ongoing development
Ventilators	1 New ventilator	Ongoing development	Ongoing development	Ongoing development	N/A

[35] https://www.medicalcountermeasures.gov/BARDA/documents/pandemic-influenza.pdf

Universal Influenza plus Cell- and Recombinant-based Vaccine Advanced Development ($342.371 million FY 2014-FY 2017)– These funds support the strategic transition of vaccine candidates in early development from NIAID and industry partners to BARDA for advanced development with potentially more effectiveness and attributes of universal influenza vaccines that provide broad spectrum protection. In FY 2014, new support began for advanced development of a fourth pandemic influenza vaccine candidate using an oil-in-water emulsion adjuvant. For recombinant vaccines, FluBlok® subsequently received an additional approval for a recombinant Quadrivalent Influenza Virus Vaccine in the winter of 2016. In November 2015, FDA approved Fluad®, the first seasonal influenza vaccine containing an adjuvant. Fluad® is a trivalent vaccine for the prevention of seasonal influenza in people 65 years of age and older. Ongoing clinical studies will further delineate the clinical benefits in this population. In addition, BARDA is extending the shelf-life of stockpiled adjuvants by conducting analytical and clinical testing in collaboration with FDA. Thus far, results are quite encouraging.

Candidate/Status	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Universal Influenza Vaccine Candidates (incremental amounts)	6 Awards made for influenza vaccine	6 Awards made for influenza vaccine	Ongoing development	1 potential new technology platform	1 potential new Universal vaccine program
Advanced R&D / Vaccine Capacity Building & Availability	4 Advanced R&D/Vaccine capacity building	4 Advanced R&D/Vaccine capacity building	Ongoing development	Ongoing development	Ongoing development and capacity building

Diagnostics Advanced Development ($13.169 million FY 2014-FY 2017)– Prompt and accurate detection of influenza is critical in providing the most effective care to patients, including use of antiviral drugs, and in enabling social distancing (e.g., staying home from school or work) by those who are sick to limit further transmission of influenza to others. The goal of the diagnostics advanced development program has been to create and advance rapid and specific diagnostic platforms for use in near-patient and point-of- care settings, such as physician's offices and pharmacies, with the goal of moving toward fast, real-time notification of infection at home.

Candidate/Status	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Diagnostics POC Platform	1 Award made	Ongoing development	Ongoing development	Ongoing development	Ongoing development

Facilities and Infrastructure ($102.472 million FY 2014-FY 2017) – BARDA has made substantial investments in developing domestic influenza vaccine manufacturing capacity toward the goal of 600 million bulk antigen doses available six months from the declaration of pandemic. BARDA accomplished the previously set goal of 500 million doses in FY2016 and will accomplish the goal of 575 million vaccine doses in FY2017. The goals outlined above were accomplished in 2015 with contributions from prior year investments in both egg, recombinant, and cell based influenza vaccine capacity. With the advent of antigen sparing programs and greater availability of adjuvanted vaccine, additional capacity can be made available for the entire United States population. BARDA's ongoing relationships with influenza vaccine manufacturers have been critical for pandemic preparedness and are one of the focal points of

BARDA's mission. Investments continue to be made on an annual basis either through supplemental influenza balances or appropriated pandemic influenza funding. On average, $100 million is required annual going forward to sustain domestic egg-, recombinant and cell-based vaccines capability and capacity.

Candidate/Status	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Cell-based influenza vaccine capacity and capability	1 award made	Ongoing management	Ongoing management	Sustainment costs	Sustainment costs

Text Only Versions of Complex Images

Office of the Assistant Secretary for Preparedness & Response
ASPR ORGANIZATION STRUCTURE

The Office of the Assistant Secretary for Preparedness and Response is managed by George W. Koch PhD, (Acting) Assistant Secretary and by the Principal Deputy Assistant Secretary, Edward J. Gabriel, MPA, EMT-P, CEM CBCP.

ASPR provides support through six program offices and there leadership. They are:

- Sally Phillips, RN, PhD, Director and Deputy Assistant Secretary for Policy, Office of Policy and Planning (OPP)
- Jess Scarbrough, MSS, MBA, DACM, Deputy Assistant Secretary and Director, Office of Acquisitions Management, Contracts, & Grants (AMCG)
- Jay Petillo, MPP Director, Office of Financial Planning & Analysis (OFPA)
- Rick Bright, PhD Deputy Assistant Secretary and Director, Office of Biomedical Advanced Research & Development Authority (BARDA)
- Don R. Boyce, Deputy Assistant Secretary and Director, Office of Emergency Management (OEM)
- Gretchen Michael, JD, COO (Acting), Office of the Chief Operating Officer (COO)

ASSISTANT SECRETARY FOR ADMINISTRATION
Cybersecurity Organization Structure

The following text provides an explanation of the current organizational structure of the Office of the Chief Information Security Office within the Office of the Chief Information Officer at the Department of Health and Human Services.

The Office of the Chief Information Security Officer, which is under the leadership of Chris Wlaschin, directly oversees the following offices and staff personnel: Leo Scanlon, Deputy Chief Information Security Officer/Security Advisor and the OCISO Chief of Staff, currently vacant.

The following offices and staff personnel are overseen by the Deputy Chief Information Security Officer: Chris Bollerer, Cybersecurity Services; Susan Dery, Office of Information Security, Security Services to the Secretary; John Richardson, Office of Information Security Enterprise Security Services, Eddie Blankenship, Business and Program Management; James Antonucci, Security Infrastructure Operations; Matthew Shallbetter, Security Design and Innovation; and Maggie Amato, Healthcare Cybersecurity Communications and Integration Center.

The following offices and staff personnel are overseen by the Office of Information Security Enterprise Security Services: Julia White, Privacy and Data Protection; and Davene Barton, Information Systems Security Officer

The following offices and staff personnel are overseen by Cybersecurity Services; Chris Bollerer (Acting), Cybersecurity Governance; Julie Chua, Cybersecurity Risk Management; and Kathleen Coupe, Cybersecurity Compliance.

OSSI Organizational Structure

HHS Deputy Secretary

- Vacant

Assistant Secretary for Administration

- John Bardis

DAS for Security, Intelligence and Counterintelligence (A)

- Captain Michael Schmoyer, PhD (PHS)

Associate DAS (A)

- Commander Brett Maycock (PHS)

The following FTE's report directly to the DAS and Associate DAS:

Director of Business Operations

- Will Young

Director of Counterintelligence

- Jason Cameron

Director of Personnel Security

- Sonya Sargent-Oliver

Director of Cyber Intelligence

- William Pachucki

Director of Physical Security and Emergency Management

- James Johnson

Director of Intelligence (A)

- Anthony Woodrome

(A) = Acting

Health Care Coalition Network Figure

Circular diagram that provides a high-level view of the health care coalition network. At the center is the Health Care Coalition (HCC). In the next ring are 4 major categories:

- Emergency Medical Services
- Emergency Management Agencies
- Hospitals
- Public Health Departments

On the outer ring are the following additional categories and examples:

- Behavioral and Mental Health Centers and Agencies
- Home Health Agencies
- Health Centers
    - Rural Health Centers
    - Community Health Centers
- Physicians
    - Primary Care
    - Specialists
- Outpatient Facilities
- Long term care
    - Skilled Nursing Facilities
    - Hospice Care
- Community Partners
    - Academic Institutions
    - Non-profits
    - Volunteers
- Local government
    - Elected officials
    - Fire departments
    - Police departments

HCC Membership Diversity and Participation Rates, June 2016 Figure

Bar graph depicting the following statistics for BP1-BP4 HCC Member Participation Rate, the first 4 provider types are called out as “HCC Core members”:

Provider Type	BP1 HCC Members	BP2-BP4 HCC Member Change from BP1	BP4 Non-HCC Members
Hospitals - 86%	4,741	629	894
Local Health Departments - 75%	1,253	954	754
Emergency Management Agencies - 46%	1,473	611	2,441
Emergency Medical Services - 23%	3,375	578	13,366
Psychiatric Residential Treatment Facilities - 31%	60	208	610
Skilled Nursing Facilities - 29%	2,042	2,281	10,337
Federally Qualified Health Centers - 26%	670	752	4,020
End Stage Renal Disease Dialysis Clinics - 16%	354	611	4,909
Community Health Centers - 16%	584	201	4,216
Rural Health Clinics - 14%	432	140	3,562
Hospices - 11%	179	332	4,155
Community Mental Health Centers - 11%	176	206	3,199

Tracie Infographic Figure

ASPR TRACIE Stats:

- 90,000 visitors to website
- 1,400 Training technical assistance requests
- Types of professional requesting TTA:
    - Healthcare Professional
    - Federal, State, Local, Tribal Government
    - Hospital
    - Healthcare coalition
    - Healthcare association
    - Academia
- More than 350 subject matter expert cadre members
- 62 topic collections
    - 43 comprehensively developed
- Most frequently viewed topic collections
    - Long term Care Facilities
    - EOP/EMP
    - Homecare and Hospice
    - Coalition models & functions
    - Continuity of operations
    - Natural Disasters
- More than 2,500 Information exchange members
- 16,500 distribution list members

Federal Disaster Recovery Diagram

Diagram showing a tiered system with the top level being the Federal Disaster Recovery Coordinator. Under that on the same level:

- State
- Health and Social Services RSF HHS-Lead
    - CNCS
    - EPA
    - DHS
    - Ed
    - HUD
    - FEMA
    - DOL
    - Justice
    - Support Orgs

These feed into a text box that reads “Shared Information, Coordinated Activities, Shared Strategy, Execution of Steady-State Programs for Recovery” which then feeds into 4 key activities:

- Information Sharing -Issues/Impact
- Information Sharing -Agency Activities
- Execution of Program Authorities for Recovery
- Establish Common Objectives

This leads to the final text box that reads “Support for Community-Driven Recovery”