DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2019

Public Health and Social Services Emergency Fund

Justification of Estimates for Appropriations Committee

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We are pleased to present the Fiscal Year (FY) 2019 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2019 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 medical and public health threats and includes the FY 2019 budget justification 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's mission at its core is to save lives and protect Americans. On behalf of HHS, ASPR leads the public health and medical response to disasters and public health emergencies, in accordance with the National Response Framework and Emergency Support Function No. 8, public health and medical services. HHS also supports other federal entities who lead Emergency Support Function No. 6 with respect to the human and social services, including recovery. HHS is also the lead coordinating agency with respect to the Health and Social Services Recovery Support Function under the National Disaster Recovery Framework. ASPR coordinates across HHS and the federal interagency, and supports state, local, territorial, and tribal health partners in preparing for, and responding to, emergencies and disasters. ASPR also enhances medical surge capacity by organizing, training, equipping, and deploying federal public health and medical personnel and providing logistical support for federal responses to public health emergencies. At the state and local level, ASPR supports readiness by coordinating federal grants and cooperative agreements and carrying out drills and operational exercises. Through coordinating the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), including the Biomedical Advanced Research and Development Authority (BARDA), ASPR oversees advanced research, development, procurement, and stockpiling of medical countermeasures (e.g. vaccines, medicines, diagnostics, and other necessary medical supplies).

Recently, ASPR responded to three catastrophic hurricanes. Over 4,800 National Disaster Medical System (NDMS), Public Health Service (PHS), Veterans Administration (VA), and ASPR personnel have been deployed to support the public health and medical responses to Hurricanes Harvey, Irma, and Maria. Over all three incidents, ASPR had more than 36,000 patient encounters, and evacuated nearly 800 patients to facilities that could provide adequate care. ASPR's actions saved lives, stabilized the healthcare system, and restored services. Years of investment have yielded this coordinated response; however, more must be done to be able to prepare and respond when disasters strike. To do this, ASPR must support health care coalitions, medical providers, and emergency managers in preparing for incidents that impact medical and public health capabilities. In addition, when an infectious disease outbreak occurs, the public expects immediate access to vaccines, diagnostics, and drugs, as was seen during the 2009 H1N1 pandemic and the 2013 Ebola virus epidemic in Africa. However, having these products readily available requires long-range investment in time and funding for the R&D and procurement of highly 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 momentum to develop new medical countermeasures – vaccines, drugs, diagnostics, and devices – so they are available immediately when needed. Enhanced partnerships with small and large companies, sustained investments made possible under Project BioShield (PBS), and funding provided for Pandemic Influenza preparedness over the last decade have successfully led to new capabilities, including 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 agents, and emerging diseases. The medical countermeasure pipeline holds more promise today than ever to combat long-standing threats and newly emerging ones.

ASPR's advanced research and development program bridges gaps in national preparedness that no other federal agency does: the late stages of development necessary to reach approval, licensure, or clearance of

medical products that prevent, diagnose, or treat illnesses or injuries from chemical, biological, radiological, and nuclear threats, as well as from emerging infectious diseases and the growing public health threat of antimicrobial resistance. All of these threats pose a dire threat to American and global health. BARDA has supported the development of 27 medical countermeasures against Department of Homeland Security (DHS)-identified national security threats through PBS, including products for smallpox, anthrax, botulinum, radiologic/nuclear emergencies, and chemical events. Fourteen of these products have been placed in the Strategic National Stockpile (SNS) and are ready to be used in an emergency. Notably, almost half of these Medical Countermeasures (MCMs) also have a "peacetime" public health use. Since 2012, six of these PBS-supported chemical, biological, radiological, and nuclear (CBRN) MCMs have been licensed by the Food and Drug Administration (FDA), including the first products approved under the Animal Efficacy Rule. ASPR also has supported the development of 23 influenza vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza. To date, ASPR has supported the FDA licensure/approval/clearance of 34 medical countermeasures for pandemic influenza and CBRN threats.

ASPR directed medical countermeasure development in response to recent public health emergencies in the U.S. and globally. 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 Centers for Disease Control (CDC) in Sierra Leone. In 2016, ASPR worked with partners to develop and evaluate MERS-CoV therapeutic candidates in Saudi Arabia. In 2017, ASPR supported six Zika diagnostics, two blood screening tests, and four vaccine candidates with industry partners. These and other achievements demonstrate how far America has come in MCM preparedness and response capabilities during the last decade.

To improve America's readiness against national disasters, including naturally occurring or man-made disease threats, ASPR will manage the SNS, and ASPR will engage in the procurement, maintenance, and deployment of SNS medical countermeasures. The addition of the SNS to ASPR will improve overall emergency response operations, providing health and medical services to communities in need. Efficiencies across the medical countermeasure enterprise are expected. In coordination with the Public Health Emergency Medical Countermeasures Enterprise, the SNS will develop strategies to meet the national priorities for federal stockpiling, to maintain and improve SNS capabilities, and to address inventory gaps. Through these strategies, the enterprise will be more sustainable, productive, and effective at developing, stockpiling, and deploying the medical countermeasures needed to save lives and protect America from 21st Century health security threats.

HHS and ASPR have made significant progress since ASPR's inception in 2006. However, to further improve national readiness and response capabilities, four key priority areas have been identified:

- First, provide strong leadership, including clear policy direction, improved threat awareness, and secure adequate resources.
- Second, seek the creation of a "national disaster healthcare system" by better leveraging and enhancing existing programs – such as the Hospital Preparedness Program (HPP) and the NDMS – to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery.
- Third, advocate for the sustainment of robust and reliable public health security capabilities, in partnership with the CDC, including an improved ability to detect and diagnose infectious diseases and other threats, as well as the capability to rapidly dispense medical countermeasures in an emergency.
- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on additional authorities provided in the 21st Century Cures Act, as well as advances in biotechnology and

science to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, and supplies to respond to emerging disease outbreaks, pandemics, and chemical, biological, radiological and nuclear incidents and attacks.

The FY 2019 budget request for ASPR is $2.2 billion, which is $722 million above the FY 2018 Annualized Continuing Resolution level, including $575 million due to the transfer of the SNS to ASPR. 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
- $575 million for the Strategic National Stockpile
- $250 million for activities by ASPR and the HHS Office of Global Affairs to develop new diagnostic tools, vaccines, immunotherapeutics and support international preparedness for pandemic influenza
- $255 million for the Hospital Preparedness Program to support cooperative agreements with state, local, and territorial health departments to improve surge capacity and enhance community health care coalitions
- $80 million for Federal emergency management, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps, including an increase of $2 million to fund a national level bio exercise for preparedness and emergency response
- $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 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 2019 budget request for Cybersecurity is $68 million, which is an increase of $18 million above the FY 2018 Annualized Continuing Resolution 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' 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 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 to respond to 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, and its ongoing programs that identify and assess trends and patterns across the Department while developing and implementing 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, OSSI manages all intelligence, counterintelligence, insider threat, and cyber threat intelligence activities for the Department – all of which are resourced with PHSSEF funds. Additionally, OSSI manages the Department's personnel security services across the Department; these are resourced by non-PHSSEF funds. The FY 2019 budget request includes $8 million for OSSI, reflecting an increase of $1 million above the FY 2018 Annualized Continuing Resolution level. The increase supports additional staff necessary to protect national security interests related to intellectual property, life sciences, medical devices, and classified information.

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 2019 Budget re-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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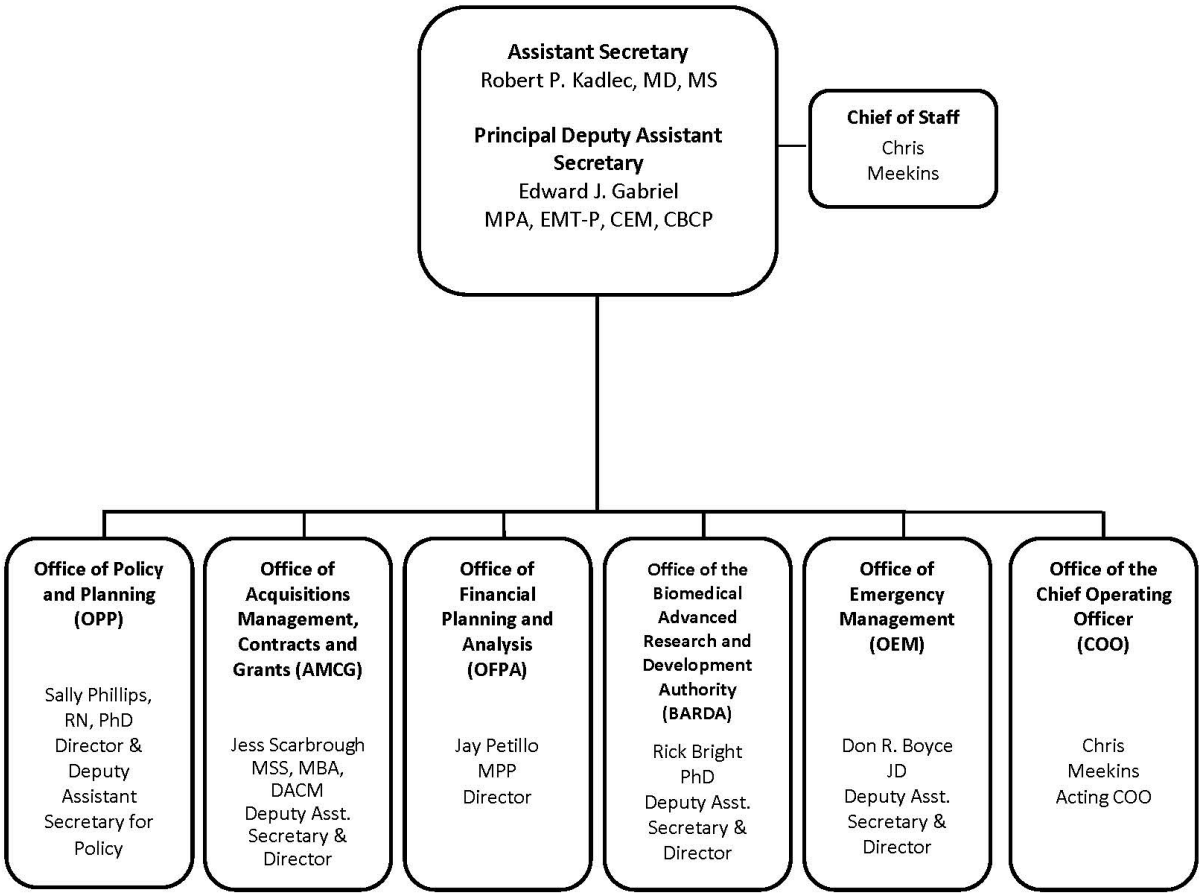
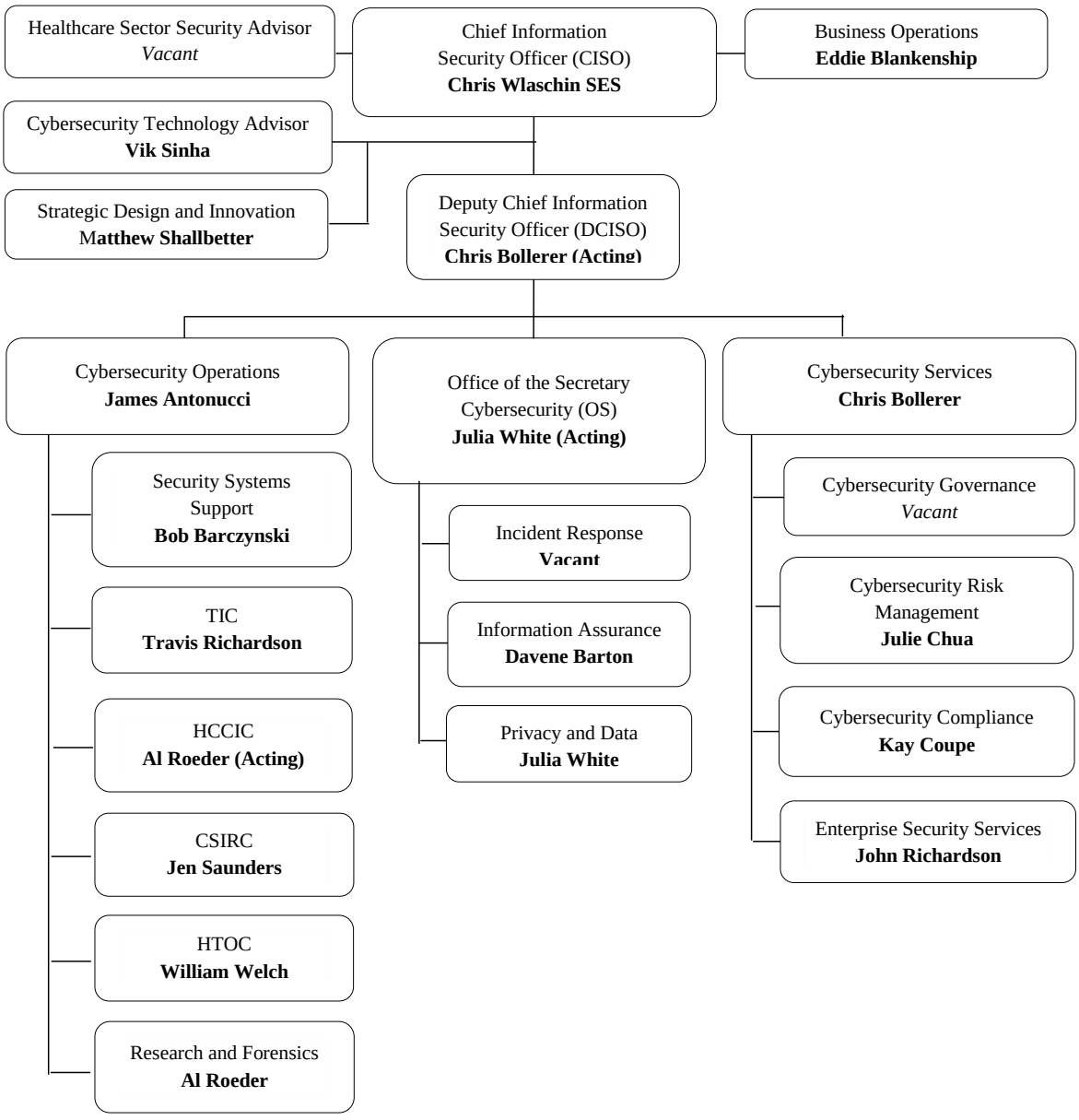
ORGANIZATIONAL CHARTS

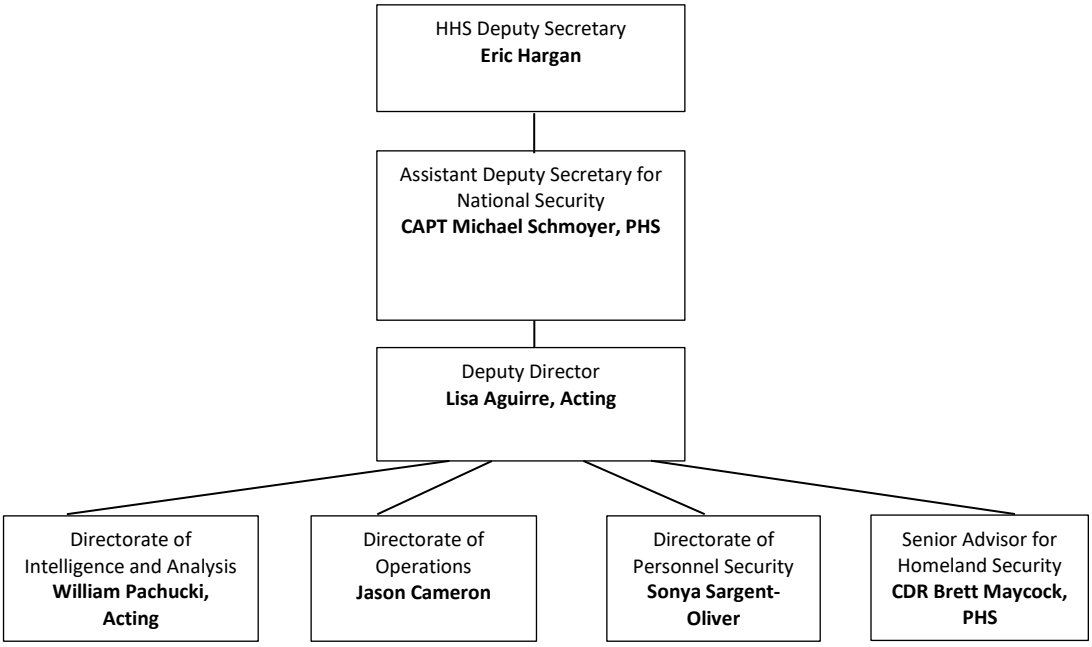
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE



CYBERSECURITY



OFFICE OF SECURITY AND STRATEGIC INFORMATION



INTRODUCTION AND MISSION

The Public Health and Social Services Emergency Fund supports the Department's cross-cutting efforts to improve the nation's preparedness against naturally occurring and man-made health threats and threats to the ability of HHS to carry out such missions. 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, radiological, and nuclear (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 and the National Disaster Recovery 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. ASPR also works across the interagency under the direction of the National Response Framework. In addition, ASPR has operational responsibilities for the advanced research and development of medical countermeasures (MCMs).

At its core, ASPR's mission is to save lives and protect Americans from manmade and naturally occurring public health emergencies. Under the statutory provisions creating it, ASPR's mission is to lead the country in preparing for, responding to, and recovering from, the adverse health effects of emergencies and disasters by supporting our communities' ability to withstand adversity, strengthening our health and response systems, and enhancing national health security. 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 (NRF) and the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework; and ASPR serves as the Lead Federal Agency when designated by the Secretary in coordinating the federal and medical response to public health emergencies. ASPR also supports HHS's role with respect to ESF-6 of the NRF, the delivery of Federal mass care, emergency assistance, housing, and human services when local, tribal, and State response and recovery needs exceed their capabilities.

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 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 to respond to 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, and its ongoing programs that identify and assess trends and patterns across the Department while developing and implementing 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 which are resourced with PHSSEF funds. Additionally, OSSI manages the Department's physical security, emergency management and personnel security services across the Department; 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 2019 Request for the Public Health and Social Services Emergency Fund (PHSSEF) is $2,303.877 million. The Request represents a program level increase of $740.840 million relative to the FY 2018 Annualized Continuing Resolution. The funds requested will provide the necessary resources to:

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

The Budget provides funds 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 2018 Annualized Continuing Resolution):

- **Pandemic Influenza (increase of $138 million, $250 million total):** Funding will be used to sustain critical domestic influenza vaccine manufacturing infrastructure, ensure that influenza vaccines and therapeutics can be produced to deploy an effective pandemic response, and maintain overall domestic pandemic readiness.

- **Preparedness and Emergency Operations (increase of $2.109 million, $26.596 million total):** Funding will be used to ensure state and local entities can prepare and plan for, respond to, and recover from, public health and medical incidents. The request will provide funding for additional training activities for a HHS biological incident exercise and National Special Security Events.

- **National Disaster Medical System (NDMS) (increase of $0.244 million, $49.809 million total):** The request supports continued NDMS operations, logistics support, and regional emergency coordination, to prepare and respond to public health emergencies and disasters. Funding will be utilized for medical response assets, including training for NDMS teams, and modernized equipment sets.

- **Biomedical Advanced Research and Development Authority (increase of $3.475 million, $511.7 million total):** 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 (2017).

- **Project BioShield (increase of $3.463 million, $510 million total):** This funding level will ensure continued development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines and new procurements of the new antibacterial drugs, chemical agent medical countermeasures, a new product to temporize burn injury, and a new radiation medical countermeasure. It will also support new intravenous formulations of currently stockpiled smallpox antiviral drugs for use in special populations or for those who are severely ill.

- **Hospital Preparedness Program (increase of $1.729 million, $254.555 million total**): Funding ensures that health care preparedness and response remains a nationwide focus (and enhances that focus), and also that all areas of the U.S. will have a base of preparedness should a disaster strike.

- **Strategic National Stockpile ($575 million total):** In FY 2019, the Strategic National Stockpile (SNS) will be transferred to ASPR. Putting the SNS under ASPR will increase operational effectiveness and efficiencies, and strengthen integration with ASPR's existing MCM program, which will streamline MCM development and medical response capabilities. In sum, the move is designed to improve the domestic preparedness posture by optimizing MCM development, response, and utilization, while also strengthening response capabilities to health security threats.

- **Operations and Policy and Planning (increase of $0.224 million, $45.728 million total):** Among other public health functions, funding for these programs supports community public health missions; continued development of ASPR's performance measurement, enterprise risk management, strategic human capital management initiatives; and establishment of strategic direction for public health and healthcare emergency preparedness and response

- **Cybersecurity (increase of $17.578 million, $68.093 million total):** Funding will support necessary activities to protect the Department's information technology systems. The investment will support the safeguarding of personally identifiable information, commercial proprietary data, and scientific research of National importance.

- **Office of Security and Strategic Information (increase of $1.077 million, $8.496 million total):** Funding will support necessary activities to mitigate counterintelligence and insider threat risks as they relate to cyber intelligence-derived threats and threats to the Nation's overall medical and public health supply chain and risk management.

Programmatic Decreases (relative to the FY 2018 Annualized Continuing Resolution):

- **Medical Reserve Corps (MRC) (decrease of $2.059 million, $3.900 million total):** Funding will provide overarching support, regional coordination and technical assistance to MRC unit leaders to guide the development of the units. Funding will also identify the key missions and/or functional areas 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 such missions and the extent to which they can assist.

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 seeks continual improvement, 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.

ASPR serves as the Lead Federal Agency when designated by the Secretary in coordinating the federal and medical response to public health emergencies, under Emergency Support Function (ESF) 8 of the National Response Framework (NRF). ASPR also supports HHS's role in the delivery of Federal mass care, emergency assistance, housing, and human services when local, tribal, and State response and recovery needs exceed their capabilities, under ESF 6. Through these functional designations, ASPR provides critical emergency management leadership and support for all major public health and medical events/incidents on behalf of the Federal Government. For ESF 6, ASPR specifically provides HHS medical workers and medical supplies and services, including medical durable equipment, and coordinates emergency medical care in shelters as needed at the request of affected State(s). For ESF 8, ASPR has a vital role in fulfilling the HHS responsibilities for responding to, recovering from, and mitigating the lasting impacts of public health and medical emergencies.

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.

For the 2018-2022 HHS Strategic Plan, ASPR will report performance in support of Objective 2.2: Prevent, treat, and control communicable diseases and chronic conditions, and also Objective 2.4: Prepare for and respond to public health emergencies.

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, address medical needs, and promote resilience and faster recovery. When requested by a state, local government, 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 medical 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. Through such collaborations, ASPR works to transition vaccine, antiviral, diagnostic, and device candidates to be ready for approval.

Performance Management Challenges

As a result of the 2017 hurricanes, some of OEM's data will be reported by the end of June 2018 instead of by the end of calendar year 2017. Specifically, due to response operations to Hurricanes Harvey, Irma and Maria in 2017 as part of ASPR's lead role for Emergency Support Function 8 under the National Response Framework, fourth quarter training was rescheduled for second quarter of fiscal year 2018. NDMS personnel were heavily engaged in response operations, and all personnel needed to be on call for potential medical response support.

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 of a focus 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 avian influenza outbreaks among chicken flocks, are raising concerns. Although the virus has not demonstrated sustained human-to-human transmissibility and remains in China, the H7N9 avian influenza virus has mutated into a more virulent strain and has spread. As a consequence, the United States Government (USG) has evaluated the risk and pandemic potential for this virus as extremely high. The USG is already taking steps to prepare for this emerging threat by generating pre-pandemic vaccine seed strains and initiating manufacturing of pre-pandemic vaccine. Clinical trials will commence once the pre-pandemic vaccine is available, in early 2018. 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 2019 Request for ASPR is $2,223,279,000 and 832 FTE. The impact of the increased resources will result in a comprehensive program to prepare for, and respond to, the health and medical consequences of bioterrorism and other public health emergencies. The resources provided through this request will also bolster the Department's pandemic influenza preparedness and response activities. The results will strengthen the nation's critical domestic influenza pre-pandemic vaccine manufacturing infrastructure, ensuring that pre-pandemic influenza vaccines and therapeutics can be produced to deploy an effective pandemic response, and maintaining overall domestic pre-pandemic readiness. The impact of increased funding for BARDA includes the advanced development of the highest priority MCMs. Project BioShield funding will continue late-stage development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines, and new procurements of new antibacterial drugs, chemical agent medical countermeasures, a new product to temporize burn injury, and a new radiation medical countermeasure. The impact of resources provided to support Preparedness and Emergency Operations will ensure state and local entities can prepare and plan for, respond to, and recover from, public health and medical incidences. The request will also provide for additional training activities for the HHS exercises, Continuity of Operations, and support for National Special Security Events.

FY 2019 ALL PURPOSE TABLE
PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

(Dollars in Millions)

Program	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018 Annualized CR
Assistant Secretary for Preparedness and Response (ASPR):				
Preparedness and Emergency Operations	24.596	24.487	26.596	+2.109
Office of Emergency Management only (non-add)	*19.608*	*19.521*	*21.596*	*+2.075*
National Special Security Events (NSSE) (non-add)	*4.988*	*4.966*	*5.000*	*+0.034*
National Disaster Medical System (NDMS)	49.787	49.565	49.809	+0.244
Hospital Preparedness	253.958	252.826	254.555	+1.729
Hospital Preparedness Program (HPP) Grants (non-add)	*228.500*	*226.948*	*228.500*	*+1.552*
Medical Reserve Corps	5.986	5.959	3.900	-2.059
Biomedical Advanced Research and Development Authority (BARDA)	510.499	508.225	511.700	+3.475
Advanced Research and Development (non-add)	*258.499*	*257.936*	*259.700*	*+1.764*
Combating Antimicrobial Resistance (non-add)	*192.000*	*190.696*	*192.000*	*+1.304*
Operations and Management (non-add)	*60.000*	*59.593*	*60.000*	*+0.407*
Project BioShield	508.803	506.537	510.000	+3.463
Strategic National Stockpile /1	--	--	575.000	+575.000
Office of Policy and Planning	14.843	14.776	14.849	+0.073
Operations	30.938	30.728	30.879	+0.151
Pandemic Influenza				
No-Year Pandemic Influenza	39.906	40.000	210.000	+170.000
Annual Pandemic Influenza	12.925	68.018	35.991	-32.027
Subtotal, Pandemic Influenza	52.831	108.018	245.991	+137.973
Subtotal, ASPR Program Level	**1,467.241**	**1,501.121**	**2,223.279**	**+722.158**
Pandemic Influenza Supplemental Balances /2	*15.000*	--	--	--
Subtotal, ASPR Budget Authority	***1,452.241***	***1,501.121***	***2,223.279***	***+722.158***
Other Office of the Secretary:				
Office of Global Affairs Pandemic Influenza	4.000	3.982	4.009	+0.027
Annual funding (non-add)	*4.000*	*3.982*	*4.009*	*+0.027*
Cybersecurity /3	50.744	50.515	68.093	+17.578
Office of Security and Strategic Information (OSSI) /3	7.453	7.419	8.496	+1.077
Subtotal, Other Office of the Secretary	**62.197**	**61.916**	**80.598**	**+18.682**
PHSSEF Total:				
HHS Pandemic Influenza Budget Authority	56.831	112.000	250.000	+138.000
No-Year Pandemic Influenza (non-add)	*39.906*	*40.000*	*210.000*	*+170.000*
Annual Pandemic Influenza (non-add)	*16.925*	*72.000*	*40.000*	*-32.000*
All Other Budget Authority	1,457.607	1,451.037	1,478.877	+27.840
Total, PHSSEF Program Level	**1,529.438**	**1,563.037**	**2,303.877**	**+740.840**
Pandemic Influenza Supplemental Balances /2	*15.000*	--	--	--
Total, PHSSEF, Budget Authority	***1,514.438***	***1,563.037***	***2,303.877***	***+740.840***
FTE				
ASPR	612	612	832	+220
OGA	5	5	5	--
OSSI	33	32	37	+5
Cybersecurity	93	123	133	+10
Total FTE, PHSSEF	**743**	**772**	**1,007**	**+235**

1/ The FY 2019 President's Budget reflects the transfer of the Strategic National Stockpile from CDC to ASPR.

2/ The FY 2017 funding level for Pandemic Influenza includes $15 million provided from prior-year supplemental balances.

3/ FY 2018 and FY 2019 totals reflect a realignment of $1.04 million from Cybersecurity to OSSI to support the cyber threat activities carried out by OSSI.

FY 2019 PROPOSED APPROPRIATIONS LANGUAGE

(Relative to FY 2018 President's Budget)

For expenses necessary to support activities related to countering potential biological, chemical, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies, [$945,753,000]$968,877,000, of which $511,700,000 shall remain available 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 [$4,990,000]$5,000,000 of the amounts made available to support emergency operations shall remain available through [September 30, 2020]September 30, 2021: [*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:]*Provided further*, That up to 10 percent of the amounts made available in this paragraph to support advanced research and development pursuant to section 319L of the PHS Act may also be used to supplement funds made available in the second paragraph for the purposes provided therein.

For expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act) and for carrying out section 319F-2(a) of the PHS Act, [$510,000,000]$1,085,000,000, to remain available until expended: *Provided*, That up to 10 percent of the amounts made available in this paragraph may also be used to supplement funds made available in the first paragraph to support advanced research and development pursuant to section 319L of the PHS Act.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic, [$206,863,000]$250,000,000; of which [$174,924,000]$210,000,000 shall be available until expended, for activities including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools: *Provided*, That 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.

APPROPRIATIONS LANGUAGE ANALYSIS

Language Provision	Explanation
For expenses necessary to support activities related to countering potential biological, chemical, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies, [$945,753,000]$*968,877,000*, of which $511,700,000 shall remain available 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 [$4,990,000] *$5,000,000* of the amounts made available to support emergency operations shall remain available through [September 30, 2020] *September 30, 2021*:	This language appropriates $5,000,000 for emergency operations available through fiscal year 2021.
For expenses necessary for procuring security countermeasures (as defined in section 319F-2 (a)(c)(1)(B) of the PHS Act) *and for carrying out section 319F-2(a) of the PHS Act*, [$510,000,000] $*1,085,000*, to remain available until expended:	This language appropriates $1,085,000,000, including $510,000,000 for Project BioShield for procuring security countermeasures and $575,000,000 for the management of the Strategic National Stockpile.
For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic [$206,863,000]*$250,000,000*; of which [$174,924,000]*$210,000,000* shall be available until expended, for activities including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools: *Provided*, That 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.	The language provides funds for preparing for and responding to an influenza pandemic through specific activities. Additionally, the language provides the Secretary with the authority to use funds for construction and renovation of private facilities that produce pandemic influenza vaccines.

AMOUNTS AVAILABLE FOR OBLIGATION

(In Dollars)

Detail	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Annual Appropriation	466,258,000	503,308,954	492,176,835
Recissions	-	-	-
Sequester Order	-	-	-
Transfers	(1,016,000)	-	-
Subtotal, Annual Appropriation	**465,242,000**	**503,308,954**	**492,176,835**
Multi-Year Appropriation	516,700,000	513,191,090	516,700,000
Recissions	-	-	-
Sequester Order	-	-	-
Transfers	(1,213,000)	-	-
Subtotal, Multi-Year Appropriation	**515,487,000**	**513,191,090**	**516,700,000**
No-Year Appropriation	550,000,000	546,536,590	1,295,000,000
Recissions	-	-	-
Sequester Order	-	-	-
Transfers	(1,291,000)	-	-
Subtotal, No-Year Appropriation	**548,709,000**	**546,536,590**	**1,295,000,000**
Total, Adjusted Appropriation	**1,529,438,000**	**1,563,036,634**	**2,303,876,835**
Unobligated balance, start of year	806,338,952	124,601,017	
Unobligated balance, end of year	124,601,017		
Unobligated balance, lapsing	34,266,199		
Total obligations	**2,243,321,343**		

SUMMARY OF CHANGES

(Dollars in Millions)

FY 2018 Annualized CR	
Total estimated budget authority	1,563.037
FY 2019 President's Budget	
Total estimated budget authority	2,303.877
Net Change	740.840

	FY 2018 Annualized CR FTE	FY 2018 Annualized CR BA	FY 2019 PB FTE	FY 2019 PB BA	FY 2019 +/- FY 2018 FTE	FY 2019 +/- FY 2018 BA
Increases:						
Assistant Secretary for Preparedness and Response						
Preparedness and Emergency Operations	86	24.487	86	26.596	--	2.109
Office of Emergency Management only (non-add)		*19.521*		*21.596*		*2.075*
National Special Security Events (non-add)		*4.966*		*5.000*		*0.034*
National Disaster Medical System	115	49.565	115	49.809	--	0.244
Hospital Preparedness Program (HPP)	49	252.826	49	254.555	--	1.729
HPP Grants (non-add)		*226.948*		*228.500*		*1.552*
BARDA	155	508.225	155	511.700	--	3.475
Advanced Research and Development (non-add)		*257.936*		*259.700*		*1.764*
Comating Antimicrobial Resistance (non-add)		*190.696*		*192.000*		*1.304*
Operations and Management (non-add)		*59.593*		*60.000*		*0.407*
Project BioShield	--	506.537	--	510.000	--	3.463
Strategic National Stockpile	--	--	220	575.000	220	575.000
Office of Policy and Planning	66	14.776	66	14.849	--	0.073
Operations	135	30.728	135	30.879	--	0.151
Pandemic Influenza						
No-year Pandemic Influenza	--	40.000	--	210.000	--	170.000
Cybersecurity	123	50.515	133	68.093	10	17.578
Office of Security and Strategic Information	32	7.419	37	8.496	5	1.077
Total Increases	761	1,485.078	996	2,259.977	235	774.899
Decreases:						
Assistant Secretary for Preparedness and Response						
Medical Reserve Corps	6	5.959	6	3.900	--	(2.059)
Pandemic Influenza					--	
Annual Pandemic Influenza	--	72.000	--	40.000	--	(32.000)
Total Decreases	6	77.959	6	43.900	--	(34.059)
Net Change					235	740.840

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Millions)

Activity	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Bioterrorism and Emergency Preparedness	1,457.607	1,451.037	2,053.877
Pandemic Influenza	56.831	112.000	250.000
Total Budget Authority	**1,514.438**	**1,563.037**	**2,303.877**
FTE	**743**	**772**	**1,007**

AUTHORIZING LEGISLATION

(Dollars in Millions)

Details	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Pandemic and All-Hazards Preparedness Reauthorization Act 2013 (PAHPRA)	1,514.438	1,563.037	2,303.877

APPROPRIATIONS HISTORY

(Dollars in Millions)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	2678.569	2100.659	2621.154	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	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	1,442.262	800.000	800.000	738.064
FY 2014				
Appropriation	1,289.531		1,304.400	1,243.430
Subtotal	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	1,909.981			1,532.958
Supplemental Appropriation (PL 114-223)				387.000
Transfer to CMS				(75.000)
Transfer to HRSA				(66.000)
Transfer to OIG				(0.500)
Transfer to GAO				(0.500)
Subtotal	1,909.981	-	-	1,777.958
FY 2017				
Appropriation	1,431.117	1,631.258	1,517.958	1,532.958
Transfer to ACF				(3.520)
Subtotal	1,431.117	1,631.258	1,517.958	1,529.438
FY 2018				
Appropriation	1,662.616	1,739.258	1,552.958	
FY 2019				
Estimated Appropriation				2,303.877

APPROPRIATIONS NOT AUTHORIZED BY LAW

(Dollars in Millions)

Program	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2018
ASPR				
Preparedness and Emergency Operations	N/A	N/A	N/A	24.487
National Disaster Medical System	FY 2018	52.700	49.565	49.565
Medical Reserve Corps	FY 2018	11.200	5.959	5.959
Hospital Preparedness Program	FY 2018	374.700	252.826	252.826
BARDA	FY 2018	415.000	508.225	508.225
Project BioShield	FY 2018	2,800.000	506.537	506.537
Strategic National Stockpile	FY 2018	533.800	571.095	571.095
Office of Policy and Planning	N/A	N/A	N/A	14.776
Operations	N/A	N/A	N/A	30.728
Pandemic Influenza	N/A	N/A	N/A	108.018
OGA Pandemic Influenza	N/A	N/A	N/A	3.982
Cybersecurity	N/A	N/A	N/A	50.515
Office of Security and Strategic Information	N/A	N/A	N/A	7.419

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

SUMMARY OF REQUEST

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Program Level	**1,467.241**	**1,501.121**	**2,223.279**	**+722.158**
Budget Authority (non-add)	*1,452.241*	*1,501.121*	*2,223.279*	*+722.158*
Other sources (non-add) /2	*15.000*	-	-	-
FTE	**612**	**612**	**832**	**+220**

1/ Totals include ASPR's portion of pandemic influenza funding.
2/ Reflects funding provided from the Public Health and Social Services Emergency Fund's unobligated pandemic influenza supplemental balances.
3/ The FY 2017 Final and FY 2018 Annualized CR BA amounts do not include a comparative adjustment for the Strategic National Stockpile.

The Fiscal Year (FY) 2019 Budget Request for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is $2,223,279,000. The request is an increase of $722,158,000 above the FY 2018 Annualized Continuing Resolution (CR) level; the ASPR CR level does not include funding for the Strategic National Stockpile.

ASPR leads our nation's progress in public health emergency response. Hurricane Katrina exposed major gaps in emergency management and response. Congress statutorily established ASPR after Hurricane Katrina, and addressing those weaknesses has been one of the most important parts of ASPR's mission. 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. Through the Office of Emergency Management (OEM) and the Hospital Preparedness Program (HPP), ASPR modernized the federal public health and medical emergency management infrastructure and strengthened states' and local communities' disaster response and recovery posture. 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. Through the office of Biomedical Advanced Research and Development Authority (BARDA), countermeasures are developed against chemical, biological, radiological, and nuclear threats as well as pandemic influenza and emerging infectious diseases that pose threats to American's health and security. BARDA, in partnership with industry, has 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 27 products under Project BioShield; 14 of these products have been procured for the Strategic National Stockpile.

Additionally, ASPR continues to dedicate efforts and resources towards the Ebola and Zika viruses. For FY 2019, ASPR's work will continue towards development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines, and procurements of new antibacterial drugs, chemical agent medical countermeasures, a new product to temporize burn injury, and a new radiation medical

countermeasure. Funding will also support new intravenous formulations of currently stockpiled smallpox antiviral drugs for use in special populations, or for 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.

ASPR will continue its efforts to provide 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 recent activations of the Emergency Prescription Assistance Program (EPAP), TRACIE developed Fact Sheets on the use of EPAP. 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.

ASPR's HHS emPOWER Program, developed in partnership with the Centers for Medicare & Medicaid Services, provides de-identified near real-time data and mapping products, including the HHS emPOWER Map, to enhance state, local and community based awareness of 3.8 million Medicare beneficiaries that may be adversely impacted by a public health emergency due to their dependence on electricity-dependent medical devices and healthcare services. More than 45,000 organizations (including healthcare, first responders, and utilities) have used these tools to advance their ability to anticipate, plan for, and respond to, the needs of these at-risk populations during disasters. ASPR is also collaborating with CMS and states to explore opportunities to develop similar Medicaid and CHIP data and mapping capabilities.

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, and monitoring. Since its inception, the NETEC has significantly impacted and improved the overall preparedness and response capabilities for a future Ebola or other incidents involving special pathogens. The NETEC has engaged and educated stakeholders through a non-punitive, non-regulatory, and non-accreditation approach that has promoted grassroots relationship-building and fostered ongoing best practice sharing across a diverse range of experts from the public and private sectors.

ASPR's goal for FY 2019 is to maintain preparedness and achieve new successes in public health emergency management. The FY 2019 budget proposes a funding increase for pandemic influenza, which will contribute significantly to advances in public health emergency management.

Increases above the FY 2018 Annualized Continuing Resolution level:

- Pandemic Influenza: The budget requests $245,991,000, which is $137,973,000 above the FY 2018 Annualized Continuing Resolution level. Funds are needed to sustain critical domestic influenza vaccine manufacturing infrastructure, ensure that influenza vaccines and therapeutics can be produced to deploy an effective pandemic response, and maintain overall domestic pandemic readiness. 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 achieve program goals, while also supporting technologies to improve, and ultimately transform, our approach to pandemic readiness and response. Of the total for medical countermeasures, $35,991,000 is annual funding and $210,000,000 is no-year funding to address preparedness sustainment costs, and continue the advanced research and development of improved vaccines, immunotherapeutics, and rapid diagnostics. The total request includes $3 million in annual funding for international policy and diplomacy programs.

- Biomedical Advanced Research and Development Authority (BARDA): The budget request for Advanced Research and Development is $511,700,000, which is $3,475,000 above the FY 2018 Annualized Continuing Resolution 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 (2017).
- Project BioShield: The budget request for Project BioShield is $510,000,000, which is $3,463,000 above the FY 2018 Annualized Continuing Resolution level. This funding level will ensure continued development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines, and new procurements of new antibacterial drugs, chemical agent medical countermeasures, a new product to temporize burn injury, and a new radiation medical countermeasure. It will also support new intravenous formulations of currently stockpiled smallpox antiviral drugs for use in special populations or for those who are severely ill.
- Preparedness and Emergency Operations (PEO): The budget requests $26,596,000 for PEO, which is $2,109,000 above the FY 2018 Annualized Continuing Resolution level. This funding ensures state and local entities can prepare and plan for, respond to, and recover from, public health and medical incidents. In this request, $1,989,000 will fund a Whole of Government/Community Exercise Program (with private partner participation) to conduct a multi-jurisdictional exercise program that examines the local, state, and federal response to biological incidents. Also within the total, $5,000,000 in three-year funding will be provided for National Special Security Events (NSSE), to prepare for, and respond to, NSSEs, public health emergencies, and other events that are not eligible for assistance under the Stafford Act.
- National Disaster Medical System (NDMS): The budget requests $49,809,000 for NDMS, which is $244,000 above the FY 2018 Annualized Continuing Resolution level. The request supports continued NDMS operations, logistics support, and regional emergency coordination, to prepare for, and respond to, public health emergencies and disasters. Funding will be utilized for medical response assets, including training for NDMS teams, and modernized equipment sets.
- Operations; Policy and Planning: The budget requests $45,728,000 for these two programs, which is $224,000 above the FY 2018 Annualized Continuing Resolution level. Among other public health functions, funding for these programs supports continued development of ASPR's performance measurement, quality improvement, enterprise risk management, strategic human capital management initiatives; and development of strategic direction for public health and healthcare emergency preparedness and response.
- Strategic National Stockpile (SNS): The budget requests $575,000,000 for the SNS. In FY 2019, the Strategic National Stockpile will be transferred to ASPR. Putting the SNS under ASPR will increase operational effectiveness and efficiencies, and strengthen integration with ASPR's existing MCM program, which will streamline MCM development and medical response capabilities. In sum, the move is designed to improve the domestic preparedness posture by optimizing MCM development, response, and utilization, while also strengthening response capabilities to health security threats.
- Hospital Preparedness Program (HPP): The budget requests $254,555,000 for the HPP, which is $1,729,000 above the FY 2018 Annualized Continuing Resolution level. Within the total, $228,500,000 will be provided for HPP cooperative agreements to states, territories and freely-associated states, the District of Columbia, and three high risk political subdivisions. The FY 2019 budget proposal ensures that health care preparedness and response remains a nationwide focus and that all areas of the U.S. will have a base of preparedness should a disaster strike. The remaining funds support HPP 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), the Division of Recovery, and Critical Infrastructure Protection (CIP).

Decreases below the FY 2018 Annualized Continuing Resolution level:

- Medical Reserve Corps (MRC): The budget requests $3,900,000 for MRC, which is $2,059,000 below the FY 2018 Annualized Continuing Resolution level. This funding will provide overarching support, regional coordination, and technical assistance to MRC unit leaders, to guide the development of the units. Funding will also 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 such missions and the extent to which they can assist.

PREPAREDNESS AND EMERGENCY OPERATIONS

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**24.596**	**24.487**	**26.596**	**+2.109**
National Special Security Events/Public Health Emergencies (non-add)	*4.988*	*4.966*	*5.000*	*+.034*
FTE	**86**	**86**	**86**	**--**

Authorizing Legislation:
Authorization ..... Public Health Service Act, Sec. 2811 42 U.S.C. 300hh-10
Authorization Status..... Indefinite
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

ASPR strives to respond to events/incidents, and to expedite recovery from such events/incidents through the promotion of resilient communities -- by preparing the Nation to withstand public health and medical emergencies. ASPR maintains situational awareness by monitoring national and international public health, healthcare and medical threats, and/or emergency response events. When ASPR responds to emergencies, the organization deploys resources (subject matter experts, medical personnel) and supporting logistics (medical caches and lifesaving supplies & equipment) to disaster areas. During times of relatively minor response activities, or "peacetime," ASPR works to enhance its internal preparedness and capabilities through training, exercises, and coordination with federal, state, local, territorial, and tribal partners. Such 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 operational planning and procedures, by conducting exercises to evaluate their programs and by collaborating within a broad health services network. This work saves lives before, during, and after disasters.

ASPR has a vital role in fulfilling HHS's 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 No. 8 (ESF 8) of the National Response Framework (NRF) and the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework. ASPR serves as the Lead Federal Agency when designated by the Secretary in coordinating the federal and medical response to public health emergencies. ASPR also supports ESF 6 of the NRF in the delivery of Federal mass care, emergency assistance, housing, and human services when local, tribal, and State response and recovery needs exceed their capabilities. ASPR supports HHS medical workers by provisioning medical supplies and services, including medical durable equipment, and coordinating emergency medical care in shelters, as needed at the request of affected State(s). Through these functional designations, ASPR provides critical emergency management leadership and support for all major public health and medical events/incidents on behalf of the Federal Government.

To support its integrated programs and initiatives, ASPR's Office of Emergency Management (OEM) developed a comprehensive Emergency Management program that 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, in order 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 incidents. 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, in order to ensure that decision-makers receive timely and updated situational analysis and information.
6. Operations – leads incident management for the ASPR by overseeing deployments and exercises, and by providing informed situational awareness and information management for the Department for all emergencies and events through the Secretary's Operation Center.
7. Logistics – provides strategic and operational resource management, mutual aid and 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 (NDMS) – augments the nation's medical response capability through the deployment of intermittent federal employees, organized in medical, mortuary, and veterinary teams.
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.

ASPR has led and supported HHS's efforts to respond to, mitigate, and recover from, 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; Sandy in 2012; and Harvey, Irma, and Maria in 2017. ASPR 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. Most recently,

as noted above, OEM provided response and recovery support to communities impacted by hurricanes Harvey, Irma, and Maria. Over 4,800 National Disaster Medical System (NDMS) personnel, Public Health Service, Veterans Affairs, and ASPR staff deployed to support HHS's response to those hurricanes. ASPR deployed 944 tons of equipment and logistics, and had over 36,000 patient encounters over all three incidents. For each response, 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. In 2014, 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 incident management coordination structure to meet the record breaking number of immigrant children entering into the United States. OEM, with ACF/Office of Refugee Resettlement (ORR), 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 (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 Unified Command Group which oversaw the response. OEM provided subject matter experts to FEMA Headquarters and provided liaison support to ACF with OEM staff. Additionally, OEM supported oversight and the actual implementation of medical care to the children through activation of the NDMS and U.S. Public Health Service (USPHS) Commissioned Corps and its 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 and ACF/ORR's efforts and provided senior HHS leaders and other government officials with up-to-date information.

ASPR has also 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. ASPR also deployed NDMS staff to work in CDC's Operations Center as subject matter experts during the Ebola response. Additionally, ASPR 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. ASPR'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 a 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, ASPR produced a 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* http://www.phe.gov/Preparedness/responders/ebola/EbolaResponseReport/Pages/default.aspx, 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 FY 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 events/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 ASPR'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.

The responsibilities of OEM's Division of Planning are expanding to include more preparedness functions, including development of the Threat and Hazard Identification and Risk Assessment (THIRA). Completion of ASPR's first THIRA is a significant accomplishment and will better align resources to need. The THIRA assessed 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, i.e., 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 events, as well as moderate events. The results validated the need for ASPR to continue to stockpile critical material at current levels and to maintain such stockpiles at a high state of readiness, in order to facilitate patient care by the NDMS and other Public Health and Medical response teams.

The Division of Planning also manages the ESF 8 Coordination Group that supports the ASPR in coordinating with relevant Federal officials to ensure integration and development of Federal preparedness and response activities for public health emergencies [see: 42 U.S.C. §§ 300hh-10(b)(4)(A)]. The ESF 8 Coordination Group serves as a forum for federal partners to support the core functions of the National Response Framework (NRF) in the context of preparing for a disaster.

The Division of Planning provides the primary support to the ASPR's EMAP. Through EMAP standards, the Division is ensuring that ASPR meets the credible standards of a national independent non-profit organization that fosters excellence and accountability in emergency management, verified through a peer review process. To comply with these standards, the Division of Planning is updating the All-Hazard Emergency Operations Plan as the Department's support plan for the NRF and the Federal Interagency Operations Plan. 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 particular types of incidents. These annexes address HHS's capabilities, essential tasks, and resources, by the phase of response. They also specify requirements for ESF 8 for HHS and other federal partners who support HHS in carrying out its response mission.

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, including maintenance of 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 policy directives, primarily Presidential Policy Directive (PPD) 40 (signed in July 2016), Federal Continuity Directive (FCD) 1 (signed in January 2017) and White House Office of Science and Technology Policy/Office of

Management and Budget (OSTP/OMB) Directive D-16-1 (signed in December 2016). PPD-40, referred to as the National Continuity Policy, and FCD-1 provide guidance to all executive branch agencies to ensure comprehensive and integrated national continuity programs, enhancing the integrity of the Nation's national security posture and enabling a more rapid and effective response to, and recovery from, a catastrophic emergency. D-16-1 establishes the minimum continuity communications requirement 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 which HHS must possess at headquarters and alternate locations are available and functional, in support of continuity of operations activities. 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 to ensure its communications ability during emergencies (including if/when relocation to an alternate site may be necessary), while reducing costs.

Similarly, and on an annual basis, OEM develops and facilitates several continuity-focused testing, training, and exercise events to strengthen and assess the HHS COOP program. Most recently in May 2016 and June 2017, OEM participated in the White House's annual continuity exercise and interagency evaluation. OEM hosted a tabletop exercise, which included the HHS Secretary, for HHS principals and other senior leadership that focused on reviewing initial decisions before and after an earthquake impacting HHS headquarters location, and that verified the expectations of the 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, to ensure HHS is fully prepared to activate its lead role for ESF 8 and its support role for ESF 6. 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, in order 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 the ASPR, other HHS leaders, and partner agencies. OEM operations personnel strengthen relationships with other programs, offices, and private-sector partners by including them as soon as emergencies occur. They also support 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. Both divisions are critical to the successful delivery of services for the HHS lead role in ESF 8 and its support role for ESF 6 missions when disasters of significance occur.

The Division of Fusion analyzes and visualizes data, 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 potential public health and medical impacts, as well as the status of healthcare infrastructure and system resources and potential population impacts. This analysis provides decision-makers with the resources they need to make informed decisions during public health emergencies. This transformation of data into actionable 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 Presidential Inauguration. The GeoHEALTH Platform was used to integrate data from multiple Federal agencies, including the US Secret Service and Department of Homeland Security, 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 as events unfolded.

Fusion tools and capabilities were used extensively in support of the back-to-back major hurricanes in 2017. There were over 1,000 Fusion products developed for Hurricanes Harvey, Irma and Maria alone, including maps of hurricane path/winds/flooding overlaid with healthcare infrastructure and data on vulnerable populations, the status of hospitals, nursing homes, dialysis centers, and pharmacies, power outage, shelter location/capacity, and deployed personnel and resources. Fusion Analytics was used for dashboard display of patient encounter information as recorded by electronic medical record (EMR) kits used at several ASPR-staffed field medical stations. Fusion's daily social media reports captured data about main themes of conversation regarding the hurricanes, specific information on hospitals, injuries, illness and shelters and any other information relevant to ASPR’s public health and medical mission. Between the time that Hurricanes Harvey and Maria hit, an additional 200+ Fusion products were created in support of minor hurricanes Nate and Jose, the Northern CA wildfires and the United Nations General Assembly. Fusion products for these events were used to brief the President, Congress, HHS and ASPR senior leadership, the Governor of Puerto Rico and many other senior Federal and State health and emergency management officials.

As with recent past disasters, Fusion collaborated extensively to share data with Federal, state and local partners. The Fusion team worked with CDC’s Center for Surveillance, Epidemiology, and Laboratory Services, in order to share de-identified EMR data captured by ASPR’s NDMS Disaster Medical Assistance Teams (DMAT) to CDC’s BioSense Platform. Through the BioSense Platform, this data was shared directly with public health departments in Texas and Florida, and resulted in numerous follow up conversations with state health department regarding potential public health concerns. Additionally, Fusion shared static maps and dynamic GIS data layers depicting healthcare infrastructure status with Federal, state and local partners. Due to operational challenges and lack of connectivity faced in the aftermath of Hurricane Maria, the Fusion team developed a Chief Medical Officer (CMO) Report to ensure full situational awareness of patient encounters as well as patient encounter trends. Initially this report focused only on HHS sites in Puerto Rico and the U.S. Virgin Islands; it was expanded to include all ESF 8 (DoD, VA) patient encounter sites in Puerto Rico and the US Virgin Islands.

Fusion continues to enhance its products that provide key demographic information for communities impacted by disasters through its GIS-based Community Analyst tool. Data from this tool is provided to relevant stakeholders to inform situational awareness about the community profile, particularly indicators of community vulnerability. Enhancements this year include a simplified demographic “infographic.” This one-page infographic was used during Hurricane Harvey and provided leadership with a quick and simple picture of demographics of the population impacted by the catastrophic flooding in Texas.

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, both anticipated and realized. OEM's assets are nimble, flexible, and adaptable, in order 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 IRCTs that are all scalable in size and function to ensure that the relevant IRCT 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, ASPR personnel develop innovative, evidence-based interventions that strengthen the Nation's medical and public health emergency response, including regional medical countermeasure initiatives. During preparedness for, and in response to, a CBRNE incident, OEM personnel provide leadership, advice, and guidance regarding strategic, technical, and operational issues; medical and public health impacts; and interventions.

HHS uses National Special Security Event (NSSE) funding to support other events that are not anticipated, but which require rapid responses and for which FEMA reimbursement is not authorized under the Stafford Act, such as evolving disasters that have a public health concern. For example, ASPR used NSSE funding to rapidly deploy mental health support after the Sandy Hook Elementary School (Connecticut) shootings, the mass shootings in Roseburg, Oregon, and the Boston Marathon bombings (to support disaster responders). 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. NSSE funding was also provided to CDC in 2014 in advance of passage of an emergency appropriation to respond to and prepare for Ebola.

Implementing and Managing the Preparedness Cycle

To manage preparedness efforts, and ensure readiness to respond and improve future responses, OEM uses the preparedness cycle of Plan, Train, Exercise, and apply Corrective Actions. The Training, Exercise and Lessons Learned Division (TELL) implements and manages this preparedness cycle within ASPR. Taking direction from the Plans Division and the published Threat and Hazard Identification and Risk Assessment (THIRA), TELL conducts training needs assessments, reviews metrics to determine which capabilities need to be exercised and conducts root cause analysis and verification of lessons learned for incorporation into plans, concepts of operation, and standard operating procedures. Through this process TELL synchronizes preparedness efforts for HHS/ASPR/OEM to ensure focus and continuity.

In FY 2016, ASPR 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 ASPR 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.

Preparing for Future Responses through Training

As a component of the preparedness cycle, TELL serves as the training manager for OEM. The following are recent examples of TELL training products and services:

- Developed, coordinated, and fostered a working relationship with state, local, federal and private entities to develop, promote, and deliver effective training relating to response and preparedness activities. The emphasis has been for the Center for Domestic Preparedness (CDP) in Anniston, Alabama to provide NDMS teams with hands-on training as well as a National Hospital Preparedness Program (NHPP) coalition leadership course.
- Provide New Employee Workshops to assist in the onboarding and indoctrination of new hires to better understand internal resources and organization.

Conduct OEM-wide training needs assessment (meetings held monthly) to identify overall mission training needs, as well as gaps and agree to comprehensive training schedule to reduce overlap and duplication.

Preparing for Future Responses through Exercises

As a primary component of the preparedness cycle, exercises serve as the recognized method within the Federal Government of assessing capabilities, preparedness to respond, and readiness to respond to identified threats or events. The Exercise Branch within TELL manages the HHS/ASPR/OEM exercise program. The following are examples of exercises supported by TELL that tested planning assumptions as well as supporting capabilities:

- Nimble Challenge exercise: Validate the Health and Medical response requirements for a mass migration situation on the southern border of the United States and a No-notice alert, assembly and deployment exercise for our Domestic Emergency Support Team.
- The Noble Lifesaver Exercise: Exercised patient evacuation operations.
- The Secretary's Quarterly Exercise Program is a series of exercises conducted quarterly to evaluate policies for emergency preparedness response, and readiness issues at the highest leadership level within HHS. The Program's objective is to advance the collective understanding of HHS's readiness, and illuminate areas which require additional focus. A recent example is the National Emergency Repatriation Plan exercise that validated the new plan to address this emerging mission.
- Tranquil Terminus Full Scale Exercise: Test and validate the nation's capability to safely and securely transport Highly Infectious Disease Patients within the United States. This exercise tested the advances in capability implemented as corrective actions from the Ebola Virus Disease event and was by far the largest full scale exercise that HHS has conducted involving 5 regions, 9 states, and 10 hospitals across the country.
- Gotham Shield Exercise: Tested the nation's response to an improvised nuclear device detonation in New York City.
- Gotham Shield Recovery Exercise: Tested the nation's processes to coordinate and synchronize recovery efforts following an Improvised Nuclear Device detonation.
- Department of Defense (DOD) Hidden Peril Exercise: Exercise DOD support to HHS during the response and management of a human pandemic.

Through these efforts the TELL Exercise Branch is fully executing the HHS preparedness cycle requirements for exercises.

Preparing for Future Responses through Implementing Lessons Learned

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.

ASPR has captured significant lessons learned from involvement in National Exercises, Trainings and Responses. The following are Corrective Actions and Lessons Learned from these events:

- 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 the Incident Response Coordination Team (IRCT) CONOPS. Standard Operating Procedures were created for: Accountability, Logistics, Disaster Leadership Group, Staging, Mobilization and Demobilization Processing, and National Special Security Events.
- Identified and tracked corrective actions which led to the professional development and standardization of response personnel through an IRCT qualification system.
- 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.
- Overall, corrective actions implemented in FY 2017 focused on standardization and documentation, significantly enhancing OEM preparedness.

Through the Corrective Action Program, ASPR takes a proactive approach in improving future responses to public health and medical incidents by:

- Providing NSSE planners with previous special event corrective actions and outcomes for consideration into planning efforts.
- Publishing a bi-annual CAP Newsletter to highlight significant lessons learned and/or finalized corrective actions.
- Deploying as members of the IRCT to provide in-person evaluation support at 2017 NSSEs such as the Presidential Inauguration, Presidential Joint Address to Congress, Peace Officers Memorial,

National Independence Day and the United Nations General Assembly, expanding the lessons learned data collection from responder only to an outside perspective.

- Tracking and reporting recurring observations to identify gaps in planning, training, and/or execution.
- Establishing a mechanism to share corrective actions and lessons learned with the ASPR response community.

Funding History	
FY 2015	$24,789,000
FY 2016	$24,654,000
FY 2017	$24,596,000
FY 2018 Annualized CR	$24,487,000
FY 2019 President's Budget	$26,596,000

Budget Request

The FY 2019 Budget includes $26,596,000 in budget authority for Preparedness and Emergency Operations activities, which is an increase of +$2,109,000 above the FY 2018 Annualized Continuing Resolution.

Preparedness and response to public health and medical emergencies requires a robust and continuous training and exercise program. This does not only include deployed medical responders through the NDMS, but also emergency management operators, policy officials, Departmental leadership and SLTT partners. HHS has deemed ongoing exercises to be a critical standard to help prepare the department for effective responses during emergencies.

In this request, $1,989,000 will fund a Whole of Government/Community Exercise Program (with private partner participation) to conduct a multi-jurisdictional exercise program that examines the local, state, and federal response to biological incidents. This exercise program will rise to a National Level Exercise (NLE) level by encompassing a Whole of Government/Community approach. The biological exercise series will afford multiple community partners the opportunity to test and evaluate current plans and to exercise information exchange, coordinate resources and make policy decisions in a Non-Stafford Act environment with a non-traditional Lead Federal Agency in accordance with the Biological Incident Annex and Presidential Policy Directive #44. This request also includes funding the Secretary's Quarterly Readiness Exercise (SQREx) Program. The overarching goal and intent of the SQREX Program is to ensure that the Department is better prepared to serve the needs of the nation during a large-scale event. The desired outcome of the SQREX series is to evaluate policies for emergency preparedness response, and readiness issues at the highest leadership level within HHS. The Program's objective is to advance the collective understanding of our readiness, and illuminate areas which require additional focus. The SQREX Program encourages information sharing and awareness, and ensures that critical operational and tactical level policy issues are addressed.

The FY 2019 request includes $5,000,000 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. 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.

NATIONAL DISASTER MEDICAL SYSTEM

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**49.787**	**49.565**	**49.809**	**+.244**
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.

NDMS's 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 is supported by a workforce of more than 5,000 intermittent federal employees organized into 72 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, transported, 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; in the course of a response, it is 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 the response to Superstorm Sandy, ASPR deployed over 20 DMATs on a rotational basis comprised of more than 2000 employees. More recently, approximately 2,500 NDMS personnel supported communities impacted by Hurricanes Harvey, Irma, and Maria; approximately 36,370 patients were treated during response.

- ***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 establishing a stand-alone field hospital. The TCCTs are configured to deploy as a 7-person TF, a 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 respect to 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 Team (NVRT*)**: The NVRT delivers 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. The NVRT is 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 element 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 participating in the same 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 Commissioned Corps Officers, and state, local, tribal, and territorial (SLTT) and territorial officials, to strengthen response capabilities.

Deployment of NDMS teams requires 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 after arrival, the resupply process is established pursuant to documented procedures. The Division of Operations conducts operational oversight for NDMS teams 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:

- Provided support to communities affected by Hurricanes Harvey, Irma, and Maria. Over 4,800 NDMS personnel, Public Health Service, Veterans Affairs, and ASPR staff deployed to support those hurricanes. ASPR deployed 944 tons of equipment and logistics, and had over 36,000 patient encounters over all three incidents.
- 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; 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, to 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, i.e., 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 these results, 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 and to maintain such stockpiles 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 maintains strategically positioned medical material, and deploys 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 the United States. 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, including 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 successfully deployed, sustained, and reset over 250 medical caches, encompassing over 1,300 tons of material and resources to support five NSSEs and multiple natural disasters, such as Hurricanes Harvey, Irma, and Maria in 2017; the historic 2016 Louisiana flood response; Hurricane Matthew responses in multiple States; sustainment of the Zika Unified Coordination Group in Puerto Rico and the Flint, Michigan Water Crisis United Coordination Group; Peace Officer's Memorial; 2017 Presidential Inauguration; 2017 Joint Session of Congress Address; the National Independence Day Celebration on the National Mall; and 35 regional and local NDMS training events.
- The Division continues to be a critical education resource to NDMS and HHS responders on curriculum related to a Public Health and Medical (ESF 8) logistics response. For example, the Division of Logistics effectively executed the "Logistics 101" course in April 2017 which resulted in the successful graduation of over 45 logisticians from NDMS and the United States Public Health Service (USPHS). The Division also provided logistics training at the NDMS Fundamentals Course and the FEMA Interagency Logistics Course, resulting in increased interoperability and standardization of processes.
- Support and participation in the above events not only underscore that prepared medical logisticians, processes, and commodities save lives, but also highlight the need to ensure HHS responders continue to modernize biomedical equipment and information technology to effectively execute missions under austere and risk adverse conditions. To ensure efficiency with the modernization effort of ESF 8 resources, the Division hosted a thorough review of its patient care and IT/Telecommunication cache capabilities against the ASPR THIRA. The review highlighted the need to reconfigure and update ASPR's patient care caches and IT/Telecommunication kits, to achieve required standards of care, and to meet minimum guidelines for HHS IT/Telecommunications guidelines. Additional efficiencies can be achieved, and risks can be reduced, by leveraging state of the art technology (e.g., inventory barcoding systems) that interfaces with interagency emergency management systems to enhance interoperability and transparency, while reducing cost, redundancy, and the potential for medication and medical supply errors being introduced in deployable caches.

The Division continues to collaborate with the private sector, SLTT governments, and inter-agency federal partners to implement best practices for supply chain management, to enhance national preparedness and response with a focus on continuous improvement of successful patient outcomes. 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 of common resources to reduce redundancy; re-engineered medical caches to be scalable and mobile; and re-established OEM's Emergency Prescription Program (EPAP), 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, thus 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 (RECs), 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 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 their 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	
FY 2015	$50,054,000
FY 2016	$49,904,000
FY 2017	$49,787,000
FY 2018 Annualized CR	$49,565,000
FY 2019 President's Budget	$49,809,000

Budget Request

The FY 2019 budget request is $49,809,000 in budget authority, which is an increase of $244,000 above the FY 2018 Annualized Continuing Resolution. The request supports continued NDMS operations, logistics support, and regional emergency coordination, to prepare for, and respond to, public health emergencies and disasters. Funding will be utilized for medical response assets, including training for NDMS teams, and modernized equipment sets. NDMS will continue to review internal operations, programs, and initiatives in FY 2019 to prioritize the highest-priority/critical activities to support NDMS in meeting the mission of the Department.

ASPR National Disaster Medical System - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
1.1 Maintain the percent of new NDMS intermittent staff that complete psychological first aid training (Output)	FY 2017: 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 (Invalid measure type)	FY 2016: 25.0 %[1] Target: 15.0 % (Target Exceeded)	10.0 %	35.0 %	+25 %

1 Due to the 2017 hurricanes, 2017 data will be reported by June 30, 2018

CIVILIAN VOLUNTEER MEDICAL RESERVE CORPS

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**5.986**	**5.959**	**3.900**	**-2.059**
FTE	**6**	**6**	**6**	**--**

Authorizing Legislation:
Authorization ..... Public Health Service Act, Sec. 2813 42 U.S.C. 300hh-15
Authorization Status..... Indefinite
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

The civilian volunteer Medical Reserve Corps (MRC) is a national network of nearly 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 to their communities – before, during, and after emergencies. MRC units' capabilities can vary according to community needs, geographic region and local investments, among other factors.

MRC units are very active in their communities, as evidenced by their 15,415 activity reports in 2017 that show more than 144,000 MRC participants contributed over 557,000 hours of volunteer service. These activities have had significant local impact: 389 activities/responses to local emergencies, 8,566 activities where MRC members strengthened the local public health system, 5,231 activities that served a vulnerable population, 6,068 activities that supported non-emergency community events, 10,032 activities that developed or strengthened the MRC unit, 8,319 activities that improved community preparedness or resilience, and 6,012 activities that trained or exercised MRC members to improve individual, unit, or community response capability and capacity.
Recent MRC accomplishments include:

- More than 1,000 MRC volunteers in Alabama, Florida, Georgia, Louisiana, Oklahoma, Pennsylvania, South Carolina, Texas, and Puerto Rico stepped forward to help meet their communities' needs and those of neighboring states in response to Hurricanes Harvey, Irma, and Maria. Efforts included, but were not limited to:
    - Behavioral health, medical, and supportive care at shelters and clinics, including dialysis support.
    - Veterinary transport and care.
    - Support services to call centers and reception/evacuation centers.
    - Emergency Operations Center (EOC) support.
    - Commodity distribution support operations (e.g., water, food, mosquito repellant).
    - Community education and outreach (e.g., vector control, sanitation, hand hygiene).

  - Recovery support (e.g., disaster case management, first responder vaccinations, donations management).

- Specific to activities in Puerto Rico, the Medical Reserve Corps of Puerto Rico – the only MRC unit in the territory – activated and deployed volunteers for several missions, including providing support for evacuees from the U.S. Virgin Islands and other Caribbean islands. Missions included: providing support to dialysis patients, staffing shelters, and staffing reception centers. Even after the widespread destruction of Hurricane Maria, when many volunteers were personally affected, MRC volunteers conducted clinical evaluations of residents and educated community members on water management, vector control, and mosquito bite prevention, as well as personal hygiene.
- In response to Hurricane Harvey, the Brazoria County MRC (TX) operated five shelters, providing a safe place for close to 1000 residents for 41 days. After the shelters were closed, the MRC unit provided water sampling for 96 potentially contaminated water wells for an underserved community, and continued to provide case management services for over 50 families who were displaced.
- MRC units have responded to other emergencies as well. Twelve MRC units supported wildfire response efforts in both Northern and Southern California by assisting with resident evacuation, sheltering (including medical support), and veterinary care for animals throughout the disaster area. After the mass shooting in Las Vegas in October 2017, MRC volunteers provided psychological first aid and other support services at a Family Assistance Center and staffed a call center for those affected.
- After tornadoes hit Oklahoma in May 2017, MRC units across the state were on hand to assist with shelters, veterinary care, donation management, and other needed support.
- There was severe flooding in several states in 2017, and MRC units were on hand to assist. In Iowa, volunteers helped move household items to higher ground and assisted with sandbagging efforts at individuals' homes. When flooding hit California in February 2017, Santa Barbara and Santa Clara MRC volunteers assisted with shelter support. Sacramento MRC volunteers supported the Oroville Dam Response effort by helping to staff the Sacramento County Office of Emergency Services EOC as well as working the overnight shift at an American Red Cross shelter for affected community members.
- Since the beginning of 2017, MRC units across the country have served as a valuable resource in combating the opioid crisis in local communities. Several MRC units are engaged in prevention activities to inform and aid communities in response to the recent increase in opioid abuse, enhance community education around opioid addiction, and reduce the number of individuals who die from opioid overdoses. (The efforts of several units have been supported by National Association of County and City Health Officials (NACCHO) Challenge Awards, which are funded by the program's cooperative agreement with NACCHO.)
- MRC units have supported a number of mass immunization clinics, including during communicable disease outbreaks.
  - After two students at the University of Massachusetts Amherst were diagnosed with invasive meningococcal disease serogroup B, South Hadley/Granby/Northampton MRC and UMass Amherst MRC volunteers were activated to support a large-scale meningitis B vaccination clinic in November 2017. Volunteers assisted with vaccine administration, triage, registration, and patient flow.
  - Units have also responded to hepatitis A outbreaks in Kentucky, California, and Utah with vaccinations and awareness campaigns in the affected areas.

  - In response to an increase in mumps cases identified in Tulsa County, Oklahoma, Tulsa County MRC volunteers provided administrative support to the local health department at a mumps vaccination point of dispensing (POD) site.
  - Albany County MRC in New York assisted the department of health's response to a mumps outbreak at the University at Albany. Volunteers supported the point of dispensing (POD) operation that vaccinated 124 students.
  - In 2017, MRC units administered flu vaccines and/or provided logistical support at more than 400 clinics, community events, employers, health departments, and schools.

- After a recent tuberculosis exposure at James T. Vaughn Correction Center in Delaware, MRC nurse volunteers were requested by the Bureau of Correctional Healthcare Services to support a tuberculosis screening clinic for all employees by administering 576 Purified Protein Derivative (PPD) Tests in response to an exposure at the JTVCC. Nineteen nurse volunteers from the New Castle, Kent, and Sussex County MRC units served 184 hours. Volunteers planted and read 576 PPDs, finding 15 positive reactors in employees who they referred for chest x-rays (for diagnostic confirmation).
- MRC units also participate in non-emergency events, many of which are useful because they simulate activities and actions that would be needed during a response. For example, more than 25 units supported large community gatherings to view the total solar eclipse in August 2017. Also, Washington, DC, and Virginia MRC units supported the Presidential Inauguration on the National Mall in January 2017. More than 170 volunteers assisted during the event with patient tracking, triage, basic life support/advanced life support aid stations, and family reunification.

Funding History	
FY 2015	$8,979,000
FY 2016	$6,000,000
FY 2017	$5,986,000
FY 2018 Annualized CR	$5,959,000
FY 2019 President's Budget	$3,900,000

Budget Request

The FY 2019 Budget includes $3,900,000 for the civilian volunteer Medical Reserve Corps, which is a decrease of $2,059,000 below the FY 2018 Annualized Continuing Resolution. 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 such missions 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. However, the proposed reduction will mean a reduction in the level of support available to the MRC units, unit leaders and volunteers, state coordinators, and the national network as a whole.

HOSPITAL PREPAREDNESS PROGRAM

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority /1	**253.958**	**252.826**	**254.555**	**+1.729**
Cooperative Agreements (non-add) /2	*228.500*	*226.948*	*228.500*	*+1.552*
Other costs (non-add) /3	*25.458*	*25.878*	*26.055*	*+0.177*
FTE	**49**	**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, D.C., three high-risk political subdivisions, and all U.S. territories and freely associated states. Currently, 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-based cooperative agreement; direct federal/intramural; contracts

Program Description and Accomplishments

The Hospital Preparedness Program (HPP) is critical to 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 consistent national focus to improve patient outcomes during emergencies, as well as enables rapid recovery. For the past 15 years, HPP investments have improved individual health care entities' preparedness and have built a system for coordinated health care delivery system readiness and response through health care coalitions (HCCs), which must be sustained in order to minimize the need for supplemental state and federal resources during emergencies.

HPP funding also enables ASPR to convene partnerships within the U.S. health care delivery system to focus on preparedness and response as well as 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 also critical for ASPR to accomplish its mission during responses to, and recovery from, large-scale public health and medical emergencies.

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, D.C., Chicago, Los Angeles County, New York City, and all freely associated states, to invest in forming and developing 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 multi-organization coordination groups that support and integrate with 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 optimizes use of resources – including health care professionals and specialized equipment – especially when one facility is too overwhelmed to provide timely and required levels of care, in addition to mitigating the impact of the incident on the facilities themselves, 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 and plan for, and respond to, emergencies.

Hurricane Harvey Health Care Response.—The Southeast Texas Regional Advisory Council (SETRAC), an HPP-supported HCC, coordinated all of the Houston region's health care response for Hurricane Harvey.[1] SETRAC support, in part, enabled the 9,600-bed Texas Medical Center to remain operational throughout the storm and the flooding that ensued. The HCC also ensured that patients from other facilities that needed to be evacuated were transported to appropriate facilities safely. To do so, they utilized response equipment and communications and emergency management systems, financed by HPP, to coordinate across the entire region's health care delivery system. Further, from 2002-2012 when HPP funding was used to build individual health care facility capacity to respond to emergencies, Houston area hospitals made facility enhancements to incorporate lessons learned from previous responses[2] (e.g., installing submarine doors in tunnels linking facilities to limit flooding, moving generators to higher levels to avoid flooding, etc.), which were funded, in part, through the HPP cooperative agreement with the Texas Department of State Health Services. Without HPP funding and its focus on health care capacity and coordination capabilities, these systems, plans, and equipment would not have been available to support response and recovery efforts.

Ultimately, HPP investments improved overall capabilities and mitigated the impact of this devastating storm. In fact, the Houston health care system response to Tropical Storm Allison in 2001 (prior to HPP) and the Hurricane Harvey response could not have been more different.[3] Immediately after Tropical

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[1] Fink, Sheri, and Andrew Burton. "After Harvey Hit, a Texas Hospital Decided to Evacuate. Here's How Patients Got Out." *New York Times*, September 6, 2017. Accessed September 18, 2017. https://www.nytimes.com/2017/09/06/us/texas-hospital-evacuation.html?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_source=hs_email&utm_medium=email&utm_content=56073607&_hsenc=p2ANqtz--hkOCJGx-v-attOO4klztPgUi-aO0W_XlGXQTQ4RUuLLUsx9_QHHh8YcGl8V2VHvUW1bmviOtsyQgVXHGiQcrTG4wi3w&_hsmi=56073607.

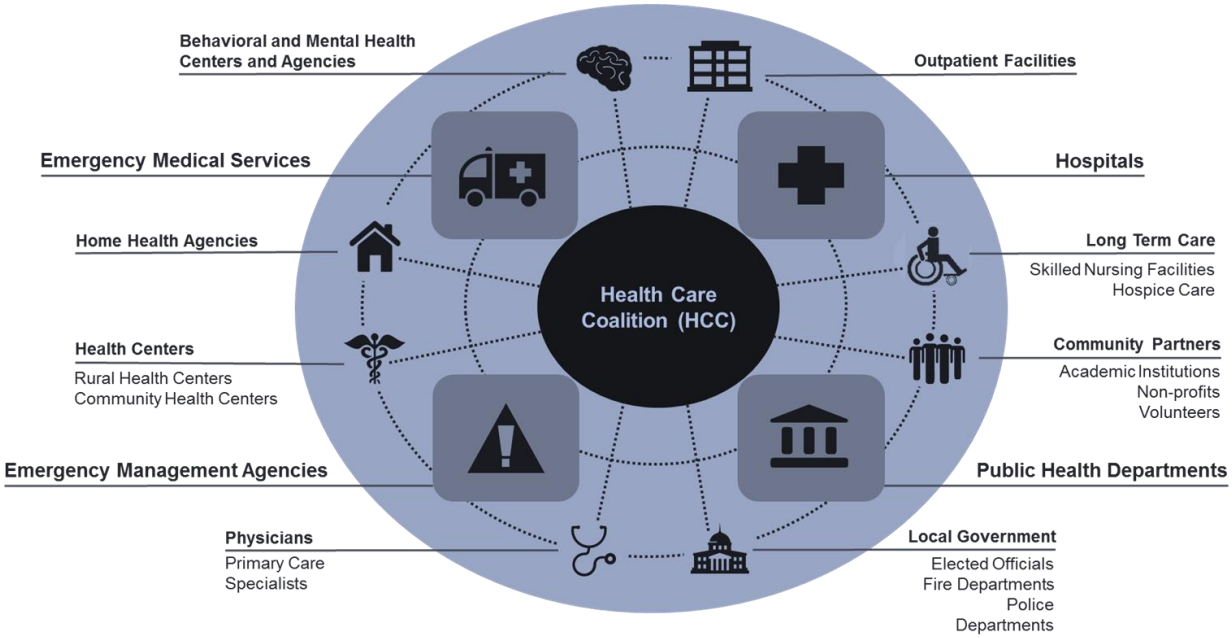
[2] Para, Jane. "Updated: Texas medical Center hospitals remain operational during historic flooding." Houston Business Journal. Published August 29, 2017. Updated September 1, 2017. Accessed September 18, 2017. https://www.bizjournals.com/houston/news/2017/08/29/texas-medical-center-hospitals-remain-operational.html

[3] Goldstein, Amy, and McGinley, Laurie. "Some hospitals evacuated, but Houston's medical world mostly withstands Harvey." *Washington Post*, August 30, 2017. Accessed September 18, 2017. https://www.washingtonpost.com/national/health-science/some-hospitals-evacuated-but-houstons-vaunted-medical-world-mostly-withstands-harvey/2017/08/30/2e9e5a2c-8d90-11e7-84c0-02cc069f2c37_story.html?tid=sm_tw&utm_term=.eea8045573f1

Storm Allison, Houston area hospitals were flooded, without power, and medical supplies (e.g., pills) were destroyed. Using HPP funding and addressing lessons learned, health care centers made structural as well as operational changes. During Harvey, SETRAC and its member organizations were able to respond to most of the health care needs of the region on their own, without significant federal assets.

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.



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 are pivotal to ensuring that the nation's health care system is ready to respond to various events and infectious disease outbreaks. Other recent examples include responses to the Ft. Lauderdale airport shooting and to Hurricane Matthew in Georgia.

Ft. Lauderdale Shooting Response — When a shooter opened fire on January 6, 2017, 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, conducting 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

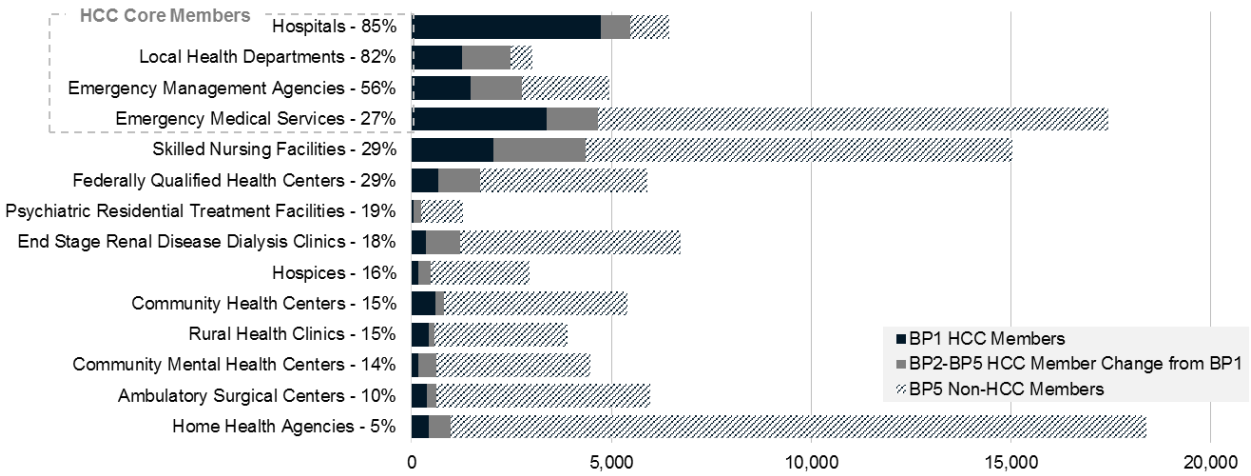
coordination enabled effective, real-time communication between health care responders, transit authorities, and law enforcement as the incident unfolded. Within seven minutes of shots being fired, the HCC EOC liaison at the airport was coordinating patient distribution with first responders on the scene, 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 from 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 with law enforcement, to ensure all patients were relocated around the state using appropriate transportation, which included 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, 2017, over 31,000 health care facilities and community organizations were participating in 476 HCCs nationwide. This is an increase in HCC membership of 92 percent since the project period began in July 2012. The diverse membership of HCCs 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 from budget period (BP) one through five of the five-year 2012-2016 HPP cooperative agreement. For example, there are currently 5,473 hospitals participating in HCCs, which represent 85 percent of all U.S. hospitals.

Figure 2. HCC Membership Diversity and Participation Rates, June 2017.



**Data from Puerto Rico and the U.S. Virgin Islands are not included in BP5 numbers due to ongoing hurricane recovery efforts.*

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 through FEMA mission assignments.

Historically, HPP funding invested in 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 for 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 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*[4] document outlines the high-level objectives that the nation's health care delivery system should undertake in order to prepare for, respond to, and recover from, emergencies.

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

[4] *2017-2022 Health Care Preparedness and Response Capabilities,* https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capablities.pdf

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 through 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 – Ebola Response and Planning
With HPP cooperative agreement funding, Kentucky's Region 7 HCC members conducted an Ebola response exercise in October 2016. The exercise scenario involved a very sick patient arriving at a Region 7 HCC member hospital, which is also one of Kentucky's Ebola assessment hospitals. In 2014, the hospital used both HPP and private funds to create a replica of its intensive care unit for conducting realistic patient care trainings. HCC members exercised inside the replica unit, where they practiced complicated clinical techniques and procedures, rehearsed navigation around tight corners and in hallways while wearing bulky protective gear, and assessed existing plans and protocols. HCC members also practiced using HPP-funded specialized equipment to prepare the deceased patient's body for transport and protect those involved with the decedent's care.

Ebola Health Care System Preparedness and Response Accomplishments
Global trends, such as the increasing mobility of people and products, have contributed to an amplified likelihood of an emerging infectious disease outbreak.[5] The United States and the world received a wakeup call in March of 2014, when 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.[6] Congress appropriated emergency supplemental funding, among other things, to respond to the outbreak and 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.

[5] Globalization and infectious disease: A review of the linkages. http://www.who.int/tdr/publications/documents/seb_topic3.pdf
[6] 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.

Prior to the 2014 Ebola outbreak, the United States did not have an organized, systematic approach to preparing for, and responding to, an outbreak of a highly infectious special pathogen. A federally-funded, systems-based approach that allows for regional flexibility is appropriate because of the specialized capabilities required for transport, treatment, and care. Building upon the state- and jurisdiction-based tiered hospital approach,[7] and meeting Congress's regional directive, HPP provided awardees with approximately $214 million of Ebola emergency supplemental funding to establish a nationwide, regional treatment network for Ebola and other infectious diseases.

FY 2019 marks the final year in which supplemental funds provided for Ebola will be available to support this regional treatment network. The funding provided through HPP Ebola Preparedness and Response activities is intended to provide the foundation required for the nation's health care system to safely and successfully identify, isolate, assess, transport, and treat patients with Ebola or under investigation for Ebola (or other highly infectious diseases). Through this mechanism, ASPR awarded cooperative agreements to all 50 states, Washington D.C., all U.S. territories and freely associated states, and select metropolitan jurisdictions, over a five-year project period. Additionally, ASPR competitively awarded funding to ten regional Ebola and other special pathogen treatment centers (one in each of the ten HHS regions).

The regional treatment network approach balances geographic need and differences in institutional capabilities, and it accounts for the potential risk of needing to care for an Ebola patient. While the initial focus was on preparedness for Ebola, it is likely that preparedness for other novel, highly pathogenic diseases has also been enhanced through these Ebola preparedness grants. 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.

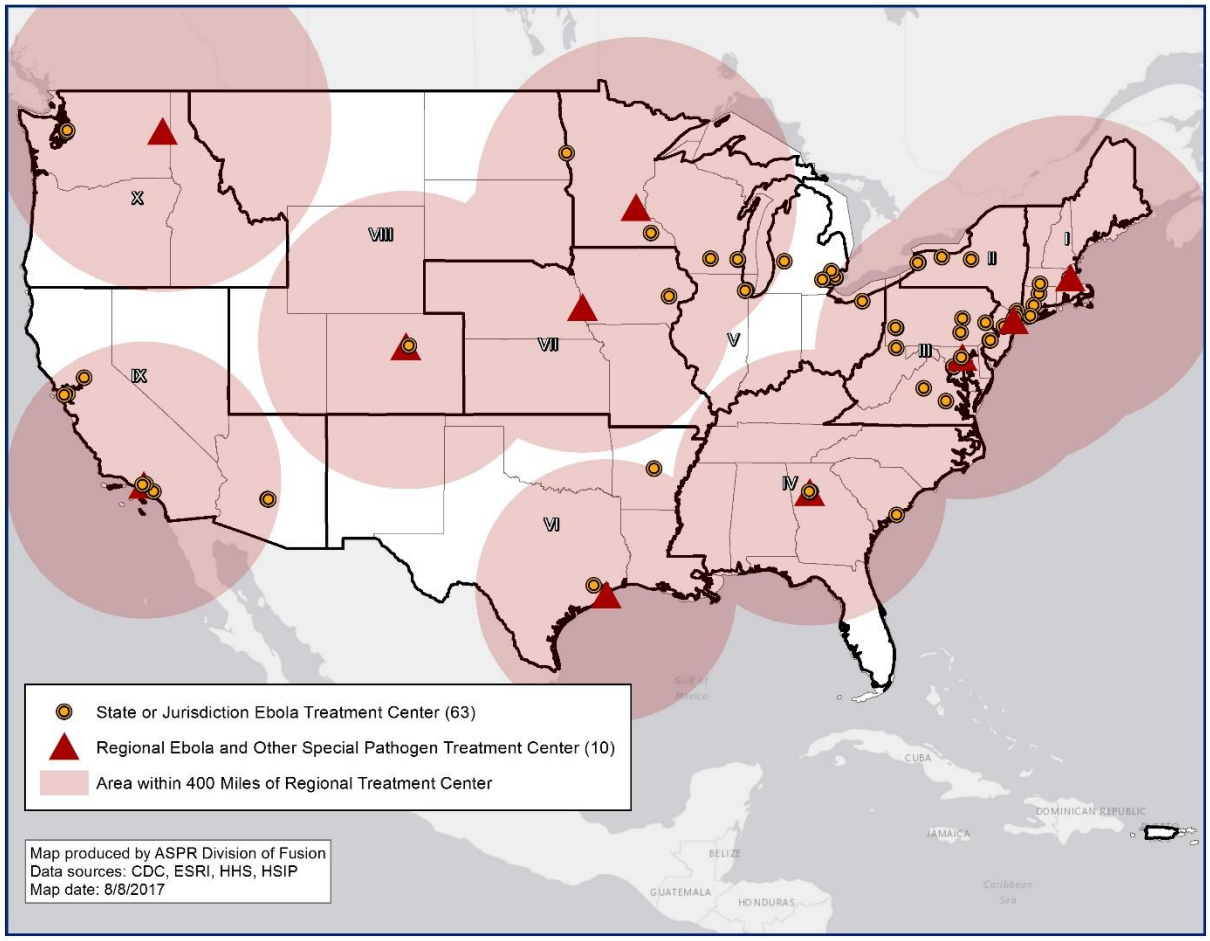
2) State or jurisdiction Ebola treatment centers (63 as of August 2017) that can safely care for patients with Ebola in the event of a cluster of Ebola patients overwhelms the regional Ebola and other special pathogen treatment center.

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.

[7] 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

Figure 4. Regional Ebola Treatment Network



Through HHS investments, the U.S. health care system has achieved marked progress in the development of a regional network of tiered hospitals. HPP's collection and analysis of annual performance and impact data indicate that supplemental Ebola funding provided through the cooperative agreements has been instrumental in enhancing awardees' tactical facility- and system-wide capacity to respond to an Ebola-like threat. HPP's cooperative agreement funding strategy and performance measures for Ebola encouraged a rapid buildup of key response capabilities at each facility tier. HPP requires awardees to engage in operational planning, tactical coordination across states and regions, workforce training, intentional purchase of necessary equipment, and exercises that promote skill-building. From the purchase of personal protective equipment (PPE) by facilities on the frontline to acquiring incinerators to handle contaminated waste at regional Ebola and other special pathogen treatment centers, hospitals at each tier used HPP's year-one funds to purchase equipment and infrastructure required to fulfill their response roles moving forward. Also in the initial funding year, nearly 7,000 rostered staff in the Ebola treatment centers and regional Ebola and other special pathogen treatment center tiers were pre-identified and trained to provide Ebola patient care. Most importantly, the regional treatment network practiced its ability to activate improved response capabilities in each region; 100 percent of regional Ebola and other

special pathogen treatment centers conducted quarterly exercises that incorporated unannounced first-person drills, patient transport, and patient care simulation.[8]

National Ebola Training and Education Center (NETEC)
Additionally, to prepare for, and provide safe and successful care of, patients with Ebola, HHS (in a collaboration between ASPR and CDC) awarded funding to establish a National Ebola Training and Education Center (NETEC). The NETEC provides expertise, training, technical assistance, peer review, monitoring, and recognition to state health departments, regional Ebola and other special pathogen treatment centers, state- and jurisdiction-based Ebola treatment centers, and assessment hospitals. 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.

Since its inception, the NETEC has significantly impacted and improved the overall preparedness and response capabilities for a future Ebola or other special pathogen event. The NETEC has engaged and educated stakeholders through a non-punitive, non-regulatory, and non-accreditation approach that has promoted grassroots relationship-building and fostered ongoing best practice sharing across a diverse range of experts from the public and private sectors. From June 2015 through July 2017, the NETEC has developed metrics to measure facility, and health care worker, readiness to care for patients with Ebola and other special pathogens; trained over 3,000 participants in special-pathogens readiness trainings; created 34 exercise templates for hospitals to maintain capabilities; and completed site visits and readiness assessments at all ten regional Ebola and other special pathogen treatment centers. Through its training and assessment activities, the NETEC identified notable gaps, and made recommendations to guide future educational activities to further enhance preparedness.[9]

Operations Tranquil Shift and Tranquil Terminus
In April 2017, ASPR participated in the Operation Tranquil Shift exercise to test the ability of the nation's health care system to provide safe medical transport to American citizens infected with Ebola while abroad. In this scenario, a cluster of 11 American health care workers were exposed to Ebola in Sierra Leone. During the exercise, the mock patients were transported back to five of the ten HPP-funded regional Ebola and other special pathogen treatment centers using specialized biocontainment units. In late fall/early winter of 2017, Operation Tranquil Terminus tested the domestic air and ground patient movement capabilities of the U.S. health care system by transporting nine patients from assessment hospitals to the regional Ebola and other special pathogen treatment centers. These exercises were funded by the U.S. Department of State, and jointly led by ASPR.

U.S. Quarantine Capacity
Through the domestic Ebola response, HHS found 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 impacted regions. To close this gap, HPP awarded nearly $20,000,000 to University of Nebraska Medical Center/Nebraska Medicine (UNMC) in Omaha, Nebraska for a Training, Simulation, and Quarantine Center. This center provides simulated clinical training to federal responders (the National Disaster Medical System and the U.S. Public Health Service

[8] Region 9 did not have an awardee for its regional Ebola and other special pathogen center during the first budget period of the grant. Cedars-Sinai Medical Center has since been named as the Region 9 Regional Treatment Center.
[9] NETEC Annual Report FY2016
https://netec.org/wp-content/uploads/2017/05/NETEC-Annual-Report-FY-2016_v7_111016-Final.pdf.

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 the start of the new project period that began in FY 2017, SHARPER developed new performance measures (PMs) to align to the core concepts of the health care preparedness and response capabilities and funding opportunity announcements to allow for the opportunity to evaluate program performance and track program progress of HPP awardees. FY 2019 will be the third year in which the 28 PMs (six of which will only apply to select territories and all freely associated states)[10] will be in use, enabling better communication of program results to policymakers, as well as various internal and external stakeholders, and informing continuous program improvement. These measures allow HPP to objectively track trends in engagement, coordination, communication, patient care, and continuous learning. Half of the PMs are exercise-based, which reduces the reporting burden on awardees, improves collection of actionable data, and permits data validation. Awardees report PM data in September of each year (the HPP year runs from July-June), and ASPR will issue results in December for the previous program year.

To measure HPP performance, a variety of measures were developed at the input-, activity-, output-, or outcome-level. While 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 identification of 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.

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;

[10] *2017-2022 Hospital Preparedness Program: Performance Measures Implementation Guidance,* https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hpp-pmi-guidance-2017.pdf.

- 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 5. TRACIE Topic Collection Categories

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 infographic snapshot of TRACIE statistics, as of January 2018, including 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.

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 percent of all acute care visits and about half of all hospital admissions. Further, 82 percent 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 threats to life and limb. Access to health care information creates educated consumers of emergency care, allowing 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.

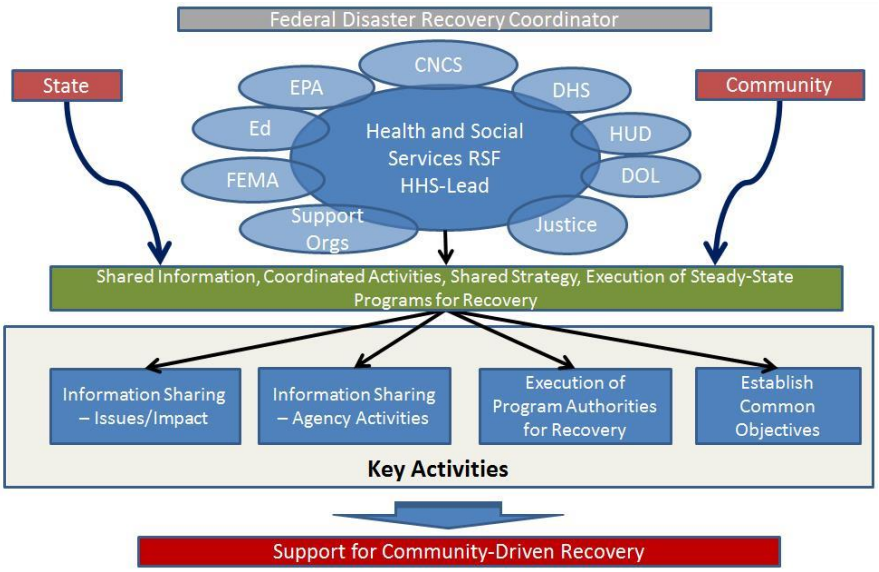
The ECCC also provides a bridge between the private-sector health care delivery system, federal partners focused on health care delivery and quality (such as the Agency for Healthcare Research and Quality, the Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration) 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 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 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.

Figure 7. Coalition Model of Recovery Support Function Leadership



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 has led the coordination and implementation of federal, state, local, tribal, territorial, non-profit, and private sector recovery activities since 2011. The Division's team coordinates and catalyzes action by a wide range of partners to provide practical solutions to fill critical gaps. Some of the recent experiences include tornadoes (e.g. Moore, Oklahoma 2013), flooding (Baton Rouge, Louisiana 2016), hurricanes (Hurricanes Sandy, Matthew, Harvey, Irma, and Maria), and "non-traditional" incidents like the 2012 drought which covered 2/3 of the continental United States and the 2016 Flint Water Crisis. 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 2017, HPP resources supported the development of critical capabilities of health care coalition members to reach to different health care and non-health care entities. In doing so, the Division of Recovery actively engaged with HPP partners, and provided technical assistance to build recovery planning and operational capabilities for constituents nationwide. This approach was facilitated through prior relationships established with representative organizations (e.g. ASTHO, NACCHO, NACHC) in which members of their constituency had the opportunity to provide perspectives and feedback over time.

In addition, the Division of Recovery has leveraged interagency-level planning and exercise initiatives like the National Level Exercise "Gotham Shield" in 2017 to facilitate further planning, capacity building,

and pre-disaster recovery planning among critical HPP partners. These resources and methods have been effective in building recovery capabilities at the state and local levels because they are built on relationships that have developed over years and emphasize local primacy, while leveraging the Division of Recovery's national-level expertise. 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 FY 2016 and FY 2017, the Division of Recovery led the activation of the Health and Social Services Recovery Support Function twice to support recovery from flooding in Louisiana (DR 4263, DR 4277). A key outcome of this engagement led to the partnership with state public health, social services, and education agencies to deliver children and youth planning workshops in the most acutely impacted parishes. This assistance was invited by local officials and, by their account, served as a critical milestone for catalyzing a more collaborative effort to address the complex behavioral health, environmental health, and developmental challenges children and youth experience after major disasters. Recovery staff are currently engaged in the ongoing recovery efforts in communities impacted by Hurricanes Harvey, Irma, and Maria. Staff are deployed to Texas, Florida, Puerto Rico, and the US Virgin Islands. Deployed staff are working closely to state, local, tribal, and territorial officials to mitigate lasting impacts to public and medical health.

Protecting Critical Health Care and Public Health Infrastructure

Under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience, HHS is the Sector-Specific Agency for the healthcare and public health (HPH) sector.[11] Specifically, HHS is the Sector Specific Agency for the Healthcare and Public Health Sector and, therefore, has specific critical infrastructure responsibilities The HHS Critical Infrastructure Protection (CIP) program within ASPR coordinates HHS's role as the Sector-Specific Agency. The health care 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 HPH critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. ASPR's 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 incident response periods.

The HPH 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 and FY 2017, CIP developed a comprehensive 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

[11] HHS also has a role as the Sector-Specific Agency for the HPH sector under Executive Order 13636, Enhancing Critical Infrastructure Cybersecurity; Presidential Executive Order on Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure (May 11, 2017); and Presidential Executive Order on Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States (July 21, 2017).

resource for facilities identified in CMS's Final Rule, "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" who may not historically have been required to implement the risk assessment methodologies set forth in that Final Rule.

In FY 2017, CIP piloted the tool with over ten healthcare coalitions, three multi-state health care systems, and two states. CIP also partnered with the DHS National Protection and Programs Directorate and HPP to assess two regional Ebola Treatment Centers using both DHS general infrastructure survey tools and ASPR's sector-specific risk assessment tool. The Healthcare and Public Health Sector Risk Assessment Tool was released for public use in FY 2018, and efforts will continue to assess its utility, improve the user interface, and tie results to mitigation resources where applicable.

In FY 2017, the HPH Sector continued to be a target for cyber-attacks with two major international cyber incidents affecting Healthcare and Public Health Sector critical infrastructure. In May and June 2017, the WannaCry and Petya ransomware incidents brought the Sector together to respond to the attacks and assess impacts to the Sector's ability to provide continuity of care across the country. Because of the foresight of HHS and HHS/ASPR leadership, the full resources of HHS's ESF 8 response capabilities were brought to bear in the response to the ransomware attacks, in partnership with HHS and DHS cybersecurity leadership. As a result, HHS was able to engage with its private sector partners and provide them with vital guidance for remediation and information on the cyber attacks.

Information-Sharing and Analysis Organizations (ISAOs), are the primary structures promoted by Executive Order 13691 to facilitate private sector cybersecurity information sharing. An ASPR-funded planning grant study showed that small health care facilities are often unable to engage with ISAOs due to high membership costs. To expand on HHS's internal efforts to reach all Healthcare and Public Health Sector partners during a cyber response, in FY 2017, ASPR awarded a cooperative agreement to the National Healthcare Information-Sharing and Analysis Center (NH-ISAC), to assist small and medium sized healthcare organizations in obtaining the useful information security (including cyber security) analysis and awareness products. ASPR will continue to provide support through the cooperative agreement in FY 2018. In FY 2017, CIP and private sector partners participated in the development of the National Cyber Incident Response Plan, as required by PPD-41, "United States Cyber Incident Coordination," and plan to exercise the Plan during participation in CyberStorm VI in FY 2018.

In December 2015, the Cybersecurity Information Sharing Act (CISA) (P. L. 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 the creation of a federal advisory committee, the Healthcare Industry Cybersecurity Task Force, to make recommendations on HPH cybersecurity issues. In FY 2016, CIP established the Task Force, and supported it through the release of the Task Force's report to Congress in June 2017. The Task Force developed recommendations on cybersecurity challenges and barriers in the Sector, and how to achieve near real-time sharing of actionable threat information at no cost to businesses. FY 2018 activities for enhancing cybersecurity will include coordinating the consideration and potential implementation of Task Force recommendations through engagement within HHS and with other Federal, State, local, Tribal, Territorial, and private sector partners. ASPR will also continue working with HHS Office of the Chief Information Officer and external partners 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 respect to Zika. Since Zika is a mosquito-borne disease, which was then without treatment or vaccine products, insect repellent and tools to aid in public health response, such as mosquito traps, became a focus of the program. CIP coordinated across federal departments and agencies to ensure that the most effective traps, which were in short supply, were available for state purchase and not constrained by federal purchasing demands. In FY 2018, 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's Regional Resilience Assessment Program team to assess supply chain challenges for healthcare facilities in New York City and, in FY 2018, will utilize that analysis to support future activities in supply chain management. CIP will also work closely within HHS and with the Interagency Working Group to address, and to implement the goals in, Presidential Executive Order on Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States on July 21, 2017.

Most recently, in response to Hurricane Maria that greatly impacted communities within Puerto Rico, CIP supported monitoring and assessing availability of oxygen supplies to ensure resources were available. Specifically, HHS formed a Medical Oxygen Supply Task Force that included representatives from across the federal government, the government of Puerto Rico, and private sector partners. This Task Force met regularly to discuss the latest information on the medical oxygen supply chain and collaborated to identify solutions to identified barriers.

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 were major goals of CIP's work in FY 2017. In FY 2018, the partnership will perform a review of its 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, and 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	
FY 2015	$254,555,000
FY 2016	$254,555,000
FY 2017	$253,958,000
FY 2018 Annualized CR	$252,826,000
FY 2019 President's Budget	$254,555,000

Budget Request

ASPR requests $254,555,000 for the Hospital Preparedness Program line item, which is $1,729,000 above the FY 2018 Annualized Continuing Resolution. Within the total, $228,500,000 will be provided for HPP cooperative agreements to states, territories and freely-associated states, the District of Columbia, and three high risk political subdivisions. The FY 2019 budget proposal ensures that health care preparedness and response remains a nationwide focus, and that all areas of the U.S. will have a base of preparedness should a disaster strike. The remaining funds support HPP 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), the Division of Recovery, and Critical Infrastructure Protection (CIP) program.

Investments made in health care preparedness since the program's inception in 2002 have led to tremendous progress to help save lives when disaster strikes. This progress is due in large part to the funds made available through HPP, as well as the private sector funds leveraged as a result of that federal investment. Through HPP, ASPR has overseen an investment of nearly $6.0 billion in the preparedness and response efforts of the nation's health care delivery system from 2002-2018.[12] This investment is less than 1 percent of the $2.4 trillion average annual U.S. health care expenditures from 2002-2015.[13] 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.

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 (1) community-level planning for emergencies with the potential to cause a medical surge, (2) HCC and individual health care facility-level exercises, and (3) trainings for health care workers. HCCs have supported communities' health care systems throughout the nation during past response operations. As HCCs mature from the development phase (encompassing the previous HPP project period 2012-2016) into the operationalization phase in the HPP project period that began in 2017, ASPR anticipates that an increased number of health care entities will join HCCs, due to enhanced understanding of how coordinated health care preparedness will work. Indeed, HCCs should include a diverse membership to ensure a successful whole community response. If segments of the community are unprepared or not engaged, there is greater risk that the health care delivery system will be overwhelmed. Scaling HCCs to be more effective in their regions, with a diverse and varied membership, will improve health care emergency response for patients, those injured or who become ill in emergencies that impact the public's health, health care provider and responders, and for the private health care system entities themselves.

In order to deliver the needed change to protect Americans from disasters that affect people's health, ASPR initiated efforts in FY 2018 to enhance health care system planning and response efforts at the state, local, regional, and territorial levels through HPP. For FY 2019, ASPR proposes to continue to build on the innovations and improvements initiated in FY 2018, driving strategic advancements in health care delivery system readiness and leveraging private sector ideas and best practices to enhance government efficiency and accountability.

In FY 2019, HPP will provide funding to all 62 awardees based on its statutory formula, which includes a risk component. ASPR will continue to incorporate FEMA's State Homeland Security Program (SHSP) risk score and a natural hazard risk score in its funding formula distribution – as it has done since FY 2014. The FEMA SHSP is a comprehensive assessment of risk to jurisdictions for security incidents. Further, it also includes a population index, which can help to determine risk for infectious disease outbreaks.

Please see the FY 2019 state-by-state funding table to see a distribution of HPP funds by awardee.

[12] For FY 2018, ASPR includes the Annualized Continuing Resolution funding amount for HPP program cooperative agreements.

[13] 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.

Also in FY 2019, ASPR will continue to utilize the performance measures that were first implemented in FY 2017 to evaluate and analyze HPP funding impact. The 2017 performance measures allow ASPR to objectively track trends in coordination, communication, patient care, and continuous learning and improvement.

Beginning in FY 2018 and continuing in FY 2019, ASPR will re-compete any HPP funding withheld from an awardee that fails to achieve performance benchmarks through its withholding authority and will give preference to alternative entities within the states or jurisdictions where the failures occur to ensure that funding is still focusing on those areas across the U.S. at greatest risk for a medical surge event.

ASPR Hospital Preparedness Program – Outputs and Outcomes Table

Measures[1,2,3]	**Year and Most Recent Result / Target for Recent Result / (Summary of Result)**	**FY 2018 Target**	**FY 2019 Target**	**FY 2019 Target +/-FY 2018 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

1 Due to the 2017 hurricanes, the FY 2017 data for both measures will be reported by June 30, 2018.

2 2017 data will be the final reported for these measures.

3 In the FY 2020 budget, these measures will be replaced with new measures.

NOTE: HPP currently has a five-year project period. Each budget 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 September). As such, HPP performance information provided here follows that timeline.

ASPR Hospital Preparedness Program – Grant Awards by State

(In Dollars)

State, *Locality*, Territory	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
Alabama	$3,316,320	$4,236,351	$4,265,552	+$29,200
Alaska	$951,914	$1,147,899	$1,155,811	+$7,912
American Samoa	$278,422	$250,000	$250,000	-$0
Arizona	$3,930,938	$3,465,573	$3,489,461	+$23,888
Arkansas	$2,002,932	$2,474,149	$2,491,203	+$17,054
California	$23,397,482	$19,503,712	$19,638,148	+$134,435
Chicago	$2,736,056	$1,942,844	$1,956,236	+$13,392
Colorado	$3,119,392	$2,423,109	$2,439,811	+$16,702
Connecticut	$2,330,641	$1,673,124	$1,684,657	+$11,533
Delaware	$1,049,193	$590,676	$594,748	+$4,071
District of Columbia	$944,353	$1,766,028	$1,778,201	+$12,173
Florida	$11,822,752	$12,164,600	$12,248,448	+$83,848
Georgia	$5,973,258	$7,310,626	$7,361,017	+$50,391
Guam	$374,754	$796,422	$801,911	+$5,490
Hawaii	$1,261,124	$1,296,378	$1,305,314	+$8,936
Idaho	$1,247,694	$1,031,416	$1,038,525	+$7,109
Illinois	$8,772,659	$7,608,925	$7,661,372	+$52,447
Indiana	$3,934,926	$4,650,950	$4,683,008	+$32,058
Iowa	$2,130,401	$2,488,485	$2,505,638	+$17,153
Kansas	$2,117,146	$2,231,879	$2,247,263	+$15,384
Kentucky	$2,759,985	$3,840,907	$3,867,381	+$26,475
Los Angeles	$9,263,958	$6,481,544	$6,526,220	+$44,676
Louisiana	$2,895,985	$4,308,280	$4,337,977	+$29,696
Maine	$1,065,567	$1,429,244	$1,439,096	+$9,851
Marshall Islands	$268,005	$250,000	$250,000	+$1
Maryland	$4,864,700	$4,080,410	$4,108,536	+$28,125
Massachusetts	$4,315,709	$3,502,919	$3,527,064	+$24,145
Michigan	$6,157,587	$3,949,993	$3,977,219	+$27,227
Micronesia	$276,806	$250,000	$250,000	+$0
Minnesota	$3,518,356	$2,609,877	$2,627,867	+$17,989
Mississippi	$2,176,032	$2,705,652	$2,724,302	+$18,650
Missouri	$3,676,990	$5,006,934	$5,041,446	+$34,512
Montana	$920,601	$905,382	$911,622	+$6,241
Nebraska	$1,373,309	$1,255,644	$1,264,299	+$8,655
Nevada	$1,911,347	$1,610,213	$1,621,312	+$11,099
New Hampshire	$1,089,878	$728,281	$733,301	+$5,020
New Jersey	$5,633,732	$4,878,644	$4,912,272	+$33,628
New Mexico	$1,527,031	$1,023,136	$1,030,188	+$7,052
New York	$9,639,512	$16,186,035	$16,297,602	+$111,567
New York City	$7,941,327	$13,122,332	$13,212,782	+$90,450
North Carolina	$6,112,501	$7,204,667	$7,254,327	+$49,660
North Dakota	$879,429	$791,017	$796,469	+$5,452
Northern Mariana Islands	$270,356	$250,000	$250,000	+$0

State, *Locality* , Territory	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 +/- FY 2018
Ohio	$7,450,278	$5,892,726	$5,933,344	+$40,617
Oklahoma	$2,602,493	$2,612,154	$2,630,159	+$18,005
Oregon	$2,577,424	$1,952,371	$1,965,828	+$13,457
Palau	$255,373	$250,000	$250,000	+$0
Pennsylvania	$8,093,898	$7,518,804	$7,570,630	+$51,826
Puerto Rico	$2,576,010	$2,733,394	$2,752,235	+$18,841
Rhode Island	$940,547	$614,051	$618,284	+$4,233
South Carolina	$3,117,650	$3,740,558	$3,766,341	+$25,783
South Dakota	$848,108	$1,075,846	$1,083,262	+$7,416
Tennessee	$4,040,788	$3,600,367	$3,625,183	+$24,817
Texas	$16,176,634	$14,838,668	$14,940,948	+$102,280
Utah	$2,271,467	$1,269,364	$1,278,113	+$8,749
Vermont	$780,333	$670,459	$675,080	+$4,621
Virgin Islands (U.S)	$305,611	$646,192	$650,646	+$4,454
Virginia	$6,075,317	$6,637,488	$6,683,239	+$45,751
Washington	$4,279,234	$3,035,010	$3,055,930	+$20,920
West Virginia	$1,405,606	$1,495,036	$1,505,341	+$10,305
Wisconsin	$3,634,631	$2,405,255	$2,421,834	+$16,579
Wyoming	$837,538	$536,000	$536,000	+$2
Total Resources	$228,500,000	$226,948,000	$228,500,000	+$1,552,000

ASPR Hospital Preparedness Program – Summary of Grant Awards

(In Dollars)

Program Name	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Number of Awards	62	62	62
Average Award	$3,685,484	$3,660,452	$3,685,484
Range of Awards	$255,373 - $23,397,484	$250,000 - $19,503,712	$250,000 - $19,638,148

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**510.499**	**508.225**	**511.700**	**+3.475**
Advanced Research and Development (non-add)	*258.499*	*257.936*	*259.700*	*+1.764*
Combating Antibiotic-Resistant Bacteria (non-add)	*192.000*	*190.696*	*192.000*	*+1.304*
Operations and Management (non-add)	*60.000*	*59.593*	*60.000*	*+0.407*
FTE	**155**	**155**	**155**	**--**

Authorizing Legislation:
Authorization ..... Public Health Service Act, Sec. 319L 42 USC 247d–6a, 42 U.S.C. 247d-7e
Authorization Status..... Indefinite
Allocation Method ..... Direct Federal/Intramural, Contracts

Support of the Administration's FY 2019 Research and Development Budget Priorities

On August 17, 2017, the President released a memorandum stating the FY 2019 Administration Research and Development Budget Priorities. The mission of BARDA is to develop and make available medical countermeasures (MCMs) to address some of the most serious threats our nation could face. These include chemical, biological, radiological, and nuclear agents/threats, pandemic influenza, and emerging (or re-emerging) infectious disease threats. BARDA has supported the licensure or approval of 34 different products since 2007 to address these threats. The development and manufacturing and availability of these products has increased American Security, provides jobs for research and development and manufacturing, will save the lives of individuals who may be exposed to the threat agents, will be enhanced by investments in innovative technologies, has been successful due to maximizing interagency coordination with NIH, DoD, FDA, and CDC, has led to establishment of state-of-the-art, domestic, manufacturing facilities, and is developing a future-focused workforce – the last two efforts under the Centers for Innovation and Advanced Development and Manufacturing (CIADMs) and the workforce training program supported under that effort. The funds BARDA is requesting will address and support the Administration's FY 2019 Research and Development Budget Priorities.

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 development and approval. In the biopharmaceutical industry, commercial medical products require 8-15 years to develop and reach licensure or approval by the U.S. Food and Drug Administration (FDA), and the same is true for MCMs. To have such MCMs with which to respond during a public health emergency, the federal government must maintain continuous development efforts over many years. 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, the Public Health Service Act, as amended by the Pandemic and All Hazards Preparedness Act, 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), FDA, and Department of Defense (DoD). Together with the Department of Homeland Security (DHS), Department of Veteran Affairs (VA), and U.S. Department of Agriculture (USDA), 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 2017 PHEMCE Strategy and Implementation Plan.[14] 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 that can be 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 managed inventory systems) to stockpiling in the Strategic National Stockpile (SNS).

Enhancing Public-Private Partnerships to Face Health Threats

To achieve success, BARDA collaborates – mostly through cost-sharing agreements – with academic, non-government organizations, and private sector companies, including both some of the largest names in the biopharmaceutical industry and some of the smallest.[15] In May 2013, BARDA leveraged a procurement tool known as Other Transaction Authority (OTA), provided under the 2006 Pandemic and All-Hazards Preparedness Act (PAHPA), to forge a unique partnership with one of the world's largest pharmaceutical companies, GlaxoSmithKline, for the development of new 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 encountered 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 decision-making process about which medical countermeasure products should proceed through development. BARDA used this type of partnership for a second OTA agreement with AstraZeneca 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 Object 4.6 of the *National Action Plan for Combating Antimicrobial-Resistant Bacteria* ahead of schedule. Pfizer has since acquired the AstraZeneca assets and by working with both companies, the OTA was successfully transferred to Pfizer to continue this important partnership. These partnerships spark broader industry interest in developing new antibiotics to treat antibiotic resistant infections and in 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 formed two

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

additional OTA partnerships with 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. As of December 2017, CARB-X has made awards to 22 different companies. CARB-X is currently investing in seven novel classes of antibiotics, ten non-traditional approaches to treating bacterial infections, and four next-generation antibiotics to overcome known resistance mechanisms. CARB-X has also invested in a rapid point-of-care diagnostic to differentiate between viral and bacterial pneumonia.

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 an outcome of the *2010 HHS Public Health Emergency Medical Countermeasure Review*[16] *(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, are filling gaps in product development and manufacturing realized 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 2019 President's 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 BARDA's 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 this 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

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

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 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 for different indications to address U.S. government (USG) requirements, 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 FY 2016-2017, BARDA continued to expand its network to include specialized capabilities in animal model development, analytical services, and toxicology services, to enhance support and development of MCMs or reagents and assays for regulatory approval or licensure in the U.S.

- *Clinical Studies Network (CSN)*: In 2014, BARDA established the CSN, comprised of five clinical research organizations, 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, and during the 2016 Zika outbreak where the CSN collected clinical samples to aid and accelerate development of Zika diagnostic tests. In FY 2016, the CSN also led the first BARDA-sponsored clinical study, the BRITE study, to evaluate the continued safety and immunogenicity of long-stored vaccine antigen and adjuvant from the National Pre-pandemic Influenza Vaccine Stockpile.

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*[17] to address the growing antibiotic crisis.

BARDA is also developing a portfolio of products to address burn injuries associated with a nuclear detonation. Many of these products also have the potential to address chemical burns and may find additional commercial everyday healthcare uses, such as for treating diabetic foot ulcers. This portfolio of candidate products addresses the continuum of care that is necessary to treat burn injuries, including field care and definitive care. Several of these thermal burn product candidates were acquired for the SNS under Project BioShield in FY 2015. These products include silver impregnated bandages, 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 by the SNS. 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 FYs 2018 - 2019, 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, has 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 27 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. In conjunction with the FDA and industry, BARDA developed new animal models to meet the requirements of this rule as a pathway to approval clarifying the approval or licensure requirements for CBRN MCMs. The FDA approved the following BARDA-supported CBRN MCMs under the Animal Rule: Raxibacumab anthrax antitoxin (2012), HBAT botulinum antitoxin (2013), Anthrasil (AIG) anthrax polyclonal antitoxin (2015), ANTHIM (obiltoxaximab) anthrax antitoxin (2016), Neupogen (2015) to treat hematopoiesis, and BioThrax (2015) for post-exposure prophylaxis in individuals suspected of exposure to anthrax. In FY 2017, the FDA approved an antibiotic candidate to treat severe drug resistant infections. Additional FDA approvals for novel antibiotics, a radiation MCM, a smallpox antiviral, and a smallpox vaccine for at-risk individuals are also projected for approval in FYs 2018–2019.

With these recent FDA approvals, BARDA met and exceeded the HHS goal of four CBRN medical countermeasures licensed by the FDA by the end of 2015. In FY 2017, six new projects were funded under PBS bringing the total number of candidates supported under PBS to 27. In FY 2017, BARDA supported two Ebola vaccine candidates, two Ebola therapeutic candidates, and two biodosimetry devices;

[17] https://www.cdc.gov/drugresistance/federal-engagement-in-ar/national-strategy/index.html

one a point-of-care device and the other a lab-based, high-throughput device. These candidates have been supported under ARD and were considered mature enough to transition to PBS. The development pipeline remains poised to continue this trend, transitioning CBRN products from advanced research and development programs to acquisition under Project BioShield (for the SNS) and towards FDA approval.

Anthrax: In response to the emphasis DHS 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 post-exposure use (Post-Exposure Prophylaxis). Recognizing the need for an anthrax vaccine that is approved for use after exposure and provides potential protection in fewer doses, 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 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 2018 and 2019.

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 DoD. FDA approved this indication in November 2015, making this the fifth CBRN MCM supported under Project BioShield to achieve FDA approval 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's 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 have earned FDA approval: Raxibacumab, ANTHIM (obiltoxaximab), and Anthrasil. 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, a monoclonal antibody based product, was approved in March 2016.

BARDA continues to support late-stage development of ANTHIM 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, in coordination with industry, 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 is superior to 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 SNS 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 all Americans, including special populations, and that a minimum of two therapeutic agents would be available to treat persons exposed to, 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, 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. BARDA is projecting FDA approval of both MVA and ST-246 in FY 2018.

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 2017. 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. BN is finalizing the data to support licensure of the new formulation; when data to support potential use of the vaccine during a declared emergency under an Emergency Use Authorization (EUA) is complete, the product will be incorporated into the SNS formulary. 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 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 (under an emergency use authorization from FDA, and the sponsor submitted their New Drug Application (NDA) to the FDA on December 8, 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 complicates the ability to respond to public health emergencies—in treatment of both primary infections and secondary infections that occur following exposure to an array of CBRN threats. 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[18] (plazomicin) against plague and tularemia, with an aspirational goal of developing a product that would have other important public health uses. Plazomicin 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. Plazomicin 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. Development of MCMs that can be commercialized because they have broader, routine health care uses is a cost-efficient approach to developing MCMs for these biothreats. BARDA is anticipating FDA approval of plazomicin in FY 2018.

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 remaining $50 million was added to a new OTA with Astra Zeneca to support a new portfolio of antimicrobial products. 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 its 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 in 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

[18] An aminoglycoside is a Gram-negative antibacterial therapeutic agent that inhibits protein synthesis.

platforms which are 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 supported many of the candidates that are in late stage development, in Phase 2 and Phase 3 clinical evaluations. Evaluation of the upstream pipeline of antibiotic candidates revealed a dearth of Phase 1 candidates that could potentially transition to BARDA. 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.

As of July 2017, CARB-X has accelerated the efforts of 21 different companies. CARB-X is currently investing in 7 novel classes of antibiotics, 10 non-traditional approaches to treating bacterial infections, and four next generation antibiotics to overcome known mechanisms of resistance. CARB-X has also invested in a rapid point of care diagnostic to differentiate between viral and bacterial pneumonia.

The FY 2019 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*, to meet the overall objectives of CARB and BARDA.

Viral Hemorrhagic Fever: Viral Hemorrhagic Fevers (VHF), such as those 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 or approval, as well as expand the scope of the program to include MCM development to address Ebola-Sudan and Marburg viruses. BARDA transitioned two vaccine candidates and two therapeutic candidates to Project BioShield in FY 2017.

BARDA's 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 such development in concert with them and other partners.

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 Zaire 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, refining 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 from a tobacco-based expression system. Further, in FY 2016, the FDA approved an Expanded Access Protocol for ZMapp, in the U.S. and the three West African countries impacted by the 2014/2015 outbreak. BARDA has worked closely with the company to develop and implement this expanded access protocol, in order 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 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 awarded two contracts under Project BioShield for the late-stage development and procurement of Ebola therapeutics in FY 2017.

In FYs 2018–2019, BARDA is planning on initiating programs to develop MCMs, particularly therapeutics, to address Marburg virus and Ebola-Sudan. These programs will help BARDA develop MCMs for a threat agent for which BARDA currently has 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 transitioned two candidates for late-stage development and potential procurement 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 viruses. 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 the 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 detonation. 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 (FY 2013-current) made by Sanofi-Aventis. These cytokine products are approved to treat neutropenia, a blood disorder 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. The HHS stockpile of Neupogen, Neulasta, and Leukine 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 vendor-managed inventory (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 purchased additional product to restore the level of preparedness and will continue to support these products under PBS in FY 2018. 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 FY 2017, BARDA continued to develop promising candidates for acute radiation syndrome, decorporation agents, and blood products. This 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. One of the key strategies is to invest in repurposing of products that are already FDA approved for other indications. In FY 2017, a contract was awarded to Novartis to evaluate their FDA approved product, Eltrombopag, for potential mitigation of radiation injury. This represents just one example of BARDA's public private partnership model to work with the pharmaceutical industry to repurpose already approved products. For FY 2018 and beyond, BARDA has identified specific pathways (e.g., coagulation) that may play an overarching role in radiation injury. A goal for BARDA's radiation/nuclear program will be to evaluate existing products that modulate the coagulation pathways to determine their capacity to treat or mitigate radiation induced injury.

To address thermal burn injuries resulting 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, such as 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 (StrataGraft), 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 provided 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.

For FYs 2018–2019, the BARDA Thermal Burn program will begin to prioritize products that help address and mitigate the effects of cutaneous radiation injury. This work will complement the previous accomplishments in developing products to transform the continuum of care for burns due to thermal energy. Further, BARDA plans on developing imaging technologies, such as those that utilize forward looking or short-wave infrared light to assess burn depth and severity.

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 transitioned two more candidates to Project BioShield. One is a point of care device and the second is a lab-based, high-throughput device. In FYs 2018–2019, these products will be managed under PBS awards with the goal of supporting FDA clearance for the devices.

Chemical Threats: The lack of antidotes for exposure to chemical threats, which can cause seizures, 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 it in CHEMPACKs as the 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.

Removal of chemical agents is the most effective way to mitigate the short- and long-term effects of exposure to these agents. Thus, decontamination is also an MCM, and BARDA has supported studies to determine the most efficient way to remove chemical agents from the skin of exposed individuals. Data

collected from demonstrations and clinical studies are being used as the foundation for experiments and additional studies needed to develop scientifically supported guidance for best practices in mass-casualty decontamination. An initial guidance was published in 2016 under the Primary Response Incident Scene Management system (PRISM). Additional studies and demonstrations will support the development and publication of additional guidance in the future. Further, expansion of the decontamination program occurred in FY 2015 and informed decontamination procedures under additional operational conditions. In August of 2017, BARDA coordinated with ASPR's Office of Emergency Management and State and Local officials to run a full-scale chemical decontamination exercise in Rhode Island. The exercise was based on the guidance published in PRISM. This type of field exercise provides federal, state and local officials and first responders the opportunity to interact with each other and test and evaluate the guidance in a simulated response environment.

To treat chemical burns, BARDA has sponsored development to repurpose a commercially available burn and wound dressing (Silverlon) since September 2013. If approved, this product would be the first ever 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 use for other types of injury that could be repurposed to treat injuries resulting from chemical agents. Under its advanced research and development program, BARDA anticipates several new programs in FY 2018–2019, 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 is no current MCMs. Alteplase is currently FDA-approved for the treatment of acute ischemic stroke. The mechanism of action is to dissolve blood clots. The same formulation has been shown to be effective at dissolving fibrin casts that develop in the lungs as a result of exposure to sulfur mustard. To date, animal model data appears promising, and BARDA is working towards further developing the product to be ready for late-stage development.

An additional example is BARDA's work with ketamine in mitigating neurological injury due to prolonged seizures from nerve agent exposure. BARDA has demonstrated in rat models that ketamine, when given in conjunction with anti-seizure drugs such as midazolam, can prevent or limit the neurological damage. During FY 2018–2019, BARDA will conduct additional studies to prepare this program for potential transition to Project BioShield.

Driving Product Innovation

In addition to the innovation that serves as the foundation for all 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 innovative 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.[19]

Funding History	
FY 2015	$473,000,000
FY 2016	$511,700,000
FY 2017	$510,499,000
FY 2018 Annualized CR	$508,225,000
FY 2019 President's Budget	$511,700,000

Budget Request

The FY 2019 Request for Advanced Research and Development is $511,700,000, which is +$3,475,000 above the FY 2018 Annualized Continuing Resolution 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 (2017). Specifically, such funding would support investments in new projects in the following programs, in addition to broad spectrum antimicrobials:

1. 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;
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): BARDA supported the licensure of anthrax vaccine absorbed (BioThrax) for post-exposure prophylaxis, in 2015. In addition, BARDA transitioned a next-generation anthrax vaccine to late-stage development and potential acquisition under Project BioShield in FY 2016. Funding provided in FY 2019 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. Additional investments will only be made in vaccines that are transformative in their operational advantages or cost.

Smallpox ($15 million): The National Academy of Medicine has recommended 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 2019 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 broad spectrum antimicrobial program supports the development of products with the potential to be used against biothreat pathogens. The SNS has inexpensive antibiotics in the formulary. However, if resistance emerged, or a resistant organism was used in an incident, there would be a need for novel or improved products. Development

[19] https://www.broadinstitute.org/files/sections/about/PCAST/2010%20pcast-influenza-vaccinology.pdf

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 the detonation of a radiological device, are examples where the resulting patient populations would be more readily susceptible to infections, increasing the possibility of the spread of drug resistant bacteria.

The FY 2019 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 support CARB-X programs that graduate out of CARB-X and can be considered for BARDA ARD support. CARB-X worked to build a portfolio of therapeutics, vaccines, and diagnostics in FY 2017, and to expand the number of companies and technology types with which it is working, 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 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 ($29.7 million): Because 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 were transitioned 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 2019 to continue development of these candidates to address the PHEMCE requirement for MCMs against viral hemorrhagic fever viruses. The current MCMs target Ebola-Zaire. There remains an outstanding requirement to develop MCMs for Ebola-Sudan or Marburg viruses. The FY 2019 funding level will support continued development of one vaccine and one therapeutic candidate as they approach sufficient maturity for potential transition to Project BioShield.

Biodosimetry and Biodiagnostics ($48 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 2019, 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 commercially marketed, or in development, to be repurposed for the additional purpose of treating 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 2019 funds will continue to support existing candidates; non-clinical, clinical, and manufacturing activities to support advancement of candidates for possible transition and support under Project BioShield in FY 2019 or 2020.

Thermal Burns ($25 million): The thermal burn portfolio has progressed significantly, with four candidates transitioning to acquisition under Project BioShield in FY 2015. Additional clinical studies were supported in FY 2017 to potentially expand a label indication to pediatric populations. 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 partial-thickness burn from converting into full-thickness burns. FY 2018 funds will support additional clinical trials for products supported previously under Project BioShield. 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. For FY 2019, the program will begin to prioritize products that help address and mitigate the effects of cutaneous radiation injury. This work will complement the previous accomplishments in developing products to transform the continuum of care for burns due to thermal energy. Further, BARDA plans on developing imaging technologies, such as those that utilize forward looking or short-wave infrared light to assess burn depth and severity.

Chemical ($50 million): BARDA's Chemical MCM program is currently initiating a new strategy that involves addressing the injuries caused by chemical agent exposure and not the agent itself. This strategy will allow BARDA to repurpose candidate drugs that are being used for routine clinical purposes 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 to treat injuries caused by chemical agents. FY 2019 funding will be used to continue development of animal models to support evaluation of candidate products. These funds will help address gaps in preparedness for multiple chemical threats, such as chlorine and vesicating agents, where there remains a need to develop robust and reproducible models of exposure and injury. BARDA anticipates the transition of a chemical MCM to Project BioShield in FY 2018–2019. Further, BARDA will support the development of drugs to prevent nerve agent induced seizures that are refractory to treatment with standard benzodiazepines.

Clinical Services Network and Non-Clinical Studies Network ($12 million): The Clinical Services Network (CSN) will continue the development of clinical protocols for evaluation and testing in FDA regulated trials. These studies will enhance and broaden the current indications of medical countermeasures to create a sustained preparedness posture against CBRN threats. 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.

Biomedical Advanced Research and Development Authority: Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
2.4.13a Increase the number of new licensed medical countermeasures within BARDA (Intermediate Outcome)	FY 2017: 5.0 Target: 3.0 (Target Exceeded)	3.0	3.0	Maintain
2.4.13b Increase the number of new countermeasures eligible for consideration by FDA for Emergency Use Authorization (Intermediate Outcome)	FY 2017: 6.0 Target: 3.0 (Target Exceeded)	2.0	1.0	-1
2.4.14a Increase the technical assistance provided by BARDA to medical countermeasure manufacturers (Intermediate Outcome)	FY 2017: 21.0 Target: 11.0 (Target Exceeded)	11.0	11.0	Maintain

PROJECT BIOSHIELD

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**508.803**	**506.537**	**510.000**	**+3.463**
FTE	--	--	--	--

Authorizing Legislation:
Authorization ..... Public Health Service Act, Sec. 319F- 2(g) 42 U.S.C. 247d-6b(g)
Authorization Status..... Indefinite
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

Disease outbreaks, both naturally occurring, such as 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 with industry, and sustained investments in potential products made possible under Project BioShield (PBS), has led to the support of 27 products that are critical to prepare for, and treat the effects of these threats. Fourteen of these products have been delivered to the Strategic National Stockpile (SNS), with additional products to be delivered in FYs 2018 and 2019. The progress achieved through Project BioShield continues to boost the nation's readiness to respond to the medical consequences of anthrax, botulism, smallpox, radiological and nuclear agents, and chemical threats. As a result, the medical countermeasure development pipeline for CBRN threats holds more promise today than ever before. BARDA, with its proven track record, is uniquely positioned to make innovative progress in the procurement of CBRN MCMs to save lives.

The *Project BioShield Act of 2004* (P.L. 108-276) provided specific authorities and funding through FY 2013 for late-stage development and procurement of CBRN MCMs. The law also provided the FDA with the legal ability 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) further amended 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 during CBRN incidents. To minimize lifecycle costs, BARDA pursues advanced development of product candidates, when possible, that also 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 an Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA). Even after procurement, 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 MCMs 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. BARDA has also invested new Project BioShield (PBS) funding authorized under PAHPRA that is provided annually. Since 2014, BARDA has invested $1.53 billion of the authorized $2.8 billion. The FY 2018 President's Budget includes $510 million for Project BioShield, which will bring the FY 2014–2018 total to $2.04 billion or 73% of the authorized funding.

Developing biopharmaceutical products through FDA approval routinely takes 8 to 15 years. BARDA's expertise and strategic approach led six products from late-stage development to FDA approval in less than 10 years. 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 FYs 2014–2016, BARDA replenished expiring stockpiles of two existing MCMs: anthrax antitoxins for inhalational anthrax and smallpox MVA vaccine for people with weakened or compromised immune systems, such as people living with HIV and cancer patients. This strategy maintained the nation's 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 replenished expiring 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. Two cytokines were also procured and held under vendor managed inventory under existing contracts with Amgen and Sanofi, Neulasta and Leukine, respectively. Neulasta was procured 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.

In the next few years, BARDA expects more companies to seek FDA regulatory approval for CBRN products. In FYs 2018–2019, at least four companies are expected to seek FDA approval of CBRN MCMs funded through Project BioShield and developed under BARDA's ARD programs. In FY 2017, the first BARDA supported antibiotic candidate was approved by the FDA. 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 devices; and, potentially four more new drugs to treat ARS and exposure to chemical agents.

In FY 2017, Congress appropriated $510 million for Project BioShield. That funding level supported acquisition of up to six new MCMs, and replenishment of certain existing MCMs. The new procurements are Ebola vaccines and therapeutics, as well as two new 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 2017 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 product and for quicker conversion to final product when needed. Procurements of the FDA-approved anthrax vaccine, Anthrax Vaccine Absorbed (AVA) were conducted to maintain the stockpile under levels consistent with previous year preparedness posture for anthrax vaccine. Additional lots of bulk drug substance of the smallpox vaccine, Modified Vaccine Ankara (MVA) were also procured. In future years (FY 2019-20), these lots will be converted to a lyophilized formulation, which will possess a substantially longer shelf life than the frozen liquid formulation previously procured, reducing lifecycle management costs. In FY 2017, six new projects were funded under PBS bringing the total number of candidates supported under PBS to 27. In FY 2017, BARDA supported two Ebola Zaire vaccine candidates and two Ebola Zaire therapeutic candidates. The vaccines are being developed to prevent the spread of disease and the therapeutics to treat individuals with disease. Additionally, BARDA supported two biodosimetry devices, one a point of care device and the other a lab-based, high-throughput device. The devices will determine an individual's level of absorbed radiation after a nuclear detonation and provide information for potential treatment.

Options under contracts supporting the continued late-stage development of burn injury care and clinical trials were exercised in FY 2017. One in support of clinical trials targeted to pediatric populations and the other focusing on the definitive care of burn injury and the removal of eschar (debridement) of adults with deep partial and full-thickness thermal burns.

Based on the successful development of CBRN MCMs in BARDA ARD programs, HHS will be prepared to acquire approximately three new CBRN medical countermeasures under Project BioShield by the end of FY 2019. The largest proportion of PBS funding that year will be prioritized for the procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccine, transition of an IV smallpox antiviral for "at risk" individuals, treatment for burn injury, point of care bio-diagnostics for radiation, and treatments to address lung injury from acute exposure to ionizing radiation. Below are potential CBRN MCM candidates that may be mature enough for consideration for purchase under Project BioShield in FYs 2018–2019.

- 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 2018 and FY 2019.
- In FY 2016, BARDA supported the late-stage development and procurement of a next-generation anthrax vaccine that will lower the number of doses required to elicit potential protective immunity. This will decrease the overall lifecycle 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 2019).
- MCMs that can mitigate or reverse the neurological injury that occurs from nerve agent-induced seizures that are refractory to currently stockpiled treatments (FY 2019).
- Additional procurements of an intravenous formulation of a smallpox antiviral drug. This formulation would be used to treat those who were severely ill and pediatric populations unable to swallow medication. Further, procurements of the oral formulation of this antiviral drug will be required to maintain preparedness (FY 2019).
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biological

threats (FY 2019).

- Product(s) capable of temporizing burn injury from radiation or thermal energy. Such products halt the progression of burn injury and complement other burn products that were supported under Project BioShield (FY 2019).
- A medical countermeasure that is capable of reversing the neutropenia and thrombocytopenia that occur from exposure to acute ionizing radiation. These MCMs would be capable of treating patients whose injury was refractory to treatment with the cytokine therapies BARDA previous procured under Project BioShield (FY 2019).

Funding History	
FY 2015	$255,000,000
FY 2016	$510,000,000
FY 2017	$508,803,000
FY 2018 Annualized CR	$506,537,000
FY 2019 President's Budget	$510,000,000

Budget Request

The FY 2019 Request for Project BioShield is $510,000,000 which is +$3,463,000 above the FY 2018 Annualized Continuing Resolution level. This funding level will support continued development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines, and new procurements of new antibacterial drugs, chemical agent medical countermeasures, a new product to temporize burn injury, and a new radiation medical countermeasure. It will also support new intravenous formulations of currently stockpiled smallpox antiviral drugs for use in special populations or in 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; 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 eight procurements which reflect the highest priority countermeasures for FY 2019, would 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 ($150 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 2019 is needed to continue procurement for those products. The Project BioShield funding in FY 2017 provided for the initial procurement and the funding in FY 2018 and 2019 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 ($150 million, 3-4 million vaccine doses).** In FY 2019, Project BioShield funds will continue procurement of a next

generation anthrax vaccine that elicits protective immunity in two doses instead of three compared with the current licensed AVA vaccine to replace the currently stockpiled anthrax vaccine. This funding is critical to the maintenance of the federal government's preparedness posture against anthrax.

4. **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.
5. **Late-stage development and procurement of an intravenous formulation of a smallpox antiviral drug ($35 million, 150,000 treatment courses).** In FY 2011, a Project BioShield contract was awarded 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.
6. **Thermal Burn product, temporizing matrix ($5 million, 5,000 units)**. 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. Funding in FY 2019 will support existing candidates and clinical studies currently underway.
7. **Smallpox Vaccine, conversion to lyophilized formulation ($50 million, 2 million doses).** In FY 2017, BARDA procured bulk drug substance lots of the IMVAUME smallpox vaccine. In FY 2019, BARDA expects to convert that product to a lyophilized formulation that will possess greater stability and a longer shelf life. This will allow the overall life cycle costs of the vaccine to be reduced. A Phase III clinical trial to demonstrate lot-to-lot consistency between the lyophilized formulation and the liquid frozen formulation will be required.
8. **Therapy for acute ionizing radiation exposure ($35 million, 3,000 treatment courses)**. In addition to neutropenia, exposure to acute ionizing radiation can induce thrombocytopenia. Further, some patients who experience neutropenia and thrombocytopenia may be refractory to treatment with cytokines (Neupogen, Neulasta, and Leukine) that were previously procured under Project BioShield. Cellular therapies or other candidate products have the potential to treat those individuals who are refractory to treatment with the cytokine products.

Project BioShield: Key Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
2.4.14b Continue ongoing transition of medical countermeasures into Project BioShield (Intermediate Outcome)	FY 2017: 6 Target: Set Baseline (Baseline Set)	3.0	3.0	Maintain

STRATEGIC NATIONAL STOCKPILE

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final /1	**Annualized CR** /1	**President's Budget**	**+/- FY 2018 Annualized CR**
Budget Authority	**573.653**	**571.095**	**575.000**	**+3.905**
FTE	**--**	**--**	**220**	**+220**

1/ Reflects funding levels within CDC.

Authorizing Legislation:
Authorization .....Public Health Service Act, Sec. 319F- 2(a) 42 U.S.C. 247d-6b(a)
Authorization Status.....Indefinite
Allocation Method ..... Direct Federal/Intramural, Contracts

In FY 2019, the Strategic National Stockpile (SNS) will be transferred to ASPR. Putting the SNS under ASPR will increase operational effectiveness and efficiencies, and strengthen integration with ASPR's existing medical countermeasures (MCM) program, which will streamline MCM development and medical response capabilities. In sum, the move is designed to improve the Nation's domestic preparedness posture by optimizing MCM development, response, and utilization, while also strengthening response capabilities with respect to health security threats. These investments will lead to better outcomes for the National Health Security Strategy, National Biodefense Strategy, and the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)[20].

The Strategic National Stockpile manages and delivers life-saving MCMs[21] during a public health emergency. It is the largest federally owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations (FMS),[22] and medical equipment available for rapid delivery to support federal, state, and local response to health security threats. If a biological, chemical, radiological, or nuclear event occurred on United States soil today, the SNS is the only federal resource readily available to respond once state and local MCM supplies are depleted. Transferring the SNS to ASPR will lead to a more predictable, streamlined process, and ensure better integration across the enterprise.

The SNS is capable of rapidly delivering material and support to the site of any anticipated response, and has regularly demonstrated that ability. Stockpiled products are configured for efficient use in likely scenarios, including the challenging delivery of products to Puerto Rico in the aftermath of Hurricane Maria. Federal Medical Stations held in the SNS have proven to be a flexible and effective capability to rapidly augment state and local capacity to receive and care for individuals requiring medical care. These FMSs have been routinely deployed and utilized for natural disaster responses since their first use in the Hurricane Katrina response.

Further, the SNS trains and deploys teams of responders to support state and local partners in receiving, distributing and using SNS MCMs. These response teams include logistics specialists to help set up and run warehouse operations, strike teams to support the establishment and opening of FMS sites, and

[20]http://www.phe.gov/Preparedness/mcm/phemce/Pages/default.
[21]http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm
[22]http://blogs.cdc.gov/cdcworksforyou24-7/2012/11/up-and-running-in-48-hours-how-federal-medical-stations-help-people-after-natural-disasters-like-hurricane-sandy/

liaisons to coordinate requirements and delivery of support. The SNS is staffed with personnel who can deploy to austere environments and work to immediately establish warehousing and distribution capability outside anticipated requirements. The integrated work of the staff and knowledge of capability then allows deployed staff to assist and advise public health and medical professionals on quality control of products during an event. The sum of these response capabilities ensures that the SNS has the flexibility and capacity to respond to any mission assigned, and sustainment of these capabilities is critical to the continued success of ASPR to provide for MCM requirements in any public health emergency.

Transportation is critical to timely delivery of MCMs, so the SNS maintains contracts with commercial transportation partners that possess the resources and capabilities to meet the most difficult delivery timelines. SNS transportation capabilities are routinely tested through no-notice, live deployment drills with participating contractors, which have proven their effectiveness during real world deployments. SNS transportation is readily equipped to maintain safety and efficacy in austere environments, ensuring products remain stable for administration. Effective transportation is not limited to SNS products, as the SNS medical logistics capability incorporates all aspects of emergent acquisitions and material movement for unanticipated requirements for medical products not normally held in stock. SNS further has the ability to receive material, both pharmaceutical and non-pharmaceutical products, at any SNS location to be packaged or kitted rapidly to address unique response requirements.

Direct integration of ASPR and SNS capabilities and experience to manage, hold, and distribute a variety of pharmaceuticals, medical devices and other relevant materials will allow for improved capability to respond to all hazards.

Funding History	
FY 2015	$534,343,000
FY 2016	$575,000,000
FY 2017	$573,653,000
FY 2018 Annualized CR	$571,095,000
FY 2019 President's Budget	$575,000,000

Budget Request

The FY 2019 request of $575,000,000 for the Strategic National Stockpile is +$3,905,000 above the FY 2018 Annualized Continuing Resolution level. At this level, and based on the assumption that anthrax vaccine in FY 2019 will be purchased for the Strategic National Stockpile using Project BioShield funds, ASPR will replace all expiring SNS countermeasures in FY 2019, but will not be able to purchase the products required to close all identified and prioritized gaps in SNS holdings. Product procurement in FY 2019 will be guided by recommendations from the 2016 SNS Annual Review Report. ASPR will coordinate with the PHEMCE to develop strategies to meet the national priorities for federal stockpiling and to maintain SNS capabilities and address inventory gaps with available funding.

Strategic procurement and stockpiling of MCMs are necessary to protect Americans' health and save lives. Medical countermeasures are FDA regulated products (biologics, drugs, and devices) that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats or emerging infectious diseases. Some MCMs are not commercially available because of small supplies and limited use. Additionally, United States pharmaceutical supply chains run on a just-in-time model, often containing no more than a 30-day supply of pharmaceuticals under normal conditions. As a result, commercially available products may not exist in necessary quantities or be positioned in ways that allow rapid distribution and use during public health emergencies. For some threats, such as anthrax and botulism, the SNS holds the primary supply of scarce

MCMs necessary for effective treatment. The rapid delivery of MCMs from SNS in support of small scale exposures to these threats provides local clinicians with the resources required to provide potentially lifesaving care to their patients and tests our ability to implement response capabilities for large scale public health emergencies.

PHEMCE establishes requirements for products that go into the SNS. PHEMCE is responsible for defining and prioritizing requirements for public health emergency MCMs, as well as establishing deployment and use strategies for SNS products. Through interagency collaboration and participation in PHEMCE, ASPR will align SNS holdings and procurement plans with the recommended PHEMCE strategy. When requirements change (including because of the addition of new MCMs) or the commercial pricing or availability changes significantly for required MCMs, ASPR will prioritize and adjust the contents of the SNS based on current threats and funding.

Projections for FY 2019 include assumptions that anthrax vaccine procurement for the SNS will be transferred to Project BioShield funded acquisition under an ongoing advanced development contract. Resulting requirements based on this assumption indicate all SNS-held products projected to expire during the fiscal year will be replaced, and quantities of some anthrax and pandemic influenza countermeasures projected to expire without replacement in FY 2018 will be replenished. Through the 2016 SNS Annual Review, PHEMCE also recommended priorities for procurement to add or increase SNS holdings of specific products if funding is available, including several products for use in pandemic influenza response.

ASPR ensures SNS assets are available and ready for use by:

- Procuring, storing, maintaining, and replacing MCM assets, valued at nearly $7 billion.
- Supporting PHEMCE with subject matter expertise and data to inform strategic MCM requirements and procurement decisions.
- Providing guidance, training, exercise support, and assistance to state and local partners who will receive and distribute MCMs in an emergency response.
- Establishing and strengthening public-private partnerships to integrate private resources into public health response plans for a fully functioning supply chain for delivery of critical MCMs.
- Providing timely, accurate, and relevant information to clinicians to respond to emerging threats and public health emergencies.

ASPR's robust medical logistics capability can move medical personnel, equipment and supplies across the nation within hours. ASPR will provide training and exercise support in FY 2019 to sustain state and local capabilities critical to the effective distribution and dispensing of stockpiled MCMs to ensure access for individuals exposed to public health threats.

SNS Projected Allocations

	FY 2018 Annualized CR Level		FY 2019 President's Budget	
	Projected Level	**Percentage of Total Appropriation**	**Requested**	**Percentage of Total Appropriation**
Total	$571.0M	100%	$575M	100%
Product				
Procurement Costs	$354.7M	86.7%[1]	$354.7M	86.7%[1]
Sustainment Costs	$143.7M		$143.7M	
Operations				
SNS Operational Costs	$72.6M	13.3%[2]	$76.6M	13.3%[2]

[1] This amount supports procurement, management, and maintenance costs to sustain the $7 billion inventory of SNS assets, including storage, transportation, and disposal.

[2] This amount supports ASPR work to develop and provide guidance, training, security, and other resources required for effective use of SNS held MCMs at the federal, state, and local level during an emergency.

OFFICE OF POLICY AND PLANNING

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**14.843**	**14.776**	**14.849**	**+0.073**
FTE	**66**	**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) performs several Congressionally designated duties and functions on behalf of the ASPR: leads HHS's emergency preparedness and response strategic direction and policy coordination; ensures a coordinated strategy for medical countermeasures; and leads international initiatives and coordination (42 USC 300hh-10). OPP also develops policies that guide the operational functions of other ASPR programs, including the Office of Emergency Management (OEM) and the Biomedical Advanced Research and Development Authority (BARDA); leads Federal policy coordination for public health and healthcare preparedness and response; and works to integrate these policies into state, local, tribal, and territorial (SLTT) governments, the private sector, academia, and international preparedness and response plans. The budget justification below describes OPP's critical activities to enhance the health security of the American people and demonstrates its leadership in four primary areas: strategic planning, policy development, research and evaluation, and leveraging partnerships.

Strategic Planning

OPP leads strategic planning efforts for public health and healthcare emergency preparedness, response, and recovery. The *National Health Security Strategy* (NHSS), *NHSS Implementation Plan*, and *Public Health Emergency Medical Countermeasure Enterprise Strategy and Implementation Plan* (PHEMCE SIP) are examples of Congressionally required, nationally recognized activities that set the strategic direction for diverse public health and healthcare stakeholders who must effectively collaborate to prepare for, and respond to, the public health and healthcare impacts associated with disasters and other emergencies. OPP also coordinates ASPR's engagement in the HHS strategic planning process to meet OMB's requirement for a Departmental strategic plan and performance measures. Each of these strategic documents will be delivered to Congress and published in FY 2018. In 2017, ASPR developed an initial draft for the 2019-2022 National Health Security Strategy, which incorporates greater emphasis on new threats to national health security.

The NHSS is the Nation's comprehensive strategy for protecting people's health during public health and healthcare emergencies and disasters. It integrates the national security, homeland security, and health security sectors. Through strategy development and policy leadership, OPP builds health resilience and enhances the public health and healthcare infrastructure needed to prevent, withstand, and recover from, threats and hazards faced by communities across the nation. OPP informs and provides guidance on

planning efforts across Federal, state, local, tribal, and territorial (SLTT) government, non-governmental, private sector and international stakeholders toward the development and implementation of a unified approach to assist HHS and its stakeholders in prioritizing critical actions for protecting health security. For example, during 2017, OPP:

- Informed and supported ASPR's National Disaster Medical System (NDMS) to help develop and revise essential doctrine for mobilizing medical responders, evidence-based medical suitability standards and protocols, team communications protocols, as well as screen for medical suitability.
- Collaborated with the Pan American Health Organization to finalize and publish a standardized toolkit to facilitate training about global International Health Regulations (IHR) National Focal Points in order to increase communication and coordination of international heath event notifications in the United States.
- Highlighted the need for multi-sectoral coordination in public health preparedness and response by developing a World Bank exercise for Ministers of Finance and collaborating with the World Bank and the World Economic Forum on a pandemic exercise for world leaders during the 2017 Davos meeting.

OPP leads the PHEMCE, which 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 capability to prioritize, develop, and deploy medical countermeasures (MCMs). The PHEMCE comprises several 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 the Departments of Homeland Security (DHS), Defense (DOD), Veterans Affairs (VA), and the Department of Agriculture (USDA). Within ASPR, OPP leads the annual review and development of the PHEMCE SIP, as required by Congress, to inform decision making about basic and advanced research, MCM development and acquisition, stockpiling, and the requisite policies needed for effective distribution, dispensing and administration of MCMs during public health emergencies and disasters. For example, OPP:

- Led interagency development of the annual PHEMCE Strategy and Implementation Plan (SIP) and fulfilled requirements established under the Pandemic and All-Hazards Preparedness Reauthorization Act. The 2017-2018 PHEMCE SIP was published during December 2017.
- Developed operational frameworks with international and domestic partners to deploy MCM and share biological material during a national or international public health emergency. Specific examples include a framework to deploy smallpox vaccine from the World Health Organization's emergency stockpile and an international toolkit to facilitate regulatory requirements for rapidly sharing biological samples.

OPP contributes its significant strategic planning skills as well as preparedness and response expertise to relevant planning initiatives. OPP collaborated with the Office of the Assistant Secretary for Planning and Evaluation to develop the *HHS Strategic Plan, FY 2018-2022*. The *HHS Strategic Plan, FY 2018-2022*, will include an objective that is focused on public health and healthcare preparedness and response, and associated performance measures. OPP also collaborates with the National Security Council, other HHS agencies, and other United States government departments in order to develop the congressionally required biodefense strategy and implementation plan. OPP:

- Coordinated input from HHS agencies and represented HHS in the policy development process of the National Biodefense Strategy.

- In partnership with the Centers for Medicare & Medicaid Services (CMS), provided de-identified and limited individual data to the States of Texas and Florida, as well as well as Puerto Rico and the United States Virgin Island territories, from the HHS emPOWER program in order to enhance the situational awareness of, planning for, and response to, the needs of 823,517 Medicare beneficiaries impacted by the 2017 Hurricanes who relied upon electricity-dependent medical and assistive equipment, including oxygen tanks, dialysis and home health care services. In partnership with Urban Search and Rescue Teams, ASPR also used data from emPOWER and other CMS sources to rapidly identify, locate, and conduct life-saving evacuations for 250 U.S. Virgin Island dialysis dependent individuals, in order to ensure continuity of care due to destruction of United Stated Virgin Island infrastructure.

Policy Development

Building on the national strategies outlined above, OPP leads the development of policy that directly impacts national public health and healthcare preparedness and response capabilities, and ensures the nation is prepared to effectively respond to, and recover from, the public health and healthcare associated impacts of disasters and other emergencies. Examples of critical OPP policy development and coordination projects for FY 2019 include:

- Perform high quality policy analyses to inform implementation of new and revised requirements resulting from the reauthorization and appropriations processes.
- Perform policy analyses on Executive Orders and Presidential Directives as they are issued.
- Set MCM requirements for biologic agents (e.g., anthracis bacillus), radiologic and nuclear agents, and influenza pandemics. These requirements will identify the number and characteristics of needed MCMs by evaluating updated threat information, current technology, and end-user capabilities of the public health, healthcare, and emergency management sectors. These requirements align HHS investments for research and development, acquisition, stockpiling, and deployment of MCMs based on sound scientific, medical, and policy principles.
- Lead the coordination of Emergency Use Authorization (EUA) policy to determine how MCMs may be used in certain emergency situations when such use would traditionally not be allowable, as well as provide guidance to the HHS Secretary on the declaration and determination of such EUAs. As an example, in 2017, OPP coordinated HHS Secretarial, CDC, and FDA EUA activities that secured the manufacturing, procurement, and stockpiling of non-FDA approved nerve agent MCMs.
- Provide liability protections to strengthen incentives for the entire MCM enterprise, including private sector industry and first responders. OPP supports issuance of Public Readiness and Emergency Preparedness (PREP) Act declarations to provide liability protection for MCM developers, manufacturers, and responders. Recently, OPP led policy coordination for PREP Act declarations associated with Zika virus and Ebola virus vaccines and therapeutics.
- Ensure 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 initiatives across HHS: (1) a framework for CDC, NIH and the FDA to standardize biosafety in HHS laboratories; (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 initiative that includes the development of a portal for scientists, laboratory staff, policy makers, and the public to locate Federal and non-Federal resources on biorisk management.

- Increase health care system preparedness, and enhance day-to-day emergency and trauma care, to serve as the foundation for response to disasters and other emergencies. OPP leads policy development 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 through the Emergency Care Coordination Center. Since the publication of the "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" Rule (CMS-3178-F), OPP and CMS have helped advance and inform implementation of the national emergency preparedness requirements for health care providers and suppliers.
- Optimize health outcomes by enhancing both health care and human services delivery during disasters and other emergencies. OPP monitors emerging issues and identifies promising practices across HHS-funded programs to address those issues. OPP leads working groups to address the needs of children, pregnant women, and people with disabilities, and behavioral health issues during disasters. In 2017, OPP led the development of the most recent Report of the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group: Update on Department Activities that details progress in integrating the needs of children and pregnant women across public health and healthcare preparedness, response, and recovery activities.
- Lead an initiative to bring public- and private-sector healthcare partners together to identify incentives for the healthcare system to manage acute injury and illness during mass casualty disasters and other emergencies.
- Lead U.S. domestic partners to coordinate the assessment of potential public health emergencies of international concern (PHEIC) which the International Health Regulations (IHRs), to which the United States has acceded, require be reported to the World Health Organization (WHO).

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 projects for FY 2019 include:

- Conduct the Strategic National Stockpile (SNS) Annual Review to determine appropriate MCM acquisition levels, and guide future SNS procurements within projected budget constraints. ASPR and CDC co-lead the annual review of essential drugs and medical supplies held in the SNS, assessing progress toward achieving our stockpiling goals. A recent OPP-led MCM preparedness assessment that informed the SNS Annual Review resulted in the reallocation of $64 million in MCM intravenous assets to better position the SNS to save lives during disasters and other emergencies.
- Evaluate and report to Congress, in the required Evaluation of Progress (EOP), the progress of several programs that address the NHSS's strategic objectives. The EOP also informs the subsequent NHSS and implementation plan.
- Lead the development of integrated capabilities documents (ICDs)—a component of the requirements framework—that provide information on operational capacities and abilities of, and limitations and constraints to using, MCMs in varying routes of administration for different threat scenarios during an incident response. ICDs help translate the estimates of need (staff, space, supplies, and systems) into stockpiling recommendations for MCMs, and are vital to well-informed

decisions on acquisition strategies for the SNS to: maximize lives saved during a response, judiciously use public funds, and provide adequate coverage for many potential threats.

- Lead research and evaluation projects before, during, and after disasters and other emergencies to inform policies and operations that improve public health and healthcare outcomes. Recent incidents (e.g., Flint Michigan water contamination, Ebola virus disease outbreak) demonstrated the need for timely scientific research. OPP administered supplemental funds for research grants after Superstorm Sandy. The results yielded by the grants have led to greater understanding about how to improve community, state, and regional recovery following such a disaster; and tangible trainings, decision support tools, and data sharing agreements.

Outcomes of recent research, evaluation, and improvement planning activities led by OPP include:

- Successfully concluding the Hurricane Sandy Recovery Science Grants program during FY 2017, which generated an evidence base of scientific information, including 29 publications from ASPR grants, and 30 additional publications from ASPR's partners in the Center of Disease Control (CDC) and National Institutes of Health (NIH). Following the program's completion, OPP worked with the National Academies of Sciences, Engineering, and Medicine to convene researchers, operational decision-makers, including those at the local, state, and Federal levels, and policy experts in order to ensure that research findings were disseminated and incorporated as widely as possible. These actions benefitted the 2017 hurricane response in several ways by, for example:
    - Identified and shared lessons learned on at-risk patients. Researchers, operational decision-makers, and policy experts analyzed findings from the Hurricane Sandy Recovery Science Grants in FY 2017 to understand their operational implications. The findings helped to identify patients who sought treatment for opioid use disorder as an at-risk population that is underserved during disaster situations. Through strong partnership with SAMHSA, the state of Texas, and the Opioid Treatment Authority, this evidence was applied in advance of Hurricane Harvey to improve policies and procedures.
    - Working with academic and Federal partners. Through this work, ASPR used satellite remote sensing to accurately determine flood levels and power outages in real-time during the 2017 hurricanes in Texas, Florida, and Puerto Rico. The information was then used to guide operational decision-making during hurricane responses and recovery operations.
- Drafting the National Health Security Strategy's Evaluation of Progress (EOP); a report which incorporates assessments of ASPR's Hospital Preparedness Program, CDC's Public Health Emergency Preparedness (PHEP) program, NDMS, BARDA's MCM Strategic Plan, and Pandemic Influenza Tracking. The EOP highlights improvements and remaining gaps based on an analysis of the National Health Security landscape and measurement indices.
- Launching a health care system monitoring pilot to assess access, utilization, and adverse outcomes for Medicare beneficiaries during the 2017 hurricanes. In addition, OPP identified mitigation, response, and recovery activities to advance health system and at-risk population resiliency in response.
- Completing a progress report indicating that 17 of the 32 corrective actions in the Ebola Response Improvement Plan (for HHS-wide improvement) are complete or nearing completion with other corrective actions in progress.
- Completing efforts to implement sample sharing protocols, which allowed the U.S. to obtain a sample from the China H7N9 outbreak in order to begin developing the candidate vaccine viruses needed for the manufacturing of a U.S. pre-pandemic vaccine.

- Establishing a national inventory of trauma, emergency, and burn care capabilities with locations that encompasses more than 4,900 U.S. hospitals and emergency services, more than 1,900 trauma centers, more than 170 American Burn Association verified burn centers, and more than 118 Veterans Health Administration facilities to ensure effective care of patients both day-to-day and following emergencies.
- Collaborating with Global Health Security Initiative (GHSI) partners (G7 countries, Mexico, the European Commission, and the World Health Organization) to finalize an international GHSI framework for the sharing of laboratory samples of non-influenza pathogens during public health emergencies.

Leverage Partnerships

The results of OPP's strategic planning, policy development, and evaluation functions provide partners with a strong foundation for effective responses to disasters and other emergencies. OPP leads and convenes Federal, private sector industry, healthcare, non-governmental, and international agencies and organizations to ensure support for public health and healthcare preparedness, response, and recovery activities; and leverages public and private resources. Examples of planned OPP-led efforts used to engage partners and leverage resources during FY 2019 are:

- Coordinate HHS-wide decision making during public health emergencies and disasters by convening the Disaster Leadership Group (DLG) to provide situational awareness updates, and inform and advise the HHS Secretary on policy issues. The DLG comprises senior leaders and subject matter experts from across HHS. Recently, the DLG was convened for: pre-pandemic planning for H7N9 influenza, should it reach the U.S., due to the evolving epidemiology of the virus in China and the lack of a vaccine; and the Zika response during the 2017 mosquito season.
- Enhance response partners' abilities to save lives by providing near real-time data and mapping products of at-risk populations that may be adversely impacted by a public health emergency or disaster through its HHS emPOWER initiative. The HHS emPOWER initiative—a partnership with CMS and OEM—provides three national capabilities: (1) a de-identified public map, (2) de-identified emergency planning datasets, and (3) a restricted dataset that a public health official can request to conduct outreach during an emergency. More than 45,000 organizations (e.g., healthcare, first responder, utility) have used these tools to advance their ability to anticipate, plan for, and respond to, the needs, during an emergency, of more than 3.8 million at-risk individuals that live independently but rely upon life-saving electricity-dependent medical equipment such as ventilators, electric wheelchairs, and home dialysis.
- Ensure that patients have access to vital prescription medication before, during, and after public health emergencies and disasters through ASPR's Prescription Medication Preparedness Initiative (PMPI)—a public-private partnership with pharmacies. During the 2017 hurricane responses, ASPR leveraged partnerships with pharmacy sector partners under the Prescription Medical Preparedness Initiative (PMPI) in order to rapidly gather evidence and situational awareness. This activity informed policy decisions, including emergency prescription of controlled substances, allocation of deployable pharmacy assets, identification and amelioration of supply chain deficiencies, and implementation of emergency prescription authorities.
- Provide strategic advice and recommendations to the HHS Secretary by coordinating, managing, and operating two Federal Advisory Committees. The 13-member National Preparedness and Response Science Board (NPRSB) and the 15-member National Advisory Committee for Children and Disasters (NACCD) assemble nationally renowned experts to advise the Secretary and the ASPR. The boards provide a public forum in which partners and the public can voice their concerns

and provide input. The NPRSB and NACCD held seven public meetings during 2017. They issued a joint report in early 2017 with strategies and objectives for engaging youth in emergency preparedness and response leadership. The NPRSB separately issued a report about Human Services and a report about Youth leadership. It also held two joint meetings with the National Advisory Committee on Children and Disasters, and voted on two task letters.

- Ensure that the needs of at-risk individuals are met during public health emergencies and disasters by disseminating best practices and providing guidance to state and local health officials. Guidance includes 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 resilience. OPP conducted a meeting on the Behavioral Health Response to Mass Violence Events, incorporating an array of interagency partners that engage in behavioral health support following events, such as mass shootings, to promote a coordinated Federal response. In partnership with CMS and the Office of the National Coordinator, ASPR's Office of Policy and Planning also launched the "emPOWERing State Medicaid and Child Health Insurance Plan (CHIP) Data Pilot" to assist States in developing complimentary Medicaid and CHIP datasets that can inform and support state, local, and community-based preparedness, response, and recovery activities for electricity and health care service dependent at-risk populations.
- Revise the Emergency Medical Services (EMS) Agenda in collaboration with the National Highway Traffic Safety Administration to anticipate the evolution of EMS services over the next 15 years.
- OPP will lead alignment with the WHO Health Emergency Program and will lead strategic partnerships with other nations, intergovernmental organizations, and public and private stakeholders to promote efforts to strengthen preparedness and response capacities for disasters and other emergencies with a domestic/international interface. One such partnership is the Global Health Security Initiative (GHSI) (involving several countries and international organizations) to prepare for CBRN threats and diseases with pandemic potential. OPP will also lead HHS's implementation of the North American Plan for Animal and Pandemic Influenza. OPP will continue to develop, exercise, and implement domestic and multilateral frameworks for international response coordination, emergency communication, and the rapid cross-border mobilization of MCMs, health care personnel, and biological specimens.

In order to promote and leverage partnerships throughout FY 2017, ASPR's Office of Policy and Planning:

- Hosted two regional workshops, a non-Federal open listening sessions, and presented at the 2017 National Association of City and County Health Officials (NACCHO) Preparedness Summit to share information about National Health Security Strategy priorities, develop partnerships, and discuss key trends and issues impacting public health and health care.
- Coordinated with NACCHO about five National Health Security Recognition Awards to recognize local health departments' achievements towards strengthening national health security.
- Facilitated multiple meetings to improve awareness and facilitate engagement with outside stakeholders, including behavioral response to mass violence events, annual meeting of pharmacy partners under PMPI, engagements of the Council on Emergency Medical Care, a learning session of private sector partners on trauma care in rural settings; and a workshop of public- and private-sector partners in health care and public health to engage in strategic foresight exercises on the intersection of the health care system and public health emergencies.
- In collaboration with the National Security Council, the Department of Homeland Security, the Federal Emergency Management Agency, and the Uniformed Services University of the Health

Sciences, the Emergency Care Coordination Center (ECCC) in the Division of Health System Policy (DHSP) launched two national campaigns. One was titled "Stop the Bleed" and one was titled "You Are the Help Until Help Arrives". These campaigns were designed to raise public awareness of the need to empower individuals to provide care to the injured. In 2017, the materials from "You Are the Help Until Help Arrives" were downloaded over 3,000 times, with over 1,500 web-based and 1,200 instructor-led certificates awarded.

Funding History	
FY 2015	$14,877,000
FY 2016	$14,877,000
FY 2017	$14,843,000
FY 2018 Annualized CR	$14,776,000
FY 2019 President's Budget	$14,849,000

Budget Request:

The FY 2019 Budget for ASPR's Office of Policy and Planning is $14,849,000, which is $73,000 above the FY 2018 Annualized Continuing Resolution level.

To set strategic direction for public health and healthcare emergency preparedness and response, OPP will lead the development and delivery of Congressionally mandated strategies and evaluations, including the annual PHEMCE Strategy and Implementation Plan and SNS Annual Review (a review of SNS holdings); and promote and evaluate NHSS implementation. OPP will respond to new strategic goals and objectives set forth by ASPR and HHS leaders.

OPP's policy priorities for FY 2019 include: developing plans, policies, and MCM requirements for CBRN threats; determining and addressing policy issues affecting Federal response operations ; strengthening, testing, and reporting healthcare system resilience, surge capability, behavioral health integration, and maturation of health care coalitions; leveraging data and innovation to build comprehensive intergovernmental health situational awareness; enhancing state and local coordination among public health, healthcare, aging, emergency management and other organizations to minimize care disruptions and adverse outcomes; advancing community resilience and mitigate adverse outcomes by disseminating tools (e.g., planning tools to address access and functional needs of at-risk individuals) and best practices; strengthening biosafety and biosecurity practices; enhancing its evaluation capability; and maintaining U.S. compliance with the International Health Regulations.

In FY 2019, OPP will lead and improve the efficiency of its engagement efforts across Federal and SLTT government, non-governmental, private sector, and international partners, to ensure that policies and resources are responsive to real needs. Formal engagements that will continue into FY 2019 include the NPRSB and NACCD for input from the public and non-Federal partners, and the DLG to coordinate departmental decision making, share situational awareness updates, and inform and advise the HHS Secretary on responses to disasters and other emergencies that impact the nation's health.

Office of Policy and Planning: Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
2.4.9 Increase engagement with stakeholders to disseminate and improve awareness of ASPR strategies for preparedness, response, and recovery (Outcome)	FY 2017: Completed a national roadmap for public health and medical preparedness to save lives; align federal, state, local, tribal, territorial, and private sector resources toward common goals and objectives to ensure a consistent national approach and efficient use of resources. Collaborated with the Pan American Health Organization to finalize and publish a standardized toolkit to train global IHR National Focal Points. Developed a World Bank exercise for Ministers of Finance to highlight the need for public health preparedness, response, multi-sectoral coordination and financial commitments. Collaborated with the World Bank and the World Economic Forum on a pandemic exercise for world leaders at the 2017 Davos meeting to promote public-private partnerships. Hosted two regional workshops, a non-federal	Conduct at least two, in-person Federal Advisory Committee meetings on relevant topics, stakeholder engagement workshops, and Working Group or public sessions as needed.	Conduct at least two, in-person Federal Advisory Committee meetings on relevant topics, stakeholder engagement workshops, and Working Group or public sessions as needed. Increase stakeholder engagement and education by 10% over FY18 to promote healthy, prepared, and resilient communities.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	open listening session and presented at the 2017 National Association of City and County Health Officials (NACCHO) Preparedness Summit. Engaged public health and medical subject matter experts to identify and prioritize the top 12 emerging trends and issues affecting the nation's national health security. The National Preparedness and Response Science Board (NPRSB) and the National Advisory Committee on Children and Disasters (NACCD) held 2 joint meetings, a public teleconference, and a public meeting. In collaboration with NSC, DHS, FEMA and USUHS, DHSP/ECCC launched two national campaigns – "Stop the Bleed" (with NSC) and "You Are the Help Until Help Arrives" (with FEMA). Launched the "emPOWERing State Medicaid and Child Health Insurance Plan Data Pilot" to assist States in developing			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	complimentary Medicaid and CHIP datasets. Provided HHS emPOWER Program de-identified and limited individual data to Texas, Florida, Puerto Rico and U.S. Virgin Islands to enhance planning and response needs of 823,517 Medicare beneficiaries. ASPR used emPOWER to rapidly identify, locate, and conduct life-saving evacuations for 250 U.S. Virgin Islands dialysis dependent individuals. (Target Exceeded)			
2.4.11 Lead and implement national and international strategic plans for public health preparedness and response (Output)	FY 2017: Coordinated 5 IHR notifications to WHO 2017. Developed an initial draft for the 2019-2022 National Health Security Strategy. Worked collaboratively with other D/As to develop the National Biodefense Strategy, under the auspices of the White House National Security Council. Served as subject matter expert to ASPR's National	Develop the updated NHSS and Implementation Plan. Develop and submit annual PHEMCE strategy and implementation plan.	Develop a plan and collaborate with associated Congressionally mandated programs to enable NHSS implementation and dissemination.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	Disaster Medical System to inform and support essential doctrine revisions and development for the mobilization of medical responders, medical suitability standards, and communications protocols for teams. In 2017, ASPR led the interagency to develop the *2017-2018 PHEMCE Strategy and Implementation Plan*, fulfilling all PAHPRA mandates. This document is anticipated for publication in December 2017. Led 30+ USG departments/agencies in developing the Joint External Evaluation (JEE) National Action Plan to Strengthen Implementation of the International Health Regulations. Led the development of multiple draft frameworks, including Operational Frameworks for the Deployment of the WHO's Smallpox Vaccine Emergency Stockpile, a DRAFT USG Framework for rapidly sharing			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	biological material, a DRAFT HHS framework for Requesting and Accepting Public Health and Medical Resources from International Entities. (Target Met)			
12 Expand an evidence base of scientific information about disasters that informs policy decisions (Outcome)	FY 2017: Developed an initial draft of the National Health Security Strategy's Evaluation of Progress, which incorporates assessments of HPP, PHEP, NDMS, BARDA/MCM Strategic Plan, and PanFlu Vaccine Tracking. Successfully concluded the Hurricane Sandy Recovery Science grants program in FY'17. This included 29 publications from ASPR grants and 30 publications with CDC and NIH. Following the completion of the grant program, we, OPP organized a meeting to bring together researchers, operational decision-makers and policy experts to ensure that the evidence base was disseminated and incorporated. The information and relationships built through	Develop the PHEMCE annual review of the contents of the strategic national stockpile. Initiate the development of the NHSS Evaluation of Progress to meet the statutory requirement.	Develop the PHEMCE annual review of the contents of the strategic national stockpile. Initiate the development of the NHSS Evaluation of Progress to meet the statutory requirement.	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	the grants program were highly beneficial in the 2017 hurricane season. For example: The Sandy Recovery Science grants program identified patients seeking treatment for opioid use disorder as an at-risk population underserved in disaster situations. Working together with academic and federal partners, OPP used satellite remote sensing to accurately determine flood levels and power outages in real-time for 2017 hurricanes in Texas, Florida, and Puerto Rico. During the 2017 hurricane responses, ASPR leveraged partnerships with pharmacy sector partners under the Prescription Medication Preparedness Initiative to rapidly gather evidence to inform policy decisions. In response to the 2017 Hurricanes, ASPR launched a healthcare system monitoring pilot to assess access, utilization and adverse outcomes for Medicare beneficiaries and identify mitigation, response and recovery			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	activities to advance health system and at-risk population resiliency. ASPR established a national inventory of trauma, emergency, and burn care capabilities and locations that encompasses >4,900 U.S. hospitals with emergency services, >1,900 trauma centers, >170 American Burn Association verified burn centers, and >118 Veterans Health Administration facilities. Facilitated multiple meetings to improve awareness and facilitate engagement with outside stakeholders, including: Behavioral response to mass violence events; annual meeting of pharmacy partners under the Prescription Medication Preparedness Initiative (PMPI); engagements of the Council on Emergency Medical Care; a learning session of private-sector partners on trauma care in rural settings with the Federal Interagency Committee on Emergency Medical Services; and a workshop of public and private sector partners in			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	healthcare and public health to engage in strategic foresight exercises on the intersection of the healthcare system and public health emergencies. (Target Exceeded)			

OPERATIONS

Budget Summary
(Dollars in Millions)

ASPR	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**30.938**	**30.728**	**30.879**	**+0.151**
Operations	*30.938*	*30.728*	*30.879*	+0.151
FTE	135	135	135	135

Authorizing Legislation:
Authorization ..... Public Health Service Act, Sec. 2811 42 U.S.C. 300hh-10
Authorization Status..... Indefinite
Allocation Method ..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

The Office of the Assistant Secretary of Preparedness and Response (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 emergencies, as well as medical emergency preparedness, response, and recovery. In addition, the 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. Additionally, ASPR's role coordinates the entire medical countermeasure enterprise to help protect the nation from chemical, biological, nuclear, radiation, and emerging disease threats.

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 (NRF) and the Health and Social Services Recovery Support Function 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 also supports ESF 6 of the NRF in the delivery of Federal mass care, emergency assistance, housing, and human services when local, tribal, and State response and recovery needs exceed their capabilities. When requested by a State, ASPR coordinates emergency medical care in shelters. ASPR provides HHS medical workers and medical supplies/services, including durable medical equipment. Through these functional designations, ASPR provides critical emergency management leadership and support for all major public health and medical events/incidents on behalf of the Federal Government.

The Office of the Chief Operating Officer (COO)

The Office of the Chief Operating Officer leads the centralized management services that 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, to strengthen ASPR's human capital and communications practices, to provide innovative technology solutions, and to create a more nimble and flexible organization. COO also leverages innovative communication tools and technologies—including social media—in order to enhance community connectedness and empower individuals to take action before, during, and after public health and medical emergencies.

Although COO has been level-funded since FY 2013, the office has continually sought efficiencies in business practices. In FY 2017, COO completed the migration of ASPR's hosting service for its web enterprise, including an external cross-agency website, multiple internal portals and collaboration sites from the National Institutes of Health servers to a more flexible and cost-efficient cloud-based solution with Amazon Web Services. Further, COO completed a portal for the National Disaster Medical System (NDMS) so that NDMS's 5,000 intermittent federal employees can communicate with each other and with NDMS and ASPR leadership in a secure environment rather than using multiple, disconnected external methods.

Carrying through FY 2019, COO will upgrade and modernize the Public Health Emergency (PHE.gov) external cross-agency web site. With the redesigned site, private industry, state and local government agencies and community organizations will be able to more quickly and efficiently obtain the information resources and tools they need to prepare, respond and recover from the health effects of disasters and members of the public will have the information they need at their fingertips to make decisions about their health during disasters. Additionally, COO is underway on Phase II of its Next-Generation (NextGen) IT project, and will move into Phase III during FY 2019, in order to streamline ASPR's disparate IT systems, create standards, eliminate redundancy, and reduce long-term costs.

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

AMCG is a multi-faceted organization that provides the ASPR with holistic, nimble, flexible, consistent and innovative acquisition and grants solutions mission support in order to enable public health emergency operational responses. 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 full acquisition, grants management, and oversight services for a diverse research/development, emergency response, and operational program support portfolio of 500+active contracts (including task orders) and 100+ Grants/Cooperative Agreements; incorporates full lifecycle management techniques from concept/inception, administration (i.e., pre/post) through closeout and A-133 audits; ensures integrity and oversight through consistent adherence to statutory, regulatory and administrative policy, which includes auditing, and facilitating the ASPR's BARDA/AMCG Decision Gate/IPR and EVMS processes; supports industry outreach, and provides expert capabilities in the conduct of acquisition strategies, requirement and grants solutions.

AMCG places its emphasis on best value to the taxpayer through best business practices and partnership with ASPR program offices. This is accomplished by managing in a leaner environment with constrained

and limited resources; collaborating with all ASPR program offices early in the acquisition lifecycle and synchronizing efforts with ASPR program offices to gain acquisition efficiencies resulting in better communications, reducing redundancy and increasing efficiency through the streamlining of reviews, and prioritizing requirements to meet a complex and critical mission. ASPR has established 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 and urgent responses to health emergencies such as Ebola, Zika, and H7N9.

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 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. AMCG continues to use Other Transaction Authorities (OTAs) to enable ASPR to partner with like consortiums to support a portfolio of multiple products on a cost share basis.

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 with respect to 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 to perform ESF 8 functions under the National Response Framework, including the responses to Hurricanes Harvey, Irma and Maria, 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, the Zika virus, and recovery from the 2017 Hurricanes.

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 ASPR's mission, and to develop strategies for ensuring effective and efficient operations.

Funding History	
FY 2015	$31,305,000
FY 2016	$30,938,000
FY 2017	$30,938,000
FY 2018 Annualized CR	$30,728,000
FY 2019 President's Budget	$30,879,000

Budget Request

The FY 2019 Budget includes $30,879,000 for ASPR's Operations, which is $151,000 above the FY 2018 Annualized Continuing Resolution level. 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 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
2.4.8 Improve strategic communications effectiveness. (Outcome)	2017: Expanded following on Facebook by 30 percent (total followers: 14,420) and on Twitter by 17.8 percent (total followers: 12,400), exceeding the target increase of 15 percent for both platforms. More than doubled the reach on Facebook (total reach: over 2.2 million impressions up from 1 million impressions	Drive modern design and integrate functionality of public facing web and social media platforms to improve external communications for emergency preparedness and response.	Continue coordinated, integrated communications with partners to maximize reach of consistent, credible messaging and to leverage info-sharing capabilities during public health	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	in FY16) and on Twitter by 76.7 percent (total reach: over 5.3 million impressions). ASPR's YouTube channel now has more than 1,100 subscribers and the videos posted generated more than 63,900 views with more than 104,000 minutes of video watched. ASPR also broadened its reach on social media with a second full fiscal year of operations on two additional platforms: GovDelivery (e-mail marketing) and LinkedIn. GovDelivery subscribers increased by 2,000 subscribers to reach 116,000 subscribers. The ASPR LinkedIn following more than doubled with more than 1,100 followers (of which, LinkedIn estimates 33.8 percent are senior managers). During the 2017 hurricane season, ASPR recruited bilingual public affairs specialists and health communications specialists from within the department to deploy to hurricane-affected areas in support of the federal health response and to provide health information in Spanish and English to affected populations through traditional and social media. This work, coupled with an expanded hyper-local media relations effort, resulted in more than 1,400 stories in	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.	emergencies. Continually maintain resilient access to ASPR web systems for mission response.	

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
	English and Spanish media outlets and contributed to the jump in social media impressions and followers on ASPR's social media platforms. ASPR became the first HHS division to move its web infrastructure to Amazon cloud hosting services, consolidating seven sites (ASPR portal, NDMS portal, MRC portal, ASPR Work Group Portal for external stakeholders, GeoHealth, and PHE.gov) and decreasing hosting costs by $275,000 a year. Coached and guided communications efforts to increase employee training response rates, making portal content user-centric, and restructuring the employee new-hire program materials, leading to consistent increases of 7-8 percentage points in employee viewpoint surveys over the past two years. (Target Met)			
11a Ensure deployment of emergency response personnel, consistent with mission timing requirements/objectives (Intermediate Outcome)	FY 2017: 97.6% Target: 80.0 % (Target Exceeded)	85.0 %	90.0 %	+5 %

ASSISTANT SECRETARY FOR ADMINISTRATION

CYBERSECURITY

Budget Summary
(Dollars in Millions)

Cybersecurity	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**50.744**	**50.515**	**68.093**	**+17.578**
FTE	**93**	**123**	**133**	**+10**

Authorizing Legislation:
FY 2019 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. In addition, the program ensures that cybersecurity threats to the organization are remediated, proactively where possible, and that the health data of the American people with which HHS is entrusted remains protected.

HHS is the repository for information on bio-defense, development of pharmaceuticals, and medical information for one hundred million Americans, as well as 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;
- Increasing information sharing and awareness of sector specific threats by 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 grow. 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 to 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 HHS's 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. The HHS Cybersecurity Program's mission is to secure the agency by ensuring access to innovative technologies and subject matter expertise 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, inappropriate usage, and insider threat, all which pose risks to HHS critical functions, services, and data. In fiscal year (FY) 2017, HHS:

- Managed 10,795 cybersecurity incidents.
- Conducted 7,995 web application vulnerability scans (scanning an estimated 2,112,968 web pages) that prevented 121,298 vulnerabilities from being exploited.
- Investigated 77,441 incidents of spam, 4,266 of which were malicious and, if gone unchecked, could have compromised HHS data.
- Enacted efforts to address the the top three IT challenges – cybersecurity, privacy and end-of-life legacy systems.

Some key initiatives that HHS is undertaking to improve information 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, is directly derived from more than 65 cybersecurity mandates and legislation with which HHS must comply, and mandates are continually added through, by example, DHS' Binding Operational Directives (BOD). In FY 2017, HHS identified 13 critical cybersecurity functions HHS must provide derived from these federal mandates. Such mandates are requirements for which HHS must implement programmatic cybersecurity activities, capabilities and initiatives. 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 cybersecurity operational readiness and assurance that strengthens the security and resilience of HHS 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 to proactively manage cyber risk to HHS IT resources from cyber-attack. In short, CSIRC is HHS's 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 in coordination with individual Operating Divisions. 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 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 2019 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 the establishment of a set of baseline security capabilities through enhanced monitoring and situational awareness of all external network connections. This program improves HHS's information security posture and incident response capability through reduction in the number of, 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 Department of Homeland Security TIC and Einstein traffic monitoring and intrusion detection program 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 transition to TIC in FY 2015, which incorporates 100% of the Operating Division internet circuits into its infrastructure. HHS began migration of Operating Division Virtual Private Network (VPN) and cloud service connections in FY 2015. HHS will continue migrating Operating Division VPN and cloud services to the TIC through FY 2019, as Operating Division 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 capabilities, intrusion detection systems, 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 2019, the program will continue to procure enterprise-wide licenses for digital investigation technology to be deployed across all Operating Divisions, procure a service desk cloud capability to enhance asset, configuration, and problem management functions in support of the CSIRC mission and security tools deployed at the Operating Division internet connections and continued enterprise deployments of security incident and event management capabilities, firewalls, web proxies, and security analytics.

Federal Information Security Modernization Act Program Management

The HHS Cybersecurity Program supports Federal Information Security Modernization Act 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 HHS 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 program, and the FedRAMP cloud security 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 information 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 on such policy, 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 with both other federal agencies and the private sector 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. This external engagement allows HHS to share healthcare-focused cybersecurity information and best practices with other government agencies delivering similar services – such as the Defense Health Agency and the Department of Veterans Affairs – as well as fulfill its legislatively mandated role of partnering with private entities in the healthcare sector.

Funding History		
FY 2015	$	41,125,000
FY 2016	$	50,860,000
FY 2017	$	50,744,000
FY 2018 Annualized CR	$	50,514,610
FY 2019 President's Budget	$	68,093,000

Budget Request

The HHS Cybersecurity Program is mandated, in whole or in part, by 66 federal mandates. A key mandate is FISMA, which requires each Department and Agency to implement a comprehensive cybersecurity program. Based on these requirements, HHS must protect the vital health and other 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 2019 request for the HHS Cybersecurity Program is $68,093,000, which is $17,578,000 above the FY 2018 Annualized CR. The request will support, sustain, and enhance the Department's information security posture, and reflects the current landscape in which our adversaries are seeking to 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 cybersecurity focus on the improvement of efficiencies in security tools, as well as deployment of enterprise-wide tool solutions to improve correlation of cyber threat and vulnerability information. These efforts will improve situational awareness and allow better response to actions that could exploit or jeopardize HHS information systems. Additionally, they aim to improve the protection of HHS assets and endpoints that store Departmental information. These efforts include not only purchasing the technology, but also building the programs and skilled workforce to ensure these technologies meet HHS objectives to protect its mission and information while also facilitating HHS's compliance against federal mandates and guidelines.

The Budget 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 to support security engineering and to 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 Operating Division IT systems and networks.

Summary of Cybersecurity FY 2017-2019 Funding by Program				
Cybersecurity Program	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget	FY 2019 PB +/- FY 2018 Annualized CR
CSIRC	$ 10,614	$ 10,643	$ 17,200	$ 6,557
TIC	$ 2,100	$ 2,100	$ 2,100	-
Enterprise Security Tools	$ 16,072	$ 16,072	$ 23,955	$ 7,883
FISMA Program Management	$ 21,958	$ 21,700	$ 24,838	$ 3,138
Total	$ 50,744	$ 50,515	$ 68,093	$ 17,578

Computer Security Incident Response Center (CSIRC) Security Incident Response & Situational Awareness: The request is $17,200,000, which is $6,557,000 above the FY 2018 Annualized Continuing Resolution, due to the effect of inflation on both pay and non-pay costs, absorbing contractor conversions, and realigning cyber threat priorities to OSSI. The request will support the continued creation, alignment, and expansion of the CSIRC services to include the Healthcare Cybersecurity Communications and Integration Center (HCCIC).

Collectively, the HCCIC and CSIRC are the realignment and expansion and enhancement of several legacy cybersecurity offerings. Combined, these services will provide cybersecurity incident response,

situational awareness, and collaboration and communication internally and within the public and private sectors.

The HCCIC, which operates under close collaboration with the Department of Homeland Security, includes the addition of private sector outreach to become a central location for information sharing across HHS and Federal Government partners. This service is an enhancement to the CSIRC services as it will provide data and tools to aid in fusion efforts to support threat analysis efforts for the healthcare sector. This service 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 private and federal sector stakeholders to reduce risk and enable risk-based decision making.

The CSIRC continues the alignment of several existing CSIRC service offerings, Security Operations Center, Research and Forensics, Health Care Threat Operations Center and Cyber Threat Intelligence into a secondary tier of support. These services include ongoing maintenance, which will enable the Department to maintain 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 cyber 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 Operating Division 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 Cybersecurity Program's successful fight against cyber threats is exemplified by its response to WannaCry and NotPetya ransomware attacks in 2017. Working collaboratively with the Assistant Secretary for Preparedness and Response (ASPR) internally, and the Department of Homeland Security (DHS) externally, the Cybersecurity Program coordinated comprehensive, cohesive responses to emerging threats. As the Sector Specific Agency for the Healthcare and Public Health (HPH) sector, HHS closely monitors developments that impact the HPH sector, domestically or internationally. As a result, when HHS identified that WannaCry had impacted foreign health care entities and facilities – e.g., it shut down a number of National Health System facilities in the United Kingdom – HHS proactively engaged the HPH sector on the threat, the risks to various entities in the HPH sector from WannaCry, and potential mitigation of such risks. The ability of HHS to undertake this proactive engagement and exchange of information, through the information sharing and Critical Infrastructure Protection programs, encourages the HPH sector to engage in information sharing about cyber threat indicators because the sector knows that it can engage with HHS, the federal agency with institutional knowledge and specialized expertise about the sector, on the issues, and knows it is engaging with the federal agency that understands their sector.

The FY 2019 request invests in information security technologies, including enterprise network intrusion detection and prevention solutions, network traffic analysis tools, security information and event management solutions (SIEM), data and log analysis, and tools to support the forensic analysis of malicious software (malware). Smartphones, and 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): The request for $2,100,000 is flat with the FY 2018 Annualized Continuing Resolution, 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 Operating Division – including firewalls, Intrusion Detection Systems (IDS), network traffic analysis, and Security Information Event Management (SIEM). Finally, the TIC provides core capabilities for the Department's continuous monitoring plan by acting as a single point of aggregation for security data collection regarding internet traffic.

Enterprise Security Tools: The request includes $23,955,000 for Enterprise Security Tools, which is $7,883,000 above the FY 2018 Annualized Continuing Resolution. This funding level will allow for the continued support and expansion of malware blocking and incident response capabilities across the Department. The enhancements will improve capabilities to the enterprise, fund an incident response readiness assessment, and provide a retainer for all major infrastructures and the CSIRC, while allowing Operating Divisions 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 Operating Divisions by pursuing and sustaining a number of high impact investments that will better enable HHS to keep pace in addressing and correcting new and any existing information security gaps. The implementation of Network Access Control was successful, and is now providing security and endpoint protection to better secure HHS computers and network resources. This request will also provide additional solutions to counter malicious software (malware) and other sophisticated computer viruses and worms that continue to plague government computer systems. In addition, this FY 2019 Budget request will provide funds to renew 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 funding to support the various Office of the Secretary-specific Departmental Continuous Diagnostic and Mitigation (CDM) licenses previously paid for by the DHS CDM program, but which must now be acquired through PHSSEF Cybersecurity funds for OS. 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, the 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: The request includes $24,838,000 for FISMA Program Management, which is $3,138,000 above the FY 2018 Annualized Continuing Resolution. The increase is due to the effect of inflation on both pay and non-pay costs, and to absorbing seven contractor conversions for the Office of the Secretary's Incident Response Team and the continued expansion of the HHS Privacy group which is chartered to create policy and programs to protect the personally identifiable and healthcare information of HHS staff, customers, and private sector partners. The request will also support the on-going maintenance support of the Enterprise eGRC tool. The tool – closely aligned with the DHS-mandated reporting dashboards under its CDM program – allows for the automated reporting of security performance measures to the Department of Homeland Security. Funds will also enable the more effective implementation of information security weakness remediation in response to recommendations and findings made in connection with various 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 Operating Division levels of compliance with the requirements of FISMA. The Department will enhance Operating Division operational IT systems continuous monitoring capability, in order to determine Operating Division compliance with Department policy and standards, including quarterly evaluation of security weakness Plans of Action and Milestones, Privacy Impact Assessments, and system of records notice compliance. Support will continue for the activities of the HHS personally identifiable information (PII) Breach Response Team that will enable the Department to evaluate Operating Division breach response assessments to determine the appropriate response to any reported breaches of PII.

Cybersecurity - Outputs and Outcomes Table

Program/Measure	Summary of Most Recent Result	FY 2018 Target	FY 2019 Target	FY 2019 Target +/- FY 2018 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 2017 Actual: 93.0% /1	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 2017 Actual: 91.0% /1	95.0%	95.0%	Maintain
Vulnerability management: Percent (%) of the organization's unclassified network(s) assessed for vulnerabilities using Security Content Automation Protocol (SCAP) validated products.	FY 2017 Actual: 96.0%/1	95.0%	95.0%	Maintain
FISMA System Inventory Compliance: Percentage of systems with current Security Authorization to Operate (ATO).	FY 2017 Actual: 97.0%	95.0%	95.0%	Maintain

1/ 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.

OFFICE OF SECURITY AND STRATEGIC INFORMATION

Budget Summary
(Dollars in Millions)

OSSI	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Budget Authority	**7.453**	**7.419**	**8.496**	**+1.077**
FTE	**33**	**32**	**37**	**+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 for the Intelligence Community (IC), and is responsible for coordination with the IC and for 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 for 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, in order to support HHS missions, enhance national security, and help keep Americans safe. This operational responsibility is in support of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA); Executive Order 13587, *Structural Reforms to Improve the Security of Classified Networks and the Responsible Sharing and Safeguarding of Classified Information*; and other relevant Executive Orders (including Executive Order 12333), Presidential Directives and policy guidance.

The Department of Health and Human Services recently realigned security functions that were within OSSI, and separated them from the Office of the Assistant Secretary for Administration (ASA). The new structure aligns national security-related functions (including intelligence, protection of classified materials, counterintelligence, and national security clearances) under the Deputy Secretary in the Immediate Office of the Secretary (IOS). The physical security, emergency management, and suitability and onboarding new civil service employees remain within ASA. The reduction in FTE from FY17 to FY18 reflects the 1 FTE that was realigned under ASA at the beginning of the fiscal year to provide administrative support.

OSSI is headed by the Assistant Deputy Secretary for National Security, who reports directly to the Deputy Secretary and also serves as the Secretary's Senior Intelligence Official on intelligence and counterintelligence issues. The Assistant Deputy Secretary has been delegated original classification authority by the Secretary. OSSI is comprised of three directorates, including the Intelligence & Analysis Directorate (IAD), the Directorate of Operations (DO), and the Personnel Security Directorate (PSD). These directorates are responsible for integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to the Department and our national security; and providing policy guidance on and managing the Office of the Secretary's implementation of the Department's national security, intelligence (including cyber

intelligence), and counterintelligence (including insider threat) programs. OSSI's programs include national security adjudication, classified national security information management, secure compartmented information facilities management, communications security, safeguarding and sharing of classified information, cyber threat intelligence, and counterintelligence/insider threat.

In addition to being designated as the FICO, the Assistant Deputy Secretary for National Security serves as the HHS Federal Senior Intelligence Coordinator (FSIC). OSSI has responsibilities to establish implementing guidance, provide oversight, and manage the Department's policy for the sharing, safeguarding, and the coordinated exchange of information related to national or homeland security with other federal departments and agencies, including law enforcement organizations and the Intelligence Community, in compliance with HHS policies and applicable laws, regulations, and Executive Orders.

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, 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 from 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		
FY 2015	$	7,470,000
FY 2016	$	7,470,000
FY 2017	$	7,453,000
FY 2018 Annualized CR	$	7,419,000
FY 2019 President's Budget	$	8,496,000

Budget Request

The FY 2019 budget request for OSSI is $8,496,000, which is $1,077,000 above the FY 2018 Annualized Continuing Resolution level. The FY 2019 funding level will fulfill a requirement for five (5) Counterintelligence FTEs needed to support the Department's requirement to protect national security interests related to intellectual property, life sciences, medical devices, and classified/sensitive information, including costs associated with the five FTE, and $100,000 in costs associated with renovations of Sensitive Compartmented Information Facility (SCIF) space to allow the space to fully support the additional staff and implementation of their duties. It will also allow OSSI to bring in staff on detail from the Intelligence Community to OSSI. HHS is requesting these five additional Counterintelligence FTEs for FY 2019, who will be assigned to both the headquarters and/or critical operating divisions. These additional FTE and IC staff will expand the Department's capability to (1) address supply chain risk management, (2) vet foreign national visitors, (3) assess potential damage to

HHS and national security from unauthorized disclosure of classified and/or sensitive information, and (4) address potential cyber threats to the Nation's public health and medical infrastructure.

In addition, the continuing cyber threats to the Department's vital systems and information, and threats to the Healthcare and Public Health sector (including ransomware), make cyber threat intelligence critical to preventing and mitigating these incidents. OSSI's ability to maintain 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 and the public health and health care sector, and provide deterrence and mitigation strategies from cyber security threats.

OSSI 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; address major cyber intelligence-related threats (especially threats directed at healthcare infrastructure); and support broader national security interests.

Mission Support

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 2017, OSSI provided support to all of the Secretary's priority items, including the opioid epidemic, terrorism threats domestically and abroad, and the Unaccompanied Alien 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 Services are just some of the HHS 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.

PANDEMIC INFLUENZA

Budget Summary
(Dollars in Millions)

ASPR and OGA	FY 2017	FY 2018	FY 2019	
	Final	Annualized CR	President's Budget	+/- FY 2018 Annualized CR
Program Level	**71.831**	**112.000**	**250.000**	**+138.000**
Budget Authority (non-add)	56.831	112.000	250.000	+138.000
ASPR No-year funding (non-add)	*39.906*	*40.000*	*210.000*	*+170.000*
ASPR Annual funding (non-add)	*12.925*	*68.018*	*35.991*	*-32.027*
OGA Annual funding (non-add)	*4.000*	*3.982*	*4.009*	*+.027*
Other sources (non-add) /1	*15.000*	-	-	-
FTE	**5**	**5**	**5**	**5**

/1 The FY 2017 total includes $15 million provided through the Public Health and Social Services Emergency Fund's unobligated pandemic influenza supplemental balances.

Authorizing Legislation:

Authorization .....Public Health Service Act, Sec. 319L; Sec. 2811 42 U.S.C. 247d-7e, 300hh-10
Authorization Status.....Indefinite
Allocation Method .....Direct Federal/Intramural, Contracts, Formula Grants/Cooperative Agreements, Competitive Grants/Cooperative Agreements, Other Direct Federal/Intramural

Program Description and Accomplishments

It is estimated that a highly contagious and virulent airborne pathogen, such as a novel influenza virus, could kill tens of millions of people globally in less than a year. Influenza and other emerging infectious diseases with pandemic potential continue to mutate, evolve, spread geographically, 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 the first emergence of this influenza virus. The virus has diversified into a new genetic lineage (Yangtze River), retains a high human threat assessment, and prompted the World Health Organization (WHO) to recommend development of a new pandemic influenza 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's borders, but previous experience with H5N1 avian influenza, which spread throughout Asia and to other continents since early 2003, shows that H7N9 could do the same – a prospect that is alarming to human and animal health authorities. Furthermore, some Yangtze Lineage H7N9 viruses have shown markers of resistance to licensed antiviral drugs. This potentially eliminates the main specific therapeutic option for people infected with this virus. It is vital that the United States remain vigilant and sustain a robust pandemic preparedness posture against these deadly pathogens.

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. To protect public health and save lives in the next pandemic, the USG must take action and maintain the momentum of previous investments to develop new medical countermeasures – vaccines, drugs,

diagnostics and respiratory protection devices – so they are available when needed. It is also essential that response capabilities are established and sustained domestically in order to prepare the nation to respond effectively to emerging 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. Most recently, HHS published the 2017 Update of the Pandemic Influenza Plan to highlight and build upon the accomplishments since the Plan was last updated, to make clear the additional efforts that are still necessary to improve pandemic preparedness, and to establish clear priority goals to improve pandemic preparedness and response.

ASPR, through BARDA, has:

- Developed new influenza vaccines using modern cell- and recombinant-based production technologies to expedite and expand domestic production;
- Advanced the development of high-throughput rapid diagnostics capable of detecting influenza strains at centralized public health and hospital-based laboratories;
- 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) for the pre-pandemic stockpile;
- 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;
- Supported development of broad-spectrum monoclonal antibodies, host-targeted therapeutic drug candidates, and small molecule antivirals with novel mechanisms of action when compared to currently licensed influenza antiviral drugs. These candidates have shown activity against drug-resistant influenza viruses and are currently under evaluation in Phase 2 and ready to enter Phase 3 clinical trials;
- Supported development of technology and processes that allow for rapid production of N95 respirators, to significantly increase respirator supply during an influenza pandemic;
- Supported development of re-usable elastomeric respirator masks;
- Expanded the surge capacity of domestic vaccine manufacturing, while increasing its flexibility to help manufacture pandemic influenza vaccines as quickly as possible;
- Conducted clinical trials that provide the necessary evidence base to rapidly deploy stockpiled and newly manufactured adjuvanted H5N1 and H7N9 vaccines in response to an emerging pandemic, and
- Responded to the 2017 H7N9 crisis, awarding three contracts for production of approximately 20 million regimens of vaccine antigen for H7N9 influenza vaccine from the 2016–2017 Yangtze River virus lineage candidate vaccine virus provided by CDC to achieve National Pre-Pandemic Influenza Vaccine Stockpile preparedness goals.

ASPR 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 to increase global pandemic influenza vaccine capacity;
- 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;
- FDA clearance of point-of-care clinical diagnostics and strengthening of the agency's regulatory science capability to speed the approval process for new products;
- Supported development towards FDA approval of next-generation portable ventilators needed for a surge in hospitalized patients of all ages during a pandemic; and
- Increased stockpiling of vaccines, ventilators, and medical supplies, including adjuvants and antiviral drugs.

ASPR investments have led to innovative technologic advancements for medical countermeasures, as enumerated as follows:

Cell-based influenza vaccines: In November 2012, FDA licensed Novartis's Flucelvax, the first cell-based influenza vaccine commercially available in the United States, which was used 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 facility 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. In 2016, FDA extended the indication for Flucelvax (both trivalent and quadrivalent), to include persons 4 years of age and older, for prevention of influenza disease. During 2017, BARDA supported manufacturing efficiency improvements to achieve a 3-4 fold boost in the number of pandemic vaccine doses produced, thereby reducing the amount of time required to meet target production goals during a pandemic.

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 speed 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. BARDA is currently supporting a clinical study to assess the safety and antigen-sparing capacity of adjuvants that are maintained in the National Pre-Pandemic Influenza Vaccine Stockpile when combined with recombinant-based vaccine for the 5th Wave/Yangtze River lineage H7N9 influenza virus circulating China.

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 BARDA 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 preliminary results of this study indicate that pre-pandemic influenza vaccines and adjuvants stored in the National Pre-Pandemic Influenza Vaccine Stockpile remain safe and immunogenic to help protect the US population. BARDA is working closely with FDA to formalize the regulatory framework for storage, testing and use of stockpiled adjuvants under appropriate regulatory mechanisms. During 2018, CSN plans to conduct additional clinical studies linked to BARDA's areas of investment, including heterologous prime boost studies of different influenza vaccines in the National Pre-Pandemic Influenza Vaccine Stockpile. 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, 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 BARDA's 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 pandemic influenza response capabilities and refining core services to provide cGMP manufacturing capacity and capability, including 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 this specific testing time from 14 to 5 days. Lastly, industry partners are evaluating alternative potency assays, such as enzyme-linked immunosorbent assay and mass spectrometric assays. Additional investments since 2016 support improved global surveillance and virus characterization to detect emerging novel viruses as early as possible, expedited production and timely availability of potency reagents, and the incorporation of technological improvements in the manufacturing process to speed-up production and regulatory approval.

Expanded domestic influenza vaccine manufacturing surge capacity: In 2004–2005, the US was subject to a near-catastrophic failure of a major vaccine producer working to manufacture seasonal influenza vaccine. This left the US with a single domestic influenza vaccine manufacturer and, therefore, highly vulnerable to vaccine shortages. To address this problem and to ensure that the US 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 US 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 US manufacturing surge capacity for the antigen in pandemic influenza vaccines closer to the ultimate goal of providing two doses – the dosage likely needed for protection against pandemic influenza – for 300 million people (600 million doses if used with adjuvants) within six months of vaccine virus delivery to manufacturers.

Providing new influenza antiviral drugs to treat critically ill populations: In severe pandemics, hundreds of thousands of people could be hospitalized with influenza in the US. 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 viral resistance to the drug class, 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 by injection. In FY 2017, the FDA approved Rapivab to treat acute uncomplicated influenza in pediatric patients above the age of 2 years. In FY 2017, BARDA made two critical awards to support portfolios of candidate products for influenza antivirals. BARDA has previously utilized the Other Transactional Agreement (OTA) authority provided under the Pandemic and All Hazards Preparedness Act to support products to address chemical, biological, radiological and nuclear threats. Two OTAs were awarded to support multiple influenza antiviral. The goal of these programs is to develop novel antiviral products that will overcome emergence of resistance during a pandemic or for seasonal influenza.

***Increasing the supply of influenza antiviral drugs for the Strategic National Stockpile*:** HHS previously met the federal stockpiling requirement for the amount of antiviral drugs to be available 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 the IV influenza antiviral 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 US 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 BARDA-supported Cepheid and Roche influenza diagnostic 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-care (POC) 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. In an effort to increase the efficacy of antivirals by promoting immediate utilization after symptom onset, BARDA will support development of home use and point of need diagnostic (and other) medical devices including wearables and advanced intelligent network-based technologies. BARDA diagnostics strategy seeks to empower patients to achieve better outcomes after influenza infection by starting treatment as early as possible and preventing further disease transmission. These devices will be integrated into a "net" of diagnostic capability to bootstrap the diagnostic robustness of these devices by exploiting the ability to capture, analyze and report real-time, geo-spatial and virologic information while supporting a more personalized pandemic preparedness and response.

Enhancing global pandemic preparedness: Diseases do not respect national borders, making global pandemic preparedness important for protecting the health and wellbeing of the US 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 US borders.

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 US foreign policy goals. Accomplishments include:

- 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. HHS leadership accomplished the logistical implementation of the US donation of H1N1 pandemic influenza vaccine to WHO, the response to the MERS-CoV, Ebola, and H7N9 Flash Appeal for support to WHO. This was accomplished in collaboration with partners in HHS, vaccine manufacturers, international transport companies, the US Department of State, and the US Agency for International Development (USAID).
- Development of new frameworks for sharing of biological specimens 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.
- Provided HHS /OGA technical support and policy leadership, analysis and support to:

- Lead logistical implementation of the USG/HHS donation of H1N1 pandemic influenza vaccine to WHO, in collaboration with ASPR/BARDA, vaccine manufacturers, international transport companies, U.S. Agency for International Development (USAID), Department of State (DOS), and WHO.
- Other USG departments and agencies, including the US Department of State, Office of the US Trade Representative, Department of Commerce, and the US Patent and Trademarks Office, for international negotiations on WHO's Pandemic Influenza Preparedness Framework for Influenza Virus Sample and Benefits Sharing.
- The National Security Council Staff and White House for policy options for donation of H1N1 pandemic vaccine from the U.S. to WHO, and for funding in response to the H7N9 Flash Appeal for Support for WHO.
- Ensure policy coherence and program coordination across all HHS OPDIVs and STAFFDIVs engaged in global health security, particularly international influenza activities.

- 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.
  - 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 WHO Pandemic Influenza Preparedness Framework (PIP-FW) and the Nagoya Protocol.
  - 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	
FY 2015	$71,915,000
FY 2016	$72,000,000
FY 2017[1]	$71,831,000[1]
FY 2018 Annualized CR	$112,000,000
FY 2019 President's Budget	$250,000,000

[1] The FY 2017 total includes $15 million provided through the Public Health and Social Services Emergency Fund's unobligated pandemic influenza supplemental balances.

Budget Request

The FY 2019 budget request for pandemic influenza activities is $250,000,000, which is $138,000,000 above the FY 2018 Annualized Continuing Resolution level. Funds are needed to sustain previous investments in critical domestic influenza vaccine manufacturing facility infrastructure, ensure that influenza vaccines and therapeutics can be produced to deploy an effective pandemic response, and maintain overall domestic pandemic readiness. 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 achieve pandemic preparedness goals, while also supporting technologies to improve, and ultimately transform, the approach to pandemic readiness and response. This increase in funds is critical to strengthen United States domestic pandemic preparedness and national security infrastructure, including development of a strong American workforce for production of medical countermeasures for pandemic influenza.

Of the total funds requested, $40 million is annual funding, and $210,000,000 million is no-year funding to account for preparedness sustainment costs and continue the advanced research and development of improved vaccines, therapeutics, and rapid in-home diagnostics. The request also includes the funds required to maintain and monitor pre-pandemic influenza vaccine and adjuvant stockpiles. These stockpiles are essential for rapid response against an emerging pandemic virus. This innovative stockpiling program also supports clinical studies to inform effective deployment. At this funding level, BARDA will invest in vaccine technologies, including adjuvant technologies, to improve the availability of safe and effective vaccines during a pandemic or other emergency. These vaccines would be transformational to pandemic preparedness and response, but are extremely challenging to develop. The requested funds are critical to support broadly effective therapeutic drugs that rely on novel mechanisms of action to treat severely ill and hospitalized patients, including monoclonal antibodies and immune modulators. These new therapeutics would address an unmet medical need in our pandemic response capacity, and reduce our vulnerability to the emergence of drug-resistant viruses. Finally, BARDA will increase efforts to support novel rapid response manufacturing platform technologies that are expected to shorten the time for deployment of effective pandemic influenza vaccines and therapeutics.

BARDA's FY 2019 funding request supports development of point of need and home use rapid diagnostic tests that empower patients and promote early detection of pandemic viruses. Efforts are also underway to leverage the power of innovative technology by marrying big data with cloud-enabled diagnostic assays that empower patients to seek faster diagnosis and treatment. Additional investments will include development of cost effective re-usable single size face masks and respirators. These strategic investments will close an important gap by enabling early detection of emerging influenza viruses, as well as preventing transmission.

The FY 2019 funding request will support critically important programs to develop and maintain domestic capacity to prevent, diagnose, and treat pandemic influenza that will ultimately save lives and enhance national security.

Annual Funding Request for FY 2019 ($40,000,000):

Vaccine Stockpiling ($32,991,000): BARDA requests funds to support risk-based maintenance, development, and testing of the manufacturing capacity readiness, vaccines, adjuvants, and vaccine components and ancillary supplies that comprise the National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS). This funding will sustain our pre-pandemic influenza vaccine stockpile preparedness goals by assessing current stockpiles of bulk vaccine antigens (essential vaccine components) to determine antigenic match to circulating influenza viruses with greatest pandemic potential, and inform the need to update the vaccine antigen stockpile. BARDA will acquire new

vaccine bulk antigens to maintain and replenish NPIVS inventory to achieve pandemic preparedness goals. BARDA procured a large inventory of adjuvants in 2009 which will require gradual replacement, as informed by stability testing results. Additional adjuvant acquisitions are critical to support the vaccine sparing strategy for pandemic response. BARDA will support clinical studies to test safety, immunogenicity, and tolerability, of stockpiled vaccines. Data from stockpile vaccine clinical trials will inform regulatory filings that establish the safety and immunogenicity of vaccines. Collectively, BARDA's Vaccine Stockpiling investments enable HHS to quickly respond to future pandemic influenza emergencies in the US.

***Office of Policy and Planning International Influenza Activities ($3,000,000*)**: To protect the health security of the United States from global threats, implementation of the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza with Canada and Mexico, and cross-border health security actions with Canada, remain priorities. HHS also will coordinate international preparedness efforts to address pandemic influenza, emerging infectious diseases with pandemic potential, and CBRN threats through the Global Health Security Initiative (G7 countries, Mexico, the European Commission, and WHO) and the Biological Weapons Convention (BWC). HHS 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 US Government's provision and receipt of international assistance during public health and medical emergencies, including addressing legal, regulatory, and logistical barriers to receiving and/or deploying biological specimens, medical personnel, and medical countermeasures. HHS will continue to provide leadership and oversight of US compliance with its obligations under the global health security framework of the International Health Regulations (IHR) and in support of the Global Health Security Agenda, including collaborations with domestic and international partners to support the development and strengthening of IHR core capacities, and conducting evaluation of those capacities through the IHR Joint External Evaluation.

OGA International Influenza Activities ($4,009,000): $4,009,000 is requested in Pandemic Influenza budget authority for the Office of Global Affairs, which is a $27,000 increase above the FY 2018 Annualized Continuing Resolution level. The increase will be used to offset operating inflation. At this level of Pandemic Influenza budget authority, the Office of Global Affairs will 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 United States. Domestic pandemic preparedness is dependent on HHS's 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 fills a unique role within HHS. OGA provides strategic coordination and policy coherence for global affairs to 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, as well as with key multilateral and international institutions involved in health security (e.g. World Health Organization, 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. 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 Request for FY 2019 ($210,000,000):

***Facilities and Infrastructure Readiness ($123,000,000)*:** Funds will sustain the three pillars of domestic influenza vaccine manufacturing capacity: egg-, recombinant-, and cell-based vaccine manufacturing infrastructure. Maintaining this capability to meet U.S. pandemic vaccine production requirements has been achieved through major investments in recent years. Since 2009, BARDA has dramatically increased the robustness of the U.S. influenza vaccine manufacturing capacity by supporting the licensure of recombinant and cell-based technologies, which are independent of egg supplies. Efforts to expand this capacity, further enhancing response capabilities, at the Centers for Innovation in Advanced Design and Manufacturing (CIADMs) have been initiated. In addition to manufacturing capacity, BARDA is continuing efforts to enhance fill/finish capacity to ensure bulk antigen and adjuvant can be filled as quickly as possible in the event of a pandemic, at both the manufacturers' facilities and through BARDA's previously established Fill/Finish Manufacturing Network. These public-private partnerships have created a lasting impact on pandemic readiness in the United States, from production to fill/finish capabilities. The funding requested will allow for continued sustainment of domestic manufacturing and fill-finish capacity for all pandemic vaccine manufacturing platforms, including production of pre-pandemic vaccine and adjuvant, at the facilities in North Carolina, New York, Texas, Maryland and Pennsylvania. These facilities could potentially support production of other MCMs in case of emergency. To ensure a rapid response, clinical trials are being conducted that show the effectiveness of pre-pandemic vaccine and adjuvant. This effort has allowed BARDA to reach previous goals of 500 million (FY 2016) and exceed the 575 million bulk antigen vaccine doses goal (FY 2017), when used with adjuvant, and will allow BARDA to maintain the targeted goal of 600 million bulk antigen vaccine doses (FY 2019), as noted in the performance metric 2.4.15a in the Key Outcomes and Outputs table below.

Improved Influenza Vaccine Advanced Development ($30,000,000): At this funding level, BARDA will invest in vaccine technologies to improve the availability of safe and effective vaccines during a pandemic or other emergency. BARDA will focus on improving the effectiveness of vaccines, improving the manufacturability of vaccines, and developing improved antigen-sparing adjuvant formulations. BARDA's primary focus will be to improve our Nation's pre-pandemic vaccine preparedness.

Advanced Development of Influenza Therapeutics ($42,000,000): 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 updated its strategy to include new 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 currently 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 addition of two immunotherapeutic candidates in FY 2017, this program should ultimately lead to the approval of at least one monoclonal antibody immunotherapeutic candidate for the treatment of critically ill influenza patients in hospital settings. BARDA will utilize OTA awards, as needed, to advance therapeutics product development.

***Diagnostics and Respiratory Protection Device Advanced Development ($15,000,000)*:** 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, with the goal of moving toward fast, real-time notification of positive influenza infection in-home. In an effort to create an integrated system of protection, and to leverage the innovation found in current and future technologies, BARDA will advance diagnostic capabilities even closer to the patient, with wearable devices that will bridge the gap between detection and treatment for influenza. These would include wearable devices which will utilize advanced data analytics and machine learning to predict pre-symptomatic illness through continuous monitoring with the end goal of predicting and diagnosing influenza. Additional and ongoing efforts in FY 2019 will look to enhance national biosecurity with advanced development programs that focus on novel and innovative designs for respiratory protective devices for healthcare providers and first responders as well as patients.

ASPR Pandemic Influenza: Key Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 Target +/-FY 2018 Target
2.4.15a Assure that domestic pandemic influenza vaccine antigen manufacturing surge capacity produces desired number of vaccine doses within six months of candidate vaccine virus being delivered to the manufacturers (Intermediate Outcome)	FY 2017: 600.0 million doses Target: 575.0 million doses (Target Exceeded)	600.0 million doses	600.0 million doses	Maintain
2.4.15b Continue advanced research and development initiatives for more effective influenza vaccines and the development of safe and broad-spectrum therapeutics for use in seriously ill and/or hospitalized patients, including pediatric patients (Intermediate Outcome)	FY 2017: 2.0 programs Target: 2.0 programs (Baseline)	2.0 programs	2.0 programs	Maintain

OGA Pandemic Influenza: Grants

Grants (whole dollars)	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Number of Awards	1	1	1
Average Award	$1,509,090	$1,509,000	$1,500,000
Range of Awards	$1,509,090	$1,509,000	$1,500,000

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Millions)

Description	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget /1	FY 2019 +/- FY 2018
Personnel compensation:				
Full-time permanent (11.1)	108.642	117.402	147.441	30.039
Other than full-time permanent (11.3)	-	-	-	-
Other personnel compensation (11.5)	0.088	0.086	0.111	0.025
Military personnel (11.7)	6.659	7.208	9.655	2.447
Special personnel services payments (11.8)	-	-	-	-
Subtotal, Personnel Compensation	**115.389**	**124.696**	**157.207**	**32.511**
Civilian benefits (12.1)	40.480	43.447	53.769	10.323
Military benefits (12.2)	2.771	3.011	3.855	0.845
Benefits to former personnel (13.0)	-	-	-	-
Subtotal, Pay Costs	**158.640**	**171.153**	**214.832**	**43.679**
Travel and transportation of persons (21.0)	6.797	7.041	17.469	10.428
Transportation of things (22.0)	0.520	0.537	0.716	0.179
Rental payments to GSA (23.1)	20.822	2.423	12.796	10.372
Rental payments to Others (23.2)	-	19.844	30.231	10.387
Communication, utilities, and misc. charges (23.3)	1.640	2.063	2.516	0.452
Printing and reproduction (24.0)	0.103	0.110	0.147	0.037
Other Contractual Services:				
Advisory and assistance services (25.1)	451.587	462.025	534.054	72.028
Other services (25.2)	58.732	50.508	109.576	59.068
Purchase of goods and services from government accounts (25.3)	111.068	111.889	122.500	10.610
Operation and maintenance of facilities (25.4)	4.022	4.229	7.830	3.601
Research and Development Contracts (25.5)	375.809	381.641	446.140	64.498
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	54.627	66.925	74.612	7.687
Subsistence and support of persons (25.8)	0.542	0.688	0.982	0.294
Subtotal, Other Contractual Services	**1,056.387**	**1,077.906**	**1,295.694**	**217.788**
Supplies and materials (26.0)	1.853	1.768	402.430	400.662
Equipment (31.0)	0.620	0.608	15.797	15.189
Land and Structures (32.0)	0.017	0.018	0.024	0.006
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	281.899	279.165	310.926	31.761
Insurance, Claims and Indemnities (42.0)	0.140	0.400	0.300	(0.100)
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-	-	-	-
Subtotal, Non-Pay Costs	**1,370.798**	**1,391.884**	**2,089.045**	**697.161**
Total, Budget Authority by Object Class	**1,529.438**	**1,563.037**	**2,303.877**	**740.840**

1/ FY 2019 estimates are subject to change due to the transfer of the Strategic National Stockpile from CDC to ASPR.

SALARIES AND EXPENSES

(Dollars in Millions)

	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget /1	FY 2019 +/- FY 2018
Personnel compensation:				
Full-time permanent (11.1)	108.642	117.402	147.441	30.039
Other than full-time permanent (11.3)	-	-	-	-
Other personnel compensation (11.5)	0.088	0.086	0.111	0.025
Military personnel (11.7)	6.659	7.208	9.655	2.447
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Insurance and Settlements (42.0)	0.540	0.400	0.300	(0.100)
Total Non-Pay Costs	**1,370.798**	**1,391.884**	**2,089.045**	**697.161**
Total Salary and Expense	**1,529.438**	**1,563.037**	**2,303.877**	**740.840**
Direct FTE	**743**	**772**	**1,007**	**235**

1/ FY 2019 estimates are subject to change due to the transfer of the Strategic National Stockpile from CDC to ASPR.

DETAIL OF FULL-TIME EQUIVALENTS (FTE)

	2017 Actual Civilian	2017 Actual Military	2017 Actual Total	2018 Est. Civilian	2018 Est. Military	2018 Est. Total	2019 Est. Civilian	2019 Est. Military	2019 Est. Total
ASPR									
Direct:	540	72	612	540	72	612	760	72	832
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	**540**	**72**	**612**	**540**	**72**	**612**	**760**	**72**	**832**
Cyber Security									
Direct:	93	-	93	123	-	123	133	-	133
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	**93**	**-**	**93**	**123**	**-**	**123**	**133**	**-**	**133**
Office of Security and Strategic Information									
Direct:	31	2	33	30	2	32	35	2	37
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	**31**	**2**	**33**	**30**	**2**	**32**	**35**	**2**	**37**
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	**668**	**75**	**743**	**697**	**75**	**772**	**932**	**75**	**1,007**

DETAIL OF POSITIONS

Public Health and Social Services Emergency Fund	FY 2017 Final	FY 2018 Annualized CR	FY 2019 President's Budget
Executive level I	2	2	2
Executive level II	6	6	6
Executive level III	0	0	0
Executive level IV	11	11	11
Executive level V	0	0	0
Total - Exec. Level Salaries	**18**	**18**	**18**
ES-6			
ES-5			
ES-4	1,740,000	1,740,000	1,740,000
ES-3			
ES-2	1,015,078	1,022,178	1,023,941
ES-1	383,800	383,800	383,800
Total - ES Salary	**3,138,878**	**3,145,978**	**3,147,741**
Commissioned Corps	2	2	2
GS-15	157	159	159
GS-14	192	220	225
GS-13	132	150	158
GS-12	101	113	115
GS-11	98	103	104
GS-10	3	3	3
GS-9	40	40	39
GS-8	1	2	2
GS-7	62	62	62
GS-6	1	0	0
GS-5	6	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	**795**	**854**	**869**
Average ES level	ES-3	ES-3	ES-3
Average ES salary	173,419	173,811	173,908
Average GS grade	13	13	13
Average GS salary	106,323	106,886	108,472
Average Special Pay categories	121,894	137,238	137,238

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 Assistant Secretary Robert P. Kadlec, MD, MS and by the Principal Deputy Assistant Secretary, Edward J. Gabriel, MPA, EMT-P, CEM CBCP.

Chris Meekins, Chief of Staff

ASPR provides support through six program offices and their 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)
- Chris Meekins, 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 (OCISO) within the Office of the Chief Information Officer (OCIO) at the Department of Health and Human Services.

The Office of the Chief Information Security Officer, which is under the leadership of Chris Wlaschin, Chief Information Security Officer (CISO), directly oversees the following offices and staff personnel: Vacant position (Chris Bollerer in an acting role), Deputy Chief Information Security Officer (DCISO); Vacant position, Healthcare Sector Security Advisor (SA); Vik Sinha, Cybersecurity Technology Advisor; Matthew Shallbetter, Cybersecurity Strategic Design and Innovation; and Eddie Blankenship, Business Operations.

The following offices and staff personnel are overseen by the DCISO: James Antonucci, Cybersecurity Operations; Chris Bollerer, Cybersecurity Services; Vacant position (Julia White in an acting role), Cybersecurity Services to the Office of the Secretary.

The following offices and staff personnel are overseen by Cybersecurity Operations; Bob Barczynski, Security Systems Support; Travis Richardson, Trusted Internet Connection (TIC); Vacant position (Al Roeder in an acting role), Health Cybersecurity and Communications Integration Center (HCCIC); Jen Saunders, Computer Security Incident Response Center (CSIRC); William Welch, Healthcare Threat Operations Center (HTOC); and Al Roeder, Research and Forensics.

The following offices and staff personnel are overseen by the Cybersecurity Services to the Office of the Secretary: Vik Sinha (in an acting role), Incident Response; Julia White, Privacy and Data Protection; and Davene Barton, Information Assurance.

The following offices and staff personnel are overseen by Cybersecurity Services; John Richardson, Enterprise Security Services; Vacant position (Chris Bollerer in an acting role), Cybersecurity Governance; Julie Chua, Cybersecurity Risk Management; and Kathleen Coupe, Cybersecurity Compliance.

ASSISTANT SECRETARY FOR ADMINISTRATION
Office of Security & Strategic Information Organization Structure

HHS Deputy Secretary
- Eric Hargan

Assistant Deputy Secretary
- Captain Michael Schmoyer, PHS

Deputy Director
- Lisa Aguirre, Acting

Directorate Intelligence and Analysis
- William Pachucki, Acting

Directorate of Operations
- Jason Cameron

Directorate of Personal Security
- Sonya Sargent-Oliver

Senior Advisor for Homeland Security
- Commander Brett Maycock, PHS

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

Tracie Infographic Figure

ASPR TRACIE Stats:

- 195,000 visitors to website
- 2,900 Training technical assistance requests
- Types of professional requesting TTA:
    - Healthcare Professional
    - Federal, State, Local, Tribal Government
    - Hospital
    - Healthcare coalition
    - Healthcare association
    - Academia
- More than 500 subject matter expert cadre members
- 63 topic collections
    - 52 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 4,100 Information exchange members
- 150,000 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”