DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2020

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) 2020 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2020 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 2020 budget justification for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Cybersecurity, the Office of National Security (ONS), and the Office of Global Affairs pandemic influenza program.

Office of the Assistant Secretary for Preparedness and Response

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 #8. HHS also supports other federal entities who lead Emergency Support Function #6 with respect to human and social services, including recovery. ASPR coordinates across HHS, 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, including the Biomedical Advanced Research and Development Authority (BARDA) and the Strategic National Stockpile (SNS), ASPR oversees advanced research, development, procurement, and stockpiling of medical countermeasures (e.g. vaccines, medicines, diagnostics, and other necessary medical supplies).

ASPR continues to respond to catastrophic hurricanes and other natural disasters by activating National Disaster Medical System (NDMS) personnel to communities impacted by the storms. NDMS is increasing its intermittent employee workforce towards a goal of over 6,000 personnel organized into 71 teams. NDMS currently has 2,941 deployable personnel. Throughout FY 2018, NDMS teams provided public health and medical support for the following: California Wildfires, the State of the Union Address, the United Nations General Assembly, the Peace Officer's Memorial, and ongoing operations in support of Puerto Rico and the United Sates Virgins Islands response and recovery efforts.

NDMS teams include clinical providers and specialized medical service professionals, including physicians, nurses, fatality management professionals, paramedics, veterinarians, and other support staff, such as logisticians and information technology specialists. During the natural disaster responses to Hurricanes Florence, Isaac, Michael, and Typhoon Yutu in 2018, ASPR deployed over 20 NDMS teams on a rotational basis comprised of more than 2000 employees that treated patients with a wide variety of illnesses and injuries. ASPR's actions saved lives, stabilized the healthcare system, and restored services. 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. 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 licensure 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, 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 that have transitioned to support under Project BioShield; 15 of these products have been procured for the Strategic National Stockpile (SNS).

BARDA 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 and provides alternate mechanisms (e.g., vendor managed inventory systems) to stockpiling in the SNS.

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. During 2018, BARDA continued to support expansion of domestic adjuvant manufacturing capacity. This effort includes both bulk adjuvant manufacturing as well as fill/finish capability. Additional efforts during 2019 and 2020, contingent upon available funding, will look to further improve adjuvant manufacturing capacity and fill/finish capability. Once completed, these efforts will ensure a ready supply of adjuvant in the event of a pandemic. In 2018, BARDA collaborated with the Department of Defense (DoD) to re-evaluate both the CIADMs and the DoD's advanced development and manufacturing (ADM) facility at Ology.

To improve America's readiness against national disasters, including naturally or man-made disease threats, ASPR has acquired the SNS and is engaging in the procurement, maintenance, and deployment of medical countermeasures. The addition of the SNS to ASPR improves 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 and to maintain and improve SNS capabilities as well as address inventory gaps. Through this, 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. Under ASPR, the SNS will make meaningful investments across a spectrum of threats, including antibiotics to treat anthrax exposure; antivirals to treat pandemic influenza; and vaccines and therapeutic drugs to protect against smallpox. At the requested funding level, the SNS, in FY 2020, will replace the highest priority expiring medical countermeasures held in inventory. The requested funding level ensures SNS assets are available and ready for use to protect America from 21st century health security threats in FY 2020 by: managing, 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; 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; and, providing timely, accurate, and relevant information to clinicians to respond to emerging threats and public health emergencies.

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

Goal 1 – Provide strong leadership. ASPR is a leader in both preparedness for and response to 21st century health security threats. ASPR provides clear policy direction, and improved threat awareness, while continuing to secure adequate resources to manage the next health threat. ASPR will continue to coordinate with public health agencies as well as the Director of National Intelligence and the Department of Homeland Security to address current and future national security threats.

Goal 2 – Support Regional Disaster Health Response Capabilities. To address the potential catastrophic medical consequences of 21st century threats, a regional approach to improve national health care readiness and medical surge capacity is needed. Supporting regional disaster health response capabilities will require collaboration among existing local healthcare coalitions, trauma centers, public and private health care facilities, and emergency medical services. This may be accomplished by integrating preparedness within the already-existing health care delivery infrastructure across the public and private sectors and increasing coordination with non-government entities, including private sector hospitals and health care providers. Ultimately, this approach will better support state, local, tribal, and territorial (SLTT) disaster risk reduction, preparedness, mitigation, response, and recovery efforts.

Goal 3 – Sustain robust and reliable public health security capabilities. ASPR supports public health agencies' ability to quickly detect, diagnose, monitor and respond to 21st century health threats. This is critical to rapidly and effectively dispense MCMs in an emergency. ASPR has responsibility for the Strategic National Stockpile and the "last mile" of MCM distribution and dispensing, in coordination with CDC.

Goal 4 – Advance an innovative medical countermeasures enterprise. Since 2006, ASPR's Biomedical Advanced Research and Development Authority (BARDA) has supported the advanced research and development of new MCMs. By using flexible, nimble authorities, multi-year advanced funding, strong public-private partnerships, and cutting-edge expertise, BARDA has successfully advanced 43 innovative products to the Food and Drug Administration for approval. ASPR will continue to develop and maintain a robust stockpile of MCMs capable of responding to 21st century health threats.

The FY 2020 budget request for ASPR is $2,587,019,000, which is $25,900,000 above the FY 2019 Enacted level. The request provides:

- $1.3 billion for BARDA, including $562 million for Advanced Research and Development, and $735 million for Project BioShield procurements of MCMs;
- $260 million for pandemic influenza preparedness activities by ASPR and the HHS Office of Global Affairs;
- $620 million for the Strategic National Stockpile (SNS) to manage and deliver life-saving medical countermeasures during a public health emergency;

- $258 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;

- $106 million for public health and medical preparedness and emergency operations, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps; and,

- $51 million for ASPR's policy, planning, acquisitions, grants, financial management, administrative operations, and executive leadership.

Cybersecurity

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 2020 budget request for Cybersecurity is $68 million, which is $9.233 million above the FY 2019 Enacted 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

Office of National Security

The Office of National Security (ONS), formerly known as 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– all of which are resourced with PHSSEF funds. ONS is also responsible for the Department's personnel security programs; these are resourced by non-PHSSEF funds. ONS 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 ONS'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.

ONS is responsible for the safeguarding of all classified information, equipment and facilities across the Department and is HHS's Federal Intelligence Coordination Office (FICO) and Secretary's Senior Intelligence Official. The FY 2020 budget request includes $7 million for ONS, remaining flat with the FY 2019 Enacted level.

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 2020 Budget re-proposes the establishment of a new transfer authority within the Office of the Secretary. HHS would have Department-wide transfer authority 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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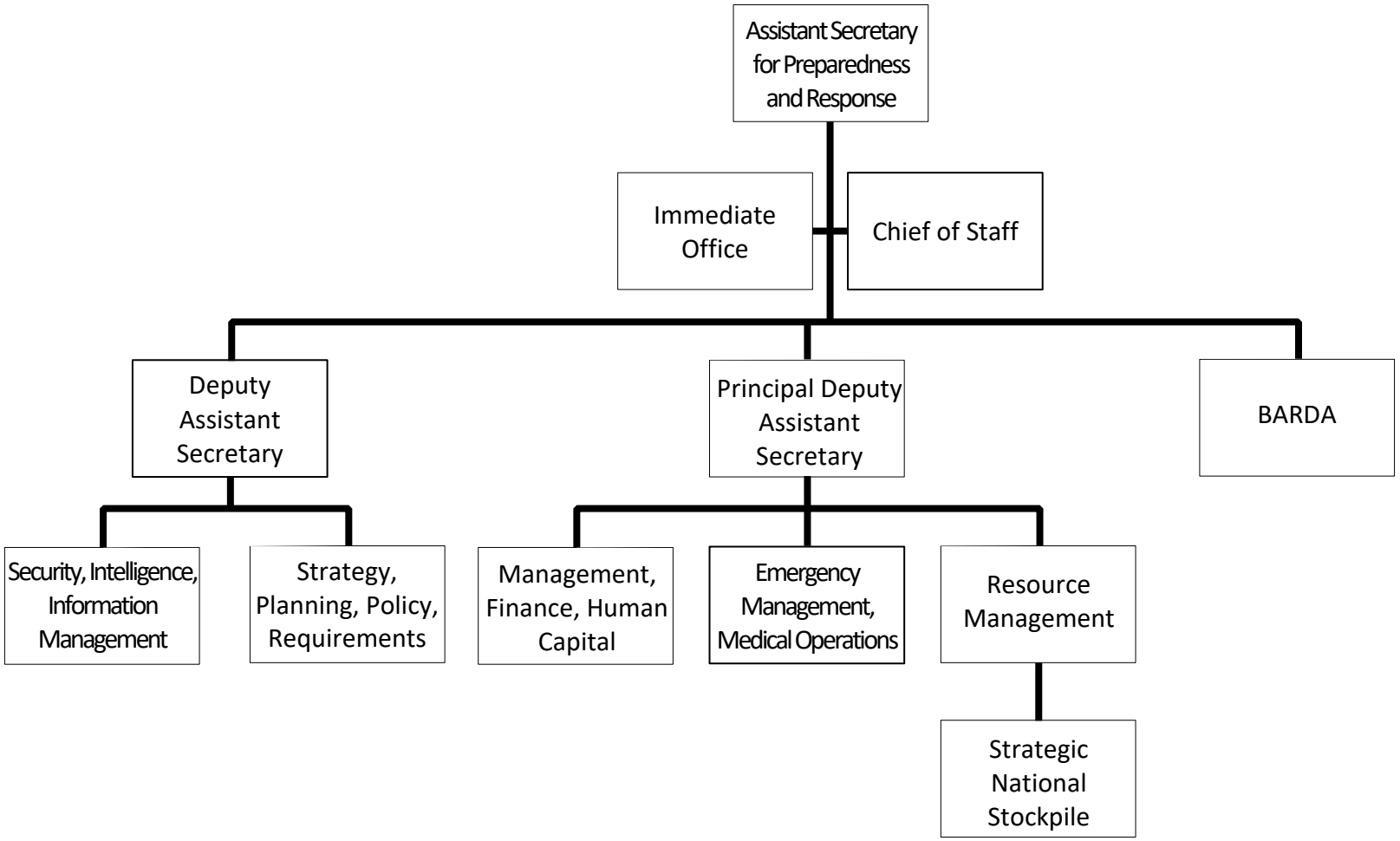
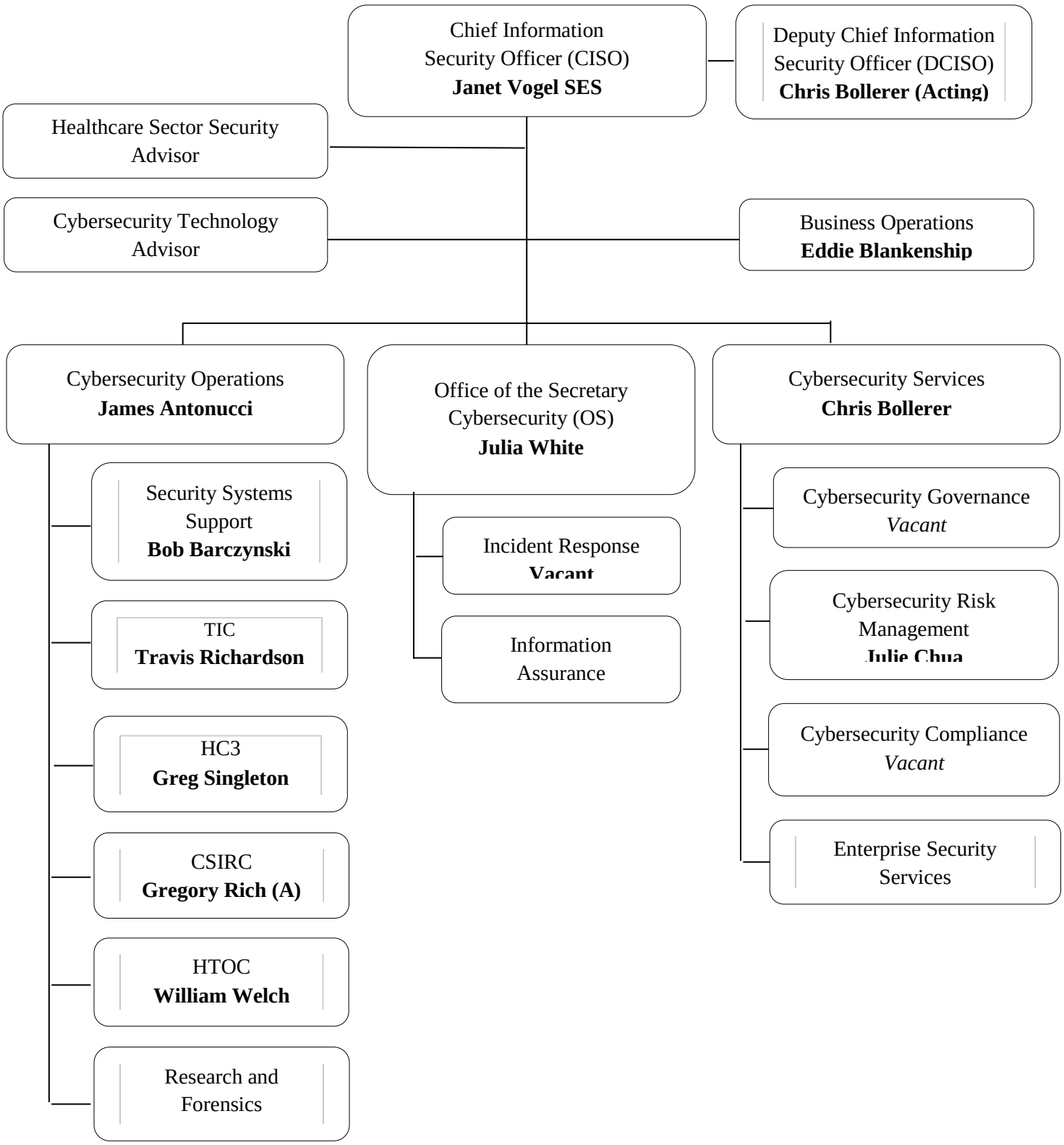
ORGANIZATIONAL CHARTS

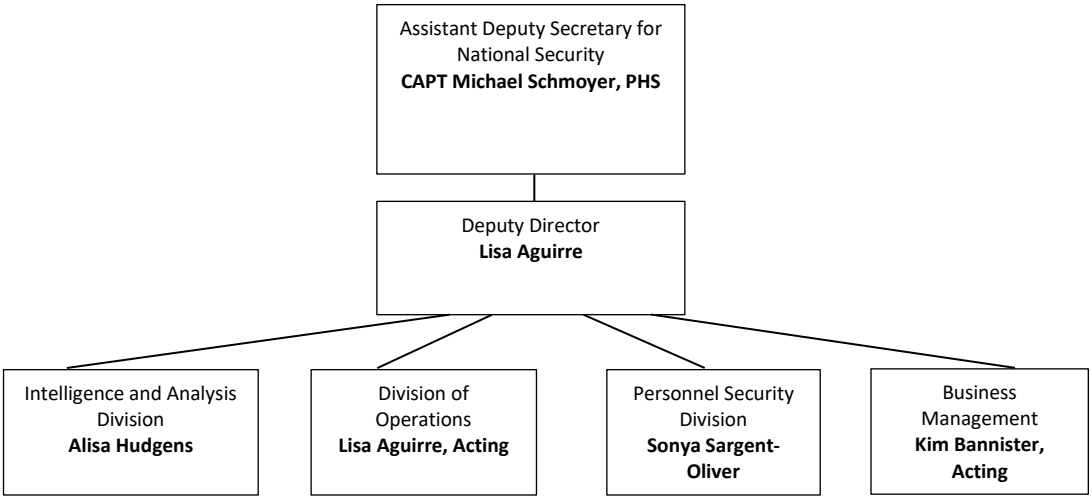
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE



CYBERSECURITY



OFFICE OF NATIONAL SECURITY



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) mission is to save lives and protect Americans from 21st century health security threats. These threats include natural disasters, pandemic diseases, and man-made threats from chemical, biological, nuclear, and radiological (CBRN) agents. ASPR coordinates across HHS and the Federal interagency to support state, local, territories, and tribal health partners in preparing for and responding to emergencies and disasters.

The ASPR serves as the principal advisor to the Secretary on public health and medical emergency preparedness and response, including incidents covered by the National Response Framework. ASPR takes a collaborative approach to the Department's preparedness, response, and recovery responsibilities by working with Operational Divisions and Staff Divisions across the Department to coordinate preparedness and response activities. In addition, ASPR has operational responsibilities for the advanced research and development and the stockpiling of medical countermeasures (MCMs) and for the coordination of the Federal public health and medical response to such incidents.

The strength of our nation's public health and medical infrastructure, as well as the capabilities necessary to quickly mobilize a coordinated national response to pandemics, attacks and disasters, are essential to save lives and protect all Americans.

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 National Security:

The Office of National Security (ONS), formerly known as 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– all of which are resourced with PHSSEF funds. ONS is also responsible for the Department's personnel security programs; these are resourced by non-PHSSEF funds. ONS 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 ONS'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. ONS is responsible for the safeguarding of all classified information, equipment and facilities across the

Department and is HHS's Federal Intelligence Coordination Office (FICO) and Secretary's Senior Intelligence Official.

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 2020 Request for the Public Health and Social Services Emergency Fund (PHSSEF) is $2,666.591 million, which is an increase of $35.133 million relative to the FY 2019 Enacted level. 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 2019 Enacted):

National Disaster Medical System (NDMS) (increase of +$20 million, $77.404 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. This increase will support the pediatric disaster care pilot initiative.

Strategic National Stockpile (SNS) (increase of +$10.0 million, $620.000 million total): This increased investment will allow ASPR to replace the highest priority expiring SNS countermeasures in FY 2020. Product procurement in FY 2020 will be guided by existing guidance and recommendations from The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). ASPR will coordinate PHEMCE activities to develop strategies to meet the national priorities for federal stockpiling and to maintain SNS capabilities and address inventory gaps.

Cybersecurity (increase of +$9.233 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.

Policy and Planning (increase of +$5 million, $19.877 million total): The request supports the development of strategic and operational plans to implement national preparedness functions and prepare for HHS's response during events. The increase will include $5 million in no-year funding to support the implementation of the National Biodefense Strategy.

Programmatic Decreases (relative to the FY 2019 Enacted):

Hospital Preparedness Program (HPP) (decrease of -$7 million, $257.555 million total): Within the total, $231,500,000 will be provided for HPP formula-based cooperative agreements to states, territories and freely-associated states, the District of Columbia, and three high risk political subdivisions. The remaining funds support HPP 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), Emergency Care Coordination Center (ECCC), the Recovery program, and the Critical Infrastructure Protection (CIP) program.

Medical Reserve Corps (MRC) (decrease of -$2.1 million, -$3.9 million total): This funding will support overarching national and regional coordination and technical assistance to MRC unit leaders to guide the development and sustainment of the units. This includes identifying and/or sharing training resources for unit leaders and volunteers, best practices in volunteer recruitment and retention, and other topics critical to unit leaders.

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 efforts.

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 (MCMs), 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

ASPR partners with the Centers for Disease Control and Prevention (CDC) to lead one of four HHS Agency Priority Goals (APG). APG's are a tool used to accelerate progress on a limited number of Presidential priority areas where implementation requires active collaboration among more than one Federal agency within the same Department. ASPR and CDC lead the Health Security APG, which is working to increase the capacity to prevent health threats impacting the United States. This APG reports HHS' efforts to increase the surveillance, workforce, emergency management, and laboratory capacity.

Examples of Key Accomplishments

When disaster strikes, ASPR 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, ASPR provides essential medical and emergency management services with advanced equipment and subject matter expertise. ASPR's response teams include clinical providers and emergency medical service professionals, such as physicians, nurses, paramedics, and other support staff, including information technology specialists.

Health care readiness is at the heart of ASPR. As the only source of federal funding to prepare the nation's mostly private health care system to respond to emergencies, ASPR has been supporting health care system readiness around the country for the past 15 years. Supporting the development and sustainment of health care coalitions (HCCs) is key to ASPR's success. ASPR encourages diverse organizations to work together through HCCs to make sure their communities are ready to respond during emergencies. When asked about the program, over 95% of HCCs state that ASPR funding, guidance, and technical support have improved their ability to decrease morbidity and mortality during disasters.

ASPR reports performance data in its budgets, including the number of new MCMs for Chemical, Biological, Radiological, and Nuclear threats under the Food and Drug Administration's Emergency Use Authority and also the technical assistance provided by ASPR to MCM manufacturers. These measures provide some of the data ASPR uses to support its 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.

Innovation combines with an evidence-based approach to help ASPR remain responsive. One of the issues faced by ASPR is the need for earlier detection of infection, creating technology that can alert people when they have been infected with a bacteria or virus even before they begin to feel sick. A second issue is the urgent need to solve sepsis, the body's life-threatening response to infection or traumatic injury. Sepsis is a top cause of hospitalization in America, leads to 250,000 deaths annually and costs approximately $24 billion a year to treat. The number of sepsis cases could skyrocket after a bioterrorism attack or pandemic. The ASPR DRIVe program will oversee the accelerator network and is recruiting a nonprofit partner that can work with private investors to fund innovative technologies and products to solve these and other systemic health security challenges. DRIVe also can invest in the projects using quick, streamlined funding methods.

Performance Management

Influenza provides a snapshot into the performance management challenges faced by a federal agency with ASPR's complex mission. ASPR continues its mission of supporting activities that also improve current manufacturing capabilities to deliver current vaccine faster in the event of a pandemic, and to improve the efficacy and utility of existing vaccines. These activities are critical to ensure the necessary response if a pandemic occurs now. Parallel goals lead to multiple simultaneous improvements. For example, many of the universal vaccine activities also benefit domestic manufacturing capacity generally, including identification of improved adjuvant as well as formulation approaches.

The transfer of oversight and operational control of the Strategic National Stockpile (SNS) from the CDC to ASPR aligns with ASPR's broad ESF 8 mission. The transfer provides an opportunity for HHS to consider how performance for the SNS is measured and reported.

The Potential Impact of Resource Changes

The FY 2020 Request for ASPR is $2,587.019 million and 832 Full Time Equivalent positions. The request is an increase of $25.9 million above the FY 2019 Enacted level. The impact of the requested 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. This includes funding to continue the pediatric disaster care pilot initiative. Also, the resources provided through this request will 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 requested funding for ASPR includes the advanced development of the highest priority medical countermeasures. ASPR 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 the resources provided will also ensure that 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 training activities for the HHS exercises, Continuity of Operations, and support for National Special Security Events.

FY 2020 ALL PURPOSE TABLE
PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

(Dollars in Millions)

Program	FY 2018 Final /1	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019 Enacted
Assistant Secretary for Preparedness and Response (ASPR):				
Preparedness and Emergency Operations	24.654	24.654	24.654	--
Office of Emergency Management only (non-add)	*19.654*	*19.654*	*19.654*	--
National Special Security Events (NSSE) (non-add)	*5.000*	*5.000*	*5.000*	--
National Disaster Medical System (NDMS)	57.404	57.404	77.404	+20.000
Pediatric Disaster Response (non-add)	--	--	*20.000*	*+20.000*
Hospital Preparedness	264.555	264.555	257.555	-7.000
Hospital Preparedness Program (HPP) Grants (non-add)	*231.500*	*231.500*	*231.500*	--
Medical Reserve Corps	6.000	6.000	3.900	-2.100
Biomedical Advanced Research and Development Authority (BARDA)	536.700	561.700	561.700	--
Advanced Research and Development (non-add)	*476.700*	*501.700*	*501.700*	--
Operations and Management (non-add)	*60.000*	*60.000*	*60.000*	--
Project BioShield	710.000	735.000	735.000	--
Strategic National Stockpile /2	603.900	610.000	620.000	+10.000
Office of Policy and Planning	14.877	14.877	19.877	+5.000
National Biodefense Strategy (non-add)	--	--	*5.000*	*+5.000*
Operations	30.938	30.938	30.938	--
ASPR Pandemic Influenza				
No-Year Pandemic Influenza	215.000	225.000	225.000	--
Annual Pandemic Influenza	30.991	30.991	30.991	--
Subtotal, ASPR Pandemic Influenza	245.991	255.991	255.991	--
Subtotal, ASPR Program Level	**2,495.019**	**2,561.119**	**2,587.019**	**+25.900**
Subtotal, ASPR Budget Authority	***2,495.019***	***2,561.119***	***2,587.019***	***+25.900***
Other Office of the Secretary:				
Office of Global Affairs Pandemic Influenza	4.009	4.009	4.009	--
Annual funding (non-add)	*4.009*	*4.009*	*4.009*	--
Cybersecurity /3	49.820	58.860	68.093	+9.233
Office of National Security (ONS) /3	8.510	7.470	7.470	--
Subtotal, Other Office of the Secretary	**62.339**	**70.339**	**79.572**	+9.233
PHSSEF Total:				
HHS Pandemic Influenza Budget Authority	250.000	260.000	260.000	--
No-Year Pandemic Influenza (non-add)	*215.000*	*225.000*	*225.000*	--
Annual Pandemic Influenza (non-add)	*35.000*	*35.000*	*35.000*	--
All Other Budget Authority	2,307.358	2,371.458	2,406.591	+35.133
Total, PHSSEF Program Level	**2,557.358**	**2,631.458**	**2,666.591**	**+35.133**
Total, PHSSEF, Budget Authority	***2,557.358***	***2,631.458***	***2,666.591***	***+35.133***
NEF				
Cybersecurity	--	34.000	--	--
FTE				
ASPR	612	832	832	--
OGA	5	5	5	--
ONS	26	37	37	--
Cybersecurity	89	133	143	+10
Total FTE, PHSSEF	**732**	**1,007**	**1,017**	**+10**

1/ Excludes supplemental emergency resources provided in the Bipartisan Budget Act of 2018.

2/ FY 2019 funding for the Strategic National Stockpile was administratively transferred from CDC to ASPR. FY 2018 funding is comparably adjusted and reflects a Secretarial transfer of $6.1 million to CDC for transition costs. FY 2019 funding does not reflect an additional Secretarial transfer of $6.1 million to CDC.

3/ FY 2018 total reflects a realignment of $1.04 million from Cybersecurity to ONS to support the cyber threat activities carried out by ONS.

FY 2020 PROPOSED APPROPRIATIONS LANGUAGE

(Relative to FY 2019 Enacted)

For expenses necessary to support activities related to countering potential biological, nuclear, radiological, chemical, and cybersecurity threats to civilian populations, and for other public health emergencies, [$1,026,458,000]$1,051,591,000, of which $561,700,000 shall remain available through September 30, [2020]2021, for expenses necessary to support advanced research and development pursuant to section 319L of the PHS Act and other administrative expenses of the Biomedical Advanced Research and Development Authority: *Provided*, That funds provided under this heading for the purpose of acquisition of security countermeasures shall be in addition to any other funds available for such purpose: *Provided further*, That products purchased with funds provided under this heading may, at the discretion of the Secretary, be deposited in the Strategic National Stockpile pursuant to section 319F-2 of the PHS Act: *Provided further*, That $5,000,000 of the amounts made available to support emergency operations shall remain available through September 30, [2021]2022[.]: *Provided further*, That $20,000,000 of the amounts made available to the National Disaster Medical System shall remain available through September 30, 2021, for activities related to the Pediatric Disaster Care Program: *Provided further*, That $5,000,000 of the amounts made available for policy and planning shall remain available until expended, for implementation activities related to the National Biodefense Strategy:

For expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)(1)(B) of the PHS Act), $735,000,000, to remain available until expended.

For expenses necessary to carry out section 319F-2(a) of the PHS Act, $620,000,000, to remain available until expended.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic, $260,000,000; of which $225,000,000 shall be available until expended, for activities including the development and purchase of vaccine, antivirals, necessary medical supplies, diagnostics, and other surveillance tools: *Provided*, That notwithstanding section 496(b) of the PHS Act, funds may be used for the construction or renovation of privately owned facilities for the production of pandemic influenza vaccines and other biologics, if the Secretary finds such construction or renovation necessary to secure sufficient supplies of such vaccines or biologics.

APPROPRIATIONS LANGUAGE ANALYSIS

Language Provision	Explanation
Provided further, That $20,000,000 of the amounts made available to the National Disaster Medical System shall remain available through September 30, 2021, for activities related to the Pediatric Disaster Care Program:	This language appropriates $20,000,000 with two-year availability for the National Disaster Medical System. This funding would continue to support a pilot that would provide specialized pediatric care to address medical needs of children in the event of a disaster.
Provided further, That $5,000,000 of the amounts made available for policy and planning shall remain available until expended, for implementation activities related to the National Biodefense Strategy:	This language appropriates $5,000,000 with no-year availability for ASPR's policy and planning budget. This funding would support administrative activities related to the implementation of the National Biodefense Strategy.
For expenses necessary to carry out section 319F-2(a) of the PHS Act, $620,000,000, to remain available until expended.	This language appropriates $620,000,000 for the management of the Strategic National Stockpile.

AMOUNTS AVAILABLE FOR OBLIGATION

Detail	FY 2018 Final /1 /2	FY 2019 Enacted /2	FY 2020 President's Budget
Appropriation	1,953,458,000	2,021,458,000	2,666,591,000
Supplemental (P.L. 115-123)	80,000,000		
Subtotal, Adjusted Appropriation	**2,033,458,000**	**2,021,458,000**	**2,666,591,000**
Transfer of Funds from: ("CDC Public Health Preparedness and Response")		610,000,000	
Comparable transfer from: ("CDC Public Health Preparedness and Response")	603,900,000	-	
Subtotal, Adjusted Budget Authority	**2,637,358,000**	**2,631,458,000**	**2,666,591,000**
Unobligated balance, start of year	124,601,017	439,160,471	
Unobligated balance, end of year	439,160,471		
Unobligated balance, lapsing	21,493,527		
Unobligated balance transferred from: ("CDC Public Health Preparedness and Response")		428,308,497	
Total obligations	**1,990,901,399**		

1/ "Excludes the following amounts for reimbursable activities carried out by this account:
2018 $190,459,855

2/ FY 2019 funding for the Strategic National Stockpile (SNS) was administratively transferred from CDC to ASPR. FY 2018 funding is comparably adjusted and reflects a Secretarial transfer of $6.1 million from the SNS budget to CDC for transition costs. FY 2019 funding does not reflect an additional Secretarial transfer of $6.1 million from the SNS budget to CDC.

SUMMARY OF CHANGES

(Dollars in Millions)

FY 2019 Enacted	
Total budget authority	2,631.458
FY 2020 President's Budget	
Total estimated budget authority	2,666.591
Net Change	+35.133

	FY 2019 Enacted BA	FY 2019 Enacted FTE	FY 2020 PB BA	FY 2020 PB FTE	FY 2020 +/- FY 2019 BA	FY 2020 +/- FY 2019 FTE
Increases:						
Assistant Secretary for Preparedness and Response						
National Disaster Medical System (NDMS)	57.404	115	77.40	115	+20.000	--
Strategic National Stockpile (SNS)	610.000	225	620.00	225	+10.000	--
Policy and Planning	14.877	66	19.88	66	+5.000	--
Cybersecurity	58.860	133	68.093	143	+9.233	+10
Total Increases	741.141	539	785.374	549	+44.233	+10
Decreases:						
Assistant Secretary for Preparedness and Response						
Hospital Preparedness Program (HPP)	264.555	49	257.555	49	-7.000	--
Medical Reserve Corps (MRC)	6.000	6	3.900	6	-2.100	--
Total Decreases	270.555	55	261.455	55	-9.100	--
Net Change					+35.133	+10

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Millions)

Activity	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Bioterrorism and Emergency Preparedness	2,307.358	2,371.458	2,406.591
Pandemic Influenza	250.000	260.000	260.000
Total Budget Authority	**2,557.358**	**2,631.458**	**2,666.591**
FTE	**732**	**1,007**	**1,017**

1/ FY 2019 funding for the Strategic National Stockpile (SNS) was administratively transferred from CDC to ASPR. FY 2018 funding is comparably adjusted and reflects a Secretarial transfer of $6.1 million from the SNS budget to CDC for transition costs. FY 2019 funding does not reflect an additional Secretarial transfer of $6.1 million from the SNS budget to CDC.

AUTHORIZING LEGISLATION

(Dollars in Millions)

Details	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Pandemic and All-Hazards Preparedness Reauthorization Act 2013 (PAHPRA)	2,557.358	2,631.458	2,666.591

1/ FY 2019 funding for the Strategic National Stockpile (SNS) was administratively transferred from CDC to ASPR. FY 2018 funding is comparably adjusted and reflects a Secretarial transfer of $6.1 million from the SNS budget to CDC for transition costs. FY 2019 funding does not reflect an additional Secretarial transfer of $6.1 million from the SNS budget to CDC.

APPROPRIATIONS HISTORY

(Dollars in Millions)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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	1,953.458
Supplemental Appropriation (PL 115-123)				162.000
Transfer to HRSA				(60.000)
Transfer to SAMHSA				(20.000)
Transfer to OIG				(2.000)
Subtotal				2,033.458
FY 2019				
Appropriation	2,303.877	2,046.458	2,813.128	2,021.458
Transfer from CDC /1				610.000
Subtotal	2,303.877	2,046.458	2,813.128	2,631.458
FY 2020				
Estimated Appropriation				2,666.591

1/ FY 2019 transfer of Strategic National Stockpiling funding from CDC to ASPR does not reflect a Secretarial transfer of $6.1 million to CDC for transition costs.

APPROPRIATIONS NOT AUTHORIZED BY LAW

(Dollars in Millions)

Program	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2019
ASPR				
Preparedness and Emergency Operations	N/A	N/A	24.654	24.654
National Disaster Medical System	FY 2018	52.700	57.404	57.404
Medical Reserve Corps	FY 2018	11.200	6.000	6.000
Hospital Preparedness Program	FY 2018	374.700	264.555	264.555
BARDA	FY 2018	415.000	536.700	561.700
Project BioShield	FY 2018	2,800.000	710.000	735.000
Strategic National Stockpile	FY 2018	533.800	610.000	610.000
Office of Policy and Planning	N/A	N/A	14.877	14.877
Operations	N/A	N/A	30.938	30.938
Pandemic Influenza	N/A	N/A	245.991	255.991
OGA Pandemic Influenza	N/A	N/A	4.009	4.009
Cybersecurity	N/A	N/A	50.860	58.860
Office of Security and Strategic Information	N/A	N/A	7.470	7.470

OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

SUMMARY OF REQUEST

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Program Level	**2,495.019**	**2,561.119**	**2,587.019**	**+25.900**
Budget Authority (non-add)	*2,495.019*	*2,561.119*	*2,587.019*	+25.900
FTE	**612**	**832**	**832**	**--**

1/ Totals include ASPR's portion of pandemic influenza funding.
2/ FY 2019 funding for the Strategic National Stockpile (SNS) was administratively transferred from CDC to ASPR. FY 2018 funding is comparably adjusted and reflects a Secretarial transfer of $6.1 million from the SNS budget to CDC for transition costs. FY 2019 funding does not reflect an additional Secretarial transfer of $6.1 million from the SNS budget to CDC.

The Fiscal Year (FY) 2020 Budget Request for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is $2,587,019,000. The request is an increase of $25,900,000 above the FY 2019 Enacted budget.

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. ASPR modernized the federal public health and medical emergency management infrastructure and strengthened states' and local communities' disaster response and recovery posture. In addition, ASPR leads policy development, collaboration, and research on medical countermeasures (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 MCMs. 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; 15 of these products have been procured for the Strategic National Stockpile (SNS), with additional products to be delivered in FYs 2019 and 2020.

ASPR continues to dedicate efforts and resources towards the Ebola and Zika viruses. For FY 2020, 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 MCMs, a new product to temporize burn injury, and a new radiation MCM. 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. BARDA 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). TRACIE also provides surge assistance and resources during and after incidents. For example, in response to the 2017 hurricane season, ASPR developed the Major Hurricanes: Potential Public Health and Medical Implications. In response to the 2017-2018 flu season, TRACIE brought together SMEs from across the country to develop the Considerations for the Use of Temporary Care Locations for Managing Seasonal Patient Surge. In response to the Las Vegas shooting and other mass violence/no-notice incidents, TRACIE developed a suite of resources listed under a Select Mass Violence Resources page to include: nine No-Notice Incident Tip Sheets, Healthcare Response to a No-Notice Incident: Las Vegas Webinar, and Issue 7 of The Exchange: Providing Healthcare During No-Notice Incidents.

Through the National Disaster Medical System (NDMS), ASPR will continue to provide assistance as requested by states whose medical infrastructure has become overwhelmed to help with their critical medical services to protect public health and help communities respond and recover faster. In FY 2018, NDMS teams provided public health and medical support for the California Wildfires, the State of the Union Address, the United Nations General Assembly, the Peace Officer's Memorial, and ongoing operations in support of Puerto Rico and the United Sates Virgins Islands response and recovery efforts. In FY 2020, ASPR will continue the Pediatric Disaster Care Program pilot initiative, which address the existing shortfalls in pediatric disaster care identified by ASPR and NDMS. The funding will allow NDMS to continue to develop and pilot a Pediatric Disaster Care Program that could become capable of effectively addressing appropriate planning decontamination considerations, and mass sheltering.

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 and protect Americans from 21st century health security threats. 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 and enables rapid recovery. In FY 2018, ASPR funded two regional disaster health response system (RDHRS) pilots. While HPP focuses on preparing the health care system to coordinate, respond as a whole, and protect its workers, the RDHRS pilots build upon that focus by coordinating intra- and interstate health care systems and by enhancing the clinical expertise for specialized care (e.g., trauma, burns, pediatrics, chemical, biological, radiological, nuclear, and explosives (CBRNE)) to increase medical surge and enhance the survival rates of the affected populations.

In partnership with the Centers for Medicare & Medicaid Services (CMS), ASPR provides de-identified near real-time data and mapping products, including the HHS emPOWER Map, to enhance state, local and community based awareness of 3.9 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 50,000 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's goal for FY 2020 is to maintain preparedness and achieve new successes in public health emergency management. The FY 2020 budget proposes funding increases in numerous areas which will contribute significantly to advances in public health emergency management.

Increases above the FY 2019 Enacted budget level:

National Disaster Medical System (NDMS): The budget requests $77,404,000 for NDMS, which is +$20,000,000 above the FY 2019 Enacted 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. The $20 million increase in requested funding will continue support for the pediatric disaster care pilot initiative and is 2-year funding.

Strategic National Stockpile (SNS): The budget requests $620,000,000 for the SNS, which is +$10,000,000 above the FY 2019 Enacted level. This increased investment will allow ASPR to replace the highest priority expiring SNS countermeasures in FY 2020. Product procurement in FY 2020 will be guided by existing guidance and recommendations from the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) from previous fiscal years. ASPR will coordinate PHEMCE activities to develop strategies to meet the national priorities for federal stockpiling and to maintain SNS capabilities and address inventory gaps with available funding.

Policy and Planning: The budget requests $19,877,000, which is +$5,000,000 above the FY 2019 Enacted level. The request supports the development of strategic and operational plans to implement national preparedness functions and prepare for HHS's response during events. The increase will include $5 million in no-year funding to support the implementation of the National Biodefense Strategy.

Decreases below the FY 2019 Enacted budget level:

Medical Reserve Corps (MRC): The budget requests $3,900,000 for MRC, which is -$2,100,000 below the FY 2019 Enacted level. This funding will support overarching national and regional coordination and technical assistance to MRC unit leaders to guide the development and sustainment of the units. This includes identifying and/or sharing training resources for unit leaders and volunteers, best practices in volunteer recruitment and retention, and other topics critical to unit leaders.

Hospital Preparedness Program (HPP): The budget requests $257,555,000, which is -$7,000,000 below the FY 2019 Enacted level. Within the total, $231,500,000 will be provided for HPP formula-based cooperative agreements to states, territories and freely-associated states, the District of Columbia, and three high risk political subdivisions. The remaining funds support HPP administration and performance evaluation and oversight, as well as other programs at ASPR that directly support the mission of HPP, including TRACIE, ECCC, the Recovery program, and the CIP program.

PREPAREDNESS AND EMERGENCY OPERATIONS

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**24.654**	**24.654**	**24.654**	**--**
National Special Security Events/Public Health Emergencies (non-add)	*5.000*	*5.000*	*5.000*	*--*
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, it 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 during "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 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. It requires extensive, continual and cross-cutting situational awareness, planning, training, exercises, incident management, contingencies and evaluation. Preparedness and Emergency Operations funding provides this ability to integrate ASPR's significant preparedness and response assets into a whole-of-agency capability to save lives and protect Americans.

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 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. 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.

ASPR has led and supported HHS's efforts to respond to, mitigate, and recover from, the lasting impacts of public health and medical emergencies since its inception twelve years ago. For example, ASPR supported responses to Hurricanes Ike and Gustav in 2007; Sandy in 2012; Harvey, Irma, and Maria in 2017; and Florence, Michael, and Typhoon Yutu in 2018. ASPR also responded to the earthquake in Haiti in 2009 and the Deepwater Horizon oil spill in 2010. In FY 2016 and FY 2017, ASPR 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 FY2018, ASPR provided support to California during the devastating wildfires near Chico, CA. In addition, ASPR supports a number of planned annual events including: the President's State of the Union Address; the Peace Officer's Memorial and Independence Day celebrations in Washington, D.C.; as well as Democratic and Republican National Conventions, Presidential Inaugurations, and Presidential addresses to Congress. In FY 2018, ASPR also supported several funeral services including the Reverend Billy Graham, Senator John McCain, and former President George H. W. Bush. Most recently, ASPR 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, ASPR coordinated all Federal assets and capabilities specific to components of emergency management to leverage all available resources and ensure that the federal government addresses requests from state and local partners in a timely and appropriate manner.

ASPR has supported a number of other important incidents with public health and medical implications. In 2018, ASPR assisted the Administration for Children and Families (ACF) to ensure it was able to meet its responsibilities to address needs of children coming to the United States across the southwest border. ASPR was subsequently reimbursed by ACF for its assistance. Previously established capabilities were not sufficient to build the needed incident management coordination structure to respond to the challenge of children referred to ACF/Office of Refugee Resettlement (ORR) after being separated from their parents or legal guardians by the Department of Homeland Security (DHS). In coordination with ORR, ASPR engaged with other federal interagency partners to coordinate the reunification of children pursuant to the President's Executive Order and the order of the Federal District Court for the Southern District of California. The command and control structure for this emergency was an HHS Incident Management Team (IMT) led by ASPR, with liaisons from ACF/ORR, DHS Customs and Border Protection (CBP), and Immigration and Customs Enforcement (ICE). It was operated out of the HHS Secretary's Operations Center, with HHS as the lead agency. ASPR provided the IMT to coordinate the reunification operation. Additionally, ASPR assisted DHS by activating and deploying personnel from the National Disaster Medical System (NDMS) and U.S. Public Health Service (USPHS) Commissioned Corps to various ICE holding sites to interview parents, collect needed information, and effect the reunification. Throughout the process, ASPR provided senior HHS leaders and other government officials with up-to-date information.

ASPR 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 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. Through its response planning programs, ASPR 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. ASPR supports hospitals and health care coalitions through the National Hospital Preparedness Program (HPP) and provided support to the nation's health care infrastructure through the Critical Infrastructure Program (CIP). ASPR 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. ASPR 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 widely distributed 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. The ASPR Exercises, Evaluations, & After Actions (EEAA) program 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.

Crisis, Contingency, and Strategic Planning

ASPR develops strategic and operational planning guidance, and strategic and operational plans to implement national preparedness functions and to prepare the Department's response during incidents and events. 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, senior-level decision makers are provided 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. ASPR ensures that HHS has the systems, response infrastructure, and logistical support, necessary to coordinate the response to catastrophic incidents, acts of terrorism, or any public health and medical threat or emergency that requires federal augmentation.

ASPR coordinates the Department's All-hazards Emergency Operations Plan and scenario specific operational plans in coordination with federal partners to support the mission in leading the Federal ESF 8 response. ASPR 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 as 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 HHS requirements for ESF 8 and other federal partners, who support HHS in carrying out its response mission.

ASPR collaborates with federal partners in the development of interagency plans. This includes coordinating the HHS input to Federal Interagency Operations Plan and co-leading, with FEMA, the development of several Incident Annexes focusing on biological events; power outage; food and

agriculture; nuclear radiation; and, federal evacuation incidents. ASPR also partnered with FEMA in 2018 and other interagency partners to develop a comprehensive national information collection and decision support system entitled 'Lifelines'. This system highlighted the interdependencies of different industries, infrastructure resources, and disciplines to better shape national decisions on resource prioritization and the focus of lifesaving efforts.

Additionally, ASPR coordinates the development of HHS contingency plans for Chemical, Biological, Radiological and Nuclear (CBRNE) and other catastrophic incidents, such as pandemics, hurricanes, and earthquakes. In addition to these plans for catastrophic incidents, ASPR 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. In addition, ASPR works with local, regional, and national partners to develop collaborative support and contingency plans and response resource packages for several high-risk special events and National Special Security Events (NSSEs), such as the President's annual State of the Union, the Super Bowl, and the immediate response to public health emergencies. For these special events, ASPR coordinated both the event and contingency support, and managed the alerting and deployment of over 500 disaster medical response personnel on average.

ASPR coordinates the HHS input to national preparedness documents, such as the Strategic National Risk Assessment, National Preparedness Goal, and National Frameworks. It also develops the Department's strategic and operational planning guidance, and implementation plans for National Strategies. For example, during 2018, ASPR led or partnered with interagency partners to produce products such as, crisis action plans for the reunification of children in July 2018; evacuation support planning for the Department of State (DOS); updates to All-Hazard Emergency Operations plans (AH EOPs); and, hurricane and earthquake plans. For example, during FY 2018, ASPR:

- Continued development of the Food and Agriculture Incident Annex, Federal Evacuation Incident Annex, Preparatory Consequence Management Incident Annex, and the Space Weather Federal Operating Concept.
- Developed a Repatriation Surge Plan, a Repatriation Guide for State Emergency Repatriation Centers, and the Evacuation Support Plan to support Department of State evacuation requests; collaborated on a DHS Repatriation Plan.
- Developed a crisis action plan for the reunification of children and incident support planning for the Unaccompanied Children (UAC) Reunification mission; provided support to Homeland Security Task Force (HSTF)-Southwest with plan updates for UAC Mass Migration.
- Updated the USVI Hurricane plan, the HSTF-Southeast update to the Operation Vigilant Sentry.

In FY 2020, anticipated planning activities include:

- Collaborate with Federal interagency to update the Federal Interagency Operation Plans (FIOP) Earthquake Annex.
- Create the Biological Annex to the All Hazards Emergency Operations Plan.
- Develop the 2020 HHS Threat Risk Assessment and the Operational Risk Management Review Planning activities to include review of the risks of interrupting recovery and emergency response efforts. Reviewing operational risk allows health care facilities and providers to prevent or limit errors while sustaining their mission, core functions, and services for patients receiving care, as well as continue response to potential surges in patients when space, staffing, equipment and supply considerations are involved.

Leading Public Health and Medical Emergency Response Operations

Early detection is critical to mitigating events that have the potential to significantly impact public health. The Secretary's Operation Center (SOC), 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 SOC 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. SOC personnel build reports informing decision-makers about potential events and 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 ASPR's operational mission effectively, the SOC works to ensure that clear, timely, reliable, valid, and comprehensive information and analyses are submitted to the ASPR, other HHS leaders, and partner agencies. SOC 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 programs 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.

In addition, ASPR 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, Now Trending, and social media analytics. These tools allow the program 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 situational awareness leads to more-targeted and rapid responses and helps better tailor resource needs to events.

Recent examples of how ASPR provides situational awareness are reflected in the products produced during the 2018 Unaccompanied Children Reunification mission. The GeoHEALTH Platform was used to integrate data from multiple Federal agencies, including the U.S. Immigration and Customs Enforcement (ICE) and HHS/Administration for Children & Families/Office of Refugee Resettlement, with ASPR data on deployed personnel. GeoHEALTH was used to create and share several mapping products for this event.

As with recent disasters, ASPR collaborated extensively to share data with Federal, state and local partners. ASPR worked with CDC's Center for Surveillance, Epidemiology, and Laboratory Services, in order to share de-identified electronic medical records data captured by 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, ASPR 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, ASPR 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 US Virgin Islands but it was expanded to include all ESF 8 patient encounter sites in Puerto Rico and the US Virgin Islands.

ASPR 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. For example, this tool produced data maps that showed the number and location of power outages; hospitals and their statuses in affected areas; and, NDMS logistics equipment "laydowns" in the region following Hurricane Florence.

Deploying Response Assets to Support Disasters

When an incident requiring federal support is identified, ASPR's focus shifts from preparedness to response by providing necessary surge support to state and local partners. All ASPR programs have supporting roles in a response and work together to address issues, both anticipated and realized. All of ASPR's response assets are nimble, flexible, and adaptable, in order to ensure that the support provided meets the requirement. This flexibility enables ASPR 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, Field Operations manages the Incident Management Team (IMT), comprised of 82 members, which include intermittent Federal employees, Officers from the USPHS and ASPR Regional Emergency Coordinators (RECs). The IMT 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. Two IMTs are maintained that are all scalable in size and function to ensure that the relevant IMT meets the needs of a disaster, incident, emergency or event.

The IMT adapts to all of the threats and responses supported by ASPR. This All Hazards IMT trains its members to a Type 3 response capability through a well-established credentialing program. Type 3 IMTs are deployed as a team of 10-20 trained personnel, representing multiple disciplines who manage major and/or complex incidents requiring a significant number of resources. They manage incidents that extend into multiple operational periods and require a written plan. Members train and demonstrate competency in their respective incident management positions.

In 2019, the ASPR IMT will be completing a significant hiring action for new members under the Direct Hire Authority given to HHS following the massive hurricane responses in 2017. ASPR will also be upgrading and modifying its incident management structure and staffing to enhance overall response capability. The ASPR IMT will focus on adaptation to the modified expectations and training its members on the new structure and functions.

Responding to Weapons of Mass Destruction Incidents

To combat and mitigate the threat and effects of Weapons of Mass Destruction (WMD), as directed under Presidential Policy Directive-25 (PPD-25), ASPR works with partner agencies (Department of Justice, Federal Bureau of Investigation (FBI), DOD Special Operations Command (SOCOM), DOS, DHS/FEMA, et. al.) to plan, coordinate, and respond to a wide range of WMD incidents. Accordingly, ASPR organizes and facilitates the public health and medical response of HHS assets with partner agencies, such that HHS's consequence management actions are coordinated with other interagency actions and do not impede any crisis response (law enforcement or military) activities. ASPR accomplishes this through both deployable response teams (HHS Field Team), as well as a centralized headquarters-based node (HHS Home Team), and liaisons to many of the aforementioned agencies.

Due to the low likelihood/high consequence of WMD-related incidents, WMD exercises play a critical role in ensuring that HHS and its partner agencies are prepared and able to execute their missions when faced with a WMD crisis. HHS currently participates with FBI, DOD, FEMA, and DOS, in eight large-scale WMD exercises per year to validate policies, plans, and procedures, in domestic and international

scenarios, with additional 30-plus smaller exercises to test more nuanced procedures (equipment and personnel readiness, et cetera). Taken together with the aforementioned policies, plans and procedures, ASPR's efforts in this area provide a critical capability in ensuring that the US government can bring forth all instruments of government power to quickly resolve an imminent WMD threat.

In FY 2018, ASPR actively participated in the WMD exercises noted above (SOCOM, FEMA, FBI), helping to test and refine both HHS and interagency response protocols as they relate to WMD incidents.

ASPR also represented the Department's interests while the Preparatory Consequence Management Incident Annex (PCMIA) to the FIOP was being authored. The PCMIA pre-designates actions which consequence management agencies like HHS can take concurrent with crisis response or anti-terrorism activities such that the whole of government is brought to bear quickly and effectively to resolve any WMD terrorist incident. In addition to the PCMIA, ASPR has also served as the Department's lead for Annex A of PPD-25.

ASPR's Tactical Medicine (TacMed) program provides direct operational medical support to HHS and its Federal partners during planned and unplanned events. In addition to that response capability, TacMed provides medical direction, liaison coordination, and medical consultation to law enforcement agencies. The program also delivers essential training to medical operators under tactical and austere environments. In FY 2017, TacMed supported 67 individual missions, deploying for 104 days. During that year, the program trained a total of 540 ASPR staff, 270 state and local medical providers, and 160 Federal law enforcement employees. ASPR deployed TacMed to 50 missions in FY 2018. As emerging threats continue to evolve, the need for a quick deploying, low signature, and small footprint medical operations/training capability continue to be mission critical.

Continuity of Operations during Emergencies

In accordance with federal and presidential directives, ASPR ensures the continuation of HHS's essential business support 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 Operating and Staff Divisions, with an overall goal of building and managing unified HHS COOP and COG programs. Similarly, the HHS Continuity program handles the day-to-day operations and implementation of the OS Continuity Program, including maintenance of a continuity facility and maintaining continuity communications systems in a state of constant readiness. ASPR COOP also drafts and refines the required overarching policy and planning documents to scope and define the HHS unified COOP and COG Programs.

Annually, ASPR integrates the separate HHS components into an overarching HHS COOP program review, plan, and related series of exercises. Most recently, in FYs 2017 and 2018, 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. It also led to the signing of the HHS Continuity of Operations Program Policy by the HHS Secretary in April 2018. Similarly, ASPR has the primary responsibility for HHS's implementation of several key policy directives, primarily the Presidential Policy Directive (PPD) 40 (signed in July 2016), the Federal Continuity Directives (FCDs) 1 (signed in January 2017) and 2 (signed in June 2017) and the 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. FCD 2 outlines the process for Executive Branch review and identification of essential

functions. D-16-1 establishes the minimum continuity communications requirements for all executive branch agencies.

ASPR serves as the HHS lead for building and implementing the HHS continuity program and for ensuring that all communication capabilities which HHS must possess at headquarters and alternate locations are available and functional, in support of continuity of operations activities. Through ASPR's COOP program, HHS has seen increased emergency communications capabilities, including the management and implementation of Government Emergency Telecommunications Service and Wireless Priority Service for continuity personnel, establishing Telecommunications Service Priority restoration for HHS facilities, 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, ASPR develops and facilitates several continuity-focused testing, training, and exercise events to strengthen and assess the HHS COOP program. Most recently in May 2018, ASPR participated in the White House's annual continuity exercise and interagency evaluation. ASPR hosted a tabletop exercise at the OS continuity facility, led by the HHS Deputy Secretary, for HHS principals and other senior leadership that focused on reviewing initial thresholds for plan activation during and after an incident impacting HHS headquarters, and orienting new HHS leadership to the continuity facility. HHS participation in the continuity of operations portion of National Level Exercise 2018 allowed HHS to verify the ability of the HHS ERG to activate, relocate, and perform HHS's essential functions from alternate locations. HHS received consistently high marks in its external evaluation, conducted by DHS and FEMA.

Implementing and Managing the Preparedness Cycle

To manage preparedness efforts, and ensure readiness to respond and improve future responses, ASPR uses the preparedness cycle of Plan, Train, Exercise, and apply Corrective Actions. Taking direction from established planning documents and the published the HHS Threat and Hazard Identification and Risk Assessment, ASPR 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 these processes, ASPR synchronizes preparedness efforts 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 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 ASPR to confirm available public health and medical assets in the event of a large-scale response requiring federal assistance.

ASPR 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. ASPR conducts training needs assessments (held monthly) to identify overall mission training needs, as well as gaps, and agree to a comprehensive training schedule that reduces overlap and duplication.

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. ASPR works within the preparedness cycle to test and assess capabilities, test and validate plans, explore response options for new and emerging missions and provide an opportunity and environment for HHS Operational and Staff Divisions, Groups, Elements and Teams to train together in a response setting. ASPR manages several established and recurring exercises that build upon past exercises and experiences and promote preparedness across the ESF 8 interagency partners. ASPR recently participated in several exercises that tested planning assumptions as well as supporting capabilities, such as, Nimble Challenge; the Noble Lifesaver Exercise; the Secretary's Quarterly Exercise Program; the Tranquil Terminus Full Scale Exercise; the Gotham Shield and Recovery Exercises; and, the DOD Hidden Peril Exercise. Through these efforts, ASPR is fully executing the HHS preparedness cycle requirements for exercises.

ASPR has a formal system to capture lessons learned and track associated corrective actions that strengthen the health and emergency response systems for future events. Following each response, ASPR meets with its HHS, federal, state and local partners to conduct an After-Action Review and develop a subsequent report. ASPR 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 *(Hurricane Season 2017, NSSE, etc.*). 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 finding resulted in renewed efforts to create a Concept of Operations at all levels in order to document and standardize actions.
- Corrective actions were identified and tracked which led to the creation of various policies and procedures, including the development and finalization of the Disaster Medical Assistance Team (DMAT) CONOPS and the Incident Management Team (IMT) CONOPS. Standard Operating Procedures were created for logistics, staging, mobilization, accountability and demobilization processing of deployed personnel, as well as convening the Disaster Leadership Group and managing National Special Security Events.
- Identified and tracked corrective actions which led to the professional development and standardization of response personnel through an IMT 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.
- Publishing of a bi-annual CAP Newsletter to highlight significant lessons learned and/or finalized corrective actions.
- Deploying as members of the IMT to provide in-person evaluation support at 2018 NSSEs such as the State of the Union, Peace Officers Memorial, National Independence Day, the United Nations General Assembly, and funerals of Senator John McCain and former President George H. W. Bush, resulting in expanded lessons learned data collection from responder only to an outside perspective.

Funding History	
FY 2016	$24,654,000
FY 2017	$24,596,000
FY 2018	$24,654,000
FY 2019 Enacted	$24,654,000
FY 2020 President's Budget	$24,654,000

Budget Request

The FY 2020 Budget includes $24,654,000 in budget authority for Preparedness and Emergency Operations activities, which is equal to the FY 2019 Enacted level.

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.

The FY 2020 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 public health emergencies and large scale gatherings such as the September 2015 Papal visit to the United States.

NATIONAL DISASTER MEDICAL SYSTEM

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	57.404	57.404	77.404	+20.000
Pediatric Disaster Care Program (non-add)	--	--	*20.000*	*+20.000*
Pediatric Disaster Care Program /1	--	*16.000*	--	*-16.000*
Subtotal, Pediatric Disaster Care Program	*--*	***16.000***	***20.000***	***+4.000***
Subtotal, NDMS Program Level	**57.404**	**73.404**	**77.404**	**+4.000**
FTE	**115**	**115**	**115**	--

1/ Reflects funding from pre-FY 2014 Prevention and Public Health Fund balances for the Pediatric Disaster Care pilot.

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) the National Disaster Medical System (NDMS) is requested by states whose medical infrastructure has become overwhelmed and require assistance with their critical medical services to protect public health and help communities respond and recover faster. NDMS capabilities in collaboration with ASPR Regional Administrators are unique assets able to deliver essential medical and emergency management services with specialized 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 and incident management to provide medical services and/or augment health and healthcare facilities in impacted communities.

NDMS has worked to increase its intermittent employee workforce towards the goal of over 6,000 personnel organized into 71 teams. NDMS currently has 2,941 deployable personnel. NDMS teams include clinical providers and specialized medical service professionals, including physicians, nurses, fatality management professionals, paramedics, veterinarians, and other support staff, such as logisticians

and information technology specialists. NDMS is capable of providing patient care, fatality management operations, federal patient movement and definitive care support. NDMS team employees are permanent excepted–service federal employees utilized on an episodic intermittent basis acting under official activation 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, in accordance with Federal guidance, 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's are 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 health and medical task force (HMTF), 14-person HMTF, and a 35-person team that are capable of deploying within eight hours of notification. During the natural disaster responses to Hurricanes Florence, Isaac, and Michael, and Typhoon Yutu in 2018, ASPR deployed over 20 NDMS teams on a rotational basis comprised of more than 2,000 employees that treated patients with a wide variety of illnesses and injuries.

- ***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, patient transport preparation, or establishing a stand-alone field hospital. The TCCTs are configured to deploy as a 9-person HMTF, a 10-person HMTF, a 28-Person TF, and a 48-person team each with the capacity to conduct specific trauma related actions The TCCTs are staffed heavily with board-certified and practicing surgical and trauma professionals.

- ***Disaster Mortuary Operational Assistance Teams (DMORT):*** The DMORTs provide services for the management of fatalities resulting from natural and/or man-made disasters. These services include, providing victim identification 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. The mission is to do this with 100% accuracy and the utmost respect, dignity, compassion, and confidentiality of the remains. DMORTs also support the National Transportation Safety Board (NTSB) through an established interagency agreement with respect to major transportation incidents that have mass fatalities. The DMORT configuration 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. NDMS maintains two portable morgue units that can be deployed nationwide to augment local morgue infrastructure. 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 service 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 the service 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.

NDMS continues to provide individual and team training to all team members based on individual roles and team mission requirements. NDMS currently trains twenty percent of its workforce per annum. 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 specific staff positions from various teams to attend each fundamental training event, ensuring each team has staff that are trained and familiar with current equipment and 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 (MRC), United States Public Health Service Commissioned Corps (USPHS) Officers, Department of Defense (DoD), and state, local, tribal, and territorial (SLTT) officials, to strengthen response capabilities.

Deployment of NDMS teams requires support from multiple programs within ASPR once teams are activated to deploy. An activation considers a request from a state, time to get a team onsite, and which teams are on-call for the period of the event. The ASPR Logistics program provides the 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 teams are fully engaged in the mission, approximately ten hours after arrival, the resupply process is established pursuant to documented procedures. The Incident Management Team (IMT) 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 all ASPR components, 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 FY 2018, NDMS teams provided public health and medical support for the following: California Wildfires, the State of the Union Address, the United Nations General Assembly, the Peace Officer's Memorial, and ongoing operations in support of Puerto Rico and the United Sates Virgins Islands response and recovery efforts.
- NDMS continues with its 2016 initiative of a mobile training platform to its DMATs that allow attendance of MRC as well as state and local emergency responders if available. These low-cost training opportunities train hundreds of NDMS personnel and allow other entities to have detailed awareness of NDMS responses so, if needed, in their community, the integration is expedient.

Logistics:

The ASPR Logistics program 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, responder travel services is coordinated and life-saving equipment and supplies are deployed to support the mission of the team. The Logistics program ensures that responders and medical capability are rapidly deployed where they are needed to provide an effective response. It is a complex, coordinated effort to rapidly deploy staff and material, support the setup of tactical hospital infrastructure, and sustain public health and medical teams with the necessary supplies and equipment in catastrophic, austere 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, ASPR is prepared for disasters, no matter where they occur within the United States and its territories. The Logistics program manages and maintains over $70 million in response materiel 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 initiatives and accomplishments:

- Successfully deployed, sustained, and reset over 250 medical caches, encompassing over 1,640 tons of material and resources to support five NSSEs and multiple natural disasters, such as Hurricanes Harvey, Irma, and Maria in 2017; the 2018 Peace Officer's Memorial; 2018 Joint Session of Congress Address; the 2018 National Independence Day Celebration on the National Mall; the Unaccompanied Children Reunification Mission; Hurricane Michael; Typhoon Yutu in Guam/Saipan; California Wildfires; and the State Funerals of President George H. W. Bush and Senator John McCain..

- Effectively executed the support for the NDMS Training Summit in July 2018 which resulted in the successful training of over 2000 responders from NDMS and the USPHSCC. The program also provided logistics training at the NDMS Fundamentals Course.
- Developed and managed multiple contracts to care for over 400 disaster survivors from Hurricane Maria medically evacuated to Atlanta, Georgia, from the U.S. Virgin Islands and Puerto Rico. The contracts provided critical life-sustaining services such as housing, nursing support, case management and incident command, and meal services to include the installation of two temporary trailers with 12 dialysis stations to supplement local constrained capacity on island as they restore permanent capacity.

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 program hosted a thorough review of its patient care and IT/Telecommunication cache capabilities and is currently modernizing the deployable cache resources with new equipment and supplies for the next generation of caches (including the Disaster Portable Morgue Unit) and kits for medical teams. 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 program 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 program 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 the Emergency Prescription Assistance Program (EPAP), with an increased medication formulary. 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 over 35,500 life sustaining medications to thousands of disaster victims in Puerto Rico and U.S. Virgin Island via real time payment at community pharmacies, thus preventing additional stress to the disaster-affected healthcare systems, particularly at Emergency Departments (ED).

Field Operations and Response:

The Field Operations and Response program 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 ASPR 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.

NDMS teams, logistics, and field operations and response 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, ASPR continues to provide surge support when requested, even though there are challenges in years when multiple response events occur.

Funding History	
FY 2016	$49,904,000
FY 2017	$49,787,000
FY 2018	$57,404,000
FY 2019 Enacted	$57,404,000
FY 2020 President's Budget	$77,404,000

Budget Request

The FY 2020 budget request is $77,404,000, which is an increase of +$20,000,000 above the FY 2019 Enacted level. The request supports continued NDMS operations, logistics, 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, initiatives, and relative threats to the nation in FY 2020 to prioritize the highest-priority/critical activities to support NDMS in meeting the mission of the Department.

The request includes +$20,000,000 in 2-year funding to continue a Pediatric Disaster Care program pilot, building on progress made in FY 2019. A Pediatric Disaster Care program will be piloted to address appropriate planning and response capabilities that supports the specific needs of children such as pediatric triage, decontamination considerations, and mass sheltering. The goal of the pilot is to enhance ASPR's capacity to provide critical care or surgical care for injured and ill children in the NDMS system..

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 2018: 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 2018: 10.0 % Target: 10.0 % (Target Met)	35.0 %	35.0 %	Maintain

CIVILIAN VOLUNTEER MEDICAL RESERVE CORPS

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**6.000**	**6.000**	**3.900**	**-2.100**
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 190,000 volunteers organized into almost 900 local community-based units that are committed to improving local emergency response capabilities, reducing vulnerabilities, and building community preparedness and resilience. MRC units organize and utilize local volunteers who want to donate their time and expertise to prepare for and respond to emergencies and to support steady-state preparedness initiatives. MRC volunteers include medical and public health professionals as well as other community members without healthcare backgrounds. MRC units bolster their community's preparedness and emergency response infrastructures by providing supplemental personnel when needed, thus making those local communities less likely to be reliant on state and federal resources. Local health departments sponsor the majority of MRC units. Other types of sponsoring organizations include emergency management agencies, local non-profits, and universities.

The MRC program office supports the MRC network by providing technical assistance, coordination, communications, strategy and policy development, cooperative agreements, contract oversight, training, and other associated services. The MRC program office also supports information sharing between units on best practices and provides situational awareness of local activities to agency leadership and to state, regional, and national level partners. MRC units are local assets, and the MRC program office does not have direct operational or tactical control over them.

MRC units are very active in their communities, as evidenced by their 17,396 activity reports in FY 2018. These reports show more than 132,000 MRC volunteers contributed over 409,000 hours of service.

These activities have had significant local impact:

- 580 responses to local emergencies;
- 9,488 activities in which MRC members strengthened the local public health system;
- 5,572 activities that served an at-risk/vulnerable population;
- 6,640 activities that supported non-emergency community events;
- 11,238 activities that developed or strengthened the MRC unit;
- 9,218 activities that improved community preparedness or resilience; and,
- 6,461 activities that trained or exercised MRC members to improve individual, unit, or community response capability and capacity.

Recent MRC accomplishments include:

- The 2018 hurricane season brought a series of significant storms, including Hurricanes Lane, Florence, and Michael. More than 200 MRC volunteers from states across the country (Alabama, Arizona, Delaware, Florida, Georgia, Hawaii, Louisiana, New Jersey, North Carolina, Oklahoma, South Carolina, and Virginia) responded to the hurricanes, primarily providing medical support at shelters and mobile disaster hospitals; supporting Emergency Operations Centers and Regional Command Centers; and providing veterinary care to injured and displaced animals.

- Recovery efforts for the 2017 hurricane season also continued throughout the year. In particular, the Brazoria County MRC in Texas continued efforts to test all private water wells in the county for contamination after Hurricane Harvey floodwaters receded. From March to June 2018, volunteers visited nearly 1,700 homes to collect and test water samples for coliform and E. coli. Hurricane recovery efforts continued in Puerto Rico as well. The Medical Reserve Corps of Puerto Rico — the only MRC unit in the territory — participated in nine mobile health clinics in municipalities across the island established to provide physical and behavioral health support to communities after Hurricane Maria. At one location in particular, six nurse volunteers and one psychologist were able to help 450 people.

- MRC units responded to a number of other large-scale natural disasters in 2018, including wildfires, volcanoes, typhoons, tornadoes, and severe storms.

    - MRC volunteers in Arizona and California contributed more than 10,000 service hours responding to wildfires, including the Camp Fire — the most destructive in California history. When the Camp Fire broke out in Northern California in early November, approximately 440 MRC volunteers responded, providing medical support at four shelters across three cities, as well as providing veterinary care for injured animals.

    - Over the course of two months, Hawaii volunteers supported response to the Kilauea volcano eruption by providing medical support at shelters and health observations at point of dispensing (POD) sites and conducting fit testing for N95 respirator masks. With assistance from local Community Emergency Response Teams (CERT) and Department of Health staff, MRC volunteers helped to distribute more than 40,000 N95 masks to vulnerable populations in the event of a large ash fall.

    - In October 2018, after Typhoon Yutu caused catastrophic damage to the islands of Tinian and Saipan in the Northern Mariana Islands, MRC volunteers conducted a community assessment in a local village that was hit particularly hard, which left them without power. Results of the assessment determined that individuals needed clean water, prompting federal responders to prioritize water delivery to affected populations.

    - Nine MRC units responded to tornadoes in their local and/or neighboring communities in 2018, contributing approximately 625 service hours. Volunteers supported medical and non-medical tasks at shelters, operated field first aid stations, removed debris, and assisted with fielding calls at Emergency Operation Centers.

    - A number of communities throughout the country experienced severe flooding over the past year, and more than 20 MRC units stepped up to respond. The Clark County MRC in Indiana assisted with a tetanus vaccination clinic for flood victims; people who don't have a current tetanus vaccination may be susceptible to tetanus if they have open wounds, or if they get cuts during flood clean-up. The Northwest Vermont MRC supported a Multi-Agency Resource Center, set up to provide community members affected by local

flooding with needed resources, including information about drinking water and food safety, clean-up guidelines, and water testing kits. Several MRC units throughout the country also assisted with operating shelters and warming centers for flood victims, staffing Emergency Operations Centers, removing debris, and conducting post-flood disaster assessments.

- During winter storms that left many without power, MRC units activated to assist with warming centers and overnight sheltering operations, including providing medical and mental health support. From January to March 2018, more than 40 MRC units from the West Coast to the East Coast were activated or placed on standby to provide these services.

- MRC units responded to other emergencies as well. In September 2018, when a series of gas explosions and fires occurred in northeastern Massachusetts, five local MRC units provided medical care at evacuation shelters, behavioral health support at claim centers, and charging stations for those without power. In Illinois, three MRC units assisted with bottled water point of dispensing sites after the local community suffered a water shortage and boil order that left residents without drinkable water for five days.

- In addition to natural disaster and emergency support, MRC units responded to a number of public health emergencies and communicable disease outbreaks in 2018.

  - The Galveston County Health District in Texas requested activation of the Galveston County MRC in response to more than 9,000 patients at two local clinics being potentially exposed to hepatitis B, hepatitis C, and HIV. The MRC was asked to open phone banks and a blood testing center. Due to the large scale of this response, MRC units from Brazoria, Fort Bend, Harris, and Montgomery Counties were also recruited to respond. These units provided volunteers to answer the phone bank hotline, schedule appointments for blood screens at the testing center, and conduct the blood screens. In total, MRC volunteers contributed more than 500 service hours.

  - MRC units responded to hepatitis A outbreaks in California, Indiana, Kentucky, Louisiana, Ohio, Utah, and Tennessee. In particular, the Louisville Metro MRC in Kentucky provided hepatitis A vaccination support on approximately 80 separate occasions in 2018, including street outreach for the local homeless population.

  - The Hampshire County MRC in Massachusetts helped set up an emergency dispensing site at Smith College to dispense meningococcal B vaccines to students following an on-campus diagnosis. More than 400 vaccines were administered.

  - The Hudson Regional Health Commission MRC in New Jersey helped administer flu vaccinations for approximately 200 children in grades 1st through 8th after a local pediatric flu-related death in early 2018.

- It is worth noting that in addition to providing medical care, MRC units are also routinely providing behavioral health/mental health support during many of these responses. To prepare themselves, many units offer and/or participate in psychological and mental health first aid (PFA/MFA) training throughout the year. In 2018, more than 100 units reported activities related to PFA/MFA.

- MRC units also participated in non-emergency events, including training for emergencies and educating the public about how to respond during emergencies. The “You are the Help Until Help

Arrives" program encourages the public to take action, such as calling 9-1-1 and stopping bleeding, in situations in which someone may have a life-threatening injury due to trauma. The MRC Program Office has been encouraging units to undertake Until Help Arrives and similar Stop the Bleed activities, and in 2018, more than 200 MRC units carried out over 500 engagement activities.

- MRC units continue to be a valued 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 increase in opioid abuse and reduce the number of individuals who die from opioid overdoses. One example is the Virginia Beach MRC, which helps instruct REVIVE! training (Virginia's Opioid Overdose and Naloxone Education Lay Rescuer Training) for community groups and partners, including the Virginia Beach Department of Health and Virginia Beach Emergency Medical Services. The Rhode Island MRC is also active in combating opioid abuse. The unit leads the state's Naloxone and Overdose Prevention Education Program (NOPE-RI), which provides education on overdose recognition and proper response techniques, including the administration of naloxone and rescue breathing. Training has been provided to community partners, law enforcement personnel, and schools.

- In 2018 – for the third consecutive year –MRC was invited to attend select National Disaster Medical System (NDMS) trainings at the Federal Emergency Management Agency (FEMA) Center for Domestic Preparedness (CDP) training center in Anniston, AL. Nearly 200 MRC participants applied to attend the trainings, and a total of 25 state coordinators, unit leaders, and volunteers were selected to participate in Disaster Medical Assistance Team (DMAT), Disaster Mortuary Operational Response Team (DMORT), National Veterinary Response Team (NVRT), and Victim Information Center (VIC) Team fundamentals trainings. Attendees gained valuable technical knowledge and also had the opportunity to increase communication and collaboration with NDMS teams from across the country.

- The MRC program office continued its cooperative agreements with the National Association of County and City Health Officials (NACCHO) and the Public Health Foundation which operates the TRAIN Learning Network. NACCHO made 80 sub-awards to MRC units, managed a mentorship program for unit leaders, and published a monthly electronic newsletter and other information resources for MRC units. The MRC program's cooperative agreement with the Public Health Foundation provides each of the almost 900 MRC units with their own MRC-TRAIN account. This allows local MRC unit leaders to track and manage their volunteers' trainings such as webinars, on-line presentations and when possible, live meetings. Through November 2018 there were 90,597 users registered on MRC-TRAIN.

Funding History	
FY 2016	$6,000,000
FY 2017	$5,986,000
FY 2018	$6,000,000
FY 2019 Enacted	$6,000,000
FY 2020 President's Budget	$3,900,000

Budget Request

The FY 2020 Budget includes $3,900,000 for the civilian volunteer Medical Reserve Corps, which is $2,100,000 below the FY 2019 Enacted level. This funding will support overarching national and regional coordination and technical assistance to MRC unit leaders to guide the development and sustainment of the units. This includes identifying and/or sharing training resources for unit leaders and volunteers, best practices in volunteer recruitment and retention, and other topics critical to unit leaders. The MRC program office will continue to promote the adoption of standardized response packages such as "Mission Ready Packages" and promote the utilization of MRC response packages in inter- and intra-state public health and medical responses. Funding will also continue to support the system used for maintaining unit profiles and for unit activity reporting as well as a means for units to access and/or track training. 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.

HOSPITAL PREPAREDNESS PROGRAM

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority /1	**264.555**	**264.555**	**257.555**	**-7.000**
Cooperative Agreements (non-add) /2	*231.500*	*231.500*	*231.500*	*--*
Other costs (non-add) /3	*33.055*	*33.055*	*26.055*	*-7.000*
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 ASPR Recovery program.

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 and protect Americans from 21st century health security threats. 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 and enables rapid recovery. Since 2002, investments administered through HPP have improved individual health care entities' preparedness and have built a system for coordinated health care system readiness and response through health care coalitions (HCCs) and other partnerships, such as the Regional Disaster Health Response System (RDHRS) pilots. These coalitions and partnerships ready health care delivery systems for disasters and emergencies.

HCCs Help Each Patient Receive the Right Care at the Right Place at the Right Time

Since 2012, HPP's formula-based cooperative agreement program 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, emergency medical services (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 Emergency Support Function (ESF) 8 (public health and medical services) activities in the context of incident command system (ICS) responsibilities. HCCs coordinate activities among their members, which include health care organizations and other stakeholders in their communities. HCC members 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 –

Northwest Healthcare Response Network leads regional coordination and patient tracking during passenger train derailment response: When a passenger train derailed on an inaugural trip from Seattle, WA, to Portland, OR, the Northwest Healthcare Response Network ("the Network") played a key role in coordinating a cross-jurisdictional health care response. The Network leveraged an HPP-funded patient tracking system to successfully track and distribute 69 patients (ten of which were children) to nine hospitals across three counties, while minimizing disruption to patient care and streamlining family reunification efforts. "It's almost hard to envision how this response might have unfolded without HPP funding," said one representative from the Network. "We're fortunate to have a community that is committed to quality of patient care and to collaboration, but HPP funding is at the core of what builds our community capacity to respond to these events."

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. 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, Houston area hospitals made facility enhancements to incorporate lessons learned from previous responses, 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. 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.

including health care professionals and specialized equipment – especially when a facility is too overwhelmed to provide timely and required levels of care. It also mitigates the impact of the incident on the facilities themselves, existing and potential patients, or event casualties.

HCCs incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. HCCs include core members, such as hospitals, EMS, emergency management organizations, and public health agencies, as well as additional HCC members that collaborate to prepare and plan for, and respond to, emergencies. **Figure 1** 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 to accommodate disasters.

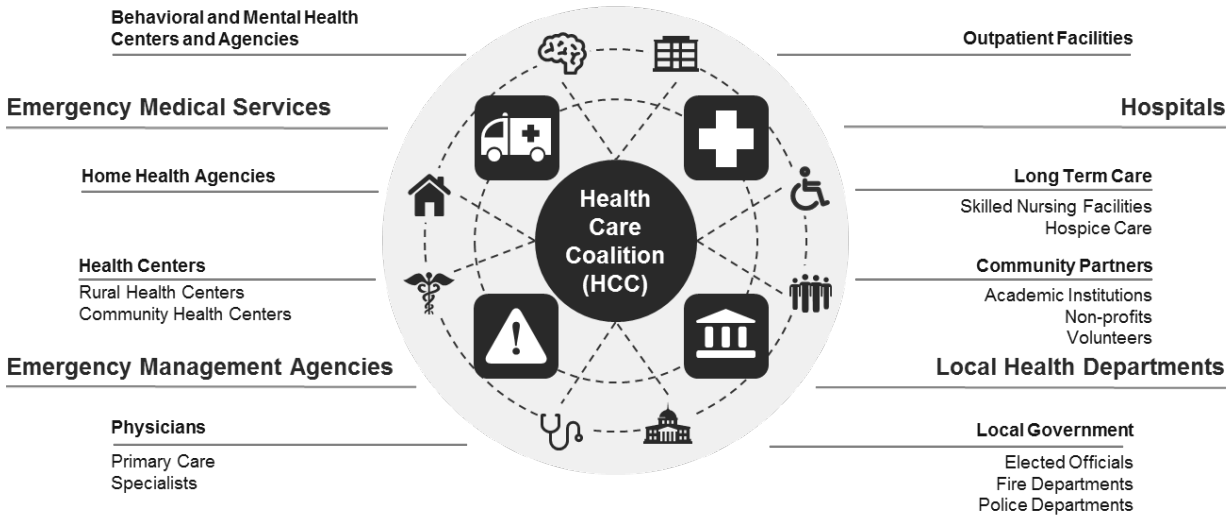


Figure 1. Health Care Coalition Network

As of June 30, 2018, there are more than 34,500 HCC members participating in 367 HCCs nationwide. In FY 2017, ASPR required that HPP recipients examine their HCC boundaries to ensure that each HCC meets core membership requirements (a minimum of two acute care hospitals, EMS (including inter-facility and other non-EMS patient transport systems), emergency management organizations, and public health agencies). As anticipated, there are currently fewer HCCs than in prior years. The number of HCC members has more than doubled since HPP began focusing on regional health care coordination through HCCs 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 is 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 displays the HCC membership diversity and the participation rates by member type as of June 30, 2018 For example, there are currently 5,227 acute care hospitals participating in HCCs, which represent 93 percent of all U.S. acute care hospitals.[1]

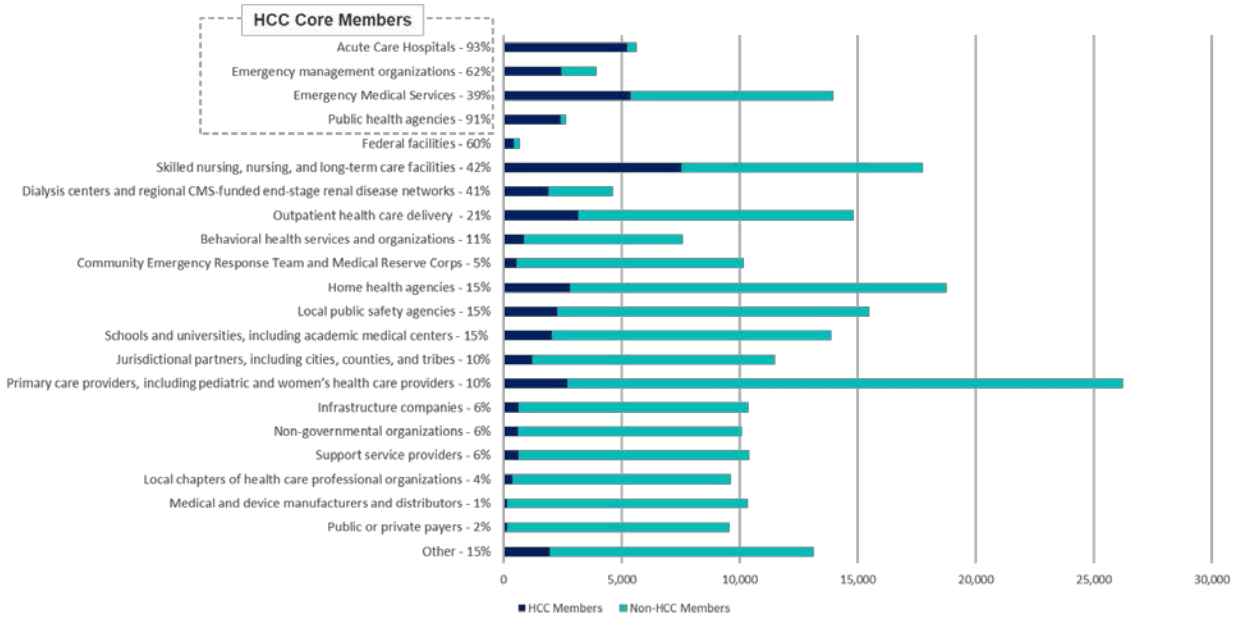


Figure 2. HCC Membership Diversity and Participation Rates, June 2018

Health Care System Emergency Readiness and Response: Capacity and Capability

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

California and Oregon lead health care system response to wildfires: In 2017, unprecedented wildfires caused historic levels of damage and destruction across California. More than 9,000 wildfires burned 1.2 million acres of land, destroying more than 10,800 structures, requiring the evacuation of over 1,160 patients, and causing at least 46 fatalities. California used HPP funds to build and sustain a robust group of health and medical partners, ensuring a standardized flow of communication and information sharing throughout the public health and medical systems. California's effective response ensured minimal impacts to local communities, safe evacuation of patients, and rapid recovery.

In 2017, Oregon experienced a total of 1,069 reported wildfires – 779 were human-ignited, with lightning strikes causing the remaining 290 – including the state's eighth largest fire. Fire burned a total area of 451,863 acres. HCCs across Oregon provided situational awareness, supported health care facility evacuations, managed scarce resources, and assisted the public health response to special needs populations due to poor air quality.

[1] These data are unverified end-of-year (EOY) performance data from the HPP project period that ended on June 30, 2018. ASPR's health system evaluation team is currently working with HPP cooperative agreement recipients to verify EOY data, which may result in some changes to these data.

(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 Federal Emergency Management Agency (FEMA) mission assignments.

Through a partnership with FEMA's Center for Domestic Preparedness in Anniston, AL, ASPR provides instruction and practical experience in best practice procedures for preparing and responding as an HCC leadership team to community and regional public health and medical emergencies. FEMA funds all training and travel expenses for participating HCCs. From September 2016 through July 2018, 40 HCCs from 25 states, Puerto Rico, U.S. Virgin Islands, and the U.S. Pacific territories and freely-associated states have participated in the HCC Response Leadership Course (HCRL). Each HCC that attends the HCRL course may invite up to nine participants who are leaders representing the four core members of HCCs: hospitals, EMS, emergency management, and public health. The three-day course offers insights and lessons learned in establishing an effective HCC framework, conducting HCC planning, and achieving preparedness. The course provides instruction on the development of indicators, triggers, and tactics for proactive coalition planning; and provides instruction on approach techniques and considerations for HCC response and recovery leadership.

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. HPP crafted the *2017-2022 Health Care Preparedness and Response Capabilities*[2] to describe what the health care delivery system, including HCCs, hospitals, and EMS, must do to effectively prepare for, and respond to, emergencies that impact the public's health. These capabilities (see **Figure 3**) 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*[3], *National Preparedness Goal*[4], and the *National Health Security Strategy and Implementation Plan*[5], to build community health resilience and integrate health care organizations, emergency management organizations, and public health agencies.

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

[2] *2017-2022 Health Care Preparedness and Response Capabilities*, https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capablities.pdf
[3] National Response Framework, 3rd Edition, June 2016. https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National_Response_Framework3rd.pdf
[4] National Preparedness Goal, 2nd Edition, September 2015. https://www.fema.gov/media-library-data/1443799615171-2aae90be55041740f97e8532fc680d40/National_Preparedness_Goal_2nd_Edition.pdf
[5] National Health Security Strategy and Implementation Plan 2015-2018, https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/nhss-ip.pdf

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.

Washington state pilots nation's first pediatric strike team: In Washington state, children represent 25 percent of the population, and only a small fraction of the state's health care capacity. The Washington State Department of Health (DOH) recognized that natural disasters and other crises may create a dangerous gap in pediatric care. HPP funding is helping the Washington State DOH close that gap by developing deployment-ready pediatric strike teams, one of the country's first state-based pediatric response units. Composed of five to seven practitioners from a broader pool of 30 clinicians, a pediatric strike team can be deployed to an impacted or isolated area to provide surge support at a pediatric hospital or expertise to a non-pediatric facility. In November 2017, a pediatric strike team deployed to Doernbecher Children's Hospital in Portland, OR, for an exercise testing the Emergency Management Assistance Compact and the Pacific Northwest Emergency Management Agreement for state-to-state mutual aid during disasters. Future practice deployments for the team will strengthen the team's and the region's pediatric response capabilities. Ensuring medical care for all populations by collaborating across state lines sets a progressive new precedent for regional health care preparedness.

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.[6] Prior to the 2014 Ebola outbreak, private health care entities in the U.S. did not have an organized, systematic approach to prepare for and respond to an outbreak of a highly infectious special pathogen. The federally-funded, systems-based approach developed by HPP with supplemental Ebola funding allowed for regional flexibility to address 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 this nationwide, regional treatment network for Ebola and other infectious diseases.

The regional treatment network approach balanced geographic need and differences in institutional capabilities, and it accounted for the potential risk of caring for an Ebola patient. While the initial focus was on preparedness for Ebola, preparedness for other novel, highly-pathogenic diseases has also been enhanced through the Ebola preparedness cooperative agreements. This regional Ebola treatment network (see **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.

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

2) State or jurisdiction Ebola treatment centers (60 as of January 2019) 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.

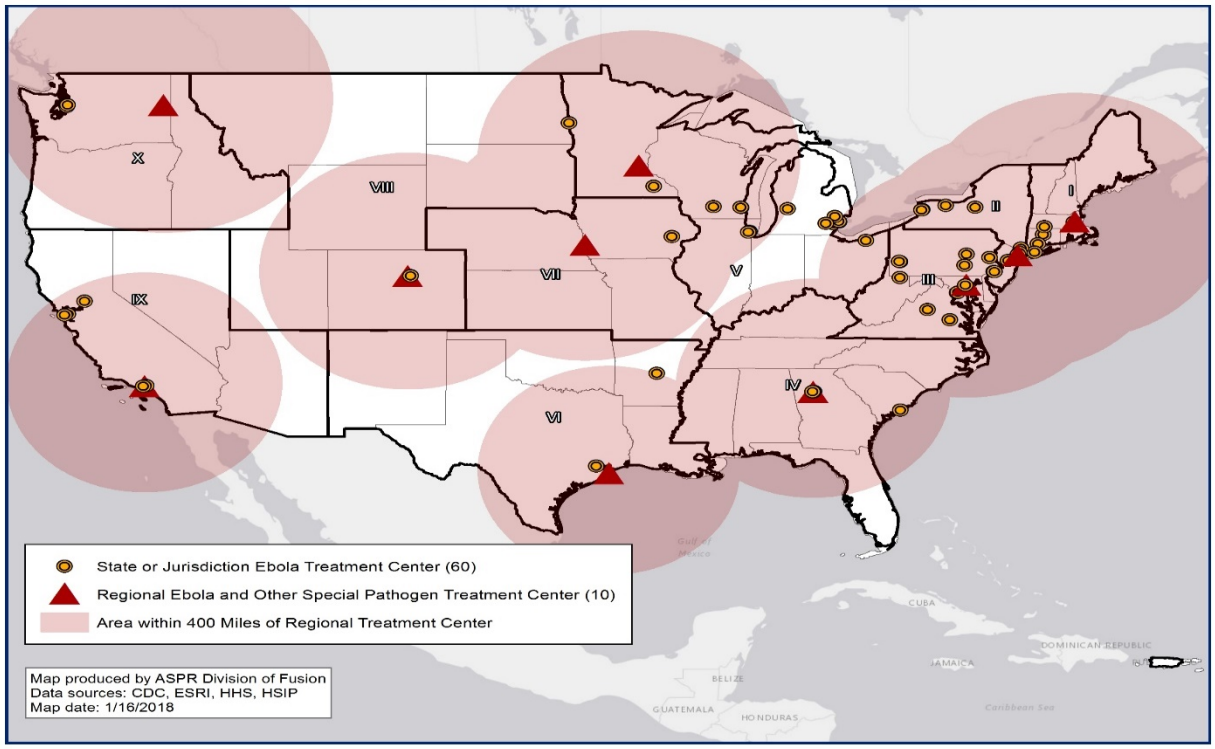


Figure 4. Regional Ebola Treatment Network

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 supplemental Ebola funding has been instrumental in enhancing awardees' tactical facility- and system-wide capacity to respond to an Ebola-like threat. HPP required awardees to engage in operational planning, tactical coordination across states and regions, workforce training, purchase of 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 funds to purchase equipment and infrastructure required to fulfill their response roles moving forward.

Beyond capacity improvements, ASPR has also seen improvement across the nation in terms of our preparedness capability for an Ebola-like event as a result of HPP investments. Recipients of HPP Ebola emergency supplemental funding report significantly higher levels of preparedness after July 2014.

Figure 5 shows improvement in awardees' reported preparedness for an Ebola event, on a scale from 1 (least prepared) to 5 (most prepared):

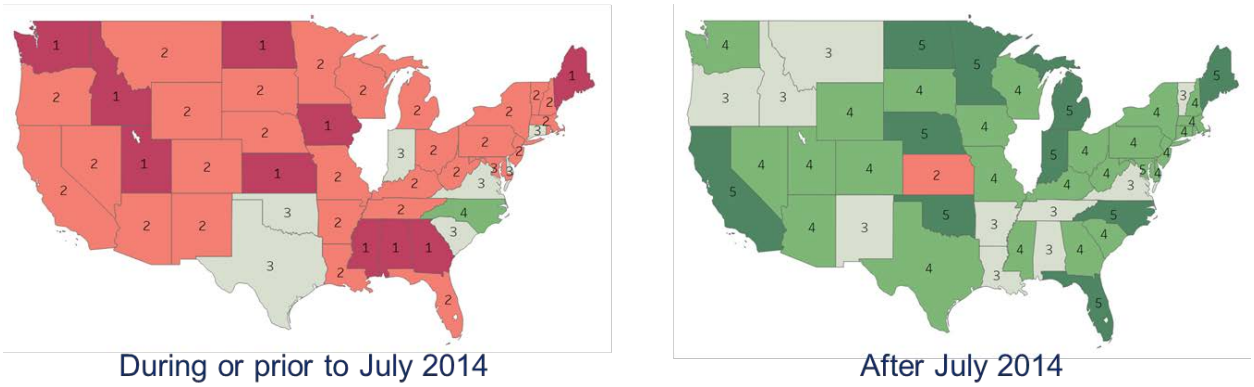


Figure 5. U.S. Ebola Preparedness Maps

National Ebola Training and Education Center (NETEC)

Additionally, to prepare for, and provide safe and successful care of patients with Ebola, HHS (in collaboration between ASPR and the Centers for Disease Control and Prevention (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. Funding for NETEC expires at the end of FY 2019. 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.

NETEC[8] 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. One of the significant NETEC achievements of the year was the development of an integrated national clinical research network. This network consists of research sites at each of the ten regional Ebola and other special pathogen treatment centers, supported by centralized resources, including a common rapid response institutional review board, a data repository, a biorepository, research training protocols, and standardized polices. Other key accomplishments in year two include:

- 15 health care facilities (all ten regional Ebola and other special pathogen treatment centers, two state-designated Ebola treatment centers, two assessment hospitals, and one frontline facility) assessed for readiness in 14 U.S. states and territories.
- 3,490 people attended NETEC educational activities, a nine-fold increase from the previous year.
- 606 technical assistance requests answered by NETEC on topics such as staffing, PPE, patient transport, and environmental hygiene.

[8] 2017 NETEC Annual Report. https://netec.org/wp-content/uploads/2018/01/NETEC-AR-2017.pdf

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 the 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 April 2018, 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 ASPR, and jointly led the two departments.

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 million to 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 (NDMS) and the U.S. Public Health Service Commissioned Corps), and now has the capacity to quarantine up to 20 individuals simultaneously, if necessary, on the UNMC campus.

Regional Disaster Health Response System Pilots

HPP funding also enables ASPR to convene partnerships within the U.S. health care delivery system to focus on readiness and response, as well as maintain relationships at the state, local, and private health care system levels. In FY 2018, ASPR funded two regional disaster health response system (RDHRS) pilots. While HPP focuses on preparing the health care system to coordinate, respond as a whole, and protect its workers, the goal of the RDHRS pilots is to build upon that focus by coordinating intra- and interstate health care systems and by enhancing the clinical expertise for specialized care (e.g., trauma, burns, pediatrics, chemical, biological, radiological, nuclear, and explosives (CBRNE)) to increase medical surge and enhance the survival rates of the affected populations.

The RDHRS pilots emphasize the use of HCCs and trauma centers that integrate their medical response capabilities with federal facilities and local EMS to:

- **Integrate Medical Response Capabilities**
  Integrating medical response capabilities, including federal facilities and EMS.
- **Expand Specialty Care Expertise**
  Expanding specialty care expertise in trauma and chemical, biological, radiological, and nuclear casualty management.
- **Coordinate Medical Response**
  Coordinating medical response through mutual aid across state, local, tribal, territorial, and regional jurisdictions.
- **Integrate Measures of Preparedness**
  Integrating measures of preparedness into daily standards of care through health care system incentives.
- **Build on Regional Health Care Coalitions**
  Building on regional HCCs and better integrating public and private sector partners to improve preparedness and response.

Improving Preparedness through Evaluation and Research

The health system evaluation team at ASPR monitors HPP awardee performance and provides analysis and research for program and policy improvement recommendations. In addition, ASPR employs quality

improvement strategies to streamline business processes and reduce unnecessary burden on HPP awardees.

The health system evaluation team developed new HPP performance measures (PMs) in FY 2017 to align to the core concepts of the health care preparedness and response capabilities and funding opportunity announcements. FY 2020 will be the fourth year in which the 28 PMs (six of which will only apply to select territories and all freely-associated states)[9] 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 the fall of each year (the HPP year runs from July-June), and ASPR issues results in winter 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 current 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.

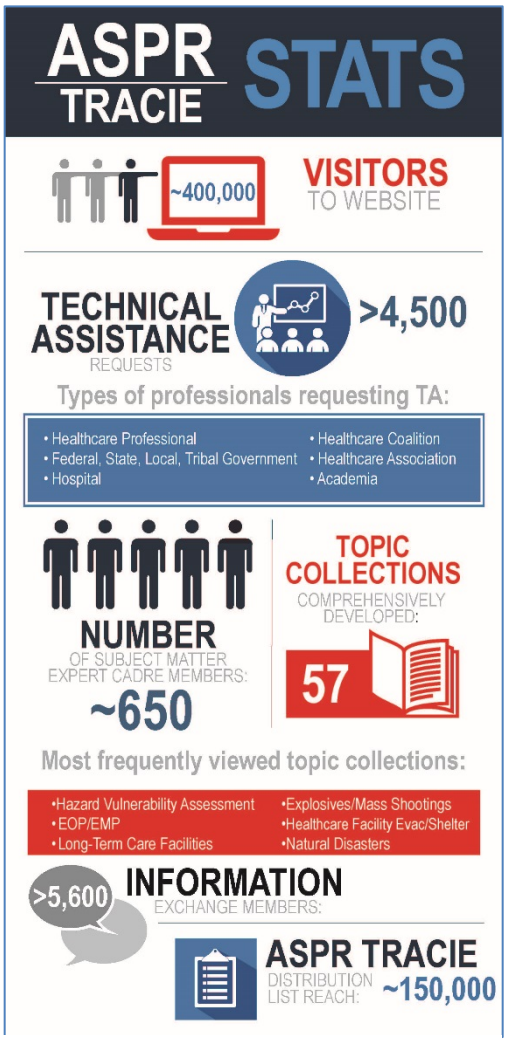


Figure 6. TRACIE Statistics Infographic

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, information, 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:

[9] *2017-2022 Hospital Preparedness Program: Performance Measures Implementation Guidance,* https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hpp-pmi-guidance-2017.pdf

- Consultation with subject matter experts (SMEs);
- Publication of SME-validated resource materials;
- 57 topic-specific collections of resource materials;
- Access to online plans, tools, templates, and trainings;
- Newsletter, *The Exchange*, featuring lessons learned from practitioners in the field;
- Webinars and virtual technical assistance (e.g., HCC- related webinars, Healthcare Challenges after Radiological Incidents, Pediatric Issues in Disasters, Healthcare Response to a No-Notice Incident);
- Facilitated, online peer-to-peer engagement and support through the Information Exchange; Tools and templates (e.g., HCC Recovery Plan Template, Hospital Personal Protective Equipment Planning Tool); and Guidance documents, fact sheets, and illustrative examples of promising practices (e.g., ASPR TRACIE HCC Overview Fact Sheet, HCC Fiscal Models Fact Sheet, Tips for Healthcare Facilities: Assisting Families and Loved Ones after a Mass Casualty Incident, No-Notice Incident Tip Sheets for Healthcare).
- Resource pages dedicated to topic areas of particular interest to our stakeholders (e.g., CMS and Disasters, CBRN, HCCs, Infectious Disease, Mass Violence, Hurricane-Related, Drug Shortages and Scarce Resources, Disaster Resources in Spanish)

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, trainings and exercises, natural disasters, mass casualty incidents, communications/public messaging, crisis standards of care planning, and pediatric-related resources. **Figure 6** provides an infographic snapshot of TRACIE statistics, as of January 2019, 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, after the 2018 shooting at a virtual gaming event in Jacksonville, TRACIE published Jacksonville Shooting: Fire Department Response to the Incident and Going with No Flow: Coping with Hospital Water Supply Issues in response to a hospital water outage. TRACIE developed the following resources following natural disasters: Major Earthquakes & Cascading Events: Potential Health and Medical Implications and tip sheet, Blood and Blood Products FAQ document, and Durable Medical Equipment in Disasters Fact Sheet.

Strengthening Day to Day Systems of Emergency Care

The health care system is a private sector entity that is relied upon during disasters and public health emergencies. Although the U.S. government delivers direct health care through the Department of Defense (DoD), the Department of Veterans Affairs (VA), and Indian Health Service (IHS), and the use of deployable assets (e.g., NDMS), significant attention is required to ensure that the health care system functions as a strong foundation to meet the health care needs of the American public. The Emergency Care Coordination Center (ECCC) was chartered in 2008 with the stated goal of “strengthening the nation’s emergency preparedness by promoting improvement in the nation’s daily emergency medical care.”

Background

The private sector health care system in the U.S. is an integral component of the response to disasters and public health emergencies. The National Academies of Sciences, Engineering, and Medicine and the Blue Ribbon Study Panel on Biodefense have called for the establishment of coordinated systems of care supported by financial incentives to encourage private sector health system engagement in readiness. This shift toward developing a ready health care system comes at a critical time - the 21st-century health security environment is increasingly complex and dangerous, the American population is aging, more medically complicated, and often managed in outpatient settings.

Recognizing that the emergency care system sits not only at the intersection of the public and private sector, but also at the intersection of public health and health care, Homeland Security Presidential Directive 21 directed the Secretaries of Health and Human Services, Transportation, and Homeland Security to create an Office for Emergency Medical Care in order to "address the full spectrum of issues that have an impact on care in hospital emergency departments, including the entire continuum of patient care from pre-hospital to disposition from emergency or trauma care." The vision for the office was to "coordinate with existing executive departments and agencies that perform functions relating to emergency medical systems in order to ensure unified strategy, policy, and implementation."

To achieve this, the ECCC convenes the Council on Emergency Medical Care, a coalition of emergency care SMEs across the U.S. government to identify synergies and efficiencies across governmental efforts to ensure the readiness of the health care system. Participants from across government include the Department of Transportation, the Health Resources and Services Administration (HRSA), the Department of Homeland Security (DHS), DoD, VA, IHS, the National Institutes of Health, the Office of the Assistant Secretary for Health, the Office of the Assistant Secretary for Planning and Evaluation, the Office of the National Coordinator for Health Information Technology (ONC), the Centers for Medicare and Medicaid Services (CMS), CDC, and the National Security Council (NSC).

The emergency care system in the U.S. has seen unprecedented challenges over the last decade. Shortages in primary care providers, an aging population, and a reduction in lower acuity hospital beds has resulted in ever-increasing numbers of Americans living at home with complex medical problems. When there are complications in their care, they seek care in urgent care centers, retail clinics, and both freestanding and hospital-based emergency departments (EDs). ED utilization has been steadily increasing. There are over 130 million patient visits to EDs annually; ED visits account for 28 percent of all acute care visits and about half of all hospital admissions. Moreover, the ED is a critical interface between the inpatient and outpatient setting as well as the entry point into the health care system for disease vectors (e.g., Ebola), injuries (e.g., bombings, shootings), and displaced individuals with chronic conditions following weather-related events (e.g., hurricanes, tornados). However, the average nongovernmental community hospital's margin is less than two percent, and cost control has top priority, so hospitals have little incentive to invest resources in preparing for low probability emergency and catastrophic events.

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 HCC development and the activities of ECCC. ECCC and HPP's work integrate to ensure that HCCs better understand emergency care patterns, financial incentives, and decision-making processes. The ECCC serves as a functional bridge between many HHS efforts focused on improving health care (e.g., interoperability, quality improvement, cost reduction) and ASPR's efforts through HPP and other programs to create a health care system that is more efficient, prepared, responsive, and resilient.

The ECCC provides a bridge between the private-sector health care delivery system, federal partners focused on health care delivery and quality (e.g., CMS, ONC, Agency for Healthcare Research and Quality, HRSA) 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. ECCC activities generally fall into the domains of (1) engaging patients and the public, (2) ensuring high quality emergency care that is integrated into the broader healthcare delivery system, and (3) creating structures and incentives that develop a sustainable business case for health care systems to engage more fully in emergency care, trauma care, and other preparedness and response activities.

Engaging patients and the public. A sample of recent projects includes the development of two public engagement campaigns focused on bystander response and public engagement. The first, the Stop the Bleed initiative, was a collaborative effort between private sector interests (the American College of Surgeons, The Hartford Consensus) and governmental representatives (ECCC, NSC, DHS, DoD) that has had a successful public adoption. The second, the Until Help Arrives initiative was a coordinated effort across FEMA, ASPR, and DoD and is being adopted by private sector professional societies with plans to disseminate widely. ECCC sponsors or co-sponsors public engagement sessions focused on strengthening emergency care and minimizing preventable deaths. Recent examples include a listening session focused on the challenges facing pre-hospital trauma care, especially in rural settings, and how to better integrate military and civilian EMS systems.

Ensuring high quality emergency care and integration of emergency care into the broader delivery system. In addition to public engagement initiatives, ECCC has worked to integrate emergency care into the broader framework for the health care delivery system by developing a conceptual model for acute care seeking and developing a number of initiatives focused on developing a quality framework for transitions of care (complete), population-based trauma outcomes (in process), health system readiness (in process), and the use of chief complaints to better understand resource utilization and situational awareness/surveillance within EDs (in process). Through ongoing partnership with CMS, ECCC continues to explore innovative ways to build systems of care that ensure the best possible outcomes from health threats. An example includes the development of a proposal for inclusion of EMS in alternative payment models that have the possibility for inclusion into ongoing health care payment efforts. Additionally, ECCC assessed the need for a system of care for high consequence infectious diseases analogous to the trauma system.

ECCC continues to collaborate with federal partners that provide direct care to ensure the delivery of high quality emergency care to all patients. A sample of recent projects includes participation in working groups and meetings to better integrate civilian and military trauma resources following the release of the National Academies of Science, Engineering, and Medicine (NASEM) report on trauma care titled, *Zero Preventable Deaths.* Via interagency agreement, the ECCC director also helped IHS implement telemedical care in all of their EDs in the Great Plains Area and also to contract ED management and staffing responsibilities in an effort to achieve Joint Commission certification and CMS payment agreements.

Creating structures and incentives. Recognizing that the private sector health care system must function as a strong foundation that can be augmented by deployable state, regional, and federal assets during times of system stress, ECCC sponsored a NASEM workshop on engaging the private sector health system in readiness activities. Moving forward, ECCC plans to continuously engage with both public and private sector health care partners to align health care system incentives with the American public's need for a health care system that is optimally-prepared and scalable to manage acutely ill and injured patients during a disaster, public health emergency, or other mass casualty event. This includes a whole-of-government approach and engagement of the private sector health care system to align incentives and

develop a business case for readiness. This will be achieved by leveraging and enhancing existing programs including HPP and NDMS, and by identifying and targeting other regulatory programs and incentives that can be aligned to make regional collaborations to save lives and protect Americans financially viable. ECCC is exploring levers to incentivize the health care sector to strengthen readiness efforts. Such levers include direct payment initiatives including payer driven incentives, alignment of grant programs, and the development of tiered system of care as well as indirect levers including tax structures, liability reform, and economic analyses that quantify return on investment for readiness. ECCC is also exploring policy and regulatory initiatives focused on licensing and credentialing, telehealth authorities, and integration with DOD and VA resources.

Access to real-time information on the capability and capacity of health care facilities allows for the efficient triage, transport, and treatment of patients in the safest appropriate level of care and is an important structure for motivating private-sector interest in preparedness. To this end, ECCC assessed the readiness for regional health information exchanges to provide regional insight into health system surge capacity and also developed a national inventory of trauma, burn, and other emergency care centers to allow for enhanced understanding of health care facilities, informed-patient decision-making, improved pre-hospital destination protocols, and support response during large scale events.

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. The ASPR Recovery program 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 (HSS) Recovery Support Function (RSF). Derived from years of lessons learned after major disasters, the NDRF identifies HHS as the coordinating agency for the HSS RSF. The ASPR Recovery program 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 Recovery program maintains situational awareness and gathers information about disaster impacts that could affect the recovery of the community.

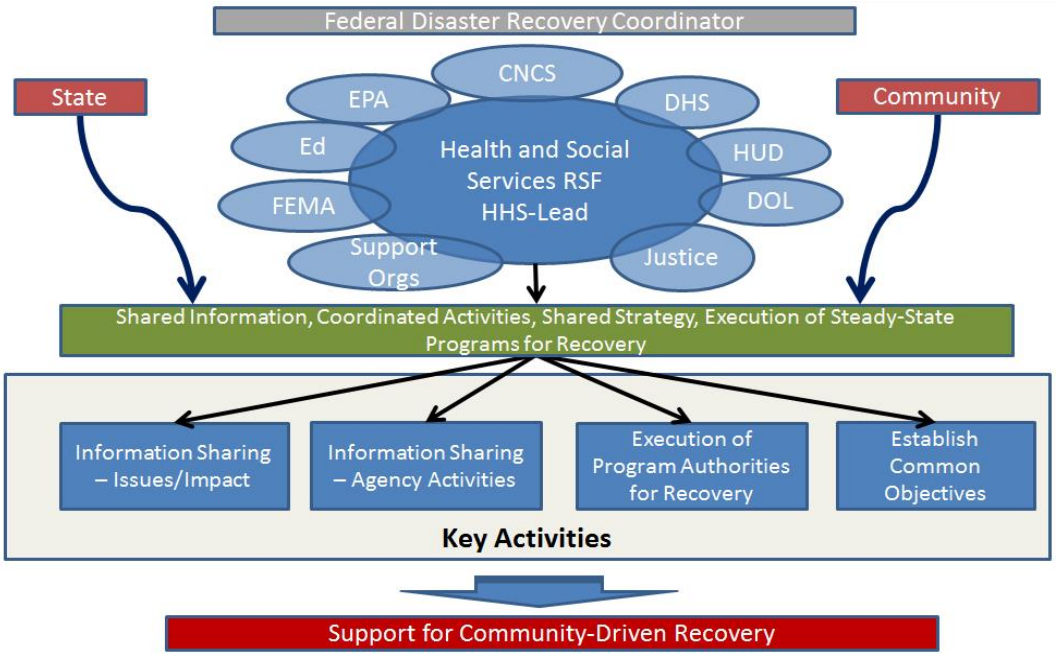


Figure 6. Coalition Model of Recovery Support Function Leadership

The Recovery program has led the coordination and implementation of federal, state, local, tribal, territorial, non-profit, and private sector recovery activities since 2011. The program's team coordinates and catalyzes recovery actions to provide practical solutions that fill critical gaps. Some of the recent experiences include flooding (e.g., Baton Rouge, Louisiana 2016), hurricanes (e.g., Hurricanes Sandy, Matthew, Harvey, Irma, Maria, Michael, and Yutu), and "non-traditional" incidents like the 2012 drought, which covered 2/3 of the continental United States. Deployment of the Recovery program subject matter experts to the impacted areas can occur with or without an activation of ESF 8 or other response efforts. **Figure 7** depicts the targeted delivery of resources and technical assistance to support the recovery and rebuilding of health and social services capabilities.

When the HSS RSF is activated, HHS is responsible for leading a coalition of 17 federal agencies to provide the impacted state and local communities with a more efficient and effective recovery effort. The Recovery team integrates the capabilities of federal, state, tribal, and local partners to conduct joint assessments of disaster-related recovery barriers and priorities, develop actionable interventions to improve the recovery of the healthcare, behavioral health, and social services systems.

In FY 2018, HPP resources supported the development of critical capabilities of HCC members to reach to different health care and non-health care entities. In doing so, the Recovery program 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., the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and the National Association of Community Health Centers) in which members of their constituency had the opportunity to provide perspectives and feedback over time.

In addition, the Recovery program has leveraged interagency-level planning initiatives to develop new resource guides to support the HCC-level and state-level planning for preparing health care facilities to cope with post-disaster issues. 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 Recovery program'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.

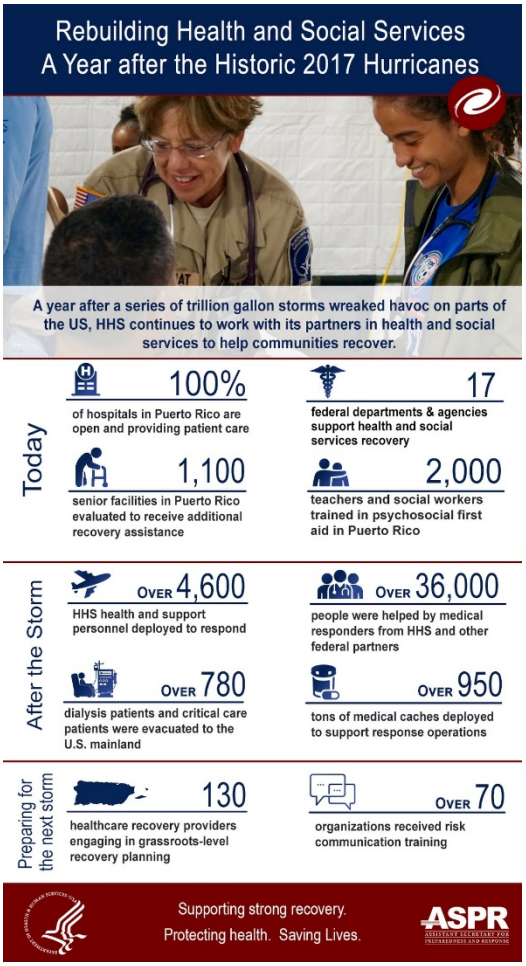


Figure 8: Highlights of ASPR Recovery Actions after One Year Post Hurricane Maria

A key outcome of ASPR-led recovery efforts is the partnership with state public health, social services, and education agencies to deliver practical and actionable solutions to meet the public health, health care facility, behavioral health, social services, and children and youth needs after disasters. Each of these topical areas are highly interconnected and require a system-wide perspective in order to support the recovery and ultimately reduce the risk of injury, illness,

and loss of life. Recovery staff are currently engaged in the ongoing recovery efforts in communities impacted by Hurricanes Irma, Maria, and Michael. The Recovery program engaged a department-wide response to solicit, train, and deploy over 350 experts to address the technical assistance and functional needs of the impacted communities in Texas, Florida, Puerto Rico, and the U.S. Virgin Islands. The sustained efforts of over 86,000 work hours from the Recovery teams, drawn from across all of HHS, have been critical to enable state and local leaders to overcome the challenges from some of the most historically devastating natural disasters in U.S. history.

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[10] and, therefore, has specific critical infrastructure responsibilities. The ASPR 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. 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. CIP'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 identifies several priorities to enhance the partnership and mitigate risks across the sector: implementing a sector-wide risk assessment tool; working together to mitigate risks to cyber systems and supply chain; and assessing and improving effectiveness of government and private sector responses to disaster.

Risk Assessment. In FYs 2016 and 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. The Healthcare and Public Health Sector Risk Identification and Sector Criticality 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 2019, CIP will assess use and satisfaction with the tool, along with identifying options for developing a web-based tool capable of storing and analyzing information to help inform ASPR's risk prioritization activities.

Cybersecurity. In FY 2017, the HPH sector was impacted by two major international cyber incidents affecting HPH 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 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.

[10] 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).

In December 2015, the Cybersecurity Information Sharing Act (CISA) (P. L. 114-113, Div. N) was enacted. CISA 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. CISA called for the creation of a federal advisory committee, the Healthcare Industry Cybersecurity Task Force, to make recommendations on HPH cybersecurity issues. The HPH Sector Cybersecurity Joint Working Group took up the task of coordinating implementation of over a dozen of the task force's priority recommendations. In FY 2018, CIP hosted a workshop of over 120 industry and government leaders to discuss the progress of 13 task groups in areas such as developing a MedTech Integrated Security Plan; a toolkit to enable any size health care facility to understand cyber risk and demand appropriate security measure from vendors; determining the risks of telemedicine; reconciling conflicting regulations that impede cybersecurity risk management; and working with partners to develop and execute cyber exercises for sector partners. Major milestones were met on these projects throughout FY 2018 and several projects will be completed in early FY 2019. During the HPH Sector Joint Councils Fall Summit held in Nashville, TN, on October 10, 2018, the full sector exercised a cybersecurity incident coupled with pandemic influenza. Fostering this collaboration between cybersecurity professionals and health care professionals will continue to be one of CIPs priorities in mitigating risks.

Supply Chain. In FY 2018, CIP continued 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 of pharmaceutical and medical/surgical supply chains. Hurricane Maria greatly impacted a large portion of the medical product manufacturing industry in Puerto Rico and led to several national shortages of products related to sterile saline. As the influenza season proved to be difficult, with numerous hospitalizations, CIP coordinated between government and private sector partners to identify impacts of the saline shortage on our ability to respond to severe flu, or another disaster with national impact. While the health system was able to nimbly adapt to those shortages and provide care throughout the influenza surge, CIP identified areas where slight changes in availability could severely impact the ability of the health care system to respond. To address these areas in FY 2018, ASPR funded a NASEM workshop on medical product shortages to identify effects on patient health and opportunities to predict, prevent, and respond to them. Participants from across industry discussed ways that novel monitoring and communications activities may bolster the community's ability to prepare and respond.

Response Coordination. The hurricanes of 2017 required full coordination of multiple aspects of the federal response system including ESF 8, the HHS RSF, and the public-private partnership of HPH critical infrastructure coordinated by HHS. There were many lessons learned throughout the process and FY 2018 found CIP working closely with ASPR and FEMA colleagues to identify short- and long-term priorities for streamlining response coordination. CIP relies closely on the National Business Emergency Operations Center and other sectors of critical infrastructure to support our requirements for power, water, communications, and transportation. In FY 2020, CIP will continue to work with DHS and FEMA to optimize use of ESF-14 to address issues of private sector interdependencies and areas of support which may not specifically fall under other ESFs.

FY 2019 HPH Sector-Specific Plan. 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 2020, the partnership will finalize and enact the next Sector Specific Plan (2019-2023). The refreshed document will include a review of the HPH Sector structure and identify the sector's critical functions to serve as a factor in prioritizing risk mitigation activities; developing new scenario-driven lists of nationally-critical infrastructure. 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 2016	$254,555,000
FY 2017	$253,958,000
FY 2018	$264,555,000
FY 2019 Enacted	$264,555,000
FY 2020 President's Budget	$257,555,000

Budget Request

ASPR requests $257,555,000 for the Hospital Preparedness Program, which is a decrease of -$7,000,000 from the FY 2019 Enacted level. Within the total, $231,500,000 will be provided for HPP formula-based cooperative agreements to states, territories and freely-associated states, the District of Columbia, and three high risk political subdivisions. The remaining funds support other programs at ASPR that directly support the mission of HPP, including TRACIE, ECCC, the Recovery program, and the CIP program, and HPP administration and performance evaluation and oversight.

HPP focuses on health care provider coordination in pursuit of an effective response to save lives and mitigate negative outcomes for those impacted by public health and medical emergencies. Together with HPP, the programs funded by the appropriation represent a functional ecosystem that identifies health care sector needs in preparedness, response, and recovery efforts; develop solutions to meet those needs; and implement action-oriented approaches with the health care provider, health care entity, health care and life sciences industry, as well as the needs of individual health care consumers at the center of efforts. HPP is the only source of federal funding devoted to readying the United States' complex health care system to save lives and protect Americans.

HPP, through HCCs, helps each patient receive the right care at the right place at the right time. With an increased emphasis on 21st-century threats, ASPR recognizes that health care system readiness must evolve and innovate. It is imperative that ASPR continues to invest in a readiness program that mirrors the existing health care referral patterns, moves beyond jurisdictional boundaries towards interstate regional coordination, and promotes disaster response clinical expertise.

In FY 2020, 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.

ASPR Hospital Preparedness Program – Outputs and Outcomes Table

Measure[1]	**Year and Most Recent Result / Target for Recent Result / (Summary of Result)**[2]	**FY 2019 Target**	**FY 2020 Target**	**FY 2020 Target +/-FY 2019 Target**
14 Increase the proportion of coalitions that reported the ability to coordinate and track patient surges and movement during an exercise or event	FY 2017: 48.3 % Target: 75.0 % (Target Not Met but Improved)	Discontinued	Discontinued	N/A

Measure[1]	**Year and Most Recent Result /** **Target for Recent Result /** **(Summary of Result)**[2]	**FY 2019 Target**	**FY 2020 Target**	**FY 2020 Target** **+/-FY 2019 Target**
14a Increase the percent of states with HCC core member organizations participating in the Coalition Surge Test exercise of at least 20 percent of the HCC's total beds	FY 2017 Baseline: 40% Target: Pending based on verification of EOY data	Maintain Baseline	Maintain Baseline	Maintain
15 Increase the proportion of health care coalitions that use an incident management structure to coordinate and respond	FY 2017: 55.0 % Target: 55.0 % (Target Met)	Discontinued	Discontinued	N/A
15a Increase the percent of HCCs that have tested the ability to coordinate among its members during an exercise or event	FY 2017 Baseline: 97% Target: Pending verification of EOY data	Maintain Baseline	Maintain Baseline	Maintain

[1] Measures 14 and 15 are being replaced with measures 14a and 15a starting with reporting of FY 2017 data (performance period is July 2017-June 2018) in 2019.

[2] Baseline result data for measures 14a and 15a are derived from unverified EOY performance data. These results may change and be more accurately reported against the measure once the ASPR health care evaluation team verifies EOY performance data results with HPP cooperative agreement recipients.

ASPR Hospital Preparedness Program – Grant Awards by State

(In Dollars)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Assistant Secretary for Preparedness and Response (ASPR)
FY 2020 MANDATORY STATE/FORMULA GRANTS
CFDA NUMBER/PROGRAM NAME: 93.889/Hospital Preparedness Program (HPP)

STATE/TERRITORY	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Alabama	$3,264,692	$3,264,692	$3,264,692	$0
Alaska	$920,591	$920,591	$920,591	$0
Arizona	$4,952,170	$4,952,170	$4,952,170	$0
Arkansas	$2,024,350	$2,024,350	$2,024,350	$0
California	$23,314,752	$23,314,752	$23,314,752	$0
City of Chicago	$2,679,362	$2,679,362	$2,679,362	$0
Colorado	$3,162,575	$3,162,575	$3,162,575	$0
Connecticut	$2,359,778	$2,359,778	$2,359,778	$0
Delaware	$1,020,276	$1,020,276	$1,020,276	$0
District of Columbia	$943,136	$943,136	$943,136	$0
Florida	$11,824,402	$11,824,402	$11,824,402	$0
Georgia	$7,255,793	$7,255,793	$7,255,793	$0
Hawaii	$1,259,212	$1,259,212	$1,259,212	$0
Idaho	$1,234,464	$1,234,464	$1,234,464	$0
Illinois	$8,601,678	$8,601,678	$8,601,678	$0
Indiana	$4,134,226	$4,134,226	$4,134,226	$0
Iowa	$2,125,436	$2,125,436	$2,125,436	$0
Kansas	$2,108,334	$2,108,334	$2,108,334	$0
Kentucky	$2,854,696	$2,854,696	$2,854,696	$0
Los Angeles	$9,189,581	$9,189,581	$9,189,581	$0
Louisiana	$3,007,721	$3,007,721	$3,007,721	$0
Maine	$1,045,686	$1,045,686	$1,045,686	$0
Maryland	$4,860,197	$4,860,197	$4,860,197	$0
Massachusetts	$4,284,082	$4,284,082	$4,284,082	$0
Michigan	$6,074,286	$6,074,286	$6,074,286	$0

Minnesota	$3,554,540	$3,554,540	$3,554,540	$0
Mississippi	$2,142,623	$2,142,623	$2,142,623	$0
Missouri	$3,776,390	$3,776,390	$3,776,390	$0
Montana	$908,265	$908,265	$908,265	$0
Nebraska	$1,362,536	$1,362,536	$1,362,536	$0
Nevada	$2,393,396	$2,393,396	$2,393,396	$0
New Hampshire	$1,066,051	$1,066,051	$1,066,051	$0
New Jersey	$5,652,463	$5,652,463	$5,652,463	$0
New Mexico	$1,516,457	$1,516,457	$1,516,457	$0
New York	$9,530,974	$9,530,974	$9,530,974	$0
New York City	$7,896,431	$7,896,431	$7,896,431	$0
North Carolina	$6,110,088	$6,110,088	$6,110,088	$0
North Dakota	$874,192	$874,192	$874,192	$0
Ohio	$7,444,587	$7,444,587	$7,444,587	$0
Oklahoma	$2,586,582	$2,586,582	$2,586,582	$0
Oregon	$2,543,741	$2,543,741	$2,543,741	$0
Pennsylvania	$8,135,187	$8,135,187	$8,135,187	$0
Rhode Island	$920,269	$920,269	$920,269	$0
South Carolina	$3,118,045	$3,118,045	$3,118,045	$0
South Dakota	$846,916	$846,916	$846,916	$0
Tennessee	$4,215,443	$4,215,443	$4,215,443	$0
Texas	$16,308,624	$16,308,624	$16,308,624	$0
Utah	$2,493,626	$2,493,626	$2,493,626	$0
Vermont	$774,802	$774,802	$774,802	$0
Virginia	$6,128,815	$6,128,815	$6,128,815	$0
Washington	$4,250,883	$4,250,883	$4,250,883	$0
West Virginia	$1,391,880	$1,391,880	$1,391,880	$0
Wisconsin	$3,596,704	$3,596,704	$3,596,704	$0
Wyoming	$829,248	$829,248	$829,248	$0
Subtotal	**$226,871,234**	**$226,871,234**	**$226,871,234**	**$0**
Indian Tribes				
Migrant Program				
American Samoa	$278,224	$278,224	$278,224	$0
Guam	$362,815	$362,815	$362,815	$0

Marshall Islands	$268,005	$268,005	$268,005	$0
Micronesia	$276,806	$276,806	$276,806	$0
Northern Mariana Islands	$273,856	$273,856	$273,856	$0
Palau	$255,373	$255,373	$255,373	$0
Puerto Rico	$2,608,473	$2,608,473	$2,608,473	$0
Virgin Islands	$305,214	$305,214	$305,214	$0
Subtotal	**$4,628,766**	**$4,628,766**	**$4,628,766**	**$0**
Total States/Territories	**$231,500,000**	**$231,500,000**	**$231,500,000**	**$0**
Technical Assistance				
State Penalties				
Contingency Fund				
Other Adjustments (specify)				
Subtotal Adjustments				
TOTAL RESOURCES	$231,500,000	$231,500,000	$231,500,000	$0

Note: FY 2019 and FY 2020 amounts are estimates. .

ASPR Hospital Preparedness Program – Summary of Grant Awards

(In Dollars)

ASPR Hospital Preparedness Program - Grant Awards Table			
Hospital Preparedness Program	FY 2018 Final	FY 2019 Enacted	FY 2020 Estimate
Number of Awards	62	62	62
Average Award	$3,733,871	$3,733,871	$3,733,871
Range of Awards	$255,373 - $23,314,752	$255,373 - $23,314,752	$255,373 - $23,314,752

Note: FY 2019 and FY 2020 amounts are estimates.

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**536.700**	**561.700**	**561.700**	**--**
Advanced Research and Development (non-add)	*476.700*	*501.700*	*501.700*	*--*
Operations and Management (non-add)	*60.000*	*60.000*	*60.000*	*--*
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

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. 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. The Act was reauthorized in 2013.

BARDA's approach to advanced research and development has a proven record of accomplishment. 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 Veterans 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 2017–2018 PHEMCE Strategy and Implementation Plan.[11] 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 and that can be repurposed to meet medical countermeasure needs or new

[11] https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx

multipurpose products with commercial indications that meet public needs. This approach increases the sustainability of these medical countermeasures 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—often through cost-sharing agreements—with academia, non--government organizations, and private sector companies, including both some of the largest names in the biopharmaceutical industry and some of the smallest.[12] 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 (GSK), for the development of new antibacterial drugs. As partners, GSK and BARDA use 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). Since then, BARDA has supported six portfolio partnerships. Four of these partnerships are under the CBRN program and two are under the Pandemic Influenza program. These OTAs allow products to move into, or out of, the advanced development portfolios as warranted based on performance, and afford BARDA a voice in the decision-making process about which medical countermeasure products should proceed through development. In 2015, BARDA awarded an OTA to AstraZeneca, supporting a portfolio of candidates to address antibiotic resistance. This award enabled BARDA to meet one of the metrics under Objective 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 successfully transferred to Pfizer to continue this important partnership. Since then, BARDA has awarded two additional OTAs to Hoffman-La Roche and The Medicines Company, both in 2016, and support development of both antibiotics and diagnostics.

These four 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. Additional OTA partnerships are being explored to support the Radiological/Nuclear Countermeasures, Chemical Countermeasures and Thermal Burn programs.

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 three life science accelerators—the Wellcome Trust, California Life Science Institute, and MassBio, which aims to identify, build, and manage a portfolio of innovative antibacterial MCMs. In FY 2018, two additional funding partners joined CARB-X. The Bill and Melinda Gates Foundation joined as an Alliance Partner and the United Kingdom Government's Department of Health and Social Care has joined as a funding partner. As of July 2018, CARB-X has made awards to 34 different companies with five projects that have moved into human clinical trials. CARB-X is currently investing in eleven novel classes of antibiotics, eleven non- traditional approaches to treating bacterial infections, and six next-generation antibiotics that overcome known resistance mechanisms. CARB-X has also invested in five diagnostic platforms. One is a rapid point-of-care diagnostics and four are hospital laboratory-based diagnostics.

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*

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

Countermeasure Review[13] (*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. 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. The core service assistance programs were also used during the Zika response in 2016 & 2017. These core service assistance programs have been a huge success for HHS and its PHEMCE partners. The FY 2020 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. In 2017, the CIADM network was employed to assist with the development of a Zika virus vaccine. 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 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.

- *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 128 non-clinical studies under 71 projects in support of BARDA product development. Projects have supported the development of animal models, reagents, and assays necessary to support product approvals, studies to evaluate repurposing of already approved products, and evaluation of countermeasures during a response.

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

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 is establishing the ability to test these products in animal models 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, and these studies will continue through FY 2020. 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 2018, the network evaluated candidates to address drug resistant bacterial pathogens identified as threats to the homeland.

- *Clinical Studies Network (CSN)*: In FY 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. The CSN supported the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) vaccine study, and during the 2016 Zika outbreak 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. This study showed that the long-term stored pre-pandemic vaccine was still effective and will save the USG 100's of millions of dollars in production and re-procurement costs. The network also is evaluating a heterologous prime-boost pre-pandemic vaccine study to expand the potential usefulness of the stockpiles. In FY 2018, the network will be used to evaluate the current anthrax vaccine's efficacy in the elderly population. The vaccine is currently licensed for healthy adults. This study, the B-SAFE study, will evaluate the current licensed anthrax vaccine and a next generation anthrax vaccine that contains an adjuvant in elderly populations; this study addresses a mandate under PAHPA to develop countermeasures for at-risk populations.

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 anthrax, plague and tularemia, and for treatment of high priority community- and hospital-acquired bacterial infections. BARDA is sponsoring advanced development of 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*[14] to address the growing antibiotic crisis. Under BARDA's CBRN Program, two antibiotics were approved in FY 2018 with additional approvals anticipated in the coming years.

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

BARDA employs a repurposing, multi-use strategy for Radiological/Nuclear, Chemical, and Thermal Burn countermeasures. The injuries from these threats likely have treatment solutions in the commercial marketplace as well as potential synergies in treatments between threats (e.g., systemic treatments to quell inflammatory cytokine storms would be applicable in Radiological/Nuclear, Chemical, and Thermal Burn portfolios). Portfolio development for all of these threat areas involves comprehensive coordination between product development teams. Several areas of synergy have been identified and are currently being leveraged such as treatment of neutropenia and thrombocytopenia for both oncologic recovery and acute radiation syndrome and treatment of cutaneous radiation injury and treatment of diabetic foot ulcers that might also have applicability in the treatment of chemical burns. The ability to use commercial products also enables the potential use of Vendor Managed Inventories (VMI) that allow for a single purchase of product and rotation of the inventory back into the commercial marketplace and consequently, significant savings to the USG and the taxpayer. The Radiological/Nuclear, Chemical, and Thermal Burn programs all plan around the potential to use VMI for commercially available products.

The Thermal Burn 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 VMI 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 2019–2020, 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 that have transitioned to support under Project BioShield; 15 of these products have been procured for the SNS.

BARDA's advanced research and development and Project BioShield programs also have led to FDA licensure or approval of eight new products since 2012 using the FDA Animal Rule and two products under the traditional approval pathway. 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), Neupogen (2015) to treat hematopoiesis, BioThrax (2015) for post-exposure prophylaxis in individuals suspected of exposure to anthrax, ANTHIM (obiltoxaximab) anthrax antitoxin (2016), Leukine to treat neutropenia (2018), and TPOXX (Tecovirimat, ST-246) to treat individuals symptomatic with smallpox disease (2018). In FY 2017, the FDA approved Vabomere, an antibiotic candidate to treat severe drug resistant infections, and in June of 2018, the FDA approved the second BARDA supported antibiotic, ZEMDRI, for the treatment of complicated urinary tract infections. This brings the total to ten unique products supported under BARDA and Project BioShield (PBS) to achieve FDA approval. The Grifols Procleix Zika Virus Assay and the Roche Cobas Zika assay, both highly sensitive, high throughput Zika virus molecular assays for screening the blood supply were developed with BARDA support and have been approved by the FDA. Additional FDA approvals for novel antibiotics, vaccines for smallpox and Zaire ebolavirus, new seizure treatments as well as the first product to be licensed for the treatment of sulfur mustard cutaneous injury, biodosimetry devices and Zika virus and biothreat diagnostics are also projected for approval in FYs 2019–2020. The development pipeline remains poised to continue this trend,

transitioning CBRN products from advanced research and development programs to potential 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 three, next-generation anthrax vaccine candidates. One enhanced anthrax vaccine candidate, NuThrax (manufactured by Emergent), transitioned to PBS in FY 2016 and offers potential, protective, immunity with fewer doses. It is anticipated that the first deliveries to the SNS will commence in FY 2019. BARDA is supporting 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 vector, and offers potential protective immunity in two or fewer doses. With support under BARDA's advanced research and development program and PBS, clinical evaluation of these new vaccine candidates will occur in FYs 2019 and 2020.

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 with the same indication as Raxibacumab.

BARDA is also supporting the development of a laboratory-based *Bacillus anthracis* molecular detection assay, and point-of-care assays for lethal factor, a toxin that is detectable in blood early during anthrax infection.

The anthrax portfolio is one of BARDA's most mature portfolios, leading to the approval of three anthrax antitoxins, licensure of an anthrax vaccine for post-exposure prophylaxis, and the licensure of a new manufacturing facility to expand domestic manufacturing capacity for anthrax vaccines. BARDA will continue to support the development of next-generation anthrax vaccines with the goal of reducing the number of doses required to generate protective immunity. This will increase operational capacity during a potential response.

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 smallpox modified vaccinia Ankara (MVA) vaccine for people with HIV or atopic dermatitis and the ST-246 smallpox antiviral drug to treat people with smallpox symptoms. MVA is currently in the SNS and may be administered to patients under an

Emergency Use Authorization from the FDA. BARDA anticipates submission of the Biological License Application (BLA) in FY 2019. ST-246 (TPOXX), approved by the FDA in July of 2018, became the eighth product supported under PBS to achieve FDA approval. HHS has a goal of developing two antiviral products with different mechanisms of action. The approval of TPOXX addresses a portion of this goal and provides for a significant increase in preparedness response for the threat of smallpox disease.

In 2013, Bavarian Nordic (BN) started a large Phase 3 study to evaluate lot-to-lot consistency and safety of MVA 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 2019, BN is expected to submit a Biological License Application to the FDA for licensure of a liquid formulation of MVA. 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 FYs 2019 and 2020.

In addition to smallpox vaccines, the United States Government committed to develop and acquire 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 was approved (as TPOXX) by the FDA July 2018. 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 12 companies for advanced development of multiple broad spectrum antibiotic candidates to treat infections caused by these biothreats and deadly multi-drug resistant pathogens acquired in community- and hospital-settings, such as carbapenem resistant Enterobacteriaceae (CRE) and methicillin resistant *Staphylococcus aureus* (MRSA). BARDA has advanced seven candidates into Phase 3 clinical development and saw its first antibiotic approval in FY 2017 with Vabomere for the treatment of severe drug resistant infections. In June of 2018, the FDA approved the second BARDA supported antibiotic ZEMDRI for the treatment of

complicated urinary tract infections. In August of 2018, the FDA approved Xerava which has been developed under a partnership between Tetraphase and BARDA. Xerava was approved for the treatment of complicated intra-abdominal infections and is the third antibiotic product supported by BARDA to achieve FDA approval. BARDA is projecting a third antibiotic within its portfolio to be approved by the FDA.

In FY 2010, BARDA awarded its first contract for the advanced development of a next-generation aminoglycoside[15] (plazomicin developed by Achaogen) against plague and tularemia, with an aspirational goal of developing a product that would have other important public health uses. Plazomicin (trade name ZEMDRI) was approved by the FDA in June 2018. This is the second antibiotic supported under the ARD program to achieve FDA approval. The first was Vabomere, approved by the FDA in August 2017. The program with Achaogen is a public-private partnership where both Achaogen and BARDA shared the costs for two Phase III clinical trials to evaluate the efficacy of ZEMDRI to treat complicated urinary tract infections and CRE infections. The safety data from both clinical trials will support the potential emergency use authorization (EUA) of ZEMDRI 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.

Since 2010, BARDA has expanded the advanced research and development portfolio to support twelve different companies. Four of the programs have been awarded using BARDA's Other Transactional Agreement authority (OTA) under the 2006 PAHPA. The OTAs allow BARDA to invest in portfolios of candidate products and all are supported in a cost-share effort by the company and BARDA. The OTAs have been awarded to GSK (2013), Pfizer (2015 - previously AstraZeneca), The Medicines Company (2016), and Hoffman-La Roche (2016). Each of these novel public private partnerships met PHEMCE priorities as well as the objectives outlined in the CARB National Strategy and supporting Action Plan noted above.

In FY 2019, BARDA will continue to support advanced research and development of promising candidates for biothreat indications and the broader public health concern of antibiotic resistant bacteria. This is critical to address the threat of potentially engineered biothreat pathogens that may be resistant to stockpiled antibiotics and to address secondary complications from the initial exposure to CBRN threat agents.

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. In 2016, BARDA expanded the program to support development of rapid point-of-care and laboratory molecular and phenotypic tools to identify high-priority 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. Under BARDA's advanced research and development program, BARDA has invested in several diagnostic platforms. Under the OTA with Roche, BARDA is supporting development of diagnostics as well as new antibiotics. In FYs 2019 and 2020, BARDA will continue to invest in point-of-care and lab-based diagnostics to decrease the time it takes to identify the organism and determine drug susceptibility from several days to hours. BARDA is supporting these efforts under both advanced research and development and CARB-X.

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

Since 2010, BARDA has supported many of the antibiotic candidates that are in late stage (Phase 2 and Phase 3 clinical studies) development. 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 antibiotic candidates soon after discovery into Phase 1 clinical testing. The creation of CARB-X was an objective 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 to be supported by CARB-X. All products address pathogens on the World Health Organization (WHO) or CDC bacterial threat list. As of July 2018, CARB-X has accelerated the efforts of 34 different companies with five projects that have advanced to clinical evaluation. CARB-X is currently investing in eleven novel classes of antibiotics, eleven non-traditional approaches to treating bacterial infections, and six next-generation antibiotics that overcome known resistance mechanisms. CARB-X has also invested in five diagnostic platforms. One is a rapid point-of-care diagnostics and four are hospital laboratory-based diagnostics. In FY 2018, two additional funding partners joined CARB-X. The Bill and Melinda Gates Foundation joined as an Alliance Partner and the United Kingdom Government's Department of Health and Social Care has joined as a funding partner.

The FY 2020 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 ASPR/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. In FY 2017, BARDA transitioned four candidates to support under Project BioShield; two therapeutics and two vaccines. Due to these earlier investments, products are available to address the ongoing Ebola outbreak in the Democratic Republic of Congo (DRC), which began in 2018. BARDA-supported vaccines, therapeutics, and diagnostics have been deployed to WHO or to the DRC to bring the outbreak under control, treat individuals, or diagnose suspected individuals or cadavers for Ebola disease.

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 Vaccines: In FY 2017, BARDA transitioned two Ebola Zaire vaccines to Project BioShield to support late-stage development and potential procurement. The Merck and Janssen/Bavarian Nordic vaccines are being supported under Project BioShield. Merck is in the process of submitting their biological license application (BLA) to the FDA under a rolling submission. The Merck vaccine is currently being used in the DRC to vaccinate contacts and contacts of contacts under a ring vaccination protocol. The vaccine available was manufactured by Merck under a preapproval purchasing agreement with the Global Alliance for Vaccines and Immunization (GAVI). The Janssen/Bavarian Nordic vaccine is being used in a clinical trial in Uganda in health care workers and front line works.

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 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 Phase1/2 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. Both products supported under PBS are being deployed for use in the DRC outbreak. Mapp Bio and Regeneron's products are part of the NIH sponsored randomized clinical trial.

In FY 2019, BARDA will continue 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 Diagnostics: In FY 2015, BARDA awarded a contract to Orasure Technologies to support development of a simple to use test to detect Ebola virus in suspect individuals and cadavers. FDA issued an EUA for this assay in July 2015 so that it could be used in the West Africa outbreak. Tests were distributed to WHO for use in the recent DRC outbreak. Orasure continues work to complete studies for FDA approval.

Biodiagnostics: Since FY 2013, BARDA has supported development of diagnostic technologies 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. In 2016, BARDA prioritized supporting the development of Zika-specific serological (IgM) assays due to the critical need to test pregnant women in and returning from endemic regions, and to prepare for Zika virus transmission in the U.S. Three of these assays are available under EUA, and FDA approval is expected in FY 2019. To further support development of biothreat 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 *B. anthracis*, *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 2019. 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: The Radiological/Nuclear Countermeasures Program focuses on developing solutions for all aspects and injuries that may result from radiological or nuclear threats. The two major radiological threats or incidents that are addressed are Nuclear Detonations and 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 has included 12 MCM candidates that target several sub-syndromes of acute radiation syndrome, as well as traumatic injury that could result from nuclear 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 has supported the development of pediatric instructions for the use of current formulations of Neulasta (a drug to treat neutropenia) and Prussian Blue (a drug needed to remove ingested radionuclides).

BARDA has repurposed commercially available products, leveraging commercial development efforts and distribution infrastructure to reduce taxpayer costs and meet public health emergency needs.

BARDA sponsored late-stage development and procurement of three products under Project BioShield: Neupogen and Neulasta (FY 2013-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. Leukine was also approved by the FDA in March 2018. 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. BARDA purchased additional product in 2016 to augment the level of preparedness and will continue to support these products under PBS in FY 2019. 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 2018, 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. Additional expanded studies also 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 2019 and beyond, BARDA has identified specific pathways (e.g., coagulation, vascular injury, inflammation) that play essential roles in radiation injury. A goal for BARDA's radiation/nuclear program will be to evaluate existing products that modulate these pathways to determine their capacity to treat or mitigate radiation-induced injury.

The preclinical studies to identify new targets and test existing targets has highlighted the importance of hemostasis and the importance of supporting existing blood products and the development of new blood products. Since 2012, BARDA has been working with the blood industry and the Office of the Assistant Secretary of Health (OASH) to ensure treatment gaps within the blood product landscape are addressed. Currently, BARDA is supporting several programs to develop next generation blood products (e.g. spray dried plasma and hemostatic agents from platelets) and platforms that will augment the safety and availability of the blood supply (e.g. pathogen reduction platforms). Additionally, BARDA is working

closely with OASH on analytical models to be able to predict availability and product distribution for mass casualty events as well as sustainability models to monitor and predict product availability and identify potential treatment gaps.

Another medical consequence of nuclear threats is burns and blast trauma. 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 needs and the types of new medical countermeasures beneficial to treat burn injuries effectively. By supporting MCMs with emergency and routine burn care, BARDA may create a more sustainable market with products pre-positioned for care in mass casualty incidents. Furthermore, as these technologically advanced products are integrated into routine care, BARDA investments bring immediate value to the American public by improving the quality of care available as well as ensuring the burn surgeons and other end-users maintain their skills and product knowledge for use in an emergency.

Within BARDA's Thermal Burn program portfolio, there are three different types of products to mitigate burn injuries undergoing evaluation in late-stage clinical development (Phase 3). One of the products received a favorable review from the FDA and a designation as 'Regenerative Medical Advanced Technology' (RMAT) under the 21st Century Cures Act (2017). This allowed the product to enter Phase 3 development ahead of schedule. The four late-stage 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. The placement of Silverlon in the Strategic National Stockpile (SNS) immediately raised the level of field care preparedness for burns injuries. In FYs 2017 and 2018, BARDA provided additional funding under the current Project BioShield contracts to support clinical studies in pediatric patients for two of these products, further addressing the PAHPA mandate to develop MCMs for at-risk individuals. In addition, BARDA's advanced research and development portfolio in burns includes four candidate products; all are in various stages of clinical evaluation and development. In FY 2018, one of these candidates received the designation as a Breakthrough Technology under the 21st Century Cures Act that enables expedited pathway for development. For FYs 2018–2019, the BARDA Thermal Burn program will also begin to prioritize products that help address and mitigate the consequences of injuries from nuclear fallout, such as cutaneous radiation injuries (CRI). BARDA is evaluating two products and is working with the FDA to develop strategies for expedited product approval. 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 advanced imaging technologies, such as those that utilize forward looking or short-wave infrared light to assess burn depth and severity as well as which incorporate machine-learning algorithms to enable 'deep-learning' features by machines.

BARDA's Thermal Burn program is also collaboratively working with other federal agencies like the Department of Homeland Security, as well as non-profit professional organizations like the American Burn Association and the American College of Surgeons and their Committee on Trauma to understand the needs and gaps in initial care as well as to evaluate and update the contents of the SNS-held Burn/Blast Kits.

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 FY 2020, 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 nerve agents, 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 of this study, along with non-clinical studies, 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). 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. Approval for the treatment of status epilepticus was received in September 2018, and approximately 700,000 multidose vials of midazolam for injection have been delivered to the SNS.

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 are 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 have supported the development and publication of additional guidance, including an app-based decision aiding tool for first responders, to be published in 2019. 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 Preparedness and Emergency Operations program 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, 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. BARDA anticipates several new programs to take this approach in the chemical MCM portfolio.

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 because 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 2019–2020, BARDA will conduct additional studies to prepare multiple programs for potential transition to Project BioShield.

Driving Product Innovation
Under the 21st Century Cures Act, BARDA was provided with an authority to invest in a medical countermeasures innovation partner (MCIP) using venture capital practices to assist in the development of products, tools, and technologies to address 21st century threats. In FY 2018, BARDA established a new division, the Division of Research, Innovation and Ventures (DRIVe) to fulfill this authority. The new division will partner with the investment and innovator communities to develop transformative solutions to the toughest health security problems that span the entire health sector. DRIVe has made significant progress since June 2018. With FY 2018 funding, eight accelerators have been established to bring innovation to BARDA and are located in innovation hubs across the country. A solicitation was posted in FY 2018 to support two initial programs: developing unique solutions to Sepsis and supporting efforts for early notification to act, control, and treat (ENACT) individuals exposed to infectious disease prior to symptoms. BARDA anticipates making multiple awards under these two programs in FY 2019.

ASPR Realignment
Under the ASPR realignment and in compliance with the 21st Century Cures Act, contracting has been moved back into the BARDA Office. This move is expected to bring efficiencies in the solicitation process from proposal review to potential award, and oversight of the project. The transition of the Strategic National Stockpile to ASPR will also allow for better alignment and transition of products between PBS and the SNS. The transition also allows for better alignment of timing for the potential transition of products to the SNS for stockpile maintenance and sustainment.

Funding History	
FY 2016	$511,700,000
FY 2017	$510,499,000
FY 2018	$536,700,000
FY 2019 Enacted	$561,700,000
FY 2020 President's Budget	$561,700,000

Budget Request
The FY 2020 Request for Advanced Research and Development is $561,700,000, which is the same as the FY 2019 Enacted level. The Request supports the advanced development of the highest priority MCMs against all 13 threats identified by DHS and prioritized in the PHEMCE Strategy and Implementation Plan (2017–2018). 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. Second antiviral candidate against smallpox;
3. New antidotes for treatment of chemical agents (for example, mustard gas exposure and chlorine gas);
4. Diagnostic devices to confirm infection with biological agents;
5. Innovations in early stage medical countermeasure research and development focusing on sepsis, wearable diagnostics and distributed manufacturing technologies;

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

Anthrax ($10 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 2020 will support further clinical evaluation of potential intranasal 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): 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. In July 2018, Tecovirimat was approved by the FDA. Approval of this candidate highlights successful transition of the candidate from NIAID and DoD funding, to advanced research and development funding, to PBS and delivery to the SNS. Funding in FY 2020 will support the continued development of a second antiviral candidate against smallpox to meet the HHS goal of having two antiviral products. This would include studies to evaluate efficacy in animal models, manufacturing, and human safety testing.

Combating Antibiotic-Resistant Bacteria ($180 million): BARDA's broad spectrum antimicrobial program supports the development of products to counter biothreat pathogens. The SNS has antibiotics in the formulary to address bacterial pathogens. However, if resistance emerged, or a resistant organism was used in an incident, there would be a potential need for novel or improved products. Development of broad spectrum antimicrobial candidates is meant to augment a medical response in case of resistance. By developing products for biothreat pathogens and supporting their commercial indications for antibiotic resistant pathogens, BARDA's goal is to have products available in hospital formularies with known efficacy against biothreat pathogens. This could potentially serve as a bridge in our operational response capability. The commercial availability of antibiotics to treat resistant pathogens could have the potential to treat the initial wave of patients until mass dispensing of stockpiled antimicrobials could be established. Further, antimicrobial resistant pathogens 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 need for novel antibiotics to treat drug resistant bacteria.

The FY 2020 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 it is working with, to promote innovation in antibacterial product development. FY 2018 saw the transition of five candidates to clinical evaluation and the expansion of the diagnostics portfolio. FY 2019 activities will build off the previous investments and transition additional products to clinical evaluation and further the development of diagnostics. The diagnostics are critical to identifying the pathogen and determining antibiotic susceptibility in less than a day compared to the current 4-5 days. BARDA anticipates transitioning one or more products to Project BioShield support in FY 2019. Three products supported under ARD received FDA approval in 2017 and 2018 and all could be considered for potential PBS

support. Funding in FY 2020 will continue to support these efforts focused on gram-negative and complicated, multi-drug resistant bacterial infections.

Viral Hemorrhagic Fever ($31.7 million): Because of the 2014 Ebola outbreak, BARDA has taken 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 with concurrence from the PHEMCE. Both vaccine and therapeutic candidates are currently being evaluated in clinical trials and additional support is necessary in FY 2020 to continue development of these candidates to address the PHEMCE requirement for MCMs against viral hemorrhagic fever viruses. The current MCMs target Ebola-Zaire. The FY 2020 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 Biothreat diagnostics ($48 million): BARDA has successfully transitioned both point-of-care and high-throughput clinical lab biodosimetry devices to final development and 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 has decreased, and the focus of funding will support expansion of the biothreat diagnostic and antimicrobial resistance diagnostics portfolios. In FY 2020, BARDA will continue ongoing investments in development of anthrax diagnostics (laboratory and point-of-care), and Ebola diagnostics (point-of-care) and 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*, 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 to treat 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 2020 funds will continue to support existing candidates to support the advancement of candidates for possible transition and support under Project BioShield in FY 2020.

Thermal Burns ($30 million): The Thermal Burns portfolio has progressed significantly, with four candidates transitioning to acquisition under Project BioShield. Additional clinical studies were supported 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. FYs 2018-2019 funds 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 2020, the program will continue to expand 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 to develop imaging technologies, such as those that utilize forward-looking or short wave infrared light, to assess burn depth and severity.

Chemical ($60 million): In FY 2018, new candidate products were supported under ARD to address the threat of chemical agents, as several promising candidates were 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. Funding in FY 2020 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 a need remains to develop robust and reproducible models of exposure and injury. 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.

Medical Countermeasures Innovation - DRIVe ($55 million): FY 2020 funding will maintain existing DRIVe projects. These include: developing innovative approaches to prevent and treat sepsis; supporting novel technologies to diagnose and identify individuals exposed to infectious disease under the Early Notification to Act, Control and Treat (ENACT) program; and, incorporating new programs to develop products, tools, and technologies, to address 21st Century threats. Current efforts to address sepsis and identify individuals infected prior to symptoms will continue in FY 2019 and FY 2020. Efforts supported under addressing sepsis and ENACT will have dramatic, positive impacts on the health care system and will also support a more rapid response for the threats that BARDA is mandated to address—CBRN, Pandemic Influenza and Emerging Infectious Diseases.

Biomedical Advanced Research and Development Authority: Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
2.4.13a Increase the number of new licensed medical countermeasures within BARDA (Intermediate Outcome)	FY 2018: 9.0 medical countermeasures Target: 3.0 medical countermeasures	3.0 medical countermeasures	3.0 medical countermeasures	Maintain
2.4.13b Increase the number of new countermeasures eligible for consideration by FDA for Emergency Use Authorization	FY 2018: 3.0 Target: 2.0 (Target Exceeded)	2.0	2.0	Maintain
2.4.14a Increase the technical assistance provided by BARDA to medical countermeasure manufacturers (Intermediate Outcome)	FY 2018: 27.0 Target: 11.0 (Target Exceeded)	11.0	11.0	Maintain

PROJECT BIOSHIELD

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**710.000**	**735.000**	**735.000**	**--**
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 Ebola outbreaks in West Africa and the Democratic Republic of Congo, 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. Fifteen of these products have been delivered to the Strategic National Stockpile (SNS), with additional products to be delivered in FYs 2019 and 2020. At the end of FY 2018, ten of these products have achieved FDA approval with additional approvals anticipated in FYs 2019 and 2020. 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 and BioThrax – anthrax vaccine). In the first example, 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.

Developing biopharmaceutical products through FDA approval routinely takes 8 to 15 years. BARDA's expertise and strategic approach led eight products from late-stage development to FDA approval. 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 2018, the FDA approved Leukine to treat the hematopoietic syndrome of acute radiation exposure and TPOXX to treat individuals symptomatic with smallpox disease. This represents eight medical countermeasures to achieve FDA approval supported under PBS and in collaboration with PHEMCE partners.

As mentioned previously, since FY 2014, BARDA has invested in fourteen unique medical countermeasures under Project BioShield. In FY 2017, BARDA transitioned four Ebola candidates to PBS. These included two Ebola therapeutic programs, both of which sent product to the DRC in 2018, and two Ebola vaccine programs, one of which is the vaccine that is being used in the DRC. In addition, new awards were made to support a point of care and a high throughput biodosimetry device. Both candidates were previously supported under ARD. A new award was made to support continued development of the smallpox vaccine for at-risk individuals and transition to a formulation that offers a longer shelf life. The remaining funds were used to support options on existing contracts for procurement of anthrax vaccine, conversion of stored equine plasma to drug substance for the heptavalent botulism antitoxin, and to support pediatric clinical trials for two of the burn programs.

FY 2018 resulted in the FDA approval of two products supported under PBS. In April 2018, Leukine was approved to treat the hematopoietic syndrome resulting from exposure to ionizing radiation. In July 2018, TPOXX (Tecovirimat, ST-246) was approved to treat individuals symptomatic with smallpox disease. With these two approvals the total number of products approved with PBS funding increases to eight. Additional product approvals are anticipated for FYs 2019–2020. In FY 2018, BARDA transitioned to PBS of a new formulation for a smallpox antiviral for use in pediatric populations or individuals who cannot swallow capsules. Additional funds were provided to support initiation of a pediatric trial for one of the burn countermeasures that transitioned in FY 2015. Both programs address BARDA's mandate under PAHPA to develop countermeasures for at-risk populations. The remaining funds were used to support additional late-stage activities or procurement for programs already under PBS. Procurements included anthrax vaccine, anthrax antitoxin, and cytokine products.

The FY 2019 Enacted level includes $735 million to support Project BioShield. At this level, PBS efforts will prioritize sustaining the development of multiple products to address Ebola, anthrax, and smallpox. FY 2019 will see the transition of programs to address bacterial pathogens, chemical nerve agents, thermal burns, and a potential candidate to address exposure to acute ionizing radiation.

Based on the successful development of CBRN MCMs in BARDA ARD programs, HHS will be prepared to acquire up to three new CBRN medical countermeasures under Project BioShield by the end of FY 2020. Since 2014, BARDA has awarded 15 contracts under PBS for late-stage development and potential procurement of medical countermeasures. BARDA will invest significant funds in FYs 2019–2020 to support additional late-stage activities for existing programs. Some program awards will also include the initial planned procurements based on data to meet requirements for potential use of the product during a declared emergency under Emergency Use Authorization (EUA). BARDA will balance previous commitments while transitioning promising programs to PBS. BARDA anticipates transition of 5–6 candidates to PBS in FY 2020. Remaining funds will continue late-stage development and potential procurement of programs previously funded under PBS.

BARDA has identified the following promising candidates that have the potential to transition to PBS in FY 2020.

- MCMs that can mitigate or reverse the neurological injury that occurs from nerve agent-induced seizures that are refractory to currently stockpiled treatments and therapeutics demonstrated to minimize nerve agent-induced neurological injury when combined with midazolam (FY 2020).
- Multiple broad spectrum antibiotics for treatment of anthrax, plague, tularemia, and other biological threats (FY 2020).
- 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 previously procured under Project BioShield (FY 2020).

Funding History	
FY 2016	$510,000,000
FY 2017	$508,803,000
FY 2018	$710,000,000
FY 2019 Enacted	$735,000,000
FY 2020 President's Budget	$735,000,000

Budget Request

The FY 2020 Request for Project BioShield is $735,000,000, which is equal to the FY 2019 Enacted level. The FY 2020 requested funding 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. The funding amounts listed below reflect the cost of procurement as well as late-stage development activities. At the requested level, the following nine procurements, which reflect the highest priority countermeasures for FY 2020, would be funded.

1. **New antimicrobial drugs to address biothreat pathogens ($100 million, ~25,000 treatment courses of each product).** At least two new antibiotic candidates, presently in the ARD program, may be available to purchase under Project BioShield. These antibiotic candidates 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 ($200 million, ~65,000 vaccine doses, 600 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 MCM preparedness requirements against Ebola, funding in FY 2020 is needed to continue procurement for those products. The Project BioShield awards in FYs 2017 and 2018 provided funding for the initial late-stage development activities and the funding in FY 2019 and FY 2020 will support any additional development activities to support licensure or approval and potential procurements to increase preparedness and move closer to the PHEMCE requirements.
3. **Sustain development and procurement of next-generation anthrax vaccine ($170 million, 3-4 million vaccine doses).** In FY 2020, 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 ($40 million, 1,600 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. FY 2020 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 ($20 million, 100,000 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. The FDA approved tecovirimat for the treatment of smallpox in July 2018. FY 2020 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 ($30 million, 30,000 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 2020 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 2020, 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 3 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 ($80 million, 6,000 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 that were previously procured under Project BioShield (Neupogen, Neulasta, and Leukine). Cellular therapies or other candidate products have the potential to treat those individuals who are refractory to treatment with the cytokine products.
9. **Biodosimetry for acute ionizing radiation ($45 million).** Funds will support late-stage activities for multiple devices that are both point of care (field use) and high-throughput laboratory-based devices.

Project BioShield: Key Outputs and Outcomes Table

Measure	**Year and Most Recent Result / Target for Recent Result / (Summary of Result)**	**FY 2019 Target**	**FY 2020 Target**	**FY 2020 Target +/-FY 2019 Target**
2.4.14b Continue ongoing transition of medical countermeasures into Project BioShield (Intermediate Outcome)	FY 2018: 1.0 Target: 2.0 (Target Not Met)	3.0	3.0	Maintain

STRATEGIC NATIONAL STOCKPILE

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**603.900**	**610.000**	**620.000**	**+10.000**
FTE		**225**	**225**	**--**

1/ FY 2019 Enacted funding for the Strategic National Stockpile (SNS) was administratively transferred from CDC to ASPR. FY 2018 funding is comparably adjusted and includes a Secretarial transfer of $6.1 million from the SNS budget to CDC for transition costs. FY 2019 funding does not reflect an additional Secretarial transfer of $6.1 million from the SNS budget to 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

Program Description and Accomplishments
The Strategic National Stockpile manages and delivers life-saving medical countermeasures (MCM)[16] during a public health emergency. It is the largest federally owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations (FMS),[17] 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.

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.

The majority of SNS appropriated funding is directed to procurement and maintenance of the stockpiled holdings of medical countermeasures. More than 98% of the 973 product lines in the SNS are commercially available countermeasures that are purchased through federal supply schedules or simple

[16] http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm

[17] https://www.cdc.gov/features/strategic-national-stockpile/index.html

contracting mechanisms to meet the government's requirements. Investments in the maintenance of stockpiled supplies include storage, quality control, compliance, transportation, security and day-to-day management of the $7 billion inventory of MCMs. In FY 2018, these investments resulted in an inventory accuracy rate of 99.89% on annual wall-to-wall inventories, and no loss of product due to compliance, security or environmental storage issues.

ASPR seeks to maximize the value of the SNS appropriation in collaboration with the Food and Drug Administration (FDA) through the Shelf Life Extension Program (SLEP). SLEP is a joint program established in 1986 and operated by the Department of Defense and FDA to avoid the need to replace entire stockpiles of medical material every few years as they reach labeled expiration. Some pharmaceuticals, if stored in accordance with the manufacturer's recommendations, may be viable beyond the manufacturer's labeled expiration date and allow for deferment of drug replacement costs. ASPR works with FDA to test stability of drugs approaching labeled expiry through SLEP. If SLEP testing confirms that the product is viable and safe to use beyond the established expiration date, FDA will typically provide an additional 12 to 24 months of extended shelf life. Products can be tested and extended multiple times, allowing for safe stockpiling and use of some SNS held pharmaceuticals from 4 – 10+ years past the manufacturer's original expiration date depending on cost, stability and other market factors. These extensions are particularly valuable for stockpiled products with limited production capacity, as the SNS can maintain capabilities even if sufficient product is not available to replace products reaching labeled expiration. For some products not eligible for the SLEP program, including biological products such as vaccines and immune globulins, SNS contracts with the manufacturers for annual potency testing to try to extend shelf life of the stockpiled products.

ASPR's robust medical logistics capability can move medical personnel, equipment and supplies across the nation within hours. Ensuring timely delivery of MCMs is critical during an emergency response. The SNS maintains contracts with commercial transportation partners that possess the resources and capabilities to meet the most difficult delivery timelines. The effectiveness of SNS transportation capabilities is tested routinely through no-notice, live deployment drills with participating contractors to prepare for real world deployments. SNS transportation arrangements are designed to maintain MCM security and efficacy in extreme environments so that deployed products are safe to dispense during a public health emergency. 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.

The SNS is prepared to deploy personnel to austere environments and immediately establish warehousing and distribution capability if required. The logistical expertise of SNS responders allows deployed staff to assist and advise public health and medical professionals on quality control of products during an event. These response capabilities ensure that the SNS has the flexibility and capacity to respond to any mission assigned. The proven SNS logistics capability seamlessly supports ASPR's mission to save lives and protect Americans from 21st century health threats. For example, in the aftermath of a natural disaster, like Hurricane Maria, Federal Medical Stations (FMS) may be requested. Within ASPR, SNS is responsible for deploying and setting up FMS. Once set up, FMS are often run by Disaster Medical Assistance Teams (DMATs) deployed by the National Disaster Medical System (NDMS).

The SNS is capable of rapidly delivering material and support to the site of any 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. ASPR works to ensure that medicines and supplies get to communities in need after large-scale natural disasters. When Hurricane Maria made landfall in Puerto Rico in September 2017, ASPR quickly stepped in to support the federal response. SNS supported ASPR directed-requirements as a primary

response asset during the response, providing critical medicines and medical supplies, medical logistics support, specialized technical assistance responders, and capability to care for affected communities and displaced persons in Puerto Rico. During the response, SNS delivered more than $4.5 million in supplies to support NDMS teams and public health needs resulting from Hurricane Maria. This includes $2.4 million for vaccines; more than $500,000 in additional medical supplies; 177,000 bottles of water; and 42,000 meals ready to eat.

SNS also deployed six Federal Medical Stations (FMS), which provided 1,500 beds, critical medicines, and medical supplies to provide care for displaced persons with health-related needs. In addition to SNS's work to support Hurricane Maria, FMS were also deployed to Texas, Louisiana, and Florida in support of Hurricanes Harvey and Irma.

Leveraging extensive experience in inventory management, rapid deployment, and distribution, SNS provided ongoing remote medical logistics support and deployed eight logisticians to manage on-the-ground operations of a 10,000 square foot warehouse in San Juan used to support the FMS, Disaster Medical Assistance Teams, and other ASPR requirements.

SNS's medical logistics support during the 2017 hurricane season allowed approximately 35,000 patients to be treated by the NDMS and United States Public Health Service (USPHS) Commissioned Corps Officers in Puerto Rico and the U.S. Virgin Islands after Hurricanes Maria and Irma.

SNS provides substantial training to prepare federal, state, and local partners for effective response to public health emergencies. In FY 2018, SNS trained 7,937 external partners. The FY 2018 training included:

- Nine Urban Area Security Initiative (UASI) tabletop exercises
- Twelve SNS led courses;
- Five virtual training events;
- Seven webinars that provided jurisdictions an operational foundation to develop and implement MCM preparedness and emergency response capabilities.

SNS is critical for both public health preparedness and responses to real-world events. SNS is focused on working with the highest risk urban areas – defined by the Department of Homeland Security as Urban Areas Security Initiative (UASIs) – with defined delivery timelines based on evolved capabilities to execute a full 60-day anthrax response, including prophylaxis and treatment of large numbers of people. As part of this process, leading logistics experts for the Stockpile modeled delivery timelines based on a number of variables to determine the minimum amount of time required to move product from an SNS warehouse to a predesignated receiving site. Once received at the site, ASPR will then transfer custody to state officials. This modeling allows jurisdictions to more realistically plan for receipt and distribution of SNS product before an emergency occurs. Once the modeling was completed, the SNS team traveled to each of the jurisdictions. At the jurisdictions, SNS logisticians were refining delivery timelines and hosted tabletop discussions to explore and validate response capabilities. These discussions included public health planners from the state and local jurisdictions in the metro area, security and law enforcement, third-party logistics partners, transportation partners, emergency management personnel and others. The SNS team presented the new timelines and planning considerations to the group and facilitated open and honest discussions about capabilities and responsibilities of federal, state and local partners. Coupled with the modeling data, these tabletops gave SNS the information it needed to revise and renew memoranda of agreement (MOA) between HHS and states that are home to these high-risk urban areas. The resulting MOA outlines responsibilities of both parties in a large-scale emergency requiring the activation of the SNS. In FY 2018, SNS worked with jurisdictions across the nation to improve access to medical countermeasures by implementing new MOUs that outline expedited delivery timelines, followed with nine validation tabletop exercises that included 13 UASI jurisdictions. SNS is

working with 31 states/jurisdictions to update and sign revised MOAs. These MOA revisions are essential to understanding roles and expectations of both HHS and the states in a large-scale public health emergency, like an anthrax incident, that would require mass dispensing to the public for post-exposure prophylaxis and treatment.

Reducing expected delivery times from 24 hours to 8 hours, and in some cases less, greatly improves state efforts in time-critical dispensing campaigns. The direct impact is lives saved, improved medical outcomes, and more time to reach those in need. The SNS Team has presented and obtained buy-in on these timelines in tabletop discussions with Dallas, Houston, Virginia, Atlanta, Pittsburgh, Philadelphia, District of Columbia, Maryland (NCR), Baltimore, Minneapolis, Tampa/St. Petersburg, Miami/Ft. Lauderdale, Newark/Jersey City, Los Angles, Sacramento and the Bay Area. These discussions ensure capabilities are vetted and best practices shared to match improved shipping times. They also provide the necessary qualitative data, along with the modeling conducted, to allow ASPR to revise MOAs in 31 target states to better define responsibilities of both the federal government as well as the state in a large-scale mass dispensing campaign. Additional exercises are planned.

Improving the resiliency of the Strategic National Stockpile by working with industry is a priority. SNS has engaged industry by forming partnerships with major industry trade associations, specifically - Health Industry Distributors Association (HIDA), International Safety Equipment Association (ISEA), Healthcare Distributors Association (HDA), National Association of Chain Drug Stores (NACDS), and Healthcare Supply Chain Association (HSCA). These partnerships improve the resiliency of the Strategic National Stockpile through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to personal protective equipment (PPE);
- Improved public access to medical countermeasures;
- Redundant distribution of medical countermeasures, information, and materiel;
- Improved coordination of the timing and quantity of release of SNS assets to best support a response; and
- Education on challenges associated with over-ordering or hoarding of needed materiel during a public health incident.

The resiliency of the Strategic National Stockpile is closely linked to the resiliency of the commercial supply chain. In June of 2018, SNS hosted an initial workshop with HSCA members representing group purchasing organizations (GPOs). GPOs have a unique line-of-sight over all aspects of the healthcare supply chain. This open dialogue illuminated how HSCA members' $200 billion purchasing power can influence market conditions, unintentionally create shortages due to over-ordering in support of their clients and enable sharing of up-to-the-minute product shortages across the commercial supply chain. This capability provides the SNS real-time visibility of market capacity, allowing better decision making in support of preparedness planning and response operations.

SNS has hosted two annual workshops with HIDA that have led to better communication and collaboration among manufacturers and distributors in responding to emergencies and disasters. These workshops identified market availability of ancillaries as related to specific needs generated from an unforeseen incident such as an aerosolized anthrax attack. HIDA has provided executive level subject matter experts to share commercial supply chain manufacturing capacity, challenges, and industry requirements for ancillaries in the stockpile. As product availability is compared to manufacturing surge capacity and just-in-time inventories, the partnership is able to make better decisions on what to purchase, how much to stockpile, and how best to collaborate in an effort to protect the supply chain.

In 2018, SNS leaders met with MCM stakeholders to share relevant information necessary to carry out an MCM response to a public health emergency. SNS stakeholder outreach activities included SNS representation at, and presentations for, 21 partner and coalition conferences and focus meetings. Some highlights from these meetings:

- SNS presented at the 2018 NACCHO Preparedness Summit, where SNS briefed to an overfilled room on the full 60 Day Anthrax Response Plan. The NACCHO Preparedness Summit provided SNS an opportunity to socialize the 60-day follow-on guidance for an anthrax response with hundreds of key MCM stakeholders.

SNS expertise in MCM supply chain optimization and logistics planning is a valuable tool in the USG's commitment to support the Global Health Security Agenda. Using funds from CDC's Center for Global Health, SNS sent staff to Nigeria, Cameroon, Liberia, Guinea, Uganda, and Sierra Leone in FY 2018 to help the countries develop national level medical materiel supply chain plans which improve their ability to respond to public health emergencies. SNS experts supported the GHSA through the following activities:

- Trained 109 participants at MCM logistics and planning workshops (total includes participants in CDC's Atlanta based Public Health Emergency Manager fellowship program);
- Conducted week-long MCM workshops in Nigeria, Liberia, and Guinea, and Sierra Leone for senior staff from the ministries of health and other partners;
- Executed MCM plan table-top exercises to validate MCM plans for Uganda and Cameroon; and
- Reviewed national-level MCM plans for Nigeria, Uganda, Senegal and Ethiopia.

Funding History	
FY 2016	$575,000,000
FY 2017	$573,653,000
FY 2018	$610,000,000
FY 2019 Enacted	$610,000,000
FY 2020 President's Budget	$620,000,000

Budget Request
The FY 2020 request of $620,000,000 for the Strategic National Stockpile is +$10,000,000 above the FY 2019 Enacted level. With the requested funds, ASPR will make meaningful investments across a spectrum of threats, including antibiotics to treat anthrax exposure; antivirals to treat pandemic influenza; and vaccines and therapeutic drugs to protect against smallpox. This increased investment will allow ASPR to replace the highest priority expiring SNS countermeasures in FY 2020. Additional product procurement in FY 2020 will be guided by the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) as coordinated by ASPR to ensure strategies are developed and activities are implemented to meet the national priorities for federal stockpiling and to maintain SNS capabilities and address inventory gaps with available funding.

The FY 2020 request includes $61,400,000 to procure two products that are transitioning to SNS from Project BioShield funded contracts. At the requested funding level, SNS plans to fulfill the stockpiling requirement for a thermal burn bandage developed through Project BioShield. Additionally, Tecovirimat, a smallpox antiviral drug, will transition to SNS in FY 2020. The requested increase will support procurement of these newly developed medical countermeasures.

Transitioning procurement of these products, which have recently been licensed by the FDA, completes the MCM pipeline. This important final step of transitioning products developed through Project BioShield to SNS procurement reflects ASPR's commitment to enhancing the medical countermeasures enterprise by streamlining MCM development, response, and utilization. SNS is committed to replacing transitioned products in order to maintain production capacity of the products for future requirements.

While the budget request makes progress in transitioning several Project BioShield products, it assumes that several products originally scheduled to transition to SNS procurement in FY 2020 will continue to be funded under Project BioShield, specifically, anthrax and botulism antitoxins. Procurement of a smallpox vaccine as well as next-generation anthrax vaccine would also continue to be funded by Project BioShield.

Procurement of MCMs alone will not protect America. State and local partners are critical to ensuring that MCMs reach the people who need them in a timely manner. Accordingly, ASPR will maintain training and exercise support in FY 2020 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.

Additionally, ASPR will use requested funds to ensure SNS assets are available and ready for use to protect America from 21st century health security threats in FY 2020 by:

- Managing, 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.
- 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.

SNS Projected Allocations[1]

	FY 2019 Enacted		FY 2020 President's Budget	
	Projected Level	Percentage of Total Appropriation	Requested	Percentage of Total Appropriation
Total	$610.0M	100%	$620.0M	100%
Product				
Procurement – New[2]	*$135.0M*	84.5%[4]	*$73.2M*	84.3%[4]
Procurement – New (above replenishment)[3]	*$10.6M*		*$25.7M*	
Procurement - Replenishment	*$209.6M*		*$290.0M*	
Procurement Total	$355.2M		$388.9M	
Sustainment Costs	$160.0M		$133.9M	
Operations				
SNS Operational Costs	$94.8M	15.5%[5]	$97.2M	15.7%[5]

[1] These amounts are estimates and are subject to change.

[2] Includes items previously purchased by BARDA

[3] This amount supports procurement of additional quantities of products currently held in SNS inventory, purchasing quantities beyond those required for 1 to 1 replacement of expiring product. The net effect of these procurements is to increase SNS holdings and capabilities in response to PHEMCE requirement goals and procurement recommendations.

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

[5] 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.

ASPR Strategic National Stockpile – Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2018 Target	FY 2020 Target	FY 2020 Target +/-FY 2018 Target
13.4.5 Number of trained and ready preparedness and response teams available for response to multiple events. (Output)	FY 2018: 17 Target: 15 (Target Exceeded)	15	15	Maintain
13.4.6 Percentage of inventory accuracies that are attained by using quality inventory management systems. (Outcome)	FY 2018: 99.9 % Target: 97 % (Target Exceeded)	97 %	97 %	Maintain

OFFICE OF POLICY AND PLANNING

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**14.877**	**14.877**	**19.877**	**+5. 000**
National Biodefense Strategy Implementation (non-add)	--	--	*5.000*	*+5.000*
FTE	**66**	**66**	**71**	**--**

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

Program Description
To save lives and protect Americans from 21st century health threats, ASPR utilizes the Policy and Planning budget account to develop, evaluate, implement, and align plans, requirements, and policies to ensure a strong foundation for public health and health care preparedness, response, and recovery activities. To deliver on the mandates of the Pandemic and All-hazards Preparedness Act and the Public Health Service Act [42 U.S.C. 300hh-10], ASPR:

- Sets strategic direction, with interagency partners, through development and implementation of the National Health Security Strategy (NHSS;
- Develops policies that address public health and emergency medical response issues, empowering ASPR personnel, the Department, and the American people to decisively respond to any national security incident, including addressing the access and functional needs of at-risk individuals;
- Generates plans that establish strategic intent and coordinates capabilities so that we are prepared to swiftly and effectively respond to 21st century health threats, including medical countermeasure (MCM) plans and guidelines; and,
- Establishes requirements for capabilities and materiel to ensure that gaps are addressed and capabilities are in place to meet the mission of the National Response Framework in the most effective and fiscally responsible manner possible.

ASPR works closely with all partners and end-users—including state, local, tribal, and territorial (SLTT) jurisdictions, interagency partners, the American public, and clinical end-users and responders—to ensure that strategic goals and deliverables are appropriate, useful, and comprehensive. ASPR provides real-time support to the Department during response to national security incidents and public health emergencies. ASPR leverages recommendations from incident reviews to improve on deliverables and enhance capabilities to meets its mission in the future.

Policy Leadership, Coordination, and Evaluation
ASPR coordinates and develops national, HHS, and ASPR strategies and policies that directly inform public health and health care preparedness and response capabilities. This includes analysis to improve "last mile" MCM distribution. ASPR leads the quadrennial NHSS. The legislatively mandated NHSS

provides a comprehensive strategy to mobilize a whole of government approach and leverage the capabilities of the private sector to support SLTT partners to address 21st century threats and prepare for, respond to, and recover from emergencies and disasters. The NHSS integrates the national security, homeland security, and health security sectors and aligns with national doctrine such as the National Security Strategy, the National Defense Strategy, and the National Biodefense Strategy.

ASPR supports leadership of ESF-8 Public Health and Medical Services and the Health and Social Services Recovery Support Function. ASPR convenes federal, private sector industry, health care, non-governmental, and international agencies and organizations to lead and support public health and health care preparedness, response, and recovery activities. These activities include coordination of the Disaster Leadership Group, which brings together senior federal leaders and subject matter experts during emergencies to promote situational awareness and inform and advise the HHS Secretary on policy issues.

ASPR coordinates participation and input into U.S. Government (USG), National Security Council, and Departmental policy and strategy initiatives. ASPR collaborates with the National Security Council on priorities, including the National Biodefense Strategy, and supports implementation of the National Biodefense Strategy to counter biological threats, reduce risk, prepare for, respond to, and recover from biological incidents. The strategy, released in September 2018, sets the course for the United States to combat the serious biothreats our country faces, whether they arise from natural outbreaks of disease, accidents involving high consequence pathogens, or the actions of terrorists or state actors.

ASPR leads ASPR mitigation and resilience policy and provides policy leadership to address the disaster-related access and functional needs of at-risk individuals (ARI).

ASPR supports the fulfillment of its international statutory mandate by providing policy oversight of the U.S. International Health Regulations (IHR) National Focal Point and by leading the implementation of the U.S. Joint External Evaluation (JEE) National Action Plan to address 40 areas for improvement in the U.S. capacities to detect, prevent, and respond to public health emergencies. ASPR leads engagement with multilateral and bilateral partners as they strengthen U.S. and international health security, which includes coordinating response policy during public health emergencies at the domestic-international interface.

ASPR provides evaluation and program improvement for health care preparedness, response, and recovery in support of the Hospital Preparedness Program (HPP) and other ASPR Programs. ASPR suggests areas for program improvement regarding health care preparedness, which includes providing technical assistance related to program evaluation for internal and external stakeholders. During FY 2018, ASPR:

- Conducted outreach and education to external partners on national health security priorities and specific threat-based risks through multiple mechanisms including three listening sessions, presentations at the 2018 Preparedness Summit, and development of educational materials;
- Developed and submitted for Departmental clearance the 2019-2022 NHSS and Implementation Plan and the NHSS Evaluation of Progress for the 2015-2018 quadrennial period;
- Coordinated input across HHS agencies and represented HHS in the policy development process of the National Biodefense Strategy and supported release of the strategy through development and implementation of a strategic communications plan involving stakeholder engagement;
- Collaborated with intra-agency leadership and staff to identify strategic priorities for the NHSS;
- Continued the response efforts for the 2017 hurricanes by supporting the life-saving evacuations of almost 250 dialysis-dependent individuals trapped on the U.S. Virgin Islands by global information system mapping HHS emPOWER Medicare data that Urban Search and Rescue and NDMS teams used to coordinate evacuations, saving all of their lives;

- Provided emPOWER data to support emergency planning and response activities for 823,517 Medicare beneficiaries that rely on electricity-dependent medical equipment and healthcare services in the impacted areas;
- Coordinated the Disaster Leadership Group for the Departmental response to the 2017-2018 Seasonal Influenza/Saline/Antivirals situation and the 2018 Ebola Virus Disease Outbreak in the Democratic Republic of Congo;
- In coordination with FEMA, exercised policies and plans for accepting critical public health and medical assistance from international sources through the National Level Exercise 2018, based on lessons learned from the response to hurricanes Harvey, Irma, and Maria;
- Highlighted the ongoing threat from pandemic influenza and the need for domestic/international coordination in preparedness and response activities by developing a facilitated discussion for Ministers of Health from the G7, Mexico, the European Commission, and the World Health Organization at the 2018 Global Health Security Initiative (GHSI) Ministerial Meeting;
- Led and participated in international engagements that strengthen U.S. and international health security, including the Global Health Security Initiative and the North American Plan for Animal and Pandemic Influenza; and,
- Led the first "Aging and Disability Taskforce" in response to the 2017 Hurricanes to promote situational awareness, assess impacts to programs that serve older adults and people with disabilities, provide direct technical assistance, and recommend response and recovery activities.

In FY 2020, ASPR will:

- Coordinate implementation of the National Biodefense Strategy with other agencies that have responsibilities or capabilities pertaining to biodefense.
    - Provide leadership as Director of the Biodefense Coordination Team and assist the cabinet level Biodefense Steering Committee (chaired by the HHS Secretary) in implementation of the strategy;
    - Support implementation of the National Biodefense Strategy's goals to strengthen the biodefense enterprise through enabling risk awareness to inform decision-making across the biodefense enterprise; ensuring biodefense enterprise capabilities to prevent bioincidents; ensuring biodefense enterprise preparedness to reduce the impacts of bioincidents; rapidly responding to limit the impacts of bioincidents; and facilitating recovery to restore the community, the economy, and the environment after a bioincident;
    - Build capacity for coordination of interagency and management of implementation of the strategy;
    - Conduct analysis including development of a biodefense assessment and public report; and,
    - Conduct stakeholder engagement to maintain awareness of biodefense activities conducted by federal agencies, relevant interagency entities, and non-federal partners in the broader biodefense enterprise.
- Assess the current and evolving threat landscape, including educating new and existing partners to identify and address health security threats in the context of ASPR priority areas including the "last mile" MCM distribution;
- Continue to coordinate HHS-wide decision making during public health emergencies and disasters by convening the Disaster Leadership Group to provide situational awareness updates, and inform and advise the HHS Secretary;
- Perform high quality policy analyses to inform implementation of new and revised requirements resulting from the reauthorization and appropriations processes and other legislation, executive orders, and new USG priorities;

- Engage in ongoing assessment of the nation's public health and health care preparedness, response, and recovery capabilities to inform the NHSS Evaluation of Progress, including identification of gaps to address through programmatic activity;
- Complete an assessment of ASPR projects and programs that could benefit from program evaluation and improve evaluation technical assistance for stakeholders;
- Develop methodologies to streamline data collection and analysis in order to enhance situational awareness specific to health care coalitions and health care preparedness;
- Lead U.S. Government partners in implementing the U.S. Joint External Evaluation National Action Plan;
- Coordinate the assessment and notification of potential public health emergencies of international concern to the World Health Organization and lead and participate in international engagements that strengthen U.S. and international health security including GHSI and the North American Plan for Animal and Pandemic Influenza;
- Develop, exercise, and implement HHS and USG policies and plans for coordinating domestic and international response policies for providing and receiving international public health and medical assistance during emergencies; and,
- Provide strategic advice and recommendations to the HHS Secretary by coordinating, managing, and operating two Federal Advisory Committees. The National Preparedness and Response Science Board (NPRSB) and the National Advisory Committee for Children and Disasters (NACCD) assemble nationally renowned experts who advise the Secretary and the ASPR as well as provide a public forum for concerns and input for partners and the public.

Requirements Setting

ASPR leads capability-based requirements setting, ensuring that statutory responsibilities are met. ASPR produces requirements that inform development and acquisition of response capabilities, using practical and cost-effective approaches for fulfilling the ASPR mission mandated by the PHS Act (42 U.S.C. 300hh-10) and guided by the NHSS.

ASPR establishes materiel requirements for MCMs that focus on flexible solutions in response to chemical, biological, radiological, and nuclear (CBRN) and emerging infectious disease threats. These requirements are established in accordance with the Federal Acquisition Regulation, through a framework premised on best practices and experience developing MCM requirements.

Through analysis of alternatives, ASPR focuses on capabilities that can be broadly applicable, when possible, to support the needs of all components of the ASPR mission in a fiscally responsible approach to address 21st century health threats (e.g., natural disaster response, CBRN incidents, and emerging infectious diseases that threaten National Security). During 2018 ASPR:

- Delivered four Integrated Capability Assessments for select CBRN threats: the assessments quantified capabilities (staff, space, supplies, and systems) needed to effectively respond to the mass casualty CBRN incidents, identified operational constraints, limitations and related capability gaps likely to impede the response, and recommend actions to close gaps and improve planning to ensure mission capability;
- Delivered 15 Medical Countermeasure Response Strategies that establish the strategic utilization of MCMs deployed from the Strategic National Stockpile (SNS), to protect and treat the US population against a variety of scenarios; and,
- Delivered multiple legal and regulatory policy instruments executed by the Secretary to empower innovative research, development, and manufacture of vaccines, therapeutics, and diagnostics against emerging infectious disease threats to national security, including, Ebola virus, Zika virus, enteroviruses, and CBRN threats.

During FY 2020, ASPR will:

- Deliver capabilities-based assessments to provide HHS with a comprehensive view of gaps, and requirements focused on the functions, performance-levels, and specifications of capabilities for HHS's emergency public health and medical response mission;
- Deliver analyses of alternatives to identify cost-effective and practical solutions to address critical capability gaps in the ASPR mission scope, to close those gaps, and to ensure ASPR can save lives, while saving resources;
- Establish requirements for the capabilities needed to deliver on the ESF-8 mission objectives of the National Response Framework; enabling ASPR to identify gaps, implement solutions, and modify resource needs to ensure readiness and adaptability to respond to any threat;
- Implement best practices in developing materiel requirements for medical countermeasures against CBRNE threats and emerging infectious diseases; shortening delivery times, providing clear guidance and flexibility leading to more effective solutions for addressing critical MCM gaps arising from 21st century health threats; and,
- Execute legal and regulatory policy solutions that enhance CBRN and emerging infectious disease MCM development and use; facilitating improvement in development and acquisition timelines for MCMs.

Cross-Cutting Strategy

ASPR ensures coordinated alignment and implementation of key HHS, national, and international health security strategies and initiatives across ASPR, HHS, and the federal government. For example, ASPR coordinates the development and implementation of the National Biodefense Strategy, NHSS, and supports the Global Health Security Strategy. ASPR provides planning, policy analysis, capability assessment, and requirements setting in support of key ASPR initiatives such as the SNS and MCM dispensing.

ASPR oversees a strategic approach and ensures seamless organizational communication to address emergency issues. For example, informing and ensuring a coordinated ASPR approach to preparedness and response to pandemic influenza and other emerging infectious disease threats. ASPR analyzes imminent and longer-term public health preparedness and response issues, identifies gaps and challenges, and coordinates policy and planning to address identified issues. For example, during 2018, ASPR coordinated input across HHS agencies and represented HHS in the policy development process of the National Biodefense Strategy as well as collaborating with intra-agency leadership and staff to identify strategic priorities for the NHSS.

During FY 2020, ASPR will work with interagency partners to ensure strategic implementation of the National Biodefense Strategy, National Security Strategy, NHSS, the Global Health Security Strategy, and other relevant HHS and national strategies and plans.

Funding History	
FY 2016	$14,877,000
FY 2017	$14,843,000
FY 2018	$14,877,000
FY 2019 Enacted	$14,877,000
FY 2020 President's Budget	$19,877,000

Budget Request:
The FY 2020 budget request for Policy and Planning is $19,877,000, which is +$5,000,000 above the FY 2019 enacted budget level.

ASPR will continue to develop strategic and operational plans to implement national preparedness functions and prepare for HHS's response during events. To set strategic direction for public health and health care emergency preparedness and response, ASPR will lead the implementation and evaluation of the NHSS and support implementation Global Health Security Strategy. The additional $5 million in no-year funding in FY 2020 will support ASPR coordination, implementation, and assessment of the National Biodefense Strategy. ASPR will continue to provide policy leadership to address USG, HHS, and ASPR strategic goals.

ASPR will improve the efficiency of its engagement efforts across federal and SLTT government, non-governmental, private sector, and international partners, to ensure that plans, requirements, and policies are responsive to real needs. ASPR's federal advisory committees, the NPRSB and NACCD, will gather expert input from the public and non-federal partners. The Disaster Leadership Group will continue to serve as a mechanism to coordinate departmental decision making, share situational awareness updates, and inform and advise the HHS Secretary.

ASPR has markedly expanded, intensified, and accelerated its support for critical national health security priorities. Biological threats are among the most serious threats facing the United States and preparing for biothreats is a critical aspect of our national security. ASPR will continue to implement the National Biodefense Strategy, released in September 2018, which sets the course for the United States to combat the serious biothreats our country faces, whether they arise from natural outbreaks of disease, accidents involving high consequence pathogens, or the actions of terrorists or state actors.

In support of implementing the National Biodefense Strategy and as chair of the Biodefense Coordination Team, ASPR will assist in coordinating programs to enable the federal government to better anticipate, prevent, prepare for, respond to, and recover from biological disasters; maintaining awareness of biodefense activities conducted by federal agencies, relevant interagency entities, and non-federal partners in the broader biodefense enterprise, including relevant private sector stakeholders; and increasing coordination with non-Federal partners, including international organizations.

The $5 million request will be used to provide staff support for the administrative management of the Biodefense Coordination Team and Biodefense Steering Committee. Funds also will provide data analytic services including collection and reporting data from federal agencies to support implementation of the strategy. ASPR also will convene federal agencies to review and plan biodefense strategies and will build capacity for coordination with Federal interagency partners in managing implementation of the strategy. Implementing the National Biodefense Strategy will strengthen our ability to anticipate, prevent, prepare for, respond to, and recover from biological incidents.

Office of Policy and Planning: Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
2.4.9 Increase engagement with stakeholders to disseminate and improve awareness of ASPR strategies for preparedness, response, and recovery (Outcome)	FY 2018: Conduct at least two, in-person Federal Advisory Committee meetings o 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. (Target Exceeded)	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.	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 15% over FY18 baseline to promote healthy, prepared, and resilient communities.	N/A
2.4.11 Lead and implement national and international strategic plans for public health preparedness and response (Output)	FY 2018: Developed and submitted for Departmental clearance the 2019-2022 NHSS and Implementation Plan and the NHSS Evaluation of Progress for the 2015-2018 quadrennial period. 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 Disaster Medical System to inform and support essential doctrine revisions and development for the mobilization of medical responders, medical suitability	Develop a plan and collaborate with associated Congressionally mandated programs to enable NHSS implementation.	Continue 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 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	standards, and communications protocols for teams. Delivered four Integrated Capability Assessments for select CBRN threats: the assessments quantified capabilities (staff, space, supplies, and systems) needed to effectively respond to the mass casualty CBRN incidents, identified operational constraints, limitations and related capability gaps likely to impede the response, and recommend actions to close gaps and improve planning to ensure mission capability. Delivered 15 Medical Countermeasure Response Strategies that establish the strategic utilization of MCMs deployed from the Strategic National Stockpile (SNS), to protect and treat the US population against a variety of scenarios. Continued the response efforts for the 2017 hurricanes by supporting the life-saving evacuations of almost 250 dialysis-dependent individuals trapped on the U.S. Virgin Islands by global information system mapping HHS emPOWER Medicare data that Urban Search and Rescue and NDMS teams used to coordinate evacuations, saving all of their lives. Provided emPOWER data to support emergency planning and response activities for 823,517 Medicare beneficiaries that rely on			

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
	electricity-dependent medical equipment and healthcare services in the impacted areas. Coordinated the Disaster Leadership Group for the Departmental response to the 2017-2018 Seasonal Influenza/Saline/Antivirals situation and the 2018 Ebola Virus Disease Outbreak in the Democratic Republic of Congo. Lead U.S. Government partners in implementing the U.S. Joint External Evaluation National Action Plan. Coordinated the assessment and notification of potential public health emergencies of international concern to the World Health Organization and lead and participated in international engagements that strengthen U.S. and international health security including GHSI and the North American Plan for Animal and Pandemic Influenza. Developed, exercised, and implemented HHS and USG policies and plans for coordinating domestic and international response policies for providing and receiving international public health and medical assistance during emergencies. (Target Exceeded)			
12 Expand an evidence base of scientific information about disasters that informs	FY 2018: Submitted for Department Clearance the National Health Security Strategy's Evaluation of	Develop the PHEMCE annual review of the contents of the	Continue PHEMCE annual review. Continue development of	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
policy decisions (Outcome)	Progress, which incorporates assessments of HPP, PHEP, NDMS, BARDA/MCM Strategic Plan, and PanFlu Vaccine Tracking. Delivered multiple legal and regulatory policy instruments executed by the Secretary to empower innovative research, development, and manufacture of vaccines, therapeutics, and diagnostics against emerging infectious disease threats to national security, including, Ebola virus, Zika virus, enteroviruses, and CBRN threats. 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 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. (Target Exceeded)	strategic national stockpile. Initiate the development of the NHSS Evaluation of Progress to meet the statutory requirement.	the NHSS Evaluation of Progress to meet the statutory requirement.	

OPERATIONS

Budget Summary
(Dollars in Millions)

ASPR	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**30.938**	**30.938**	**30.938**	**--**
FTE	**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.

ASPR uses Operations funding to support its 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, funds provide 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, radiological 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.

Operations support the centralized management services that enable ASPR to carry out its mission. It supports oversight of 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. ASPR continually seeks to improve business operations for maximum return on investment, to strengthen its human capital and communications practices, to provide innovative

technology solutions, and to create a more nimble and flexible organization. ASPR 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.

In FY 2019 and FY 2020, ASPR 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.

Operations activities are a multi-faceted part of ASPR with holistic, nimble, flexible, consistent and innovative acquisition and grants solutions mission support in order to enable public health emergency operational responses. In support of the acquisition function for ASPR, Operations activities foster ASPR's mission through the procurement oversight of awarding of contracts, grants, cooperative agreements and other transaction authority agreements. Operations helps coordinate with ASPR's largest programs for medical countermeasure development and procurement, as well as emergency preparedness and response in pursuit of the mission to save lives and protect Americans. ASPR's Operations activities provide 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 Earned Value Management System (EVMS) processes; supports industry outreach, and provides expert capabilities in the conduct of acquisition strategies, requirement and grants solutions.

ASPR's acquisition approach places emphasis on best value to the taxpayer through best business practices and partnership throughout its programs. This is accomplished by collaborating with all ASPR programs early in the acquisition lifecycle and synchronizing efforts with 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 that enables responders to obtain the supplies and services as needed to effectively lead the public health and medical response to emergencies under ESF 8 and urgent responses to health emergencies such as Ebola, Zika, and H7N9 (influenza with pandemic potential).

A wide range of program management implementation mechanisms are provided to all ASPR programs. This mission support includes 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. This bandwidth further supports ASPR through the inclusion of EVMS 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. ASPR grants management function is instrumental in answering the call to build community resilience through its management support of grants awarded by the Hospital Preparedness Program. Through grants management supports, there is general emergency response, the resolution of A-133 audit findings, and grant policy. ASPR continues to use Other Transaction Authorities (OTAs) to enable it to partner with like consortiums to support a portfolio of multiple products on a cost share basis.

ASPR aligns its financial resources to its strategic priorities and conducts annual planning under a multi-year strategy, measuring financial performance and course correcting when necessary. ASPR carries out its responsibilities by formulating, monitoring, and evaluating budgets and financial plans to support program activities and assure efficient expenditures. In FY 2018, ASPR prepared the submission to Congress of the PHEMCE Multiyear Budget report for FY 2016 – FY 2020. This report provides estimates for HHS PHEMCE partners at ASPR BARDA, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration for activities related to the basic and advanced research and development, procurement, regulatory science, and stockpiling of medical countermeasures for use against potential chemical, biological, radiological, nuclear and emerging infectious disease threats. During FY 2019, ASPR continued this coordination role for the FY 2017-2021 Multiyear Budget report.

ASPR also ensures oversight of 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 Incident Management Team (IMT) is activated to perform ESF 8 functions under the National Response Framework, including the responses to Hurricanes Harvey, Irma and Maria, ASPR's finance function integrates with the IMT under the structure of the Incident Command System. ASPR 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. ASPR's financial management function also coordinates HHS's requests 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, ASPR's Operations activities ensure the accountability and effectiveness of its financial programs and operations by establishing, assessing, correcting, and reporting on internal controls, as required by OMB Circular A-123 and consistent with 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, ASPR coordinates cross-disciplinary reviews of high-impact, high-visibility programs to identify risks that could impede the completion of its mission, and to develop strategies for ensuring effective and efficient operations.

Funding History	
FY 2016	$30,938,000
FY 2017	$30,938,000
FY 2018	$30,938,000
FY 2019 Enacted	$30,938,000
FY 2020 President's Budget	$30,938,000

Budget Request

The FY 2020 Budget includes $30,879,000 for ASPR's Operations, which is level with the FY 2019 Enacted 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; rent and service charges; equipment costs; travel; telecommunications; training; and continued implementation of acquisition management innovations, long-term fiscal planning, and internal controls. Funds will support the continued development of ASPR's performance measurement, quality improvement, Enterprise Risk Manamgement, and strategic human capital management initiatives.

ASPR Office of Operations - Outputs and Outcomes Table

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 Target
2.4.8 Improve strategic communications effectiveness. (Outcome)	FY 2018: Progress was made in modernizing the current ASPR website by initiating the redesign of the Information Architecture to meet customer specifications based on feedback and data analysis. Progress was made in development of the site consistent with responsive resign for use on mobile devices. (Target Met)	Improve public communication by establishing a cadre of academic and private sector experts to provide accurate information about emergency threat risks and steps. Continue coordinated, integrated communications with partners to maximize reach of consistent, credible messaging and to leverage info-sharing capabilities during public health emergencies. Continually maintain resilient access to ASPR web systems for mission response. Launch modernized ASPR website.	Improve public communication by establishing a cadre of academic and private sector experts to provide accurate information about emergency threat risks and steps. Continue coordinated, integrated communications with partners to maximize reach of consistent, credible messaging and to leverage info-sharing capabilities during public health emergencies. Continually maintain resilient access to ASPR web systems for mission response. Launch modernized ASPR website.	N/A
11a Ensure deployment of emergency response personnel, consistent with mission timing requirements/objectives (Intermediate Outcome)	FY 2018: 97.0 % Target: 85.0 % (Target Exceeded)	90.0 %	90.0 %	Maintain

ASSISTANT SECRETARY FOR ADMINISTRATION

CYBERSECURITY

Budget Summary
(Dollars in Millions)

Cybersecurity / 1	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**49.820**	**58.860**	**68.093**	**+9.233**
FTE	**88**	**133**	**143**	**+10**

1/ In addition to Budget Authority, the Cybersecurity Program relies on the Nonrecurring Expenses Fund (NEF) as necessary to finance capital investments. The NEF section in this document provides further information about the Cybersecurity Program's recent OMB-approved NEF projects.

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.

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) 2018:

- HHS managed 10,134 cybersecurity incidents.
- HHS conducted 9,239 web application vulnerability scans (scanning an estimated 2,702,196 web pages) that prevented 950,038 vulnerabilities from being exploited.
- HHS investigated 140,997 incidents of spam, 7,299 of which were malicious and, if gone unchecked, could have compromised HHS data.
- Cybersecurity, privacy and end-of-life legacy systems have been identified as the top three IT challenges facing HHS.

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. Specifically:

Health Sector Cybersecurity Coordination Center (HC3)

The Health Sector Cybersecurity Coordination Center (HC3), previously the HCCIC, was developed and implemented through a collaborative partnership with the Assistant Secretary for Preparedness and Response (ASPR) internally, and the Department of Homeland Security (DHS) externally. HC3 has already coordinated comprehensive, cohesive responses to emerging threats. 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.

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 2020 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 2020, 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 2020, 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 Management Act Program Management

The HHS Cybersecurity Program supports Federal Information Security Management 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 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 2016[1]	$49,820
FY 2017[1]	$49,820
FY 2018[1]	$49,820
FY 2019	$58,860
FY 2020 Request	$68,093

1/ The FY 2016 – FY 2018 Enacted levels were $50.86 million; the $49.82 million accounts for a realignment of funds totaling $1.04 million from PHSSEF Cybersecurity to ONS. This realignment is consistent with the 2012 Cyber Threat Intelligence Memo which resulted in the $1.04 million reallocation of funds beginning in FY 2014.

Budget Request

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

cybersecurity needs while ensuring HHS has the ability to meet the needs of an ever-changing threat landscape.

The FY 2020 President's Budget for the HHS Cyber Security Program is $68,093,000 an increase of $9,233,000 above the FY 2019 Enacted. The Budget will continue to support, sustain and enhance the Department's security posture and reflects the current landscape in which our adversaries are seeking breach our defenses and extract sensitive information. The protection of the HHS mission that delivers healthcare services to tens of millions of American citizens remains a priority. HHS is seeking to increase its protections against cyber threats, such as unauthorized access, denial of service, malicious code, and inappropriate usage, insider threats that pose risks to HHS critical functions, services, and data. Some key initiatives that HHS is undertaking to improve security are focused around improving efficiencies in security tools and deploying enterprise-wise tool solutions to improve HHS's correlation of cyber threat and vulnerability information for better situational awareness and response to actions that could exploit or jeopardize HHS information systems, and to improve protection of HHS assets and endpoints that process and store the information. These efforts include not only purchasing the technology, but building the programs and skilled workforce to ensure these technologies meet HHS objectives to protect its mission and information while also facilitating HHS's compliance against Federal mandates and guidelines.

The Budget 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 OpDiv IT systems and networks.

Summary of Cybersecurity FY 2018-2020 Funding by Program

(dollars in thousands)

Cybersecurity Program	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 President's Budget +/- FY 2019 Enacted
CSIRC	$10,643	$15,644	$17,200	$1,556
TIC	$2,100	$2,100	$2,100	$0
Enterprise Security Tools	$16,072	$20,025	$23,955	$3,930
FISMA	$21,005	$21,091	$24,838	$3,747
Total	$49,820	$58,860	$68,093	$9,233

Computer Security Incident Response Center (CSIRC) ($17,200,000): The request is $17,200, an increase of $1,556 above the FY 2019 Enacted. The request will support the continued creation, alignment, and expansion of the CSIRC services to include the Healthcare Cybersecurity Coordination Center (HC3).

Collectively, The HC3 and CSIRC are the realignment of several legacy cybersecurity offerings. Combined these services will provide cybersecurity incident response, situational awareness, and collaboration and communication internally within the public and private sectors.

The HC3 ($7,000) 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 capability was implemented by 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 ($10,200) continues the alignment of several existing CSIRC service offerings, Security Operations Center ($3,500), Research and Forensics ($5,000), Health Care Threat Operations Center (HTOC) ($700) and Cyber Threat Intelligence (CTI) ($1,000) 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 attacks. Since establishing the CSIRC, the Department has provided cybersecurity situational awareness across the entire enterprise. It has also addressed several threat vectors simultaneously by having a central view into all OpDiv networks. Numerous attacks have been minimized Department-wide as a result of CSIRC's capabilities, in many cases before the attacks occurred within those networks.

The FY 2020 request continues to invest in security technologies including enterprise network intrusion detection and prevention solutions, network traffic analysis tools, SIEM solutions, data and log analysis, and tools to support the forensic analysis of malicious software (malware). Smartphones, 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) ($2,100,000): The request of $2,100 is flat with the FY 2019 Enacted and will allow for the ongoing operations support of TIC.

The implementation of four physical TIC sites in FY 2013 and FY 2014 allowed the Department to align with DHS initiatives to provide greater security in the government's internet connections and facilitate the necessary infrastructure to implement Einstein for the entire Department. Additionally, the TIC sites have a security solution suite which allows the Department to provide real time redundancy and failover capability in the event of a security infrastructure failure at any OpDiv – this includes firewalls, Intrusion Detection Systems (IDS), network traffic analysis, and SIEM. Finally, the TIC provides core capabilities for the Department's continuous monitoring plan by acting as a single point of aggregation for security data collection regarding internet traffic.

Enterprise Security Tools ($23,955,000): The request of $23,955 is $3,930 above the FY 2019 Enacted. This level will allow for the continued support and expansion of the malware blocking and incident response capabilities across the Department. The enhancements improve capabilities to the enterprise, fund an incident response readiness assessment, and provide a retainer for all major infrastructures and

the CSIRC while allowing OpDivs to quickly engage expert-level incident response resources in the event of a significant cybersecurity incident. As threats continue to evolve from new variations of malicious software used by attackers, HHS will continue to enhance the IT security at the OpDivs by pursuing and sustaining a number of high impact investments that will better enable us to keep pace in addressing and correcting new and any existing security gaps. The implementation of Network Access Control (NAC) was successful and is now providing security and endpoint protection to better secure HHS computers and network resources. This request will provide additional solutions to counter malicious software (malware) and other sophisticated computer viruses and worms that continue to plague government computer systems. This FY 2020 Budget request will also renew the Department-wide licenses for a number of security technologies including solutions for encryption, enterprise malware and content filtering, data loss prevention, vulnerability scanning software, and automated tools for FISMA reporting, and security weakness tracking.

The request also includes funding to support the various Departmental Continuous Diagnostic and Mitigation (CDM) licenses previously paid (FY 2014 through FY2018) for by the DHS CDM program, but which must now be acquired through PHSSEF Cybersecurity funds. The licenses ensure these security activities are implemented fully and consistently at all levels of HHS. An effective IT Security program will decrease the number and severity of exploits of sensitive HHS information systems, including compromise of mission critical data. In relation to CDM, maintenance and updating of infrastructure will be required Department-wide in order to proactively identify and address vulnerabilities before they are successfully exploited.

FISMA Program Management ($24,838,000): The request of $24,838 is $3,747 above the FY 2019 Enacted. The request supports the on-going maintenance support Enterprise eGRC tool. The tool allows for the automated reporting of security performance measures to the Department of Homeland Security. Funds will also enable the more effective implementation of 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 OpDiv levels of compliance with the requirements of FISMA. The Department will enhance OpDiv operational IT systems continuous monitoring capability, in order to determine OpDiv compliance with Department policy and standards, including quarterly evaluation of security weakness Plans of Action and Milestones (POA&M), Privacy Impact Assessments (PIA), and system of records notice (SORN) compliance. Support will continue for the activities of the HHS personally identifiable information (PII) Breach Response Team that will enable the Department to evaluate OpDiv breach response assessments to determine the appropriate response to any reported breaches of PII.

Cybersecurity - Outputs and Outcomes Table

Program/Measure	Summary of Most Recent Result	FY 2019 Target	FY 2020 Target	FY 2020 Target +/- FY 2019 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 2018 Target: 95.0% FY 2018 Actual: 98.0% /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 2018 Target: 95.0% FY 2018 Actual: 91.0% /1	95.0%	95.0%	Maintain
Vulnerability management: What percentage of hardware assets are evaluated using an automated capability that identifies NIST National Vulnerability Database vulnerabilities (CVEs) present with visibility at the organization's enterprise level?	FY 2018 Target: 95.0% FY 2018 Actual: 80.0%	95.0%	95.0%	Maintain
FISMA System Inventory Compliance: Percentage of systems with current Security Authorization to Operate (ATO).	FY 2018 Target: 100.0% FY 2018 Actual: 96.0%	100.0%	100.0%	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.

Nonrecurring Expenses Fund

Budget Summary
(Dollars in Thousands)

	FY 2018[2]	FY 2019[3/4]	FY 2020[5]
Notification #6 Total[1]	--	$34,000	TBD

[1] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.
[2] There was no Congressional notification for the planned uses of NEF funds in FY 2018.
[3] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on December 4, 2018.
[4]Amounts notified are approximations of intended use. Amounts displayed here are current best estimates.
[5] HHS has not yet notified for FY 2020.

Authorizing Legislation:
Authorization……...Section 223 of Division G of the Consolidated Appropriations Act, 2008
Allocation Method…….……...……Direct Federal, Competitive Contract

Program Description and Accomplishments

The Nonrecurring Expenses Fund (NEF) permits HHS to transfer unobligated balances of expired discretionary funds from FY 2008 and subsequent years into the NEF account. Congress authorized use of the funds for capital acquisitions necessary for the operation of the Department, specifically information technology (IT) and facilities infrastructure acquisitions.

HHS Office of Information Security: Cybersecurity Program

The HHS Office of Information Security (OIS) 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.

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

- Implementing specific cybersecurity capabilities
- Cultivating cybersecurity partnerships in the public and private sectors
- Engaging in HHS-wide security collaboration activities
- Providing security services and solutions to the enterprise
- Enhancing HHS' security capabilities through current and future programs and projects
- Directly providing cybersecurity and privacy support for the Office of the Secretary (OS)

OIS is tasked with executing the HHS Trusted Internet Connection (TIC). The TIC program aims to improve the Federal Government's security posture through the consolidation of external telecommunication connections and establishing a set of baseline security capabilities through enhanced monitoring and situational awareness of all external network connections.

In order to execute its mission and adhere to the multitude of mandates, directives, guidance, and executive orders, OIS is engaged in the initiatives below using NEF funding.

- HHS Cybersecurity Automation Program (HCAP) (SGRC, CDM, Enterprise Log Management and Cybersecurity Security Information and Event Management)
- Health Sector Cybersecurity Coordination Center (HC3)
- Enterprise Packet Capture Solutions Refresh
- Enterprise Network consolidation and Trusted Internet Connection (TIC) migration to Managed Trusted Internet Protocol Service (MTIPS)

The projects described below are the current list of approved projects for FY 2019. Additional projects may be funded from the FY 2019 notification letter upon approval from OMB.

HHS Cybersecurity Automation Program (HCAP) Integration ($20.7 million)
The HCAP integration establishes a cybersecurity solution development, governance, leadership, and operational capability within the Office of Information Security organization to improve cybersecurity visibility, efficiencies and standardization across the Department.

The program will leverage and integrate information and resources from the Security Governance, Risk and Compliance (SGRC), Continuous Diagnostic and Mitigation (CDM) and the Enterprise Log Management and Cybersecurity Security Information and Event Management projects being implemented for sharing and consolidation of data sources and analysis across the agency to produce useable cybersecurity risk management information for the Department. The key HCAP outcomes include:

1. Provide a comprehensive and near real-time understanding of cybersecurity risk information across the Department,
2. Enable prioritization of mitigation activities and resource alignment through actionable information
3. Standardize cybersecurity information and risk assessment via consistent and automated measurement and trending, and
4. Provide a centralized resource to coordinate and optimize Departmental IT risk management activities.

OCIO will invest $20.7 million in FY19 to establish the HCAP program and integrate the SGRC, CDM and Data Analysis projects into one program that will also transition them to operations and maintenance (O&M) status. These activities are eligible for NEF funding as they fall under Development, Modernization, and Enhancement (DME) efforts. The total, $20.7 million represents the following individial initiatives that collectively encompass “HCAP”:

1. Enterprise Cybersecurity Governance, Risk, and Compliance Integration Tool Management ($7.8 million)
2. Enterprise Log Management and Cybersecurity Security Information and Event Management ($7.6 million)
3. Enterprise Healthcare Cybersecurity Data Consolidation Reporting and Analytics Management ($5.3 million)

Enterprise Network consolidation and Trusted Internet Connection (TIC) migration to Managed Trusted Internet Protocol Service (MTIPS) (FY19 $5 million)

This project will consolidate HHS Enterprise WAN components currently residing in two separate investments and programs (HHSNet and TIC) as well as migrate to a Managed Trusted Internet Protocol Service (MTIPS) including security services. The HHS TIC includes network infrastructure and security tools connecting each of the four Trusted Internet Access Points (TICAP) locations (Bethesda, Ashburn, Atlanta, and Albuquerque). The TIC locations manage internet traffic and perform federally mandated

security services for HHS including internet service points of presence (POP). HHSNet includes network infrastructure that connects OpDivs to each other for HHS intranet traffic provided through a service provider Private Internet Protocol (PIP) network. Consolidating these two networks would result in a more cost effective service that meets mission requirements and provides the infrastructure to support OMB mandated TIC requirements.

Dual operations are required to ensure mission and security requirements are met during migration to the service provider infrastructure. This period of dual operations is the cost driver for the majority of the capital investment requirements.

Enterprise Packet Capture Solutions Refresh (FY19 $5.5 million)

In conjunction with a lifecycle refresh of our existing enterprise packet capture solution, this project will migrate our platform to a through-put based enterprise licenses construct and remove the dependency on any vendor specific hardware platform as required in our current appliance based solution.

To accomplish this migration, a three to six month procurement followed by a two to six month migration period is planned running current legacy operations while establishing and migrating to the target architecture. Dual operations are required to ensure mission and security requirements are met during migration to the refreshed solution.

OFFICE OF NATIONAL SECURITY

Budget Summary
(Dollars in Millions)

ONS	FY 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Budget Authority	**8.510**	**7.470**	**7.470**	**--**
FTE	**26**	**37**	**37**	**--**

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

Program Description and Accomplishments

The Office of National Security (ONS), formerly known as 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, ONS is the HHS point of contact for the Intelligence Community (IC), and is responsible for coordination with the IC and for intelligence support to HHS senior policy makers and consumers of intelligence across the Department. Additionally, ONS 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. ONS is headed by the Assistant Deputy Secretary for National Security, who reports directly to the HHS Deputy Secretary. The Assistant Deputy Secretary for National Security serves as the HHS Secretary's Senior Intelligence Official on national security, intelligence and counterintelligence issues, and as the Department's Federal Senior Intelligence Coordinator (FSIC). He has also been delegated original classification authority by the Secretary.

ONS is comprised of four divisions, including the Intelligence & Analysis Division (IAD), the Division of Operations (DO), the Business Management Division (BSD) and the Personnel Security Division (PSD). These divisions 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), personnel security and counterintelligence/insider threat programs. ONS 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.

ONS's programs also include national security clearance 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. 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. ONS 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

HHS is 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. As such, 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. ONS 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. ONS 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, ONS 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. ONS also leads the Department in policy and operations regarding counterintelligence and insider threat matters that could cause disruptions and harm to HHS personnel, facilities or information.

Funding History	
FY 2016[1]	$8,510,000
FY 2017[1]	$8,510,000
FY 2018[1]	$8,510,000
FY 2019 Enacted	$7,470,000
FY 2020 President's Budget	$7,470,000

1/ The FY 2016-2018 Enacted levels were $7.47 million; the $8.51 million accounts for a realignment of funds totaling $1.04 million from PHSSEF Cybersecurity to ONS. This realignment is consistent with the 2012 Cyber Threat Intelligence Memo which resulted in the $1.04 million reallocation of funds beginning in FY 2014.

Budget Request

The FY 2020 President’s Budget request for ONS is $7.47 million, which is flat with the FY 2019 Enacted level.

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

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. ONS’s ability to maintain and work closely with other federal departments and agencies, including law enforcement organizations and the Intelligence Community, will help 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.

Mission Support

ONS 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 2018, ONS 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 Office of the Chief Information Security Officer, the Office of the Inspector General, the Assistant Secretary for Preparedness and Response, the Office of Global Affairs, the Administration for Children and Families, the Food and Drug Administration, the National Institutes of Health, and the Centers for Medicare & Medicaid Services are just some of the HHS customers that ONS supports with intelligence, law enforcement and homeland security information, and its intelligence, cyber, insider threat, counterintelligence and special security programs. To meet these needs, ONS 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 2018	FY 2019	FY 2020	
	Final	Enacted	President's Budget	(+/-) FY 2019 Enacted
Program Level	**250.000**	**260.000**	**260.000**	**--**
Budget Authority (non-add)	*250.000*	*260.000*	*260.000*	*--*
ASPR No-year funding (non-add)	*215.000*	*225.000*	*225.000*	*--*
ASPR Annual funding (non-add)	*30.991*	*30.991*	*30.991*	*--*
OGA Annual funding (non-add)	*4.009*	*4.009*	*4.009*	*--*
FTE	**--**	**--**	**--**	**--**

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. This virus belongs to 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 candidate. 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 in West Africa, 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 United States Government (USG) must continue to develop new medical countermeasures – vaccines, drugs, diagnostics, and respiratory protection devices – and the manufacturing capacity 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 internationally. 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 (2017-2018), 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 establish clear priority goals to improve pandemic preparedness and response.

ASPR, through BARDA, has:

- 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 influenza bulk vaccine antigen (the component of vaccine that stimulates the human immune system) for the National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS);
- Developed through FDA licensure new influenza vaccines using modern cell- and recombinant-based production technologies to expedite and expand domestic production capacity;
- Advanced the development of sensitive diagnostic tests to detect influenza viruses that can be used in near-patient settings, and high-throughput diagnostics capable of detecting influenza strains at hospital-based, reference and public health laboratories;
- Developed and stockpiled new antigen-sparing adjuvants which are required for vaccines to stimulate sufficient immunity and decrease the amount of antigen needed in each vaccine dose for the vaccine to be effective;
- 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,
- 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 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 towards FDA approval of next-generation portable ventilators needed for a surge in hospitalized patients of all ages during a pandemic;
- Supported development of re-usable elastomeric respirator masks; and
- Responded to the 2017 H7N9 influenza threat, awarding contracts for production and clinical trial testing of vaccine antigen for H7N9 influenza vaccine from the 2016–2017 Yangtze River Delta virus lineage candidate vaccine virus provided by CDC.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 actions 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; 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: Building on BARDA's partnership with Novartis (now owned by Seqirus), FDA licensed Flucelvax, the first cell-based influenza vaccine commercially available in the United States, which was used during the 2013-2014 influenza season and subsequent seasons. BARDA also invested in domestic manufacturing capacity for Flucelvax, building the Holly Springs facility in collaboration with Novartis (now Seqirus). Production of influenza vaccines in cell culture eliminates the vulnerability of current pandemic vaccines to disruption in the supply of eggs that might accompany a pandemic caused by a virus of avian origin. Cell-based vaccines also would have potentially greater fidelity with the circulating virus since they may eliminate the possibility of mutations that may occur during adaptation of the vaccine strain to production in eggs, and thus decrease its effectiveness. 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. In 2018, BARDA continued to support manufacturing efficiency improvements to achieve a two or more fold boost in the number of pandemic influenza vaccine doses produced, thereby reducing cost and the amount of time required to meet target production goals during an influenza pandemic without expanding the facility's physical plant and equipment. In 2018, BARDA also supported efforts to improve fill/finish of the vaccine, allowing more vials of vaccines to be available in a shorter time. Both of these efforts will continue in 2019 and 2020.

Recombinant Vaccines: Since 2009, BARDA has supported the development of recombinant-based vaccine for seasonal and pandemic influenza. Development and manufacturing of new influenza vaccines using recombinant technology is faster in response to an outbreak or pandemic than cell or egg-based vaccines because they do not depend on the availability of eggs or on a new influenza virus strain to grow in eggs or cells. In addition, recombinant vaccines can be produced with the specified protein sequence that is an exact match for any particular circulating virus strain, maximizing the likelihood of its effectiveness. In January 2013, FDA licensed Protein Sciences Corporation's 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. Since 2017, BARDA has supported 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 Delta lineage H7N9 influenza virus circulating in China. Support for this clinical trial will continue until its completion in 2019. In 2019 and 2020, further clinical trials of pre-pandemic strains with different adjuvants will be performed to allow selection of the optimal vaccine formulation. Finally, in 2018 BARDA continued to support expanding capacity to fill the vaccine into final container vials to make it available for use. Support for this work will continue until completion, projected to be during the year 2020. These efforts will combine to make more vaccine available to the public sooner in the event of a pandemic, as stated in the HHS Pandemic Plan.

Expanding vaccine capacity with adjuvants: BARDA continues to support advanced development of multiple adjuvants to achieve dose sparing of antigen, broad immunity across antigenically divergent

viruses, and significant long-lasting immunity. Together, these products represent a major technological breakthrough for pandemic vaccine preparedness.

Adjuvants were instrumental in producing an immunogenic vaccine during HHS's H7N9 vaccine responses in 2013 and 2017. 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. Q-PAN was subsequently licensed and approved for pediatric patients in September 2016. In 2018, efforts continued to license additional pre-pandemic adjuvanted vaccines, with funding expected to continue through 2020. If approved, these additional adjuvanted vaccines will significantly enhance HHS's ability to respond during a pandemic.

Close collaboration between BARDA's Pandemic Influenza and Advanced Research and Development (ARD) programs resulted in the launch of 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 Pre-Pandemic Influenza Vaccine Stockpile (NPIVS) for over 10 years. The results of this study indicate that pre-pandemic influenza vaccines and adjuvants stored in the NPIVS remain safe and immunogenic to help protect the US population. During 2018, BARDA initiated a heterologous prime and boost study to determine the priming potential of different H5 influenza vaccines in the NPIVS. This study will provide important clinical evidence to optimize vaccination strategies using stockpiled influenza H5 vaccines during a pandemic response. Additional studies to be conducted during 2019 and 2020 will determine the most effective formulation, as well as to test new adjuvants to ensure that sufficient clinical evidence is available to support rapid response options in the event of a pandemic.

During 2018, BARDA continued to support expansion of domestic adjuvant manufacturing capacity. This effort includes both bulk adjuvant manufacturing as well as fill/finish capability. Additional efforts in 2019 and 2020 will look to further improve adjuvant manufacturing capacity and fill/finish capability. Once completed, these efforts will ensure a ready supply of adjuvant in the event of a pandemic.

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 collaborate 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. In 2018, BARDA collaborated with the Department of Defense (DoD) to re-evaluate both the CIADMs and the DoD's advanced development and manufacturing (ADM) facility at Ology.

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 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. During 2018, BARDA supported efforts to further advance this sterility assay towards regulatory approval. Lastly, industry partners are evaluating alternative potency assays, such as enzyme-linked immunosorbent assay and mass spectrometric assays. During 2019, BARDA plans to move these improved release tests closer to regulatory approval through a combination of continued financial support and interactions with manufacturers and discussion with regulatory authorities.

Expanded domestic influenza vaccine manufacturing surge capacity: Since 2005, BARDA has supported a series of efforts to increase manufacturing capacity through retrofitting of existing structures and construction of new facilities. This, combined with licensure of new manufacturing technologies and process improvements, has expanded domestic manufacturing capacity for pre-pandemic bulk antigen. These improvements have both diversified and expanded the seasonal influenza vaccine production base that will provide the primary infrastructure for a pandemic response. These improvements also bring U.S. manufacturing surge capacity pandemic influenza vaccines closer to the ultimate goal: providing two doses for the entire U.S. population within six months of vaccine virus delivery to manufacturers. The initiatives that BARDA has undertaken have established a sound and robust base for further improvements in the speed and capacity for supply of vaccine in a pandemic emergency. In 2018, BARDA continued to support this critical infrastructure by funding efforts to maintain sufficient quantities of raw materials to allow a year-round response to a pandemic, as well as maintain facility infrastructure, and train personnel on the manufacturing process. These efforts, critical to maintaining pandemic influenza production capacity, are planned to continue in 2019 and 2020.

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. 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 two years. To improve preparedness, protect health, and potentially save lives during an influenza pandemic, BARDA continues to support the advanced development of additional antiviral drugs for critically ill persons with influenza. The 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 FY 2017, BARDA used the Other Transactional Agreement (OTA) authority provided under the Pandemic and All Hazards Preparedness Act to award two OTAs to support development of multiple influenza antiviral drugs. The goal of these programs is to develop novel viral and host directed therapeutic products that will overcome the emergence of resistance during an influenza pandemic or for seasonal influenza. FYs 2019 – 2020 funds will continue to support ongoing and new programs to develop novel influenza antiviral drugs and other therapeutics.

***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.

Diagnostics: Accurate, robust influenza tests are needed for patient management, rapid treatment decisions, and for public health surveillance. BARDA's diagnostic strategy is focused on building a "net" of diagnostic capabilities to capture, analyze and report real-time, geo-spatial and virologic information while supporting personalized patient care, rapid treatment decisions and pandemic

preparedness and response. In the past, BARDA supported the development of sensitive molecular tests that can be used in hospitals settings, and in point-of-care (POC) settings. These tests are more sensitive than the traditional rapid antigen detection tests. Three of the platforms (Simplexa, Roche Liat, Cepheid, Xpert) are now FDA-cleared, and two have CLIA-waived designation that allows use in POC settings for easier patient access and faster treatment decisions. In 2018, the innovations strategy expanded to seek out technologies such as home use tests, medical devices including wearables, and advanced intelligent network-based technologies that will empower patients to achieve better outcomes after influenza infection by starting treatment as early as possible and preventing further disease transmission. As part of this strategy, in 2018, BARDA awarded contracts to Cue Health Inc., in an effort to make at-home flu tests as easy as home pregnancy tests, with the goals of speeding access to treatment and providing information for tracking of annual influenza epidemics.

Respiratory Devices and Ventilators: BARDA continues to support development of next-generation portable ventilators needed for a surge in hospitalized patients of all ages during a pandemic, including the Trilogy Evo Respirator. BARDA is also supporting efforts at Halyard Health to develop high-speed manufacturing for surge production capability for respiratory protection devices (RPD). In addition, ARA was funded in FY 2018 for early stage development of a reusable RPD as alternative to the N95.

Enhancing global pandemic preparedness: Diseases do not respect national borders, making global pandemic preparedness important for protecting the health and wellbeing of the U.S. population. Led by OGA, HHS international pandemic influenza policies and programs focus on strengthening preparedness and response for diseases with pandemic potential that can affect the U.S. To support these activities, OGA continually coordinates with the White House National Security Council, the Departments of State (DOS), Agriculture, and Defense, 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, other emerging or re-emerging infectious diseases of epidemic or pandemic potential, and other biological threats that can spread to our U.S. borders.

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

- New procedures for WHO to recommend and facilitate emergency use authorization of medical countermeasures donated by developed countries or provided by manufacturers during public health emergencies in countries around the world to save lives and/or slow disease spread globally.
- Licensure of eleven influenza vaccines in six countries (Indonesia, Brazil, Romania, Thailand, South Korea, India) and late-stage development of five influenza vaccines (Vietnam, Thailand, Serbia, and China).
- 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 U.S. support during emergencies, thus making sure assets are available to protect the U.S. population. HHS leadership accomplished the logistical implementation of the U.S. donation of H1N1 pandemic influenza vaccine to WHO, the response to the MERS-CoV, Ebola, and H7N9 Flash Appeal for support to WHO. This was accomplished in collaboration with partners in HHS, vaccine manufacturers, international transport companies, the U.S. Department of State, and the U.S. Agency for International Development (USAID).
- Development of new frameworks for sharing of biological specimens to accelerate development of diagnostics and medical countermeasures. Through this process, the U.S. was rapidly able to

obtain samples from foreign countries to expedite the development of Zika and H7N9 influenza virus diagnostics and vaccine.

Provided technical assistance, policy leadership, and analysis to support:

- Development of key WHO tools including: WHO Pandemic Influenza Risk Management Framework and Implementation Strategy; Pandemic severity assessment tool; updated clinical guidance for the use of antiviral agents; generic training modules for case detection; sample and management; and, WHO Disease Outbreak News.
- Development and implementation of the WHO Influenza Vaccine Sustainability assessments for low and middle-income countries: Indonesia, Mexico, South Africa, Vietnam, Thailand, Serbia, Argentina, Morocco, Brazil, and others.
- Development of 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 thus enhancing the global requirement should a pandemic vaccine be needed.
- Facilitating the request from the China-FDA for technical assistance to evaluate submissions from Chinese manufacturers for live attenuated influenza vaccines (LAIV) and quadrivalent inactivated vaccines.
- Development of a report from WHO consultations on the effectiveness of LAIV.
- Convening, in coordination with the WHO and U.S. CDC, of a multi-ministerial meeting of the five global WHO National Influenza Collaborating Centers (NICC) in Beijing, to review programmatic challenges and find solutions for rapid sharing of influenza viruses of pandemic potential.
- Convening of a high-level stakeholder meeting and action plan for development and updating of National Pandemic Influenza Preparedness Plans.
- Decision-making and 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 U.S. Department of State, Office of the U.S. Trade Representative, Department of Commerce, and the U.S. Patent and Trademarks Office, for international negotiations on WHO's Pandemic Influenza Preparedness Framework for Influenza Virus Sample and Benefits Sharing, as well as for non-influenza pathogens.
- The National Security Council Staff and White House for policy options for donation of H1N1 pandemic influenza virus 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 diplomatic and political support for:

- Renewed engagement with the World Health Organization and its new Global Influenza Strategy to prioritize the need to increase the global surge capacity for influenza vaccine manufacturing through increasing sustainable influenza vaccine manufacturing capacity in developing countries. From a global estimate of 400 million doses in 2006, to an estimated 6.5 billion doses in 2016 of a pandemic vaccine within nine months of recognition of a novel strain, the world remains short of the global requirement for over 10 billion doses of a pandemic influenza vaccine.
- The National Security Council by developing the interagency diplomatic engagement strategy on Influenza/H7N9 sample sharing, which identified opportunities and to engage at the

technical and diplomatic levels with the Chinese government to identify inter-ministerial barriers and other obstacles to timely virus sharing, and to encourage WHO to continue to highlight the expectations of the National Influenza Centers within the WHO Global Influenza Surveillance and Response System to share viruses as committed to under the Pandemic Influenza Preparedness Framework (PIP-FW).

- Developing, fostering, and maintain a diplomatic relationship with the Chinese National Health Commission to facilitate the continuous and rapid sharing of Influenza viruses of pandemic potential with the non-health Chinese ministries involved in the export of virus samples from the China-CDC (e.g. Ministry of Finance and Commerce).
- The development of a WHO report providing guidance on principles and practical tools to facilitate and accelerate multi-stakeholder engagement and equitable sharing of samples and benefits.
- Development of global and regional strategies for pandemic influenza preparedness and response (e.g., WHO Global Influenza Strategy, WHO Western Pacific Region Asia Pacific Strategy for Emerging Diseases).
- Ensuring that USG policies enable continuous influenza virus and emerging disease surveillance and public health response worldwide.
- Developing countries to improve self-sustainability in ways that provide surveillance, detection, and response for influenza virus and emerging threats affecting their countries and region. OGA directly supports efforts to leverage global political will to make global health security and influenza initiatives more sustainable, including the 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 detection, preparedness and response at the national level. For example, ASPR has worked directly to create surveillance networks, enhance laboratory capacity, train personnel and develop preparedness plans in countries in West Africa, South East Asia, and Central America.

Promoted integration of pandemic influenza preparedness and response with 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, including:

- Leading policy coordination for key international treaties, agreements, and arrangements including implementation of the PIP-FW and the Nagoya Protocol including troubleshooting for challenges created by other nations' implementation of the Nagoya Protocol that impedes pathogen sample sharing.
- Developing 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.
- Contributing to the expansion of the WHO Strategic Partnership Portal Dashboard for Health Security by integrating newly developed influenza preparedness tools (e.g., costing, influenza preparedness check list), sharing of information and coordination among influenza stakeholders, and consolidated data collection for National Pandemic Influenza Preparedness Plans.

Funding History	
FY 2016	$72,000,000
FY 2017[1]	$71,831,000
FY 2018	$250,000,000
FY 2019 Enacted	$255,991,000
FY 2020 President's Budget	$255,991,000

[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 2020 Request for pandemic influenza activities is $260,000,000, which is the same as the FY 2019 Enacted 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 that maintain the significant pandemic preparedness and response capabilities 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. Funds are critical to United States domestic pandemic preparedness and national security infrastructure, including development of a strong American workforce for production of medical countermeasures for pandemic influenza. A key component of the strategy is to accelerate the transition to and further increase capacity of domestic vaccine manufacturing and filling capacity using modern, egg-independent, cell or recombinant-based approaches so the right vaccine is available in the right place at the right time. This will be achieved by expanding both the number of licensed vaccines and the domestic production capacity, including adjuvant production and vaccine filling capacity. Funds are also 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.

Of the total funds requested, $35,000,000 is annual funding, and $225,000,000 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 update pre-pandemic influenza vaccine and adjuvant stockpiles. These stockpiles are essential for rapid response against an emerging pandemic virus. This nimble stockpiling program also supports clinical studies to inform effective deployment. At the requested funding level, BARDA will invest in vaccine technologies, including adjuvant technologies, to improve the availability of safe and effective vaccines during a pandemic influenza emergency and the sustainability of our preparedness. These vaccines would be transformational to pandemic preparedness and response, but are extremely challenging to develop. The requested funds are also 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 designed to shorten the time for deployment of effective pandemic influenza vaccines and therapeutics.

The FY 2020 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 facemasks and respirators. These strategic investments will close important gaps by enabling early detection of emerging influenza viruses, as well

as preventing transmission. The FY 2020 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 2020 ($35,000,000):

Vaccine Stockpiling ($27,991,000): The request includes funds to support risk-based stewardship of the National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS) including development, procurement, testing and maintenance of antigens, adjuvants, vaccine ancillary supplies and the necessary manufacturing capacity to support pandemic influenza responses.

This funding will also support our pre-pandemic influenza vaccine stockpile preparedness goals. Specifically, it will allow BARDA to create new vaccine seed viruses to match newly emerged viruses with pandemic potential and acquire vaccine bulk antigens to maintain and replenish NPIVS inventory to match the strains posing the highest pandemic threat as appropriate. 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 effective pandemic response. Finally, BARDA will support clinical studies to test the safety, immunogenicity, and tolerability of stockpiled vaccines. Data from these vaccine clinical trials will inform the optimization of pandemic vaccination strategies. Collectively, BARDA's Vaccine Stockpiling investments enable HHS to quickly respond to future pandemic influenza emergencies in the U.S.

ASPR 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 U.S. 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): The budget request is $4,009,000, which is the same as the FY 2019 Enacted level. 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 influenza and other emerging infectious disease threats.

Influenza viruses and other emerging infectious diseases with pandemic potential continue to mutate, evolve, and infect animals and humans, posing continued significant threats to global public health and to the U.S. The world is unprepared for an influenza pandemic and experts maintain that influenza remains the pathogen of highest probably for causing a severe pandemic. U.S. domestic pandemic preparedness is dependent on HHS' continued leadership and investments with key global partners in international settings to prepare, prevent, detect, and respond to emerging influenza viruses and other pathogens 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 the Department and within the U.S. Government (USG) interagency process regarding international health policy development and diplomacy. OGA synthesizes, integrates, and translates policy, science, and diplomatic 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; key multilateral and international institutions involved in health security [e.g. the United Nations (World Health Organization and Food and Animal Organization), the Organization for Animal Health, 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 in developing countries. To that end, OGA is the critical interface among international influenza health/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 international pandemic preparedness activities. OGA focuses on the development of new global partnerships to bolster global health security efforts through the advancement of the prevention and control of influenza. Having this structure in place is a pre-requisite for coordinating internationally for a pandemic, epidemic, or public health emergency of international concern. This is based on experience and lessons learned during the 2005-2007 Influenza H5N1 outbreaks, the 2009 Influenza/H1N1 pandemic, the 2013 – on-going Influenza H7N9 outbreak in China, and other key ongoing outbreaks including Zika, Yellow Fever, Lassa Fever, plague, and Ebola.

In accordance with the National Security Strategy, the National Biodefense Strategy, the Global Health Security Strategy, Global Health Security Agenda 2024, and the HHS Strategic Plan, OGA will bring its technical, policy, and diplomatic expertise to promote policies that include:

- expansion of medical, veterinary, and laboratory expertise and capacity, and enhancement of laboratory diagnostic capacity and technical capabilities abroad;
- strengthening of emerging disease networks to improve risk-communication to enhance seasonal influenza vaccination;
- promotion of sustainability of influenza vaccine manufacturing in developing countries;
- improvement of surveillance and response; support for international implementation of the International Health Regulations core competencies, critical to global health security and pandemic preparedness and response;
- establishment of new multisectoral partnerships for pandemic influenza preparedness and health security;
- 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 2020 ($225,000,000):

Facilities and Infrastructure Readiness ($90,000,000): Funds will sustain the three pillars of domestic influenza vaccine manufacturing capacity: egg-, recombinant-, and cell-based vaccine manufacturing infrastructure. This effort has allowed BARDA to reach previous goals of 500 million antigen vaccine doses (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.

Maintaining this capability to meet U.S. pandemic vaccine production requirements will continue in FY 2020. In order to meet the pandemic response timelines in the DHHS 2017 Pandemic Influenza Plan Update Objectives, work in FY 2020 will also look to expand and diversify domestic bulk antigen and adjuvant manufacturing capabilities. In addition to bolstering manufacturing capacity, BARDA is continuing efforts to enhance fill/finish manufacturing capacity to ensure bulk antigens and adjuvants 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 transformed pandemic readiness infrastructure in the U.S., taking us from production to fill/finish capabilities. The FY 2020 funding 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.

Improved Influenza Vaccine Advanced Development ($60,000,000): At this funding level, BARDA will invest in vaccine technologies to improve the availability of safe and effective influenza vaccines during a pandemic. BARDA will focus on improving our Nation's pre-pandemic vaccine preparedness by improving vaccine efficacy, manufacturability, and delivery, including development of improved antigen-sparing adjuvants and formulations. In FY 2020, BARDA will continue clinical development of these approaches, including testing of new adjuvants as well as new vaccine formulations. Funding will also support efforts to advance development of influenza vaccines with transformative technologies to alleviate some of the current pandemic vaccine administration challenges. These include development of technologies that utilize needle-free delivery such as patch/patch-like devices. Finally, adjuvants with improved efficacy and storage characteristics will be further developed and tested to support enhanced stockpile capabilities.

Advanced Development of Influenza Therapeutics ($55,000,000): 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 U.S. 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. 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). Further, host targeted therapeutics have the potential to treat individuals at later stages of infection, where the host physiological response, rather than the virus itself, may be causing illness. In FY 2020, funds requested will support advanced development, including at least one clinical trial, for this three-pronged approach - small molecules targeting the virus, monoclonal antibodies acting on the virus, and host directed therapeutics - to identify the best treatment options for this critical population. BARDA will utilize OTA awards, as needed, to advance therapeutics product development.

Diagnostics and Respiratory Protection Device Advanced Development ($20,000,000): Funding will be used to continue supporting 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. This includes wearable devices that utilize advanced data analytics and machine learning to predict pre-symptomatic illness through continuous monitoring with the end goal of predicting and diagnosing influenza. In FY 2020, BARDA will also look to enhance national biosecurity with advanced development programs that focus on novel or 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 2019 Target	FY 2020 Target	FY 2020 Target +/-FY 2019 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 2018: 600.0 million antigen vaccine doses Target: 600.0 million antigen vaccine doses (Target Met)	600.0 million antigen vaccine doses	600.0 million antigen vaccine 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 2018: 7.0 programs Target: 2.0 programs (Target Exceeded)	2.0 programs	2.0 programs	Maintain

OGA Pandemic Influenza: Grants

Grants (whole dollars)	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Number of Awards	1	1	1
Average Award	$1,679,090	$1,609,000	$1,606,000
Range of Awards	$1,679,090	$1,609,000	$1,606,000

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Millions)

Description	FY 2018 Final /1,2	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel compensation:				
Full-time permanent (11.1)	115.049	138.957	140.031	+1.074
Other personnel compensation (11.5)	0.056	0.059	0.059	--
Military personnel (11.7)	6.952	9.395	9.395	--
Subtotal, Personnel Compensation.....	**122.057**	**148.411**	**149.485**	**+1.074**
Civilian benefits (12.1)	42.095	52.558	53.225	+0.667
Military benefits (12.2)	2.896	3.739	3.739	-0.000
Total Pay Costs.....	**167.049**	**204.708**	**206.449**	**+1.741**
Travel and transportation of persons (21.0)	6.998	9.432	9.432	--
Transportation of things (22.0)	0.526	0.705	0.705	--
Rental payments to GSA (23.1)	7.508	11.338	11.344	+0.006
Rental payments to Others (23.2)	14.000	17.000	17.000	--
Communication, utilities, and misc. charges (23.3)	1.501	1.953	1.955	+0.002
Printing and reproduction (24.0)	0.107	0.145	0.145	--
Other Contractual Services:				
Advisory and assistance services (25.1)	736.459	775.420	805.016	+29.596
Other services (25.2)	33.781	32.183	30.791	-1.392
Purchase of goods and services from government accounts (25.3)	114.706	122.291	122.291	--
Operation and maintenance of facilities (25.4)	4.172	7.730	7.730	--
Research and Development Contracts (25.5)	503.077	637.120	636.060	(1.060)
Operation and maintenance of equipment (25.7)	81.225	74.641	76.976	+2.335
Subsistence and support of persons (25.8)	0.569	0.982	0.982	--
Subtotal, Other Contractual Services.....	**1,473.989**	**1,650.367**	**1,679.846**	**+29.479**
Supplies and materials (26.0)	1.875	409.009	402.917	(6.092)
Equipment (31.0)	0.553	15.742	15.742	--
Land and Structures (32.0)	0.018	0.024	0.024	--
Grants, subsidies, and contributions (41.0)	279.335	311.035	321.032	+9.997
Total Non-Pay Costs.....	**1,786.410**	**2,426.750**	**2,460.142**	**+33.392**
Total, Budget Authority by Object Class.....	**1,953.458**	**2,631.458**	**2,666.591**	**+35.133**

1/ Excludes Strategic National Stockpile funding within CDC.

2/ Excludes supplemental emergency resources provided in the Bipartisan Budget Act of 2018.

SALARIES AND EXPENSES

(Dollars in Millions)

Description	FY 2018 Final /1	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel compensation:				
Full-time permanent (11.1)	115.049	138.957	140.031	+1.074
Other personnel compensation (11.5)	0.056	0.059	0.059	--
Military personnel (11.7)	6.952	9.395	9.395	--
Subtotal personnel compensation	**122.057**	**148.411**	**149.485**	**+1.074**
Civilian benefits (12.1)	42.095	52.558	53.225	+0.667
Military benefits (12.2)	2.896	3.739	3.739	--
Total Pay Costs	**167.049**	**204.708**	**206.449**	**1.741**
Travel and transportation of persons (21.0)	6.998	9.432	9.432	--
Transportation of things (22.0)	0.526	0.705	0.705	--
Rental payments to GSA (23.1)	7.508	11.338	11.344	+0.006
Rental payments to Others (23.2)	14.000	17.000	17.000	--
Communication, utilities, and misc. charges (23.3)	1.501	1.953	1.955	+0.002
Printing and reproduction (24.0)	0.107	0.145	0.145	--
Other Contractual Services:				
Advisory and assistance services (25.1)	736.459	775.420	805.016	+29.596
Other services (25.2)	33.781	32.183	30.791	-1.392
accounts (25.3)	114.706	122.291	122.291	--
Operation and maintenance of facilities (25.4)	16.949	21.895	24.230	+2.335
Research and Development Contracts (25.5)	503.077	637.120	636.060	(1.060)
Operation and maintenance of equipment (25.7)	68.448	60.476	60.476	--
Subsistence and support of persons (25.8)	0.569	0.982	0.982	--
Subtotal, Other Contractual Services	**1,473.989**	**1,650.367**	**1,679.846**	**+29.479**
Supplies and materials (26.0)	1.875	409.009	402.917	(6.092)
Total Non-Pay Costs	**1,506.504**	**2,099.949**	**2,123.344**	**23.395**
Total Salary and Expense	**1,673.553**	**2,304.657**	**2,329.793**	**+25.136**
Direct FTE	**732**	**1,007**	**1,017**	**+10**

1/ Excludes Strategic National Stockpile funding within CDC.

DETAIL OF FULL-TIME EQUIVALENTS (FTE)

	2018 Actual Civilian	2018 Actual Military	2018 Actual Total	2019 Est. Civilian	2019 Est. Military	2019 Est. Total	2020 Est. Civilian	2020 Est. Military	2020 Est. Total
ASPR									
Direct:	540	72	612	760	72	832	760	72	832
Reimbursable:			--			--			--
Total:	540	72	**612**	760	72	**832**	760	72	**832**
Cyber Security									
Direct:	89		89	133		133	143		143
Reimbursable:			--			--			--
Total:	89	--	**89**	133	--	**133**	143	--	**143**
Office of Security and Strategic Information									
Direct:	23	2	25	33	2	35	33	2	35
Reimbursable:	1		1	2		2	2		2
Total:	24	2	**26**	35	2	**37**	35	2	**37**
OGA Pandemic Influenza									
Direct:	5		5	5		5	5		5
Reimbursable:			--			--			--
Total:	5	--	**5**	5	--	**5**	5	--	**5**
PHSSEF FTE Total	658	74	**732**	933	74	**1,007**	943	74	**1,017**

DETAIL OF POSITIONS

Public Health and Social Services Emergency Fund	**FY 2018 Final**	**FY 2019 Enacted** /1	**FY 2020 President's Budget** /1
Executive level I	1	1	1
Executive level II	5	6	6
Executive level III	--	--	--
Executive level IV	11	11	11
Executive level V	--	--	--
Subtotal Executive Level Positions	16	17	17
Total - Exec. Level Salaries	**3,196,000**	**3,381,000**	**3,381,000**
ES-6	--	--	--
ES-5	--	--	--
ES-4	--	--	--
ES-3	--	--	--
ES-2	--	--	--
ES-1	1	1	1
Subtotal ES positions	1	1	1
Total - ES Salary	**176,000**	**176,000**	**176,000**
GS-15	160	159	156
GS-14	105	131	144
GS-13	137	147	140
GS-12	111	136	143
GS-11	98	89	94
GS-10	3	2	1
GS-9	38	48	43
GS-8	1	1	1
GS-7	62	51	52
GS-6	--	--	--
GS-5	--	--	--
GS-4	--	--	--
GS-3	--	--	--
GS-2	--	--	--
GS-1	--	--	--
Subtotal	715	764	774
Total - GS Salary	**77,451,153**	**80,736,837**	**82,573,413**
Average ES level	3	3	3
Average ES salary	192,273	192,273	192,273
Average GS grade	13	13	13
Average GS salary	108,323	105,676	106,684
Average Special Pay categories	97,561	99,768	99,936

1/ FY 2019 and FY 2020 levels do not include Strategic National Stockpile positions.