DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2021

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) 2021 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2021 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 2021 budget justification for the Office of the Assistant Secretary for Preparedness and Response (ASPR), Cybersecurity, the Office of National Security (ONS), the Office of Global Affairs pandemic influenza program, and the U.S. Public Health Service Commissioned Corps led by the Office of the Assistant Secretary for Health (OASH).

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 the 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 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 supported by a workforce of up to 6,700 authorized intermittent federal employees organized into 71 teams. Throughout FY 2019, NDMS teams provided public health and medical support for the following: Hurricane Dorian in Florida and Puerto Rico, Presidential State of the Union Address, the National Police Officer Memorial, and the National Independence Day Celebration, United Nations General Assembly, and Representative Elijah Cummings lying in state at the United States Capitol. NDMS teams contain 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. Years of investment have yielded this coordinated response; however more must be done to be able to prepare and respond when disasters strike. To do this, ASPR supports health care coalitions, medical providers, and emergency managers in preparing for incidents that impact medical and public health capabilities. In addition, when an infectious disease outbreak occurs, the public expects immediate access to vaccines, diagnostics, and drugs as was seen during the 2009 H1N1 pandemic and the 2013 Ebola virus epidemic in Africa. However, having these products readily available requires long-range investment in time and funding for the research and development as well as the procurement of highly specialized products. To meet this public demand, protect health, and save lives in the next pandemic or disease epidemic, the federal government must continue to take action and maintain momentum to develop new medical countermeasures – vaccines, drugs, diagnostics, and devices – so they are available immediately when needed. Enhanced partnerships with small and large companies, sustained investments made possible under Project BioShield (PBS), and funding provided for Pandemic Influenza preparedness over the last decade have successfully led to new capabilities and capacities, 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, pandemic influenza, 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 14 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; 16 of these products have been procured for the SNS.

BARDA 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 multipurpose products with commercial indications that meet public needs. This approach increases the sustainability of these medical countermeasures, makes them less dependent on federal government support, and provides alternate mechanisms (e.g., vendor managed inventory systems) to stockpiling in the SNS.

Pandemic Influenza funding supports HHS' efforts to prepare for and respond to a pandemic influenza outbreak. These funds support the development of next-generation antivirals, ongoing activities to promote the development of rapid diagnostic assays for the diagnosis of pandemic influenza, and the accelerated development and production of influenza vaccine worldwide. On September 19, 2019, the White House reaffirmed that we must take deliberate, decisive, and comprehensive action to combat the threat of both seasonal and pandemic influenza with the issuance of an Executive Order "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health." ASPR is proud to have a leadership role in the implementation of many key aspects of that plan. During 2019, BARDA continued to support expansion of domestic manufacturing capacity by issuing a six-year, $226 million contract to increase capacity to produce recombinant influenza vaccine in the United States. In FY 2021, BARDA will continue these efforts to expand manufacturing capacity along with subsequent licensure of pre-pandemic vaccine.

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, the UK and German governments, Bill and Melinda Gates Foundation, and the Wellcome Trust, which aims to identify, build, and manage a portfolio of innovative antibacterial MCMs. As of January 2020, CARB-X has made awards to 53 different companies with six projects that have moved into human clinical trials. CARB-X is currently investing in novel vaccines targeting drug-resistant superbugs, non- traditional approaches to treating bacterial infections, and next-generation antibiotics that overcome known resistance mechanisms. CARB-X has also invested in diagnostic platforms such as rapid point-of-care diagnostics and hospital laboratory-based diagnostics.

To improve America's readiness against national disasters, including naturally or man-made disease threats, the SNS, transferred to ASPR in FY 2019, engages in the procurement, maintenance, and deployment of medical countermeasures. The addition of the SNS to ASPR is improving overall emergency response operations providing health and medical services to communities in need. Efficiencies are being identified across the medical countermeasure enterprise. In coordination with the Public Health Emergency Medical Countermeasures Enterprise, the SNS is implementing strategies to

meet the national priorities for federal stockpiling and to maintain and improve response 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.

HHS and ASPR have made significant progress since ASPR's 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 – Develop a Regional Disaster Health Response System. To address the potential catastrophic medical consequences of 21st century threats, a tiered regional system based on existing local healthcare coalitions and trauma centers is needed. The Regional Disaster Health Response System (RDHRS) will leverage the modernization of the National Disaster Medical System, integrate all medical response capabilities, expand specialty care expertise in trauma and other threat and high risk areas, including pediatrics, and incentivize the healthcare system to integrate measures of preparedness into daily standards of care.

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 53 innovative products to the Food and Drug Administration for approval, including ten in FY 2019 alone. ASPR will continue to develop and maintain a robust stockpile of MCMs capable of responding to 21st century health threats.

The FY 2021 President's Budget for ASPR is $2,550,519,000, which is $116,600,000 below FY 2020 Enacted. The Budget provides:

- $1.1 billion for BARDA, including $562 million for Advanced Research and Development, and $535 million for Project BioShield procurements of MCMs;
- $310 million for pandemic influenza preparedness activities by ASPR and the Office of Global Affairs;
- $705 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;

- $119 million for public health and medical preparedness and emergency operations, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps;
- $15 million for a new Preparedness and Response Innovation (PRI) program that will develop, prototype and procure revolutionary health security products, technologies and other innovations to equip responders to meet the unique needs that result from disasters; and,
- $51 million for ASPR's policy, planning, acquisitions, grants, and financial management; administrative operations; and 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 2021 budget request for Cybersecurity is $67 million, which is $9.233 million above the FY 2020 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 $9 million for ONS, $375,000 above the FY 2020 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 2021 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.

Eric Hargan
HHS Deputy Secretary

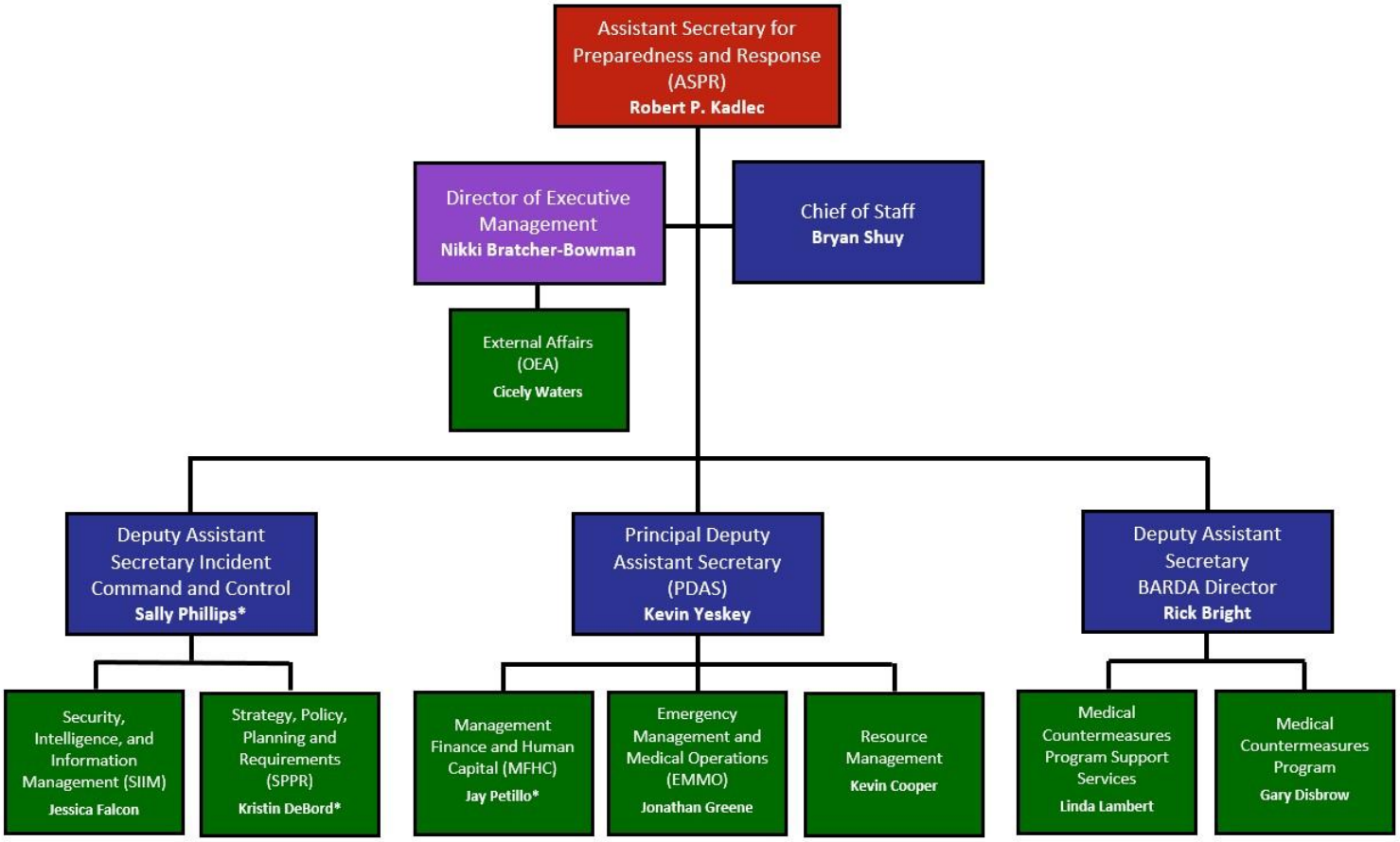
Robert P. Kadlec
Assistant Secretary for Preparedness and Response, Ph.D.

Janet Vogel
HHS Chief Information Security Officer

Michael Schmoyer
Assistant Deputy Secretary for National Security, Ph.D.

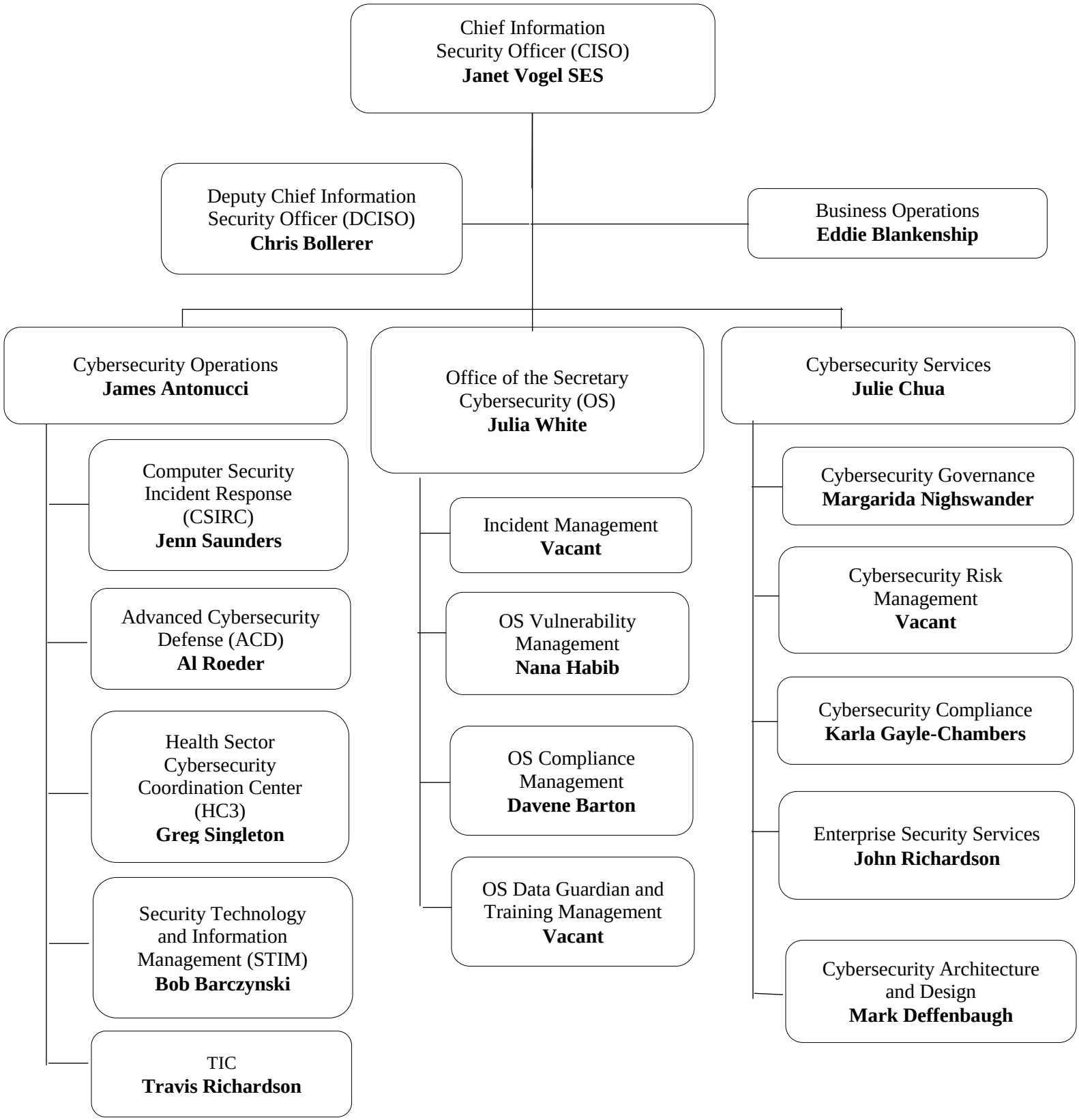
ORGANIZATION CHARTS

Assistant Secretary for Preparedness and Response

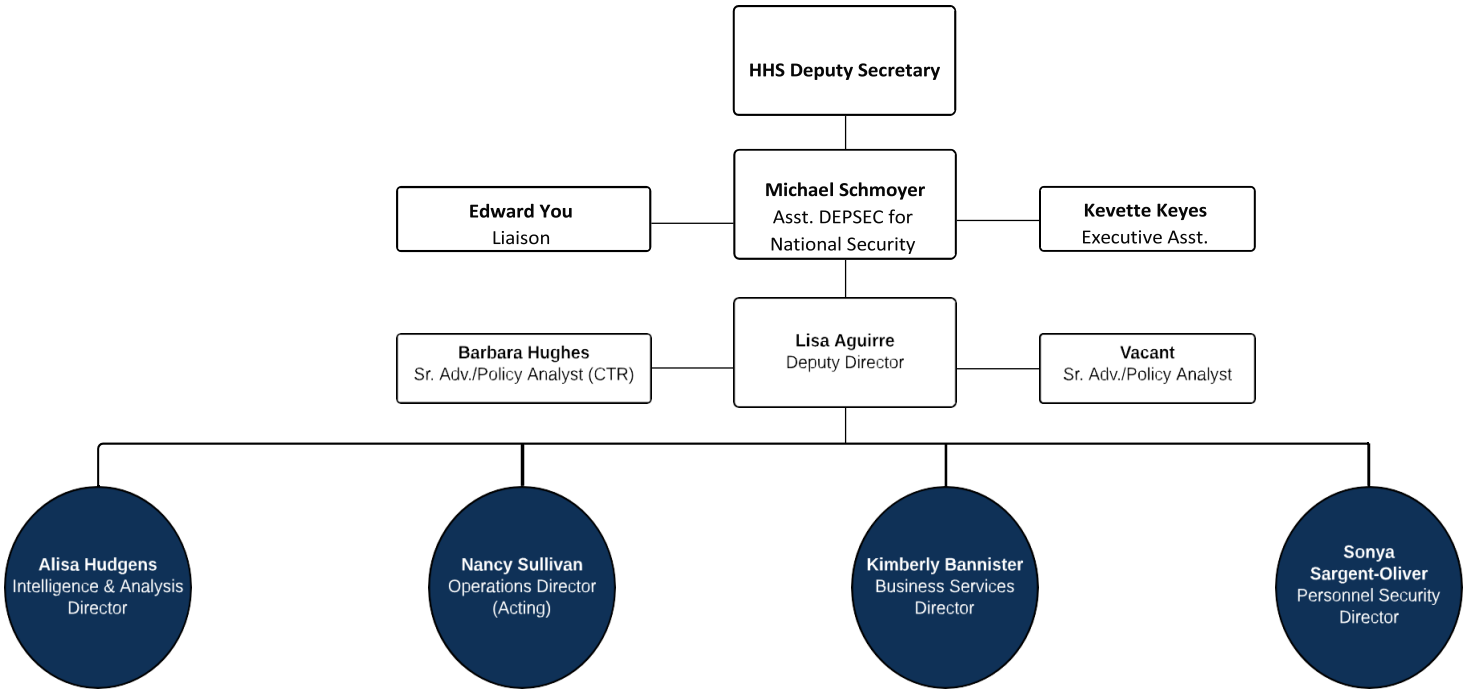


*Acting Office Directors

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's (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, radiological, and nuclear (CBRN) agents. ASPR coordinates across HHS and the Federal interagency to support state, local, territorial, and tribal health (SLTT) partners in preparing for and responding to emergencies and disasters.

The ASPR serves as the principal advisor to the Secretary of HHS on public health and medical emergency preparedness and response, including incidents covered by the National Response Framework (NRF). ASPR takes a collaborative approach to the Department's preparedness, response, and recovery responsibilities by working with HHS Operational Divisions and Staff Divisions 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 emergencies and disasters.

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 (ASA), Office of the Chief Information Officer (OCIO), coordinates the Department's cybersecurity efforts and provides program management and oversight. The program works to ensure that the automated information systems are designed, operated, and maintained with the appropriate information technology security and privacy data protections.

Office of National Security:

The Office of National Security provides strategic information and intelligence for the Department as well as physical and personnel security policy, security awareness, classified information communications security, and related medical, public health, and biomedical information matters.

U.S. Public Health Service Commissioned Corps:

The United States Public Health Service Commissioned Corps (Corps) is a cadre of approximately 6,400 full-time officers dedicated to promoting and advancing public health and disease prevention programs. As one of America's seven uniformed services, the Corps fills essential public health leadership and service roles within the Nation's Federal Government agencies and programs.

Officers serve as physicians, nurses, pharmacists, dentists, dietitians, engineers, environmental health officers, health service officers, scientists, therapists, and veterinarians. In addition to their regular duties such as providing patient care to underserved populations or conducting biomedical research, Corps officers respond to public health crises, natural disasters, disease outbreaks, and terrorist attacks and serve on humanitarian assistance missions around the world. To protect the health of the American people for

the next century, the Corps has engaged in an historic modernization initiative that will transform its force structure and ensure its readiness in order to meet the full spectrum of public health challenges facing the nation.

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 2021 President's Budget Request for the Public Health and Social Services Emergency Fund (PHSSEF) is $2,641,465,000, which is a decrease of $95,993,000 relative to the FY 2020 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;
- Support the Department's pandemic influenza preparedness and response activities; and
- Support U.S. Public Health Service Commissioned Corps training and deployments.

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

Programmatic Increases (relative to FY 2020 Enacted):

Pandemic Influenza (PI) (increase of +$50 million, $310 million total): The requested resources will be used to sustain previous investments in critical domestic influenza vaccine manufacturing facility capacity, ensure that influenza vaccines can be produced to deploy an effective pandemic response, and maintain overall domestic pandemic readiness. Funding will also address functional and design gaps in current respiratory capabilities along with advancing infrastructure and facility readiness. These efforts will support the Presidential Executive Order released in September 2019.

National Disaster Medical System (NDMS) (increase of +$31 million, $88.404 million total): The request includes +$20,000,000 for pediatric disaster care, +$5,000,000 for sustainment of portable dialysis unit leases, maintenance, consumables, and user instruction; +$5,000,000 for responder training to increase the number of responders trained annually and the proficiency of responders in additional technical fields including highly infectious diseases and patient transport; and +$1,000,000 for emPOWER to support critical services to federal-to-community level awareness, adoption, implementation and use of critical data, maps, artificial intelligence and other innovative tools, informational resources, and new tech platforms. The request also 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, modernized equipment sets, and the pediatric disaster care program pilot.

Preparedness and Response Innovation (PRI) (increase of +$15 million, $15 million total): The request includes funding for a new program supporting two projects: portable/in-home dialysis care ($6,000,000) and the manufacture of sterile saline on demand ($9,000,000). This will include conducting research and development on portable dialysis platforms that can create dialysate from potable water sources and ensure the safety of patients using the technology at home or in a temporary outpatient care facility. The program will fabricate and demonstrate a prototype that extends the capabilities of the next-generation home hemodialysis systems under evaluation by the Food and Drug Administration (FDA). Additionally, the PRI program will engineer demonstration units and perform multiple demonstrations and begin transition activities of prototype units. The program will also begin validation of sterile saline on-demand technologies.

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.

Preparedness and Emergency Operations (PEO) (increase of +$2.5 million, $27.154 million total): The request supports preparedness and response efforts to public health and medical emergencies and a robust and continuous training and exercise program. The increase provides +$1,300,000 to establish an Insider Threat Program, +$600,000 for additional Secretary's Operation's Center (SOC) staff to meet requirements of the new Incident Response Framework, and +$600,000 for infrastructure and technology improvements to ensure the readiness of the primary HHS Continuity of Operations (COOP) site and its synchronization with the SOC. This request also includes $5,000,000 in three-year funding to prepare for, and respond to, National Special Security Events (NSSEs), public health emergencies, and other events that are not eligible for assistance under the Stafford Act.

Cybersecurity (increase of +$9.233 million, $67.053 million total): The requested resources will increase and invest in the Department's protections against cyber threats, such as unauthorized access, denial of service, malicious code, and data automation, services, and data.

Office of National Security (ONS) (increase of +$0.374 million, $8.884 million total): The requested resources will enhance the ability of ONS to safeguard classified national security information and provide intelligence and national security support to the Secretary, senior policy makers, and consumers of intelligence across the Department.

Assistant Secretary for Health (increase of +$11 million, $11 million total): The request includes +$10,000,000 to support the development of an integrated program and deployment of U.S. Public Health Service Commissioned Corps (Corps) officers to provide services or assistance to unsheltered homeless individuals in impacted cities. The request also includes +$1,000,000 to support a readiness and training program for the Corps to prepare for complex missions both domestically and internationally.

Programmatic Decreases (relative to FY 2020 Enacted):

Project BioShield (PBS) (decrease of -$200 million, $535 million total): The request will support continued development and procurement of 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. The request reflects Congress' forward-funding of procurement of Ebola countermeasures via emergency supplemental funding in FY 2020.

Hospital Preparedness Program (HPP) (decrease of -$18 million, $257.555 million total): The request supports $231,500,000 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 contribute to the mission of HPP, including the Technical Resources, Assistance Center, and Information Exchange (TRACIE), Emergency Care Coordination Center (ECCC), the Recovery program, the Critical Infrastructure Protection (CIP) program, as well as HPP administration, and performance evaluation and oversight.

Medical Reserve Corps (MRC) (decrease of -$2.1 million, $3.9 million total): The request supports 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. ASPR will leverage its existing programs and infrastructure, along with these changes, to yield efficiencies, savings, and a more effective MRC program.

OVERVIEW OF PERFORMANCE

ASPR's 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 is actively engaged in HHS Enterprise Risk Management (ERM) efforts. ASPR uses an evidence-based approach that pursues the integration of performance management with ERM.

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, thus 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.

The use of the best available evidence and ASPR's own performance data to promote ongoing improvements is critical because 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). For ESF 8, ASPR has a vital role in fulfilling HHS responsibilities for responding to, recovering from, and mitigating the lasting impacts of public health and medical emergencies. ASPR also supports HHS' role in the delivery of Federal mass care, emergency assistance, housing, and human services when local, tribal, and State response and recovery needs exceed existing capabilities, under ESF 6. Through the 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, Local, Tribal, and Territorial areas (SLTT).

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 countermeasure (MCMs), and funding evaluation and research.

ASPR sets strategic direction, with interagency partners, through the development and implementation of the National Health Security Strategy (NHSS). To addresses health security threats, ASPR is coordinating the implementation of the National Biodefense Strategy (NBS) with other agencies that have responsibilities or capabilities pertaining to biodefense. This includes providing leadership as Director of the Biodefense Coordination Team and assisting the cabinet level Biodefense Steering Committee (chaired by the HHS Secretary) in implementation of the strategy. In this role, ASPR continues to support the implementation of the NBS's goals to strengthen the biodefense enterprise through enabling risk awareness to inform decision-making across the enterprise; ensuring biodefense enterprise capabilities to prevent bioincidents; ensuring biodefense enterprise preparedness to reduce bioincidents impacts; rapidly responding to limit bioincidents impact; and facilitating recovery to restore the community, economy, and environment after a bioincident.

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. In contribution to these objectives, ASPR data has shown that 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. ASPR has contributed to the persistent need for approved influenza antiviral drugs indicated for use in severely ill and hospitalized patients.

During FY 2019, ASPR supported HHS Strategic Plan Objective 2.2 by completion of six BARDA-supported products that 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. This result exceeded the target. In support of HHS Strategic Plan Objective 2.4, ASPR increased the number of new licensed MCMs across BARDA programs by seven new MCMs, which also exceeded the target.

Aligning ASPR's Performance with National Priorities

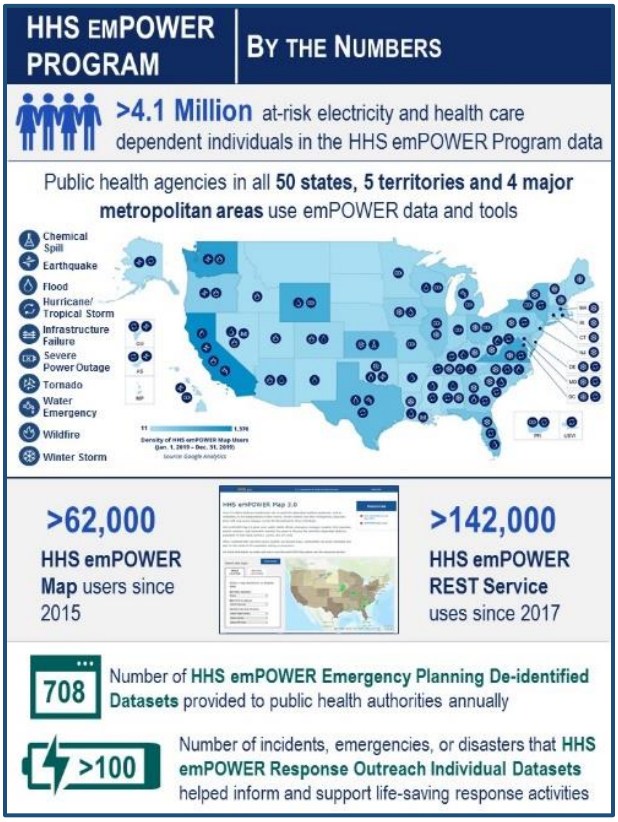
BARDA's priorities include helping to meet the requirements of a new Executive Order (EO) called Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, signed by President Trump on September 19, 2019. Because influenza is a very serious threat to human health and poses a significant national security risk, it leads to hundreds of thousands of hospitalizations, placing a significant strain on our healthcare system. A pandemic influenza outbreak would be even worse, costing up to $3.79 trillion dollars. Mitigating the impact of both seasonal and pandemic influenza is critical to saving lives and reducing economic and healthcare burdens. To mitigate such risks, the EO requires accelerated vaccine development with expanded domestic manufacturing. Consistent with the EO, ASPR promotes the modernization of facilities and infrastructure in ways that expand the domestic manufacturing capacity for non-egg based vaccines and adjuvants. ASPR is dedicated to advancing the development of broad-acting antivirals, transition to near-patient or in-home diagnostics, and addressing gaps in capabilities.

HHS Agency Priority Goals (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. During 2018 – 2019, ASPR partnered with the Centers for Disease Control and Prevention (CDC) to lead the HHS APG on Health Security. When this APG successfully concluded, there were demonstrated increases in the capacity to prevent health threats impacting the United States. During 2020-2021, ASPR contributes to the APG focusing on Kidney Care.

As part of the NBS and NHSS efforts, ASPR coordinates the implementation of the National Security Presidential Memorandum. This includes focusing on threats and consequences as well as addressing biological risk management. In the FY 2021 President's Budget, ASPR includes new performance measures designed to effectively and advance quickly these important focus areas. The new quantitative performance measures related to implementation of the NBS and the NHSS replace previous more difficult to analyze, qualitative measures.

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 an SLTT or other 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 supports the development and sustainment of health care coalitions (HCCs). ASPR encourages diverse organizations to work together through the HCCs as one means of making sure that communities are ready to respond during emergencies. For 2018, over 98 percent of HCCs tested the ability to coordinate among their members during an exercise or event. During 2019, 100 percent of new intermittent staff within the National Disaster Medical System had completed psychological first aid training. This assures that an evidence-informed approach helps children, adolescents, adults, and families in the immediate aftermath of disaster and terrorism.

The HHS emPOWER Program, provides dynamic data and mapping tools, informational resources, training and real-time technical assistance to support federal and SLTT public health authorities, and their community partners, as they protect the health of more than 4.1 million individuals who live independently and rely on life-maintaining and assistive electricity-dependent medical and assistive equipment, including ventilators, oxygen concentrators, wheelchairs and also health care services, such as dialysis, home oxygen, and home health.

The HHS emPOWER Program harnesses the power of federal health data, artificial intelligence and federal-to-community level partnerships. By leveraging Medicare data, emPOWER provides first responders, emergency managers, health care providers/coalitions, aging agencies, public utilities with data driven tools that provide situational awareness, advance readiness and information and support response activities across ten emergency support functions. In 2019, emPOWER launched its first free and publicly available "HHS emPOWER Program Web-Based Training" that provides comprehensive information on the tools and featured partner and stakeholder case studies of how they used the data in different responses during different types of responses spanning 2016-2018. emPOWER also continues to advance the "emPOWERing State Medicaid and CHIP Data Pilot" that provides voluntary training to states and territories to build partnerships and develop complementary datasets that will provide critical pediatric and other adult at-risk population data that are only available in their state-operated Medicaid and Child Health Insurance Programs. Bringing these capabilities and tools together, ASPR has further advanced federal to community level responders abilities to rapidly anticipate needs, take action to support at-risk populations, mitigate potential healthcare system surge, provide safe alternate options, and conduct life-saving assistance and outreach. During the 2017 hurricanes, emPOWER data helped emergency responders to rapidly locate and conduct life-saving evacuations of more than 200 dialysis patients in the U.S. Virgin Islands to ensure continuity of care. From local to federal disasters, emPOWER data has informed critical emergency response planning, supported life-saving outreach activities and aided in reconstitution of critical outpatient oxygen, dialysis and medical equipment supplier services to healthcare-dependent individuals during the 2018-2019 historic wild fires, mudslides, hurricanes, critical infrastructure failures, and other severe weather events.

Within ASPR's Pandemic Influenza (PI) program, during 2019, ASPR continues to assure production of 600 million doses of vaccine antigen within six months of a candidate vaccine virus being delivered to manufacturers. If all goes well, this closely approximates being able to produce 600 million doses of vaccine antigen within six months from the onset of an influenza pandemic.

In FY 2019, six advanced research and development initiatives were completed in support of 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. ASPR fostered development of the first cell-based influenza vaccine in the country. Since 2009, the PI program has supported the first recombinant-based vaccine for seasonal influenza licensed in the United States. This recombinant vaccine technology offers the shortest time to first dose delivered in response to an outbreak or pandemic. ASPR's investments in the domestic manufacturing capacity of vaccines in cell culture eliminates the vulnerability of current egg-based pandemic vaccines, which depend upon egg supplies. During 2018, ASPR received regulatory approval that increases cell-based vaccine production two-to-three fold. Also during 2018, the PI program supported efforts to improve fill/finish production processes, allowing more vaccine to be available in a shorter time. These efforts are critical to ensuring rapid vaccine production response capability. During FY 2019, the PI program initiated efforts to expand domestic manufacturing capacity for the recombinant influenza vaccine technology. These efforts will continue in FY 2020 and 2021.

Performance Management Challenges

The complexity of some areas addressed by ASPR requires clear communication of performance data in order to promote ongoing improvements. To achieve ongoing improvements, data must be understood when it is analyzed and fed back to those who use it. Clear communication helps to advance the policies associated with complex areas of science.

ASPR's Strategic National Stockpile (SNS) manages and delivers life-saving MCMs during a public health emergency. The management of the SNS aligns with ASPR's broad ESF 8 mission. It is the largest federally owned repository of pharmaceuticals, critical medical supplies, and medical equipment available for rapid delivery to support SLTT response to health security threats. If a CBRN event occurred on United States soil today, the SNS is the only federal resource readily available to respond once SLTT MCM supplies are depleted. In addition to transferring the existing performance measures used by the CDC, ASPR has added two new additional performance measures. The measures add support to ASPR's data analysis and improvement efforts. The SNS makes meaningful investments in strategic procurement and stockpiling of the MCMs necessary to protect Americans' health and save lives. Additional SNS resources will allow ASPR to replace expiring MCMs during FY 2021. This includes replenishment of Project BioShield products for transition to SNS and "last mile" distribution of MCMs at the community level. ASPR will use data from existing and new SNS metrics to analyze and improve the use of resources used to manage and deliver life-saving MCMs during a public health emergency.

Influenza provides a snapshot into the performance management challenges faced when the mission is complex. For example, it is hard to measure meaningfully the outcomes underlying modernization of the domestic influenza vaccine enterprise needed to replace reliance on egg-based influenza vaccine production or licensure of a universal vaccine that relies on rapid technology advancement. As additional resources are invested in FY 2021, ASPR will advance measurement of the activities designed to improve advanced research and manufacturing capabilities. Analysis and feedback of performance data helps ASPR to understand and develop ways to improve the delivery of vaccines faster in the event of a pandemic.

The Potential Impact of Resource Changes

The impact of the resources requested by ASPR for FY 2021 will facilitate the comprehensive programs needed to prepare for, and respond to, the health and medical consequences of bioterrorism and preparedness and response activities. The results will strengthen the nation's critical domestic influenza pre-pandemic vaccine manufacturing infrastructure, ensuring that pre-pandemic influenza vaccines and therapeutics can be produced to deploy an effective pandemic response, and maintaining overall domestic pre-pandemic readiness. The impact of increased funding for ASPR includes the advanced development of the highest priority MCMs for pandemic influenza as well as the preparedness of ASPR's response assets.

ALL PURPOSE TABLE

(Dollars in Millions)

Program	FY 2019 Final	FY 2020 Enacted /1	FY 2021 President's Budget	FY 2021 +/- FY 2020 Enacted
Assistant Secretary for Preparedness and Response (ASPR):				
Preparedness and Emergency Operations	24.654	24.654	27.154	+2.500
National Special Security Events (NSSE) (non-add)	*5.000*	*5.000*	*5.000*	--
National Disaster Medical System (NDMS)	73.404	57.404	88.404	+31.000
Pediatric Disaster Care (non-add)	--	--	*20.000*	*+20.000*
Prevention and Public Health Funds (non-add)	*16.000*	--	--	--
Hospital Preparedness Program	264.555	275.555	257.555	-18.000
Medical Reserve Corps	6.000	6.000	3.900	-2.100
Preparedness and Response Innovation	--	--	15.000	+15.000
Biomedical Advanced Research and Development Authority (BARDA)	561.700	561.700	561.700	--
Advanced Research and Development (non-add)	*501.700*	*501.700*	*476.700*	*-25.000*
Operations and Management (non-add)	*60.000*	*60.000*	*85.000*	*+25.000*
Project BioShield /2	735.000	735.000	535.000	-200.000
Strategic National Stockpile (SNS) /3	603.900	705.000	705.000	--
Pediatric Disaster Care (non-add)	--	--	*10.000*	*+10.000*
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	225.000	225.000	275.000	+50.000
Annual Pandemic Influenza	30.991	30.991	30.991	--
Subtotal, ASPR Pandemic Influenza	255.991	255.991	305.991	+50.000
Subtotal, ASPR Program Level	**2,571.019**	**2,667.119**	**2,550.519**	**-116.600**
Subtotal, ASPR Budget Authority	*2,555.019*	*2,667.119*	*2,550.519*	*-116.600*
Subtotal, ASPR Prevention and Public Health Funds	*16.000*	--	--	--
Other Office of the Secretary:				
Office of Global Affairs (OGA) Annual Pandemic Influenza	4.009	4.009	4.009	--
Cybersecurity /4	8.510	8.510	8.884	+0.374
Office of National Security (ONS) /4	57.820	57.820	67.053	+9.233
Office of the Assistant Secretary for Health (OASH)	--	--	11.000	+11.000
Homelessness (non-add)	--	--	*10.000*	*+10.000*
Commissioned Corps Readiness Training (non-add)	--	--	*1.000*	*+1.000*
Subtotal, Other Office of the Secretary	**70.339**	**70.339**	**90.946**	**+20.607**
PHSSEF Total:				
HHS Pandemic Influenza Budget Authority	260.000	260.000	310.000	+50.000
No-Year Pandemic Influenza (non-add)	*225.000*	*225.000*	*275.000*	*+50.000*
Annual Pandemic Influenza (non-add)	*35.000*	*35.000*	*35.000*	--
All Other Budget Authority	2,365.358	2,477.458	2,331.465	-145.993
Total, PHSSEF Program Level	**2,641.358**	**2,737.458**	**2,641.465**	**-95.993**
Total Prevention and Public Health Funds	*16.000*	--	--	--
Total, PHSSEF, Budget Authority	***2,625.358***	***2,737.458***	***2,641.465***	***-95.993***
NEF				
Cybersecurity	34.000	--	--	--
FTE				
ASPR	837	837	854	*+17*
OGA	5	5	5	--
Cybersecurity	90	133	143	*+10*
ONS	26	37	37	--
OASH	--	--	--	--
Total FTE, PHSSEF	**958**	**1,012**	**1,039**	**+27**

1/ Excludes supplemental appropriations for procurement of Ebola vaccines, therapeutics, and diagnostics ($535 million).

2/ In addition to BioShield funds, a total of $200 milllion from emergency supplemental Ebola funding appropriated in FY 2020 will be available to procure medical countermeasures in FY 2021.

3/ Transferred administratively from CDC to ASPR in FY 2019. Reflects a FY 2019 Secretarial transfer of $6.1 million to CDC for transition costs.

4/ Reflects a realignment of $1.04 million from Cybersecurity to ONS to support the cyber threat activities carried out by ONS.

APPROPRIATIONS LANGUAGE

FY 2021 Proposed Appropriations Language

(Relative to FY 2020 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, [$1,037,458,000]*$1,081,465,000*, of which $561,700,000 shall remain available through September 30, [2021]*2022*, 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, [2022]*2023: Provided further, That $20,000,000 of the amounts made available to the National Disaster Medical System shall remain available through September 30, 2022, 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]*$535,000,000*, to remain available until expended.

For expenses necessary to carry out section 319F-2(a) of the PHS Act, $705,000,000, to remain available until expended.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic, [$260,000,000]*$310,000,000*; of which [$225,000,000]*$275,000,000* 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.

For an additional amount to supplement amounts otherwise available for programs in the Department to provide authorized assistance or services to individuals who are homeless or who have experienced homelessness, $10,000,000: Provided, That such funds may be transferred to other accounts in the Department for such purposes: Provided further, That the transfer authority provided in the previous proviso is in addition to any other transfer authority available to the Department of Health and Human Services.

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, 2022, 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 an additional amount to supplement amounts otherwise available for programs in the Department to provide authorized assistance or services to individuals who are homeless or who have experienced homelessness, $10,000,000: Provided, That such funds may be transferred to other accounts in the Department for such purposes: Provided further, That the transfer authority provided in the previous proviso is in addition to any other transfer authority available to the Department of Health and Human Services.	This language appropriates $10,000,000 to assist homeless individuals under authorized programs. This amount would supplement other amounts in the Department that could be used for this purpose and would be available to transfer to other accounts in the Department.

AMOUNTS AVAILABLE FOR OBLIGATION

Detail	FY 2019 Final /1 /2	FY 2020 Enacted	FY 2021 President's Budget
Appropriation	2,021,458,000	2,737,458,000	2,641,465,000
Supplemental (P.L. 116-94)		535,000,000	
Subtotal, Adjusted Appropriation	**2,021,458,000**	**3,272,458,000**	**2,641,465,000**
Transfer of Funds from: ("CDC Public Health Preparedness and Response")	603,900,000		
Subtotal, Adjusted Budget Authority	**2,625,358,000**	**3,272,458,000**	**2,641,465,000**
Unobligated balance, start of year	439,145,924	695,908,088	
Unobligated balance, end of year	695,908,088		
Unobligated balance, lapsing	22,897,755		
Unobligated balance transferred from: ("CDC Public Health Preparedness and Response")	474,337,852		
Unobligated balance transferred from: ("Prevention and Public Health Fund")	16,000,000		
Total obligations	**2,809,117,731**		

1/ "Excludes the following amounts for reimbursable activities carried out by this account:
2019 $91,084,533

2/ FY 2019 funding for the Strategic National Stockpile was administratively transferred from CDC to ASPR. The FY 2019 Final level reflects a Secretarial transfer of $6.1 million to CDC for transition costs.

SUMMARY OF CHANGES

(Dollars in Millions)

2020 Enacted	
Total budget authority	2,737.458
2021 President's Budget	
Total estimated budget authority	2,641.465
Net Change	-95.993

	FY 2020 BA	FY 2020 FTE	FY 2021 PB BA	FY 2021 PB FTE	FY 2021 +/- FY 2020 BA	FY 2021 +/- FY 2020 FTE
Increases:						
Assistant Secretary for Preparedness and Response						
Preparedness and Emergency Operations	24.654	86	27.154	90	+2.500	+4
National Disaster Medical System	57.404	115	88.404	117	+31.000	+2
Preparedness and Response Innovation	0.000	0	15.000	6	+15.000	+6
Policy and Planning	14.877	66	19.877	71	+5.000	+5
Pandemic Influenza	255.991	--	305.991	--	+50.000	--
Office of National Security	8.510	37	8.884	37	+0.374	--
Cybersecurity	57.820	133	67.053	143	+9.233	+10
Office of the Assistant Secretary for Health	--	--	11.000	--	+11.000	--
Total Increases	419.256	437	543.363	464	+124.107	+27
Decreases:						
Assistant Secretary for Preparedness and Response						
Hospital Preparedness Program (HPP)	275.555	49	257.555	49	-18.000	--
Medical Reserve Corps (MRC)	6.000	6	3.900	6	-2.100	--
Project BioShield	735.000	--	535.000	--	-200.000	--
Total Decreases	1016.555	55	796.455	55	-220.100	--
Net Change					-95.993	+27

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Millions)

Activity	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Bioterrorism and Emergency Preparedness	2,365.358	2,477.458	2,331.465
Pandemic Influenza	260.000	260.000	310.000
Total Budget Authority	**2,625.358**	**2,737.458**	**2,641.465**
FTE	**958**	**1,012**	**1,039**

1/ FY 2019 funding for the Strategic National Stockpile was administratively transferred from CDC to ASPR. The FY 2019 Final level reflects a Secretarial transfer of $6.1 million to CDC for transition costs.

AUTHORIZING LEGISLATION

(Dollars in Millions)

Activity	FY 2020 Amount Authorized	FY 2020 Amount Appropriated	FY 2021 Amount Authorized	FY 2021 President's Budget
National Disaster Medical System	57.400	57.404	57.400	88.404
Hospital Preparedness Program	385.000	275.555	385.000	257.555
Medical Reserve Corps	11.200	6.000	11.200	3.900
BARDA	611.700	561.700	611.700	561.700
Project BioShield	710.000	735.000	710.000	535.000
Strategic National Stockpile	610.000	705.000	610.000	705.000
Pandemic Influenza	250.000	260.000	250.000	310.000

APPROPRIATIONS HISTORY

(Dollars in millions)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
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 (PL 113-235)				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				
Appropriation	2,666.591	3,008.458	2,642.458	2,737.458
Supplemental Appropriation (PL 116-94)				535.000
FY 2021				
Estimated Appropriation				2,641.465

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 2020
ASPR Preparedness and Emergency Operations	N/A	N/A	N/A	24.654
ASPR Policy and Planning	N/A	N/A	N/A	14.877
ASPR Operations	N/A	N/A	N/A	30.938
Cybersecurity	N/A	N/A	N/A	57.820
Office of National Security	N/A	N/A	N/A	8.510
OASH - Homelessness and Corps Training	N/A	N/A	N/A	--

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Summary of Request

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final /2	**Enacted**	**President's Budget**	**FY 2021 +/- FY 2020**
Program Level /1	**2,571.019**	**2,667.119**	**2,550.519**	**-116.600**
Budget Authority (non-add)	*2,555.019*	*2,667.119*	*2,550.519*	*-116.600*
Prevention and Public Health Funds (non-add)	*16.000*	--	--	--
FTE	**837**	**837**	**854**	**+17**

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 2019 total reflects a Secretarial transfer of $6.1 million from the SNS budget to CDC.

The Fiscal Year (FY) 2021 President's Budget for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is $2,550,519,000, which is a decrease of -$116,600,000 below FY 2020 Enacted. ASPR's goal for FY 2021 is to maintain preparedness and achieve new successes in public health emergency management. The FY 2021 budget proposes funding targeted increases along with strategic reductions, which will contribute significantly to advances in public health emergency management.

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 14 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; 16 of these products have been procured for the Strategic National Stockpile (SNS), with additional products to be delivered in FY 2020 and 2021.

In FY 2021, ASPR also seeks to establish an advanced research and development program called Preparedness and Response Innovation (PRI) that focuses on emerging technologies that are not medical countermeasures and work to improve ASPR response capabilities. These technologies, such as portable in-home dialysis platforms, and on-demand sterile saline production have the potential to dramatically improve health outcomes for patients during a public health emergency. Development of these technologies also aligns with the Secretary's kidney care initiative where these projects are called out as

specific goals. They are seen as a novel way to establish the right patient and product baselines to meet the Secretary's goals of improving access to end-stage renal disease (ESRD) treatment options, with the eventual goal of having 80 percent of ESRD patients receiving in-home dialysis. Additionally, ASPR's Priority Medicines on Demand initiative would enable distributed critical medicine production in emergency situations and aligns with the Secretary's goal to reduce prescription drug prices and increase drug availability in the United States. Currently, there is no cross-cutting advanced development and transition program within ASPR outside of medical countermeasure development. Establishing an individual funding line signals the importance of ASPR's mission in developing technologies beyond medical countermeasures and adapting these technologies and practical solutions to ensure the availability of the highest standards of care for emergency response and preparedness, when they are needed the most.

ASPR continues to dedicate efforts and resources towards the Ebola and Zika viruses. For FY 2021, ASPR will continue to develop and procure next-generation anthrax vaccines, new antimicrobial drugs, chemical agent MCMs, a new product to temporize burn injury, and a new radiation MCM. Funding will continue to 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. 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.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019 requires a review of the National Disaster Medical System (NDMS) and an assessment of the medical surge capacity relating to the availability of healthcare workforce for both a widespread and multiple public health emergencies at one time. PAHPAIA also requires the Secretary of HHS to notify Congress when the NDMS workforce is insufficient to address a public health emergency and to include information on the effect such insufficiencies will have and potential ways to address the issue. New authorities are also provided to allow for faster recruitment of NDMS to decrease the shortage in the health care emergency response workforce. NDMS has worked to increase its intermittent employee workforce towards the goal of over 6,700 personnel organized into 71 teams. ASPR currently has over 4,600 deployable personnel for NDMS, logistics response and incident management.

Through the use of emergency supplemental funding provided to respond to Ebola after the 2015 outbreak in West Africa and separately to the 2017 hurricanes in the Gulf of Mexico and Caribbean Sea, ASPR has augmented it training program to include specialty care curriculum for response to highly infectious diseases and aeromedical evacuation and transport treatment. These supplemental funds will no longer be available after FY 2020 and have supported salaries and travel of intermittent personnel training, as well as cache replenishment of materiel used in training and for contracts to curriculum providers. In addition, these funds supported training nearly 1,000 new intermittent responders. ASPR anticipates that another 2,000 new staff that will require training over a three year period. The President's Budget provides secure, predictable funding for these critical needs.

emPOWER provides public health agencies and their partners with Medicare datasets, mapping tools, training, and technical assistance to protect the health of more than 4.1 million individuals who live independently and rely on life-maintaining electricity-dependent equipment (including ventilators) and healthcare services (such as dialysis and oxygen). Over 53,500 individuals have used the public HHS emPOWER Map to help communities address electricity-dependency needs. emPOWER's planning and just-in-time emergency datasets have helped responders to anticipate, plan for, respond to, and conduct life-saving outreach in over 100 local to federal emergencies. emPOWER also provides voluntary training to states and territories to help them develop state Medicaid datasets to protect at-risk children and adults.

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. Supported by the President's Budget, HPP would work with a national-level expert in this area to define appropriate and timely requirements for all health data management and sharing systems funded by the cooperative agreements and publish a standard set of essential elements of information that would augment the ability to share data across disparate networks. HPP would use this level of funding to provide grants to the current cooperative agreement recipients to begin the process of updating existing technologies and/or purchasing new software to meet these requirements.

Increases above the FY 2020 Enacted level:

Pandemic Influenza (PI): The budget requests $310,000,000, which is +$50,000,000 above the FY 2020 Enacted level. The additional resources will be used to expand domestic manufacturing for non-egg based vaccines and adjuvants, modernize vaccine technology in ways that decrease manufacturing timelines, develop broad-acting antivirals, and transition diagnostics to home-based. Functional and design gaps in current respiratory capabilities will be addressed. Infrastructure and facility readiness will advance.

Preparedness and Response Innovation (PRI): The budget requests $15,000,000, which is +$15,000,000 above the FY 2020 Enacted level, to support two projects: portable/in-home dialysis care ($6,000,000) and the manufacture of sterile saline on demand ($9,000,000). This will include conducting research and development on portable dialysis platforms that can create dialysate from potable water sources and ensure the safety of patients using the technology at home or in a temporary outpatient care facility. The program will fabricate and demonstrate a prototype that extends the capabilities of the next-generation home hemodialysis systems under evaluation by the FDA. Additionally, the PRI program will engineer demonstration units and perform multiple demonstrations and begin transition activities of prototype units. The program will also begin validation of sterile saline on-demand technologies, to include the build-out of one modular GMP facility, establishment of analytical capabilities and cGMP protocol design.

National Disaster Medical System (NDMS): The budget requests $88,404,000 for NDMS, which is +$31,000,000 above the FY 2020 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 $31,000,000 increase in requested funding will continue a pediatric disaster care pilot program and provide funding for portable dialysis sustainment, training, and the emPOWER program.

Preparedness and Emergency Operations (PEO): The budget requests $27,154,000, which is +$2,500,000 above the FY 2020 Enacted level. The increase provides +$1,300,000 to support risk assessors and information specialists to establish an Insider Threat Program, +$600,000 for SOC staffing to meet requirements of the new Incident Response Framework, and +$600,000 for infrastructure and technology improvements to ensure the readiness of the primary HHS COOP site and its synchronization with the SOC. Additionally, the request supports preparedness and response efforts to public health and medical emergencies, a robust and continuous training and exercise program. It also includes $5 million for National Special Security Events.

Policy and Planning: The budget requests $19,877,000, which is +$5,000,000 above the FY 2020 Enacted level. The increase provides +$5,000,000 to support ASPR's coordination, implementation, and assessment of the National Biodefense Strategy (NBS). ASPR will continue to implement the NBS, which sets the course for the United States to combat the serious bio-threats our country faces, whether they arise from natural outbreaks of disease, accidents involving high consequence pathogens, or the actions of terrorists or state actors. The request includes support management of the Biodefense Coordination Team and Biodefense Steering Committee, enhanced data analytic services, and build capacity to convene and coordinate with Federal partners. Implementing the NBS will strengthen our ability to anticipate, prevent, prepare for, respond to, and recover from biological incidents.

Preparedness and Emergency Operations

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**24.654**	**24.654**	**27.154**	**+2.500**
National Special Security Events/ Public Health Emergencies (non-add)	*5.000*	*5.000*	*5.000*	--
FTE	**86**	**86**	**90**	**+4**

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 Assistant Secretary for Preparedness and Response (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 other federal and State, Local, Tribal, and Territorial (SLTT) 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 (PEO) 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 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 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 those 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. 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 FY 2018, ASPR provided support to California during the devastating wildfires near Chico. 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.

ASPR provided response and recovery support to communities impacted by hurricanes Harvey, Irma, and Maria. Over 4,800 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 across 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 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. 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). 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 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.

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 Federal ESF 8 response missions. ASPR is updating HHS's 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 response phase. 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 the Federal Emergency Management Agency (FEMA), the development of several Incident Annexes focusing on biological events; power outage; food and agriculture; nuclear radiation; and federal evacuation incidents. ASPR also collaborated with FEMA and other interagency partners in 2018 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 CBRN 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 coordinates both the event and contingency support, and manages the alerting and deployment of over 500 disaster medical response personnel on average.

ASPR has developed an internal contingency planning capability to quickly develop operational plans to address real-time threats that must be rapidly implemented ahead of the traditional planning cycle. The biggest challenge facing ASPR today is keeping up, and quickly responding, to changing threats. Where a static planning process forces a compromise between getting a plan right and getting it done, the adaptive planning process has enabled ASPR to quickly plan and adapt without compromise. Adaptive planning allows ASPR to quickly develop requirements to facilitate continuous budget planning and rolling forecasts in real time during the adaptive planning process, allowing HHS to respond faster to a changing threat environment. For example, adaptive planning has allowed ASPR to quickly identify significant gaps in HHS's ability to support medical repatriation in OCONUS locations in support of the HHS repatriation mission and State Department evacuation planning. Through the adaptive planning process, ASPR was able to quickly coordinate with interagency, intra-agency, state, and private sector partners to acquire critical infrastructure and award service contracts to mitigate significant risks in HHS's ability to conduct medical repatriation in support of a major "All-Hazards" emergency event.

ASPR is also spearheading a major national planning effort to enhance the Nation's ability to quickly dispense MCMs during a public health emergency. The initiative, known as the "The Last Mile," is designed to conduct a "Whole-of-Nation" planning approach in looking at federal, SLTT, and private sector coordinated capabilities to advance mass dispensing activities in response to a public health

emergency. The Last Mile supports the National Health Security Strategy's goal to protect the nation from the health effects of emerging and pandemic infectious diseases and CBRN threats.

In FY 2020, ASPR's current 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.
- Update of Homeland Security Task Force HSTF-SE Operation Vigilant Sentry Medical Health and Safety Annex

In FY 2021, anticipated planning activities include:

- Integrated planning with federal partners to update the National Biodefense Strategy
- Updates to ESF 8 and ESF 6 portions of FEMA's National Disaster Recovery Framework
- Participate in development of FEMA Nation-State Plan for National Security emergencies
- Revision of Nuclear-Radiological Annex to Federal Interagency Operational Plan
- Development of Medical Critical Infrastructure Disruption Annex
- Update of Natural Disaster Annex and Earthquake Appendix to ASPR's All-Hazards Plan

ASPR Incident Response Framework

On May 2, 2019, ASPR announced the official release of the HHS ASPR Incident Response Framework (IRF). It describes the organizational structure, functional roles and responsibilities, and operational concepts that form part of the ASPR organization's overarching approach to incident response and special event preparedness. This framework now forms the basis from which ASPR personnel (permanent, intermittent, augmentees, and contract staff) and agency representatives, both internal and external to HHS, will execute their assigned missions throughout the life cycle of any incident or special event. The IRF also includes specific guidelines for participation in ASPR headquarters-level incident support operations, as well as, incident management operations conducted in the field.

The IRF is the product of after action findings after the 2017 hurricane season, which necessitated an extensive, coordinated federal public health and medical response after three devastating hurricanes affected Texas, Florida, Puerto Rico, and the Virgin Islands simultaneously. This response involved great communication and coordination amongst not only HHS and ASPR offices, but federal, SLTT, non-governmental organizations, and private-sector partners. Extensive after action reporting and lessons learned research post response and recovery, identified the need for ASPR to develop and implement a single, overarching framework linking the principal components of its structure for incident response in a comprehensive and integrated way. It also defines incident support versus incident management roles. It is intended to address gaps identified in these lessons learned, while still maintaining approaches, procedures, and protocols that have proven effective over time. It incorporates additional enhancements based upon more recent 2018 incident responses, as well as new information and best practices provided in the National Incident Management System (NIMS), updated in October 2017.

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 Operations 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, SLTT, 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 better prepared for 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 is 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 FY 2021, the SOC will work towards further meeting mission-essential functions of monitoring and detection, alerting and notification, and incident support by:

- Developing a comprehensive monitoring and detection program that includes all available data sources including open source and classified to support enhanced situational awareness, early notification and decision-support to HHS Senior Leadership, in coordination with SIIM.
- Implementing a standardized SOC certification program to ensure all support personnel are trained and capable to support the SOCs mission.
- Further development of notification systems to ensure the right people are getting the right information at the right time.
- Increasing the number of staff trained to support the ASPR's mission at the FEMA National Response Coordination Center, in coordination with Information Management.

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 Geospatial 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 rapid and effective 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/ ACF/ORR, with ASPR data on deployed personnel. GeoHEALTH was used to create and share several interactive mapping products for this event. Additionally, the GeoHEALTH platform has been leveraged to create the ASPR Common Operating Picture (COP), which is a 24/7/365 tool for real time situational awareness. Features of the ASPR COP include, monitoring and

tracking weather hazards, tracking the status of HHS resources, including facilities, personnel, equipment, and reporting the operating status of local healthcare facilities throughout the country.

As with recent disasters, ASPR collaborated extensively to share data with Federal and SLTT 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 officials regarding potential public health concerns. Additionally, ASPR shared static maps and dynamic GIS data layers depicting healthcare infrastructure status. 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 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. Relevant stakeholders receive data from this tool 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.

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.

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, etc.). 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 national 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.

Continuity of Operations before, during, and after 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 FY 2017-2019, 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 COOP Policy by the HHS Secretary in April 2018, and the ASPR COOP Plan by the ASPR in October 2019. 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 July 2019, ASPR hosted two exercises to meet the White House's annual continuity exercise and interagency evaluation requirements. Specifically, the first exercise featured a table-top exercise (TTX) for senior leadership, as part of Eagle Horizon 2019, which occurred at the continuity facility for the Office of the Secretary. The exercise had over 120 principals and successors, and they discussed HHS' continuity and devolution expectations, functional roles, and existing gaps during an influenza pandemic and high-consequence, no-notice events.

The second continuity-based exercise for 2019 occurred in conjunction with the HHS-wide, influenza

pandemic-themed, Crimson Contagion exercise. In August 2019, Operating and Staff Divisions participated from headquarters locations, via telework sites, from the continuity facility for the Office of the Secretary, and from HHS devolution sites. Continuity activities at the OS Continuity Facility featured implementation of activation, notification, and relocation procedures. Headquarters and Regional leadership also participated in a series of devolution discussions, communications tests, and an influenza pandemic-focused tabletop exercise, also known as "Determined Accord." Specific devolution activities included a discussion of HHS's continuity and devolution expectations, functional roles, and existing gaps during an influenza pandemic and high-consequence, no-notice events. Lastly, HHS hosted the Determined Accord table top exercise with the Atlanta Federal Executive Board, which included over 50 participants from HHS, Department of Agriculture (USDA), Department of Labor (DOL), and General Services Administration (GSA).

For FY 2020, the annual continuity exercises will occur during the first two weeks of May 2020. In 2020, the National Level Exercise scenario will be a cyber-event, causing severe consequences across several HHS regions. The scenario will examine how HHS and the federal government will organize to manage a cyber-event response, anticipate local and state cyber event response challenges, and identify HHS and the federal government's capabilities and available resources to support local and state response efforts during a cyber-event. A common scenario, and control and simulation architecture, will link each exercise component into one common, synchronized exercise environment. Continuity of operations participation in the exercise will focus on performance of essential functions by a dispersed workforce, leadership coordination, continuity communications and devolution coordination. Additional milestone accomplishments in FY 2020-2021 are expected to include:

- Approval and signature of the updated overarching HHS Continuity of Operations Plan
- Creation of a multi-year strategy and program management plan for HHS covering CY 2020-2024
- Delivery of two HHS-wide continuity exercise events with HHS senior leadership, and two with all HHS continuity personnel
- Procurement and installation of electro-magnetic pulse protections for critical HHS continuity communications capabilities
- Further enhancement of HHS Directive 16-1 continuity communications capabilities related to high frequency-automatic link establishment and satellite email technologies
- Implementation of an HHS-wide alert and notification system

Insider Threat Program Establishment and Maturation

The Office of the Director of National Intelligence (ODNI) and the National Counterintelligence and Security Center mandated through the U.S. Insider Threat Program (version 1.), dated 16 December 2013, that every department, and by extension every operating and staff division in HHS, establish an insider threat program. Currently, ASPR is working with HHS's Office of National Security (ONS) and ODNI to outline an ASPR insider threat program. Additional resources in FY 2021 will allow for formal documentation of process, procedures, and training to be established. The establishment of these documents will lead to the implementation of ASPR's Insider Threat Program. In addition to implementing the program, ASPR will train a group of individuals to work as risk assessors and conduct an ASPR-wide risk assessment.

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 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.

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, overall preparedness, 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, and SLTT 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 examples of 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 2017	$24,596,000
FY 2018	$24,654,000
FY 2019	$24,654,000
FY 2020 Enacted	$24,654,000
FY 2021 President's Budget	$27,154,000

Budget Request

The FY 2021 President's Budget for PEO is $27,154,000, which is +$2,500,000 above the FY 2020 Enacted level. The increase provides +$1,300,000 to establish an Insider Threat Program, to train personnel in risk assessments, and to complete an ASPR-wide risk assessment. In addition, it provides +$600,000 for SOC staffing to meet requirements of the new IRF; and +$600,000 for infrastructure and technology improvements to ensure the readiness of the primary HHS COOP site and its synchronization with the SOC. This request also continues $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.

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.

National Disaster Medical System

Budget Summary
(Dollars in Millions)

ASPR NDMS	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**57.404**	**57.404**	**88.404**	**+31.000**
Pediatric Disaster Care Program (non-add)	--	--	*20.000*	*+20.000*
Pediatric Disaster Care Program /1	*16.000*	--	--	--
Subtotal, Pediatric Disaster Care Program	***16.000***	--	***20.000***	***+20.000***
Program Level	**73.404**	**57.404**	**88.404**	**+31.000**
FTE	**115**	**115**	**117**	**+2**

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, states, localities, territories, and tribes whose medical infrastructure has become overwhelmed and require assistance with their critical medical services to protect public health, can request the National Disaster Medical System (NDMS) to help their communities respond and recover more rapidly. NDMS capabilities in collaboration with ASPR Regional Administrators are unique assets able to deliver essential medical and emergency management services and subject matter expertise when requested by a Federal or State, Local, Tribal, or Territorial (SLTT) agency. NDMS also leverages the HHS emPOWER Program's federal health data to advance their and SLTT partners capabilities to anticipate and plan for healthcare system surge and pre-emptively take action to protect health and save lives of community-based at-risk populations that may be rapidly and adversely impacted in the event of an emergency or disaster.

NDMS's mission is to augment communities with medical services after a disaster or public health emergency, and to support the DOD 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, two international incidents to support communities in need. 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 personnel to provide medical services and/or augment health and healthcare facilities in impacted communities.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019 requires a review of the NDMS and an assessment of the medical surge capacity relating to the availability of healthcare workforce for both widespread and/or multiple public health emergencies at one time. PAHPAIA also requires the Secretary to notify Congress when the NDMS workforce is insufficient to address a public health emergency and to include information on the effect such insufficiencies will have and potential ways to address the issue. In addition, PAHPAIA allows for faster recruitment of NDMS personnel to decrease the shortage in the health care emergency response workforce.

ASPR has worked to increase its intermittent employee workforce, which include NDMS response teams, logistics response personnel, and incident management personnel, toward the goal of over 6,700 people organized into 71 teams. There are currently over 4,600 deployable personnel available. 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, mortality services, 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 began to develop fitness for duty standards to ensure its personnel deploy in an increased healthy and safety posture that does not obstruct ability to conduct the mission of the Department. Those standards are under careful programmatic and legal review with full implementation of the fitness for duty policy to begin in FY 2020.

NDMS Teams:

- ***Disaster Medical Assistance Teams (DMAT):*** The DMATs 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, these teams are 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.

  In 2019, NDMS has supported several National Security Special Events (NSSE) to include the Presidential State of the Union Address, the National Police Officer Memorial, and the National Independence Day Celebration, United Nations General Assembly, and Representative Elijah Cummings lying in state at the United States Capitol. NDMS deployed a number of DMATs to Puerto Rico and Florida in response to Hurricane Dorian, plus provided subject matter expertise in support of fatality management in the Bahama's.

  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.
- ***Trauma Critical Care Teams (TCCT):*** The TCCTs 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 team, 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 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. This is done 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 percent 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.

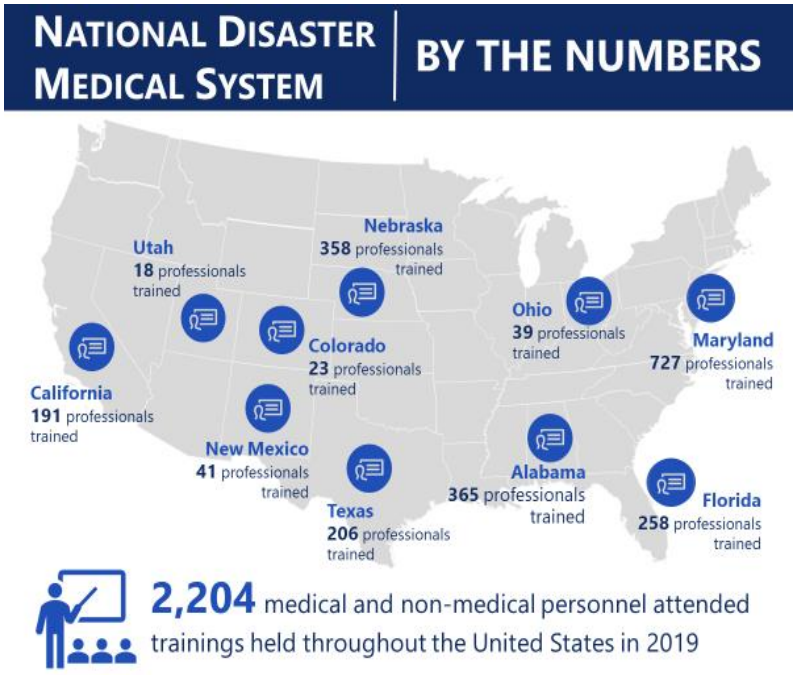
- ***National Veterinary Response Team (NVRT*)**: The NVRT delivers disaster medical care for large and small service animals during large-scale disaster responses. In addition, the team provides support, upon request, to federal service animals during designated NSSEs. The NVRT is primarily composed 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.

NDMS continues to provide individual and team training to all team members based on roles and team mission requirements. NDMS currently trains a minimum of 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, DoD, and SLTT officials, to strengthen response capabilities.

Through the use of emergency supplemental funding provided to respond to Ebola after the 2015 outbreak in West Africa and separately to the 2017 hurricanes in the Gulf of Mexico and Caribbean Sea, ASPR has augmented its training program to include specialty care curriculum for response to highly infectious diseases and aeromedical evacuation and transport treatment. These supplemental funds, which expire after FY 2020, have supported salaries and travel of intermittent personnel training, cache

replenishment of materiel used in training, and contracts to curriculum providers. In addition, these funds supported training nearly 1,000 new intermittent responders. ASPR anticipates that the staffing of intermittent response employees will increase to the target of 6,720 personnel in FY 2021 including 2,000 new staff that will require training over a three-year period.

Once NDMS teams are activated to deploy, they require support from multiple programs across ASPR. An NDMS activation considers multiple variables, including the request from a state, the 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 necessary for a mission, 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 their 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.
- ASPR's Tactical Medicine (TacMed) program provides direct operational medical support to HHS and its Federal partners during planned and unplanned events. In addition, TacMed provides medical direction, liaison coordination, and medical consultation to law enforcement agencies across the country. The program also delivers essential training to medical operators under tactical and austere environments.

NDMS's recent initiatives and accomplishments include:

- Provided support to communities affected by Hurricanes Harvey, Irma, and Maria. Over 4,800 NDMS personnel, USPHS, VA, and ASPR staff deployed to support those hurricane responses. ASPR deployed 944 tons of equipment and logistics and had over 36,000 patient encounters across 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--,if needed in their community the integration is expedient.

Logistics:

ASPR's 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 synchronized for rapid deployment where they are needed to provide an effective response. It is a complex, coordinated effort to rapidly deploy staff and materiel, support the setup of tactical hospital and incident management infrastructure, and sustain public health and medical teams with the necessary supplies and equipment in catastrophic, sometimes austere environments. Staff located and operating in regional-based Strategic National Stockpile (SNS) warehouses maintain strategically positioned medical material and deploy resources at a moment's notice. By supporting a regional footprint and maintaining assets in various geographic locations, ASPR maintains preparedness for disasters, no matter where they occur within the United States and its territories.

ASPR manages and maintains response materiel and supplies, including vehicle fleet assets, medical material, laboratory kits, pharmaceuticals, mortuary caches, communication kits, and shelter systems. Logistics program subject matter experts provide critical services to support response 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. Through use of emergency supplemental funding, ten new aeromedical caches are under development and 40 existing caches (37 for DMATs and three for trauma) will upgrade this year. This will bring the total number of NDMS medical caches to 50. In addition, now caches also include portable dialysis units. The addition of these portable units will ensure that vulnerable population are met in a timely manner. Based on 2017 Hurricane Lesson Learned, a typical response requires the relocation/airlift of approximately 100 dialysis outpatients; approximately 180 dialysis patients required treatment during Hurricane Maria. This new dialysis capability reduces the burden of transport of patients and material by sustaining portable hemodialysis.

To ensure a response is properly resourced and logistically supported, ASPR relies on Logistics Response Assistance Teams (LRAT), which includes intermittent Federal employees, augmented Officers from the USPHS, and full time logistics staff. The LRAT is a rapidly deployable, competent and agile logistics team that deploys to an area of operations to conduct reception, staging, mobilization, onward movement, and integration of HHS response assets into the response. The LRAT can deploy in different team configurations (scalable to the event) to provide critical field services such as IT and telecommunications, transportation, and material management during disaster, incident, emergency or special event. The ASPR LRAT is capable of conducting logistics operations supporting all missions and responses conducted by ASPR. This All Hazards logistics team trains its members to an expert level of proficiency on ASPR's response resources through a structured credentialing program. The ASPR LRAT team also trains to achieve competency in resource management and logistics areas associated with the FEMA National Qualification System and NIMS.

Following the transition of the SNS from CDC to ASPR, NDMS began working with this program to integrate ASPR's logistics functions. In May 2019, the SNS assumed inventory management responsibility for NDMS materiel. Additionally, seven logisticians from NDMS joined SNS in July 2019 to support SNS logistics operations. Fully integrating NDMS materiel into the SNS's inventory management systems and logistics operations will continue into FY 2020. Moving all of ASPR's medical materiel and logistical operations to SNS streamlines ASPR operations and better positions ASPR to respond to health threats.

In support of NDMS program activities and response activations, the following logistical accomplishments have been achieved:

- Deployed, sustained, and reset over 737 medical caches, encompassing over 451 tons of material and resources to support five NSSEs and multiple emergency response and recovery operations such as: 2018 Typhoon Yutu, 2018 Hurricane Isaac, 2018 Reunification of Children, 2018 Hurricane Lane, 2018 Hurricane Olivia, 2018 Hurricane Florence, 2018 Hurricane Michael, 2018 California Wildfires, 2019 State of the Union Address, 2019 Typhoon Wutip, 2019 Peace Officers Memorial, 2019 National Independence Day Celebration, 2019 Hurricane Barry, 2019 Hurricane Flossie, and 2019 United Nations General Assembly (Scheduled NSSE), and 2019 Hurricane Dorian.
- Deployed and maintained a mobile dialysis trailer capability in the USVI resulting in the sustained treatment of approximately 180 dialysis patients in support USVI 2017 Hurricane Recovery Operations. This operation continues and has been ongoing since December 2018.
- Deployed, setup, and reset over 230 medical, veterinary, mortuary, communications, and high infectious disease caches and kits in support of over 125 NDMS training events to enhance responder preparedness.

Field Operations and Response:

The Field Operations and Response program also plays an important role for NDMS in all aspects of the preparedness cycle. First, Regional Emergency Coordinators (RECs), led by a Regional Administrator (RA), are located in each of the ten HHS Regions, to build and maintain relationships with SLTT officials and healthcare representatives. These established relationships help identify capability gaps, support SLTT preparedness efforts, and, once an SLTT requests a federal response, lay the foundation for an effective, informed, and coordinated response.
During emergencies, the:

- RECs are the points of contact for information flowing within the Regions to and from SLTT partners. The RECs help inform deployments, so that ASPR provides only the capabilities and assets that are useful to the requestor. The RECs also continue to provide coordination for recovery efforts in the wake of an event.
- ASPR Incident Management Teams (IMT), led by a Federal Health Coordinating Official (FHCO), functions as command and control in the impacted Region for engagement of federal medical support during responses. The IMT directly and indirectly supports not only the work of HHS in response, but other federal agencies as well.
- Medical Countermeasures Operations Program (MCOP), in coordination with the Strategic National Stockpile, serves as a key bridge between local communities and federal initiatives in medical countermeasure (MCM) dispensing. These MCM efforts include planning for The Last Mile (TLM) initiative. Collectively, Field Operations and Response performs essential functions for HHS in several major areas: prevention, mitigation, response, recovery, and agency-wide coordination.

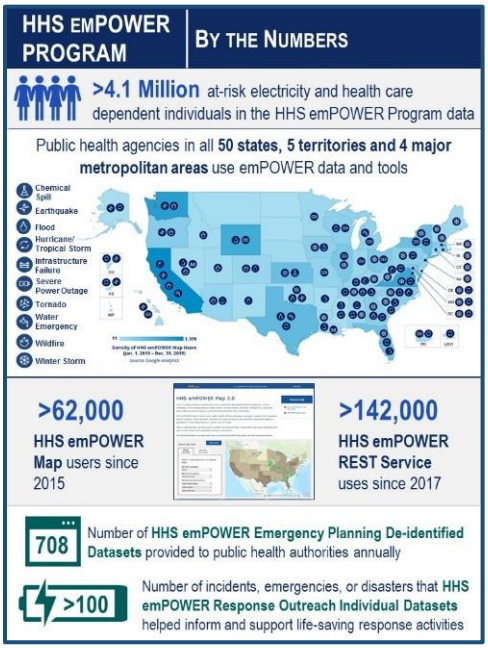
Once an incident is identified that requires federal support, ASPR's shifts focus from preparedness to response by providing necessary surge support to SLTT partners. All ASPR programs have supporting roles in a response and work together to address both anticipated and realized issues. All of ASPR's response assets are nimble, flexible, and adaptable, which ensure 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 SLTT partners.

To support a response, Field Operations manages the IMT, which includes intermittent Federal employees, Officers from the USPHS, and ASPR RECs. The IMT is a rapidly deployable, competent and

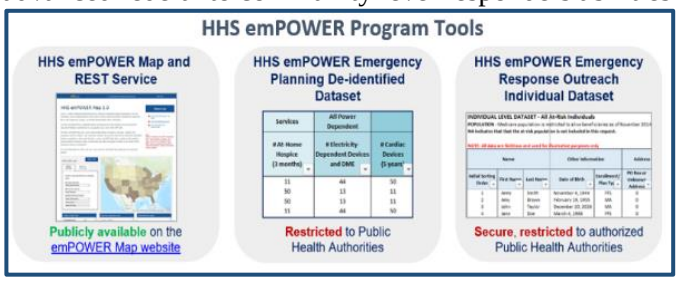
agile command and control element within the area of operations that is essential to the success of a response and/or recovery operation. To ensure an IMT meets the needs of a disaster, incident, emergency or event, IMTs are scalable in size and function.

The IMT adapts to all of the threats and responses supported by ASPR. These all hazards IMTs train its members to a Type 3 response capability through a well-established credentialing program. Type 3 IMTs deploy 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 must demonstrate competency in their respective incident management positions.

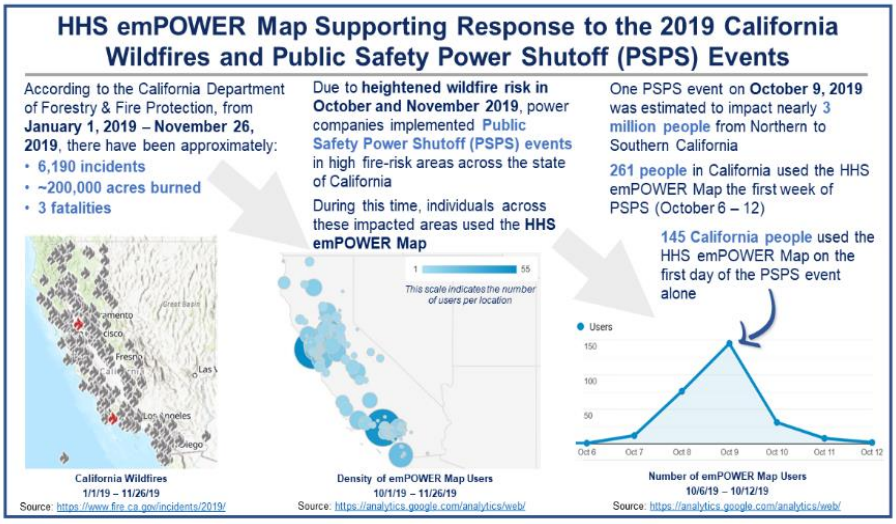
HHS emPOWER Program (emPOWER):



The HHS emPOWER Program is at the forefront of government innovation, harnessing the power of federal health data, artificial intelligence and federal-to-community level partnerships to protect health and save lives. By leveraging Medicare data, emPOWER provides NDMS, PHAs and their partners (e.g. first responders, emergency managers, health care providers/coalitions, aging agencies, public utilities, etc.) with data driven tools that provide unmatched situational awareness, advance readiness and information and support response activities across 10 emergency support functions. In 2019, emPOWER launched its first free and publicly available "HHS emPOWER Program Web-Based Training" that provides comprehensive information on the tools, and featured partner and stakeholder case studies of how they used the data in different responses during different types of responses spanning 2016-2018. emPOWER has also continued to advance the "emPOWERing State Medicaid and CHIP Data Pilot" that provides voluntary training to states and territories to build partnerships and develop complementary state emPOWER Medicaid datasets that will provide critical pediatric and other adult at-risk population data that are only available in their state-operated Medicaid and Child Health Insurance Programs. Bringing these capabilities and tools together, has further advanced federal to community level responders abilities to rapidly anticipate needs, take action to support at-risk populations, mitigate potential healthcare system surge, provide safe alternate options (e.g. shelters, charging stations, etc.), and conduct life-saving assistance and outreach, as appropriate, in an incident, emergency or disaster.



Since 2013, emPOWER has protect Americans from 21st-century threats nationwide. During the 2017 hurricanes, emPOWER data helped emergency responders to rapidly locate and conduct life-saving evacuations of more than 200 dialysis patients in the U.S. Virgin Islands to ensure continuity of care. From local to federal disasters, emPOWER data has informed critical emergency response planning, supported life-saving outreach activities and aided in reconstitution of critical outpatient oxygen, dialysis and medical equipment supplier services to healthcare-dependent individuals during the 2018-2019 historic wild fires, mudslides, hurricanes, critical infrastructure failures, and other severe weather events. Through emPOWER, federal to community partners are able to leverage data, innovative technology and best practices to advance data driven decision-making, readiness and integration across all partners and their emergency preparedness, response, recovery and mitigation activities. emPOWER continues to provide right data, in the right tool, to the right person and at the right time to help inform and support the needs of at-risk populations across all communities.



NDMS teams, logistics, field operations and emPOWER work together to ensure the right support is provided to communities in need. Due in large part to innovative thinking, finding efficiencies, and dedicated staff, ASPR continues to provide surge support when requested, even though there are challenges in years when multiple responses occur.

Funding History	
FY 2017	$49,787,000
FY 2018	$57,404,000
FY 2019	$73,404,000
FY 2020 Enacted	$57,404,000
FY 2021 President's Budget	$88,404,000

Budget Request

The FY 2021 President's Budget for NDMS is $88,404,000, which is +$31,000,000 above FY 2020 Enacted. The requested increase includes: +$5,000,000 for sustainment of portable dialysis unit leases, maintenance, consumables, and user instruction; +$5,000,000 for responder training to increase the number of responders trained annually and the proficiency of responders in additional technical fields including highly infectious diseases and patient transport; and, +$1,000,000 for emPOWER to support critical services to federal-to-community level awareness, adoption, implementation and use of critical data, maps, artificial intelligence and other innovative tools, informational resources, and new tech platforms.

The request contains $20,000,000 in 2-year funding to continue a Pediatric Disaster Care pilot program, building on progress made in FY 2019. The cohort of pediatric Centers of Excellence (CoE) pilots in 2019 funds up to two Pediatric Disaster Care CoE's to address appropriate planning and response capabilities that support the specific needs of children during public health emergencies and disasters, such as mass casualty incidents. ASPR aims to address known gaps in pediatric disaster care of all pediatric patient populations by augmenting the existing clinical capabilities within states and across multi-state regions. A specific focus of these pilots is the management of pediatric care related to trauma, infectious diseases including pandemic influenza (PI) and other emerging infectious disease (EID), burn, and CBRN incidents. 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 United States.

The pediatric CoE's are required to build upon the existing foundations for pediatric clinical care, specialized clinical care providers, and emergency response by enhancing coordination mechanisms and incorporating relevant capabilities at the local, state and regional levels. More specifically, they are required to develop coordinated pediatric care plans in their region, improve statewide medical surge capacity for pediatric care, educate and train the healthcare and medical workforce on preparedness and response gaps related to pediatric patients, and conduct a regional exercise.

The CoE's will incorporate lessons learned from the Regional Disaster Health Response System (RDHRS) pilots. In December 2019, the RDHRS sites will share lessons learned, newly developed guidelines, and tools and products that are relevant to the care of pediatric patients with the pediatric CoEs. The FY 2021 President's Budget does not include continued funding for the RDHRS pilot projects. In future years, the pediatric CoE's will lead on regional pediatric preparedness and response efforts and continue to provide seamless care to pediatric patients under the all-hazards infrastructure being developed in each region.

Year 2 (2020) of the Pediatric Disaster Care, CoE's continue work on the two initial pilots, building on lessons learned and focusing on identifying strategies for expanding those local and statewide capabilities into a truly regional (i.e. multi-state) presence. Year 3 (2021) of the Pediatric Disaster Care CoE's further expand the pilot program described above, building on lessons learned from previous pilot sites. Funding continues amongst previously funded pilot sites and expands to an additional site. The pilots will continue building on lessons learned and expand local and statewide capabilities to develop a truly regional/nation-wide capability to respond to the needs of pediatric patients in disasters and public health emergencies.

Further building on the capability of our nation to respond to the needs of pediatric patients in disasters and public health emergencies, ASPR will convene a panel of pediatric subject matter experts across the United States. Funds will secure meeting space and meeting support, develop the meeting agenda, convene up to 75 subject matter experts, and develop a final meeting report and recommendations.

Additionally, in FY 2021, the ASPR will expand its capacity and capability to respond to the needs of pediatric patients in disasters and public health emergencies through the acquisition of Fold-Out Rigid Temporary Shelters (FORTS) medical field hospitals.

ASPR National Disaster Medical System - Outputs and Outcomes Table

Program: National Disaster Medical System

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2019 Target	FY 2021 Target	FY 2021 Target +/-FY 2019 Target
1.1 Maintain the percent of new NDMS intermittent staff that complete psychological first aid training (Output)	FY 2019: 100 % Target: 100 % (Target Met)	100 %	100 %	Maintain
1.3 Increase training and resources to address the access and functional needs of at risk individuals who live independently and are impacted by emergencies and disasters (Invalid measure type)	FY 2019: 71,061 trained Target: 71,061 trained (Baseline)	71,061 trained	Baseline +	N/A
1.4 Maintain the percent of NDMS intermittent staff who complete basic, advanced, or specialized training (Intermediate Outcome)	FY 2019: 39.5 % Target: 35.0 % (Target Exceeded)	35.0 %	35.0 %	Maintain

Civilian Volunteer Medical Reserve Corps

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
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 more than 175,000 volunteers organized into roughly 850 local community-based units committed to improving local emergency response capabilities, reducing vulnerabilities, and building community preparedness and resilience. MRC units organize and utilize local volunteers who donate their time and expertise to prepare for and respond to emergencies and to support various 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 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 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 partners. MRC units are local assets, and the MRC program does not have direct operational or tactical control over them.

MRC units are very active in their communities, as evidenced by their 15,491 activity reports during FY 2019. These reports show more than 117,000 MRC volunteers contributed nearly 350,000 hours of service.

These activities have had significant local impact:

- 445 responses to local emergencies;
- 5,836 activities that trained or exercised MRC members to improve individual, unit, or community response capability and capacity;
- 8,741 activities that improved community preparedness or resilience;
- 9,935 activities that developed or strengthened the MRC unit;
- 8,178 activities in which MRC members strengthened the local public health system;
- 4,926 activities that served an at-risk/vulnerable population; and

- 6,028 activities that supported non-emergency community events.

Recent MRC activities and accomplishments include the following:

- MRC units responded to a number of weather-related events and natural disasters in 2019. These events included – but were not limited to – Hurricane Dorian along the east coast; wildfires out west; tornadoes in Alabama and Mississippi; severe flooding throughout the Midwest; an earthquake in Ridgecrest, California; and heat waves and winter storms across the country.
    - MRC units in Florida, Georgia, North Carolina, South Carolina, Tennessee, and Virginia responded to Hurricane Dorian. Volunteers provided shelter set-up and operations support; medical care to shelter residents; emergency operations center support; HAM radio and communications equipment testing; and support contacting medical special needs registrants to provide emergency information and arrange transportation, if necessary, to/from local shelters.
    - MRC units in Northern and Southern California supported wildfire response efforts and related public safety power shutoffs. MRC volunteers most commonly assisted with sheltering operations and medical care for affected residents; veterinary care for displaced and injured animals; operations center support; and well-check outreach calls to community members, including those who were identified as having durable medical equipment at home and potentially without power.
    - In early 2019, MRC members devoted more than 2,000 hours in response to tornadoes in Alabama. The PROJECT H.E.L.P. USA MRC (Birmingham, AL) provided a variety of medical services ─ MRC volunteers triaged tornado victims, provided first aid, and verified and replaced medication for affected residents. The Black Belt MRC - Macon and Bullock County (Tuskegee, AL) also responded to the tornadoes, assisting the county sheriff's office and local emergency management agencies with debris cleanup. Also in early 2019, when a tornado hit Mississippi's Lowndes County, volunteers with the Mississippi Behavioral Health MRC's Mobile Crisis Counseling Team (Jackson, MS) provided mental health counseling at shelters for individuals affected by the storm.
    - Over the course of 2019, MRC units responded to flooding emergencies by volunteering nearly 5,000 hours. In response to severe flooding in the Omaha, NE, area, the Eastern Nebraska/Western Iowa MRC (Omaha, NE) provided medical and behavioral health support at shelters for more than 10 days. The Southeast Nebraska MRC (Crete, NE) also assisted in this response through a mutual aid agreement, providing general and psychological first aid at shelters in Omaha. In response to flooding in North Iowa, the North Iowa CERT & MRC (Mason City, IA) pre-deployed shelter trailers to sites, delivered sandbags and pumps to communities, prepared for possible evacuation of several apartment complexes, and supported an emergency operations center.
    - When an earthquake and series of aftershocks occurred in Ridgecrest, CA, in early July 2019, medical volunteers from the Kern MRC (Bakersfield, CA) responded by staffing the overnight shift at a general population shelter for four nights.
    - In response to Tropical Storm Karen in September 2019, the MRC of Puerto Rico (San Juan, PR) assisted with setting up and providing medical care at four specialized shelters intended for patients who use ventilators and intravenous infusion pumps, both of which depend on electricity.
    - From January – March 2019, MRC members volunteered more than 3,000 hours in response to emergencies caused by winter storms and severe winter weather. During an

impending winter storm, Orange County MRC (Goshen, NY) supported a local emergency operations center, assisting with call center operations. Several other MRC units staffed cold weather shelters, including the Rutland-Addison County MRC (Rutland, VT), the Hendricks County MRC (Danville, IN), and the New Orleans MRC (New Orleans, LA). During one particularly long stretch of extreme temperatures, the Snohomish County MRC (Everett, WA) assisted at multiple local cold weather shelters, including one shelter that was open for 41 nights from January to March.

- MRC units responded to a number of other emergency and public health events in their communities as well.
    - Over the span of several months, MRC volunteers in New Mexico assisted with staging, staffing, and providing medical assessments at shelters and medical clinics for migrants arriving to the U.S. seeking asylum.
    - In June 2019, when a mass shooting occurred in Virginia Beach, VA, MRC volunteers assisted at volunteer reception centers and provided mental health support to City of Virginia Beach employees. Similarly, in August 2019, after a mass shooting took place in Dayton, OH, the Clark County MRC (Springfield, OH) crisis response team provided mental health resources and support to families at the local family assistance center.
    - On October 12, 2019, when the Hard Rock Hotel construction site partially collapsed in New Orleans, the New Orleans MRC (New Orleans, LA) was activated to staff a family reunification center for individuals looking for information about loved ones who were in the area of the collapse. Volunteers also assisted New Orleans Health Department and New Orleans Emergency Management staff in confirming EMS and hospital patient counts and calling individuals displaced from their apartments in the surrounding area to determine immediate needs.
    - When a hazardous material spill resulted in the evacuation of an area business, daycare, and 20 nearby homes, the Allentown Volunteer MRC (Allentown, PA) was activated to assist at a family reunification center established for the daycare staff and children, and at an evacuation center for the residents who were evacuated from their homes.

- In addition to weather-related and other emergency support, MRC units helped their communities during communicable disease outbreaks.
    - The nation saw an increase in measles cases in 2019. In Washington State, where a state of emergency was declared as a result of measles outbreaks, five MRC units across the state supported emergency response efforts during the peak of measles case development. Volunteers primarily conducted surveillance and case and contact investigations. MRC units in New York, Pennsylvania, and Illinois also responded to measles outbreaks, contacting potentially exposed residents, conducting medical screenings and patient surveillance, and administering vaccinations, as necessary.
    - Several MRC units in more than a dozen states across the country provided vaccination support in response to hepatitis A outbreaks. Units were particularly focused on high-risk and vulnerable populations, providing vaccination support at a number of outreach clinics held at local libraries, family shelters, fire departments, and other community-based centers.

  - In April 2019, after a student was diagnosed with tuberculosis, MRC Georgia East Metro (Dacula, GA) devoted more than 350 hours to testing nearly 3,000 students and faculty for the disease at a local high school.

- It is important to note that in addition to providing medical care, MRC units are also routinely providing behavioral health/mental health support to affected community members during the course of emergency response activities. Many MRC units have already established – or are in the process of establishing – mental health and/or crisis response teams within their units that are pre-trained and can quickly deploy, if necessary. One example is the Clark County MRC (Springfield, OH), which has both a trained suicide response team and a crisis response team. Combined, the Clark County MRC teams were activated more than 30 times to provide mental health support in 2019.

- MRC units also participated in non-emergency events throughout the year, including training for emergencies and educating the public about how to respond to emergency events. During National Stop the Bleed Month in May 2019, more than 50 MRC units across the country participated in or led Stop the Bleed training events in their communities. Stop the Bleed is a national initiative that encourages the general public to become trained and empowered to help in a bleeding emergency before professional help arrives. MRC units also conducted similar personal preparedness trainings – such as CPR/AED, first aid, naloxone administration for opioid overdoses, and active shooter training – for community audiences throughout the year.

- In 2019 – for the fourth consecutive year – the 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. Seventeen MRC state coordinators, unit leaders, and volunteers participated in Disaster Medical Assistance Team (DMAT) fundamentals training, gaining valuable technical knowledge and increasing communication and collaboration with NDMS teams from across the country.

- The MRC program 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.

  - In January 2019, as part of their cooperative agreement with the MRC program, NACCHO launched the "MRC Deployment Ready Project," which was aimed at developing a suite of medical and public health response mission sets and deployment readiness standards for MRC volunteers. The project was a collaboration between NACCHO, seven MRC units serving as pilot sites, and NACCHO's MRC Advisory Group, which is composed of 15 MRC unit leaders from across the network. Products from this project were released to the MRC network in August 2019 and included a comprehensive "MRC Deployment Readiness Guide" that features a suite of volunteer management tools and checklists, a core competency volunteer training plan, and a series of emergency response mission sets for MRC units.
  - Also as part of their cooperative agreement with the MRC program, NACCHO announced a funding opportunity for MRC units in Fall 2019 called the "2020 Operational Readiness Awards." More than 200 MRC units applied for the awards, which aim to build the operational readiness capabilities of MRC volunteers and units to meet the emergency preparedness and response needs of their local, regional, and statewide stakeholders.

- The MRC program's cooperative agreement with the Public Health Foundation provides each of the roughly 850 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.

Funding History	
FY 2017	$5,986,000
FY 2018	$6,000,000
FY 2019	$6,000,000
FY 2020 Enacted	$6,000,000
FY 2021 President's Budget	$3,900,000

Budget Request

The FY 2021 President's Budget for the civilian volunteer MRC is $3,900,000, which is -$2,100,000 below FY 2020 Enacted. This funding supports 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 and mission sets and promote the utilization of MRC response packages in inter- and intra-state public health and medical responses. Funding also will 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 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority /1	**264.555**	**275.555**	**257.555**	**-18.000**
Cooperative Agreements (non-add) /2	*231.500*	*231.500*	*231.500*	*-*
Other costs (non-add) /3	*33.055*	*44.055*	*26.055*	*-18.000*
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. HPP does not directly fund hospitals.

3/ Other costs include HPP cooperative agreement administration, evaluation, and performance management, the Regional Disaster Health Response System demonstration sites (in FYs 2019 and 2020), the National Ebola Training and Education Center and support for ten regional Ebola and other special pathogen treatment centers (in FY 2020) 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

Aligning Efforts to Modernize Emergency Preparedness and Response
ASPR's mission is to save lives and protect Americans from 21st-century health security threats. As the threat landscape evolves, it is critical to invest in programs that seek to further integrate and modernize the nation's readiness and response capabilities. The Hospital Preparedness Program (HPP), and supporting activities including the Technical Resources Assistance Center, and Information Exchange (TRACIE), Emergency Care Coordination Center (ECCC), Critical Infrastructure Protection Program (CIP), and Recovery–are essential to creating and sustaining a health care sector that can adapt to the new threat landscape and capably respond to disasters when they occur. This entire portfolio of programs is critical for engaging health care stakeholders from all 50 states, U.S. territories, and freely associated states and from across the entire life sciences and health care industry–empowering private health care to share ownership in addressing risks and vulnerabilities across every aspect of disaster care delivery.

Although significant progress has been made, especially with regard to improved collaboration and coordination across the public and private health care sectors, continued investment and innovation are necessary to maintain momentum on key priorities, which include improving:

1) Surge capacity;
2) Access to specialty care;
3) Health care situational awareness;
4) Health system readiness; and,
5) Patient transport and tracking.

An integrated 21st-century health care response ecosystem must be truly national, ensuring alignment and agile coordination at the local/coalition level, the regional level, and at the federal level. HPP health care preparedness, response, and recovery programs play a central role in developing and strengthening partnerships among all levels to optimize readiness and response.

Hospital Preparedness Program: Increasing Health Care Emergency Response Capacity and Capability

Historically, HPP funding invested in increasing health care *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. Current HPP investments not only focus on health care organization capacity, but also enhance health care systems' *capability* to ensure that a region can prepare for and respond to emergencies as soon as they occur, decreasing their reliance on federal medical assets during disasters. Health care coalitions (HCCs), which has been HPP's focus since 2012, improve regional health care and medical coordination, as do other partnership awards administered by HPP, such as the Regional Disaster Health Response System (RDHRS) pilots.

On June 24, 2019, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) was signed by the President. This legislation amended the Public Health Service Act to reauthorize funding and enhance authority for the Hospital Preparedness Program. This legislation introduced new statutory imperatives for HPP to accomplish, including expanding the purpose of the program to include both preparedness *and* response, adding new preparedness goals for the program to achieve, and requiring HPP to develop an evaluation of the program's evidence-based benchmarks.

The *2017-2022 Health Care Preparedness and Response Capabilities*[1] describe what the health care delivery system, including HCCs, hospitals, and EMS, must do to effectively prepare for and respond to emergencies that affect the public's health. These capabilities – 1) Foundation for Health Care and Medical Readiness, 2) Health Care and Medical Response Coordination, 3) Continuity of Health Care Service Delivery, and 4) Medical Surge – 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*[2], *National Preparedness Goal*[3], and the *National Health Security Strategy and Implementation Plan*[4] to build community health resilience and integrate health care organizations, emergency management organizations, and public health agencies.

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. As of December 9, 2019, HPP has seen the following changes in HCC progress toward meeting 100 percent of each capability[5]:

Capability	FY 2016	FY 2017	FY 2018
Foundation for Health Care and Medical Readiness	77%	83%	81%
Health Care and Medical Response Coordination	67%	71%	74%
Continuity of Health Care Service Delivery	65%	69%	68%
Medical Surge	67%	71%	69%

HPP examines HCC progress toward fully building these capabilities as part of their understanding of recipient performance for the annual cooperative agreement; therefore, it is important to examine capability progress in a broader context. While progress on three of four of the capabilities have not

[1] *2017-2022 Health Care Preparedness and Response Capabilities*, https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capablities.pdf

[2] National Response Framework, 3rd Edition, June 2016. https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National_Response_Framework3rd.pdf

[3] National Preparedness Goal, 2nd Edition, September 2015. https://www.fema.gov/media-library-data/1443799615171-2aae90be55041740f97e8532fc680d40/National_Preparedness_Goal_2nd_Edition.pdf

[4] National Health Security Strategy and Implementation Plan 2015-2018, https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/nhss-ip.pdf

[5] These data are currently undergoing validation, and were taken from end-of-year (EOY) HPP Coalition Assessment Tool data from the last completed HPP budget period (July 1, 2018 through June 30, 2019).

improved in FY 2018, overall, HCC progress in the four capabilities has shown improvement since FY 2016[6].

Progress related to Health Care Response and Medical Coordination continued to increase steadily. Hospitals in Los Angeles, California demonstrated the impact of HPP funds on medical coordination this year following a liquid oxygen spill; a network of hospitals and other health care partners was able to quickly coordinate to deploy resources (see more information in the text box).

Hospital Resource Coordination After a Liquid Oxygen Spill
On the morning of January 28, 2019, a pipe leading to a 2,000-gallon tank of liquid oxygen ruptured at Cedars-Sinai Marina del Rey Hospital in Los Angeles, California. When the hospital discovered that there were no oxygen tanks available statewide from vendors, it reached out through Los Angeles County's Disaster Resource Center (DRC) Program to borrow a liquid oxygen trailer from Cedars-Sinai Medical Center. This trailer was refurbished in 2013 using funding from the Hospital Preparedness Program (HPP). The DRC Program, funded by LA County using HPP funds, consists of 13 hospitals, one community clinic association, and approximately 130 active umbrella hospitals and health care coalition partners. Since the liquid oxygen trailer was listed as a deployable resource for the DRC program, Cedars-Sinai Marina del Rey Hospital was able to request the equipment from Cedars Sinai Medical Center and receive the oxygen trailer the next morning. This quick coordination and resource deployment helped Cedars-Sinai Marina del Rey Hospital avoid transferring the approximately 70 patients that required oxygen or evacuating the hospital on a larger-scale.

Leveraging Coalitions and Partnerships to Drive Coordination

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 demonstration projects and pilots for the Pediatric Disaster Care Initiative. These coalitions and partnerships ready health care delivery systems for disasters and emergencies by operating at the local, state, regional, and federal level and integrating activities across each level. HPP enables individual facilities and coalitions to access a truly national response network, enabling the health care system to save lives and protect Americans from 21st-century health security threats.

Since 2012, HPP's formula-based cooperative agreement program has required its recipients[7] to invest in HCCs. HCCs are groups of individual health care and response organizations 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 activities in the context of incident command system (ICS) responsibilities. HCCs coordinate activities among their members, which include health care organizations and other community stakeholders. HCC members actively contribute to 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

[6] HPP Coalition Assessment Tool data from the FY 2017 HPP budget period.
[7] HPP's recipients are 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.

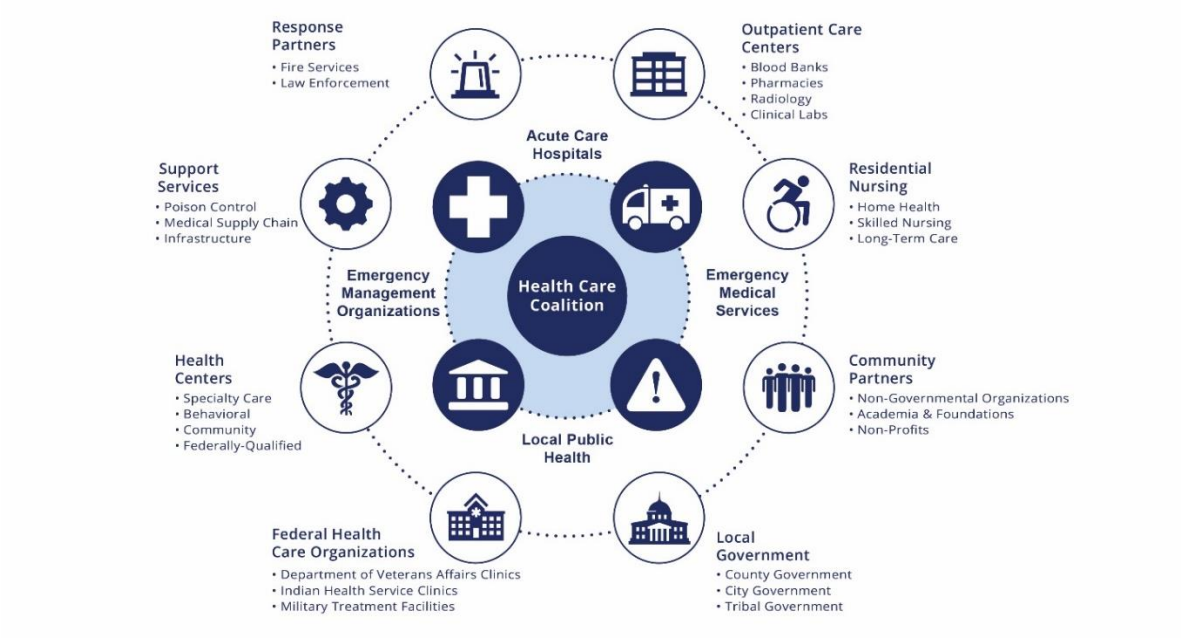
improves situational awareness and optimizes use of resources including health care professionals and specialized equipment–especially when one facility is too overwhelmed to provide timely and required levels of care. This ability also mitigates the impact of an incident on the facilities themselves, existing and potential patients, or event casualties. For example, during Hurricane Florence, eight HCCs in North Carolina were able to coordinate innovative response activities to better manage hospital surge and care for vulnerable populations – not only at the coalition level, but working across coalitions to operate regionally (see more information in the text box).

Hurricane Florence Health Care Response
The North Carolina *State Medical Response System (SMRS)* activated the eight HPP-supported regional HCCs across the state to manage the health care response to Hurricane Florence. Once activated, HCCs began command and oversight for five State Medical Support Shelters, coordinating staffing and logistics for each. HCCs held daily calls with hospitals to receive patient lists, verify information, and initiate over 112 patient transfers to hospitals across the state and over 300 patient transfers to a State Medical Support Shelter. HCCs teamed up to establish a 100-bed State Medical Support Shelter, which provided 24/7 medical care to at-risk patients who required nursing home-level care beyond what a general shelter could provide. Without HPP funding, the advanced plans needed to set up the shelter operations, obtain equipment, and staff the shelter with qualified physicians, nurses, and paramedics may not have existed. The HCCs played a vital role in integrating the shelter with the community, both by connecting with health care stakeholders across the state for supplies and by facilitating a continued sense of compassion within the shelter. The HCC coordinated response allowed the state to not only direct patients to the right shelter, but also ensure that one of North Carolina's most vulnerable populations was not overlooked.

HCCs incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together.

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

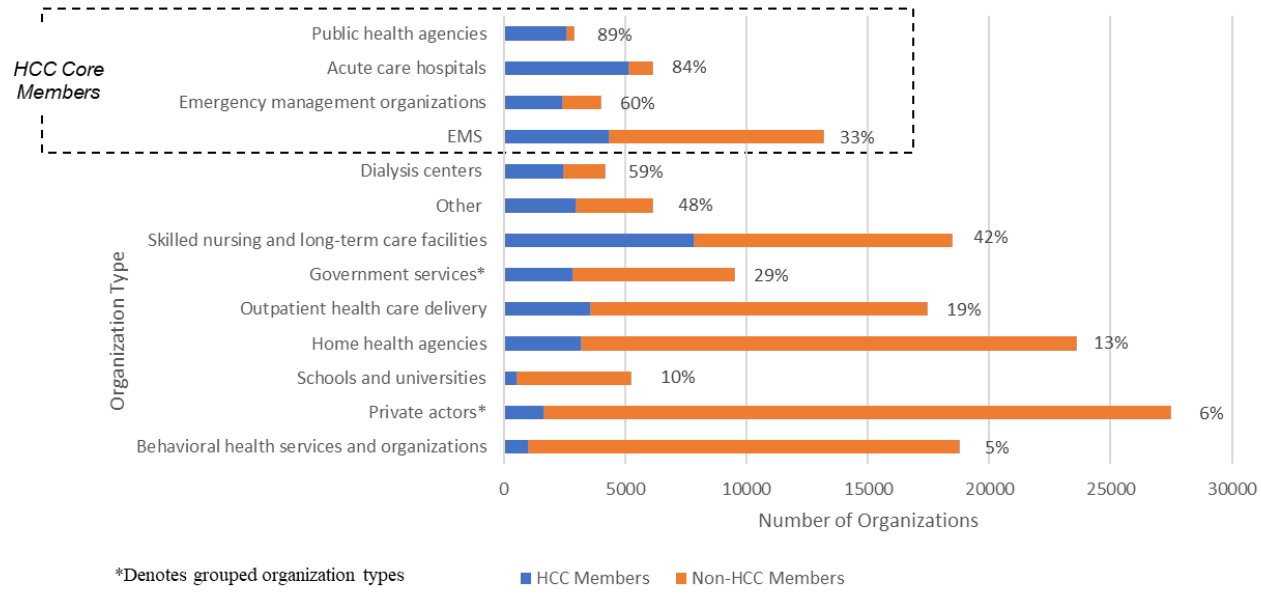


As of June 30, 2019, there were 38,750 HCC member organizations participating in 360 HCCs nationwide.[8] ASPR requires that each HCC funded by cooperative agreement recipients meets core membership requirements: a minimum of two acute care hospitals, EMS (including inter-facility and other non-EMS patient transport systems), emergency management organizations, and public health agencies. The number of HCC members has more than tripled 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, 2019. For example, there are currently 5,139 acute care hospitals participating in HCCs, which represents 84 percent of all U.S. acute care hospitals.[9,10]

[8] These data were validated and taken from end-of-year (EOY) performance data from the last completed HPP budget period (July 1, 2018 through June 30, 2019).
[9] Ibid.
[10] For clarity and concision, all HCC Member categories with a participation rate below 10 percent were grouped together and narratively described instead of being shown individually in Figure 2. "Private Actors" include

Figure 2. HCC Membership Diversity and Participation Rates



Areas for Continued Investment and Improvement

While HPP has dramatically improved the nation's ability to prepare, surge, respond, and recover from major disasters, the program continues to track and prioritize action to mitigate nationwide vulnerabilities and gaps in capabilities at the coalition level. For example, emergency medical transport can present special challenges during large-scale disasters: surge test data from HPP's coalition assessment tool show that the percentage of patient evacuations with acceptance for transfer to another facility that have an appropriate mode of transport identified in 90 minutes has decreased from 51.5 percent to 36.3 percent[11]. Additionally, the total number of patients matched to a confirmed, appropriate mode of transport to their receiving facility at the end of the exercise has decreased from 38.8 percent in FY 2017 to 22.8 percent in FY 2018[12]. These data highlight a critical gap in our health care preparedness capabilities related to emergency medical transportation and patient movement at large. It is essential to address this gap to ensure the reduction of morbidity and mortality of individuals affected by disasters.

In order to prioritize specific focus areas for improvement, HPP has aligned program requirements to nationwide infrastructure vulnerabilities. For example, in FY 2021, recipients will be required to conduct a supply chain integrity assessment to evaluate equipment and supplies that will be in demand during emergencies and develop mitigation strategies to address potential shortfalls. As of June 30, 2019, only 22 percent of HCCs have completed an assessment; over one-third (34.6 percent) of HCCs have not yet started that process[13]. It is critical to improve situational awareness related to supply chain and to resolve supply chain vulnerabilities, as access to medical supply (elements of which include blood banks, fuel, pharmaceuticals, biomedical and durable medical equipment, PPE, etc.) is both vital during emergencies

infrastructure companies, local chapters of health care professional organizations, medical and device manufacturers and distributors, non-governmental organizations, and primacy care providers and "Government Services" include federal facilities, jurisdictional partners and local public safety agencies.

[11] These data are currently undergoing validation and were taken from end-of-year (EOY) performance data from the last completed HPP budget period (July 1, 2018 through June 30, 2019).

[12] Ibid.

[13] Ibid.

and essential to the overall resiliency of a 21st-century national disaster health care ecosystem.

Preparing Health Care Coalition Leaders in Emergency Response

Through a partnership with the Federal Emergency Management Agency (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 emergencies through the Health Care Coalition Leadership Response (HCRL) course. FEMA funds all training and travel expenses for participating HCCs.

From September 2016 through November 2019, 67 HCCs from 30 states, District of Columbia, Puerto Rico, U.S. Virgin Islands, and the U.S. Pacific territories and freely associated states have participated in the HCRL.

Each HCC that attends the HCRL course may invite up to nine participants including 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 techniques and considerations for HCC response and recovery leadership. Each coalition participates in three table-top exercises during the class. At the end of each class, participating coalitions develop plans to implement key activities that will advance their preparedness and response capabilities.

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.[14] 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 regional flexibility to address the specialized capabilities required for transport, treatment, and care.

The regional Ebola treatment network consists of 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. In FY 2018, it also included 44 state or jurisdiction Ebola Treatment Centers (ETCs) that can safely care for patients with Ebola in the event that a cluster of Ebola patients overwhelms any of the regional Ebola and other special pathogen treatment centers.[15] Building on the state- and jurisdiction-based tiered hospital approach,[16] and meeting Congress's regional directive[17], HPP provided recipients with approximately $254 million of Ebola emergency supplemental funding from FY 2015 through FY 2019 to establish this nationwide, regional treatment network for Ebola and other infectious diseases. While emergency supplemental Ebola funding obligations have concluded, reflections on the program's many accomplishments and lessons learned will inform and drive future HPP activities.

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

[15] FY 2018 data are currently undergoing validation and were taken from end-of-year (EOY) Ebola data from the last completed HPP budget period (May 18, 2018 through May 17, 2019). Other sources include FY 2017 HPP Ebola Data, FY 2016 HPP Ebola Data, and FY 2015 HPP Ebola Data.

[16] 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

[17] See explanatory statement accompanying Title VI of Division G of the Consolidated and Continuing Appropriations Act, 2015 (P.L. 113-235)

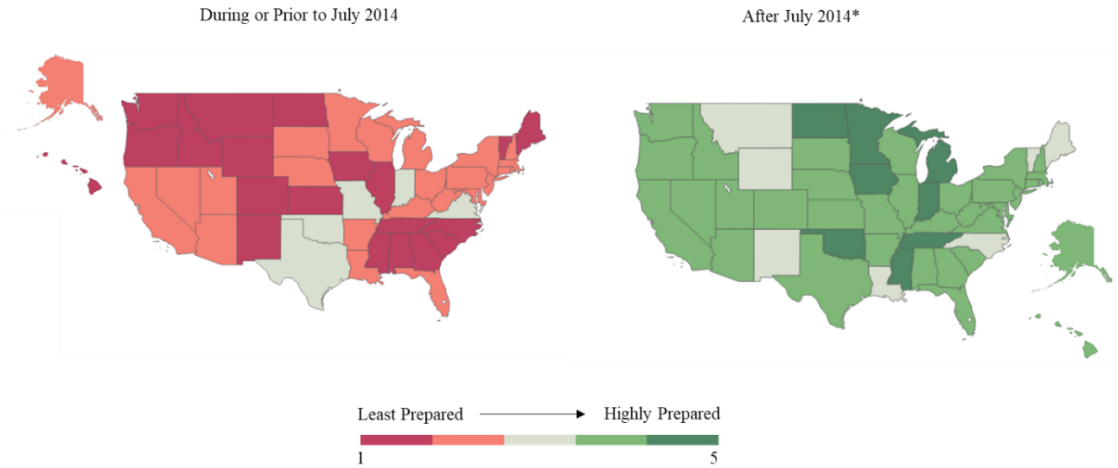
Through HHS investments, the U.S. health care system has achieved marked progress in the development of a regional network of tiered hospitals. In FY 2018, the average time it took an ETC to be prepared to admit an Ebola patient was 8.1 hours – well below the program goal of 72 hours. This was an improvement from 14 hours in FY 2017 and 22 hours in FY 2016. Preparedness to admit a patient with an other special pathogen (OSP) has also improved among ETCs: in FY 2018, the average time it took an ETC to be ready to admit an OSP patient was 5.5 hours (down from ten hours in FY 2017 and well within the 72-hour program goal). In FY 2018, 76 percent of Ebola funding recipients demonstrated operational readiness to move a patient across jurisdictions by ground or air to a regional Ebola and other special pathogen treatment center – an increase from 60 percent of funding recipients in FY 2017 and from 48 percent of funding recipients after the first year of funding (FY 2015)[18].

HPP's supplemental Ebola funding has been instrumental in enhancing recipients' tactical facility- and system-wide capacity to respond to an Ebola-like threat. In FY 2018, 48 percent of funding recipients reported that HPP Ebola funding improved overall readiness beyond Ebola. For instance, the funding has enabled recipients to prepare for and exercise other special pathogens such as measles, MERS, viral hemorrhagic fever, highly pathogenic avian influenza, and the Nipah virus. The benefits were also seen in real-world events – when a measles outbreak in New York City tested frontline facilities' ability to 'isolate, identify, and inform,' health care partners reported they felt that HPP Ebola funding had improved their infectious disease plans and staff preparedness[19].

Because of HPP investments, ASPR has seen improvement in preparedness capability for an Ebola-like event. In FY 2018, 83 percent of recipients responded that they have incorporated lessons learned from Ebola and OSP exercises into their regional concept of operations.

Figure 3 represents changes in recipient self-reported preparedness for an Ebola event, on a scale from one (least prepared) to five (highly prepared)[20]:

Figure 3. Self-Reported Ebola Preparedness

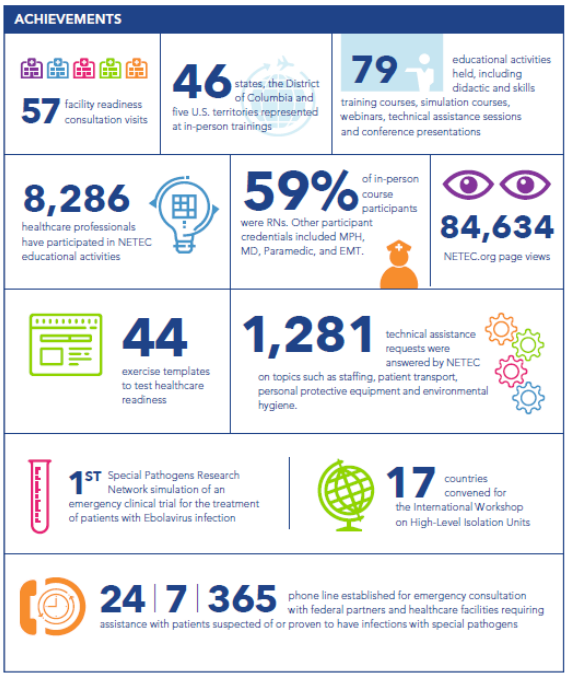


[18] FY 2018 data are currently undergoing validation and were taken from Part B end-of-year (EOY) Ebola data from the last completed Part B budget period (June 15, 2018 – June 14, 2019). Other sources include FY 2017 HPP Ebola Data, FY 2016 HPP Ebola Data, and FY 2015 HPP Ebola Data.
[19] FY 2018 data are currently undergoing validation and were taken from Part A end-of-year (EOY) Ebola data from the last completed Part A budget period (May 18, 2018 – May 17, 2019). Other sources include FY 2017 HPP Ebola Data, FY 2016 HPP Ebola Data, and FY 2015 HPP Ebola Data.
[20] Ibid.

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 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 ETCs, and assessment hospitals. NETEC is a consortium of the three U.S. health facilities that safely and successfully treated a confirmed Ebola patient – Emory University in Atlanta, Georgia; University of Nebraska Medical Center/Nebraska Medicine (UNMC) in Omaha, Nebraska; and the New York City Health and Hospitals Corporation/HHC Bellevue Hospital Center in New York, New York.

Figure 4. NETEC FY 2018 Achievements



NETEC[21] has significantly influenced 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, non-accreditation, and consultative 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 significant NETEC achievements has been the development of an integrated national clinical research network. Other key accomplishments are depicted in **Figure 4**, and include establishing resources such as a 24/7/365 phone line for emergency consultation with federal partners and health care facilities requiring assistance with patients suspected of or proven to have infections with special pathogens. 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. NETEC will continue to improve national preparedness for potential Ebola or other special pathogen events, introducing a new focus on frontline facility health care worker training in 2020, the final performance year of the cooperative agreement.[22] This focus aligns with the national preparedness goals in PAHPAIA (Sec. 2802(b)), which introduces new language on "protecting health care workers and health care first responders from workplace exposures during a public health emergency or exposures that could cause a public health emergency" such as special pathogens.

Increasing U.S. Quarantine Capacity and Accomplishments

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. possibly 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 (TSQC). TSQC has the capacity to quarantine up to 20 individuals simultaneously, if necessary, on the UNMC campus.

[21] 2018 NETEC Annual Report. https://netec.org/wp-content/uploads/2019/01/NETEC-Annual-Report-FY2018.pdf
[22] FY 2019 is the final year of NETEC funding, with the performance period taking place from June 30, 2019-June 29, 2020.

This center provides simulated clinical training to federal responders (National Disaster Medical System (NDMS) teams and the U.S. Public Health Service Commissioned Corps) in the appropriate care of individuals with Ebola or other highly pathogenic diseases, in both sophisticated and austere environments. In FY 2018, and in coordination between HPP and NDMS, UNMC provided short-term curriculum development and hands-on training on the proper donning and doffing of the type of PPE needed to respond to CBRN events, training 1,714 NDMS responders over the course of three days. As of August 2019, the HPP, NDMS and UNMC collaboration trained 293 NDMS staff and responders, having developed curriculum to provide simulated and virtually reality clinical training for health care personnel treating individuals with Ebola or other highly contagious diseases. In FY 2019, UNMC began developing additional courses to train NDMS responders on 1) the complexities of preparing patients for transport; 2) how to coordinate patient movement with other jurisdictions; and 3) transportation of patients with Ebola or similar highly infectious diseases. By the end of October 2020, UNMC will train 400 additional NDMS staff and responders.

Piloting a Regionalized Approach to Preparedness and Response

Leveraging the structure of HPP and the HCCs, the Regional Disaster Health Response System (RDHRS) demonstration projects provided funding directly to hospitals and health systems. The two pilots, which were initiated at the end of FY 2018 at Nebraska Medicine and Massachusetts General Hospital, focus primarily on building and maturing the partnerships required to effectively prepare for and respond to the management of patients in disasters, including those that facilitate rapid expansion of medical surge capacity of the existing health care system, coordination of patient and resource movement to support the response, and the swift involvement of specific clinical specialists.

Advancements in the RDHRS pilots reduce the need for federal support during multi-state, regional responses and simultaneously ensure that the wealth of assets and expertise held in private sector health care can be brought to bear in disasters. These sites improved all-hazards regional preparedness with a focus on the highly specialized clinical care capabilities related to specific 21st-century threats as well as to specific populations with additional health care needs in disasters. Initial results of these pilots have been promising in achieving these five aims:

- **Designing a Regional Approach to Partnering with Hospitals and Health Care Facilities**
  Collaborate and integrate with HCCs and developed a regional approach to identify hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by public health emergencies and disasters.
- **Identifying and Developing Guidelines Related to a Regional All-Hazards Approach**
  Ensure hospitals and health care facilities can provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases.
- **Expanding Specialty Care Expertise**
  Expanding specialty care expertise in trauma and chemical, biological, radiological, and nuclear casualty management.
- **Coordinating Medical Response**
  Coordinating medical response through mutual aid across state, local, tribal, territorial, and multi-state regional jurisdictions.
- **Integrating Measures of Preparedness**
  Integrating measures of preparedness into daily standards of care through health care system incentives and establish measures of health care system readiness at the state-, coalition-, and regional-levels.

Both RDHRS recipient sites have significantly improved clinical collaboration across the private health care sector in their states and HHS regions. By December 30, 2019, recipients developed and finalized

several tangible products that can be leveraged to advance the state of health care system readiness by providing clear frameworks, metrics, and guidelines related to medical surge capacity for all hazards.

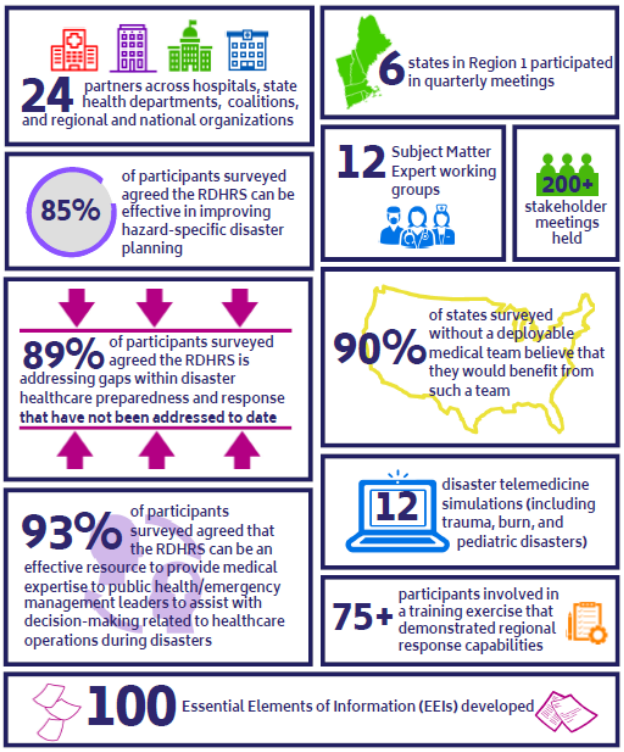
Products include:

- sample charter language and a governance structure for multi-state regional partnerships,
- model legislative language that addresses common state-level barriers to the allocation of personnel, resources, and equipment in disasters, and
- guidelines for the inclusion of clinical providers in state-level preparedness and response activities, including a medical component in the state emergency operations center.

The pilots also developed an inventory of potential models for state- or hospital-hosted deployable medical teams and strategies related to the creation and long-term sustainability of such teams as well as an analysis of potential financial incentives for health care system participation in disaster preparedness and response activities. To address operationalization of a regional system, the pilots generated frameworks for the essential elements of information (EEI) necessary to facilitate medical surge response at the statewide and multi-state regional levels and a roadmap to create an interoperable IT system that allows for the collection and sharing of EEIs and other real-time situational awareness of the operating status of the health care system. Finally, the pilots created recommendations for readiness metrics that can be used for peer review assessments, monitoring, recognition reporting, and a "Response Ready" designation program for HCCs.

The pilot sites have already demonstrated impact and potential for return on investment. In Massachusetts, pilot recipients found that 89 percent of surveyed participants agreed that RDHRS is addressing gaps within disaster health care preparedness and response that have not yet been addressed (see **Figure 5** for additional accomplishments)[23]. In Nebraska, use of a new situational awareness tool was able to decrease response time during a test for a resource request, with respondents completing the resource request within one-third of the time necessary prior to the introduction of the tool[24]. Through the development of their Legal Reference Guide, Nebraska found that familiarity with federal and state disaster laws had the potential to save significant costs (for example, up to $1,150,000 for each avoided State Health Insurance Portability and Accountability Act penalty and $1,295,000 in avoided Emergency Medical Treatment and Active Labor Act penalties)[25].

Figure 5. Massachusetts General Pilot Year Accomplishments

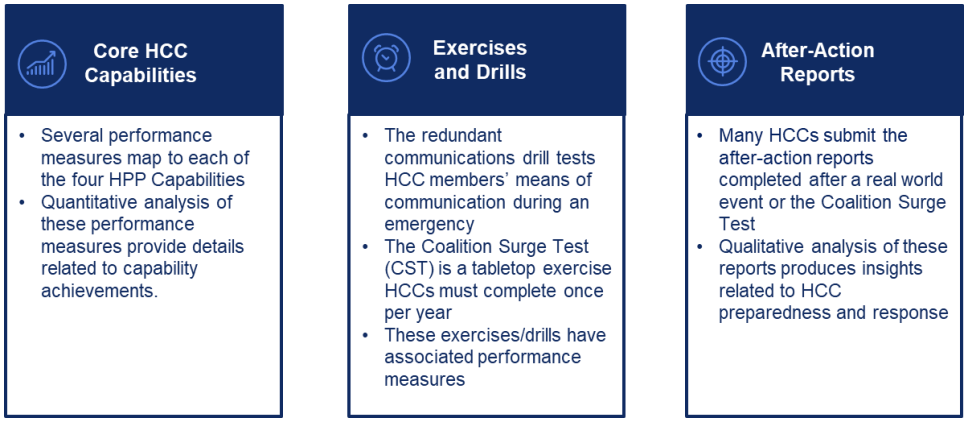


[23] MA/Region 1 Partnership for Regional Disaster Health Response: Year One Summary Report
[24] Nebraska Medicine, "Enhancing Situational Awareness across Nebraska Through Implementation of an Interoperable Communications Platform"
[25] Nebraska Medicine, "Nebraska Legal Reference Guide Overview"

Improving Preparedness through Evaluation and Research

ASPR monitors HPP recipient performance through a comprehensive health system evaluation process that 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 recipients. The health system evaluation process supports the development and monitoring of HPP performance measures (PMs) and ensures their alignment to the core concepts of the health care preparedness and response capabilities and funding opportunity announcements.

Figure 6. HPP Measurement Methods



FY 2021 will be the fifth year in which the 28 PMs will require reporting at the HPP recipient level, HCC level, and territories, freely associated states, and isolated frontier hospitals. Consecutive use of PMs fosters better communication of program results and continuous program improvement. These measures allow HPP to track trends in engagement, coordination, communication, patient care, and continuous learning, objectively. **Figure 6** depicts the methods used to measure HPP performance, which include capturing progress against the four HPP capabilities, evaluating success during exercises and drills, and examining after-action reports to produce new insights.

Over half of the PMs are exercise-based, which reduce the reporting burden on recipients, improve collection of actionable data, and permit data validation. Use of mixed reporting requirements to include exercise-based and program performance indicators over the course of the fiscal year/budget period provide context and nuance that can be used to analyze and understand programmatic achievements, identify promising practices, and readily identify areas for program improvement. Recipients report PM data in the fall of each year (the HPP cooperative agreement performance year runs from July-June), and ASPR issues results in the winter for the previous performance year. To measure HPP performance, a variety of measures was developed at the input-, activity-, output-, or outcome-levels. 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.

Providing Technical Assistance and Resources

HPP's staff play an important role in the success of the HPP cooperative agreement recipients. One HPP field project officer (FPO) is assigned in each of the ten HHS regions to provide technical assistance to the recipients and HCCs. The FPO is responsible for ensuring compliance with the programmatic aspects of the cooperative agreement (e.g., compliance with statutory, regulatory, accounting, and administration rules) and must work with recipients to ensure HHS programmatic objectives are met (e.g., recipients develop well performing HCCs capable of maintaining continuity of health care operations while addressing a surge in patients). The relationship between recipients and program management is a vital component of efficient and effective stewardship of federal funds. In addition to their project officer roles,

FPOs play a unique role in providing information about the health care systems in their region, attaining and maintaining situational awareness on the operational status of the health care systems and organizations within their assigned regions and providing technical assistance during health care emergencies.

Beginning in FY 2015, ASPR's Technical Resources Assistance Center, and Information Exchange (TRACIE) 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 recipients, coordinating the immediate health and medical response needs of at-risk communities, or promoting the recovery of communities after a disaster. **Figure 7** provides an infographic snapshot of TRACIE statistics and accomplishments, as of December 2019, including the number of visitors to the TRACIE website, number of technical assistance requests received, number of members in the TRACIE information exchange, and subscribers to the TRACIE Listserv. In addition to these accomplishments, TRACIE has published over 200 SME-validated resource materials and has developed nine issues of the newsletter, *The Exchange*, featuring lessons learned from practitioners in the field.

Figure 7. ASPR TRACIE Statistics

In direct support of HPP cooperative agreement requirements, TRACIE has: conducted webinars and provided virtual technical assistance to help better inform HPP recipients and their HCCs on a number of preparedness topics (e.g., HCC- related webinars, Hospital-Based Incident Command System); conducted online peer-to-peer engagement and support through the Information Exchange; created tools and templates (e.g., HCC Pediatric Surge Annex Template); and shared resource documents, tip sheets, and illustrative examples of promising practices (e.g., Federal Recovery Programs for Healthcare Organizations, updated list of peer-reviewed state and local plans and templates in the HCC Select Resources page).

In 2019, TRACIE developed an HCC template for the Pediatric Surge Annex and a HCC Surge Estimator Tool (Hospital Data Collection Form and Aggregator). Additionally, TRACIE partnered subject matter experts to develop a Partnering with the Healthcare Supply Chain During Disasters tip sheet that includes an HCC Supply Chain Integrity Self-Assessment. TRACIE also provides surge assistance and resources during and after incidents, to be particularly helpful for ASPR deployable personnel (e.g., NDMS). After fielding numerous calls over the last five years for issues related to Disaster Behavioral Health support for deployed health care personnel, TRACIE developed information modules focused on Disaster Behavioral Health Self Care for Healthcare Workers. Ongoing threats and mass violence events led to the development of a Mass Casualty Trauma Triage: Paradigms and Pitfalls resource that provides information to health care planners on mass casualty triage considerations with uncontained, unsafe incident scenes with extremely large numbers of casualties.

Engaging the Private Sector Health Care to Innovate and Invest in Readiness

The Emergency Care Coordination Center (ECCC), chartered in 2008, promotes federal, state, tribal, regional, and private sector collaborations designed to enhance the nation's delivery of primarily in-

hospital daily emergency medical care. The ECCC strives to improve the efficiency and readiness of the public and private health care sectors by promoting improvements to day-to-day emergency medical care capabilities that can create greater resiliency for our community emergency health care systems during and after a public health emergency.

To ensure the private sector health care system in the U.S. is able to respond to meet the needs of the public, the ECCC engages private health care sector stakeholders at the executive level from across the life sciences and health care industry – including hospitals, health plans, supply chain, biotechnology companies, and others – to develop financial incentives encourage private sector health system investment and participation in readiness. ECCC occupies a critically important position as the key federal convener in this space, leveraging this role to create a meaningful dialogue between federal partners across the U.S. government and health system CXOs (i.e., top senior executives, such as the chief executive officer, chief financial officer, chief operating officer, etc.) and to call upon those leaders to act on implementation of innovative financial levers for readiness.

Most recently, in the spring and summer of 2019, the ECCC sponsored a series of a National Academy of Sciences, Engineering, and Medicine (NASEM) workshops on engaging the private sector health care system to build capacity and preparedness. These discussions targeted health care executives from across the nation, who worked alongside federal leaders to build a business case for health system readiness. These workshops resulted in the prioritization and advancement of incentives for private health care engagement in readiness – including recommendations for readiness metrics and accreditation criteria, supply chain assessments and interventions, and administrative streamlining.

In addition to leading activities that strengthen public-private partnerships and incentives, the ECCC also explores accelerators that can increase the American public's capacity to respond effectively in an emergency. A recent national poll shows that most adults in the United States feel they lack preparation to provide help in a medical emergency during the minutes before professional responders arrive; however, 90 percent report that they would be more willing if they received appropriate training. ECCC drives innovation in this area by contributing to the following training initiatives:

- The Stop the Bleed campaign, launched in 2015, is a collaborative effort between private sector interests (the American College of Surgeons, The Hartford Consensus) and governmental representatives (ECCC, the National Security Council, the Department of Homeland Security (DHS), and the Department of Defense (DoD) that has had a successful public adoption.
- The Until Help Arrives initiative, launched in 2017, was a coordinated effort across FEMA, ASPR, and DoD and is being adopted by private sector professional societies with plans to disseminate widely.
- In partnership with the Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum, ECCC facilitated the creation of a framework for:
    - measuring health system readiness.
    - measuring population-based trauma outcomes.
    - using emergency department chief complaints to better understand resource utilization and as a means of surveillance for emerging health threats.
- Partnership with the CMS Center for Medicare & Medicaid Innovation in their effort to sponsor an alternative payment structure for EMS called the Emergency Triage, Treat, and Transport model.

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, the ECCC will continue to engage public and private sector health care partners to align health care system incentives with the American public's need for a prepared health care system. To achieve this goal, ASPR and

ECCC are leveraging and enhancing existing programs and identifying and targeting other regulatory programs and incentives that can be aligned to develop regional systems of care.

Protecting Critical Health Care and Public Health Infrastructure

The nation depends on the continuity of its health care systems, especially during disasters and emergencies. Over 92 percent of health care and public health infrastructure is privately owned and operated[26], with health care and public health systems relying on a complex network of staff, supplies, systems, and space to provide care in steady state and response. The complex networks of interdependencies often go beyond individual HCCs – with risks spanning the nation. ASPR's Critical Infrastructure Protection (CIP) program complements work of coalitions, focusing on nationwide risks and mitigation strategies. Under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience, HHS is the Sector-Specific Agency for the healthcare and public health (HPH) sector[27] and the Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) designates relevant critical infrastructure protection activities fall to ASPR. CIP, therefore, has specific responsibilities for protecting the nation's health critical infrastructure, ensuring enhanced capability and capacity-building across the nation.

Driven by partnership with private sector partners, CIP work serves as a mechanism to raise the overall health care system readiness and response. CIP core functions include:

1. **Network of Partners**: One of the primary ways CIP provides support and enhancement to the security and resilience of the nation's health critical infrastructure is through facilitating a collaborative voluntary public-private partnership between all levels of government and private sector critical infrastructure owners and operators. This partnership collaborates to identify risks from all hazards, including physical and cyber threats and explores mitigation strategies.
2. **Readiness & Response**: CIP builds decision-support and response capacity to enable government and private sector to respond to all hazard incidents, including both physical and cyber-related incidents. CIP also facilitates opportunities for these partners to exercise capabilities and plan to enhance preparedness.
3. **Risk Management**: CIP understands and supports mitigation of risks to HPH critical infrastructure, including cyber and supply chain risks. CIP analyzes health 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.

CIP operationalizes these functions to promote the resilience of the nation's health infrastructure by leading a dynamic public-private partnership, drawing from all aspects of the HPH sector, to manage risk and coordinate effective response to 21st-century threats. CIP's partnerships include coalition representatives, but also the infrastructure supporting national level health care and public health. In this way, CIP's partnerships can advise on a broad range of topics that support not only federal-level policy development but distill tools for implementing best practices at the local level. CIP work benefits HPP recipients by providing an avenue for information sharing, identifying gaps that individual recipients may not have identified themselves or within their coalition, and providing opportunities to

[26] CRITICAL INFRASTRUCTURE PROTECTION: Progress Coordinating Government and Private Sector Efforts Varies by Sectors' Characteristics. GAO Report. (2006.) https://www.gao.gov/assets/260/252603.pdf

[27] 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).

learn from and implement nationwide promising practices. Coalition partners can also work through CIP's partnership to identify broad areas of policy or regulatory challenges that impede infrastructure resilience. Through this network of trusted partners, collaborative preparedness efforts include better understanding risk profiles, exercising, sharing promising practices, supporting mechanisms to share sensitive information, and both sharing and planning response procedures. Robust collaboration continues through from preparedness to response.

Supporting Objective, Repeatable, Actionable Risk Assessments

In FY 2018, CIP launched a comprehensive risk assessment tool specific to the needs of the HPH Sector Partnership including HCCs. In FY 2019, CIP funded an initiative to expand the user base of the tool, serving as a nexus for risk management strategic alignment among the public health stakeholder community. The enhancement of the HPH Sector Risk Identification and Site Criticality (RISC) Toolkit will build the capability for owners and operators to identify key risks and gaps in capabilities and will support enhanced decision making by the HPP federal program managers and award recipients in resource allocation and strategic capacity building. This toolkit 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.

Translating Cybersecurity Priorities for Health Care

Since the enactment of the December 2015 Cybersecurity Information Sharing Act (CISA) (P. L. 114-113, Div. N) the HPH sector continues to prepare for and respond to unique challenges facing cybersecurity in the health care system. Through collaborative work between private and public sector representatives of over 120 industry and government leaders in the HPH Sector Partnership Cybersecurity Joint Working Group products, resources, and recommendations have been developed. These resources are of direct benefit to HPP recipients, who can implement nationwide recommendations.

In FY 2020, CIP will be preparing for the National Level Exercise, which will feature cybersecurity incidents, by working across ASPR, other federal partners, state, local, tribal, and territorial (SLTT) partners, and the private sector to develop an HHS Cyber Incident Response Plan. This plan will consider how cybersecurity attacks can not only hamper access to patient records and potentially impact patient care at an affected facility, but also how cybersecurity attacks may challenge responses to other natural disasters or threats.

As required by PAHPAIA, CIP will also work with partners to develop a "strategy for public health preparedness and response to address cybersecurity threats." This strategy will dovetail with issues highlighted during the incident response planning process and will identify areas for national action, modeled after the National Health Security Strategy.

Promoting Resilient Medical Supply Chains

Following the impacts of Hurricane Maria to a large portion of the medical product manufacturing industry in Puerto Rico, a high number of unidentified shortfalls within our nation's supply chain were identified. Since that time CIP has worked to coordinate exploration into root causes of potential impacts to the medical supply chain, including product shortages during disasters, and opportunities in with HPP recipients can support mitigation to such causes. CIP continues to coordinate between government and private sector partners to identify challenges within the nation's supply chain and potential solutions. The sharing of cybersecurity and medical supply chain coordination lessons learned and best practices on a nationwide scale will enable HPP recipients to better coordinate within their networks and on a national scale.

In FY 2020, CIP is creating an official public-private Working Group on Supply Chain to tackle a variety of issues including analyzing the recommendations from the 2019 FDA Drug Shortages Task Force report, *Drug Shortages: Root Causes and Potential Solutions* and the Homeland Security & Governmental Affairs Committee report, *A Price Too High: Cost, Supply, and Security Threats to Affordable Prescription Drugs* to identify ways government and private sector might innovate to prevent future shortages.

Supporting Federal and SLTT Decision-Making During Responses and Exercises

CIP works to connect partners and share information bi-directionally to support both private sector and government for more effective response. CIP supports federal senior leadership decision-making by providing analysis and expertise in critical infrastructure concerns, challenges, and interdependencies. Additionally, CIP provides information and decision to support to private sector partners, leading HPH Sector Partnership calls, supporting amplification of private sector concerns and issues, and helping to field and direct requests for assistance. Through this network of trusted partners, collaborative preparedness efforts include better understanding risk profiles, exercising, sharing promising practices, supporting mechanisms to share sensitive information, and both sharing and planning response procedures. Robust collaboration continues through from preparedness to response, with both gaps and successes bi-directionally shared throughout.

In FY 2019, CIP organized and led four partnership exercises to identify gaps and enhance response capabilities, with over 40 public and private sector organizations participating in the private sector complement to the Crimson Contagion National Level Exercise. Over 100 representatives from over 40 agencies, associations, organization, and facilities participated in each of the four daily calls throughout the Crimson Contagion 2019 Functional Exercise. The calls served as mini tabletop exercises that explored the impacts, challenges, and potential best practices during a severe pandemic influenza. There were rich, varied, conversations across each of the four days of play, discussing supply chain challenges, information sharing and communication mechanisms, sector interdependencies, and options to increase workforce protection. Before Crimson Contagion, the sector practiced with Flu Breaker, a tabletop exercise at the spring joint meeting with 20 sector coordinating council member organizations and five government coordinating council member organizations.

In FY 2019, CIP worked across the HPH Sector Partnership to develop and implement a Response Coordination "Playbook" to foster enhanced communication, information sharing, and coordination across public and private sector partners. During response, the Partnership serves as a critical information sharing node, with public and private partners working together on sharing and addressing nationwide challenges. These efforts complement internal coordination among coalitions by engaging nationwide partners and working directly with interdependent critical infrastructure sectors. In FY 2020, CIP will continue to work with DHS and FEMA to optimize use of ESF-14, Cross-Sector Business and Infrastructure, to address issues of private sector interdependencies and areas of support, which may not specifically fall under other ESFs. ESF-14 integration can further benefit HPP recipients through fostering connections across private sector partners and identifying nationwide solutions.

The HPH Sector looks forward to enacting the next iteration of the HPH Sector Specific Plan in FY 2020 to build the executive level participation in the regular partnership activities, ensuring a clear understanding of risks and gaps in capabilities through exercises and bi-directional information-sharing. Through coordination with government and private sector representation, the plan will include the sector's critical functions to serve as a factor in prioritizing risk mitigation activities; provide a framework to guide identification of emerging threat areas and ensure the ability of public and private sectors to collaborate during steady state and responses. CIP will continue to engage with HCCs, 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.

Recovering from Disasters and Other Public Health Emergencies

Critical to how a community will persevere and endure the consequences of emergencies and disasters is their capacity to recover. The ASPR Recovery program coordinates federal efforts to support sustainable restoration of the health care system, and to address disaster-caused health and social services recovery challenges, so American individuals and families affected by disasters experience better outcomes in terms of health and well-being. 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).

When the HSS RSF is activated, HHS (led by the ASPR Recovery program) 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 program integrates the capabilities of federal and state, local, tribal and territorial (SLTT) partners to conduct joint assessments of disaster-related recovery barriers and priorities and develop actionable interventions to improve the recovery of the health care, behavioral health, and social services systems. This capability has been repeatedly beneficial for HPP recipients, HCC members, and partners to help expedite recovery actions and gain access to critical recovery resources.

Disasters can create formidable challenges for health care systems to recover, particularly in rural areas where impacts to a single provider can imperil access to health care services for an entire community. The Recovery program's deployed teams coordinate efforts to address those critical gaps so coalitions—and the communities they serve—can recover. When 2018's Hurricane Michael devastated Northwest Florida, one hard-hit HCC member, the only provider within a two-hour drive for survivors, was left with roughly $5 million in uninsured damages. This gap in funding jeopardized care for community residents. The Recovery program worked alongside the coalition to troubleshoot the recovery barriers and help the coalition gain access to additional recovery resources from other federal and non-federal sources.

The Recovery program coordinates and catalyzes recovery actions to provide practical solutions that fill critical gaps. In addition to direct efforts to restore the health care system, the Recovery program prioritizes interventions designed to reduce the post-disaster burden on health care systems by addressing the critical drivers of injury and illness in disaster survivors. These behavioral health, environmental health, and social services interventions reduce the demand for hospitalization through prevention and mitigation, thus enabling the health care system to manage the post-disaster needs of the community.

In November 2018, the Camp Fire, the deadliest American wildfire in a century, struck the city of Paradise and other areas of Butte County, California. The Recovery program has since worked in Butte County to support local leadership of health and social services. The Recovery program deployed teams to conduct environmental health and behavioral health needs assessments to inform decision making, delivered specialized behavioral health training to first responders, local officials, and community leaders; and worked with local school systems to reduce the behavioral health burden on children and youth.

The Recovery program works in close partnership with HCCs to help health care systems rebuild to be more resilient in the next disaster, better able to withstand the pressures of emergency events and to respond to the needs of the population. At the conclusion of the Recovery program mission for Hurricane Harvey in Texas, the program developed a planning guide for affected coalitions for improved readiness for recovery in future disasters.

Following the catastrophic effects of Hurricane Maria, the Recovery program partnered with the Puerto

Rico Department of Health and existing HCCs to establish a more efficient model to support recovery and resilience. By working at the territorial, regional, and local levels, the Recovery program helped Puerto Rico establish new "hub-and-spoke" preparedness plans that embody a more effective approach to providing medical access throughout the territory. In FY 2019 and 2020, ASPR Recovery program coordinates training, capacity building, and a series of functional exercises for all the "hub-and-spoke" systems to build a health care system in Puerto Rico that will be more resilient in future disasters, and better able to save lives during emergencies. This model is depicted in **Figure 8.**

Figure 8. Puerto Rico Regional Recovery Hub-and-Spoke Coalition Readiness Model

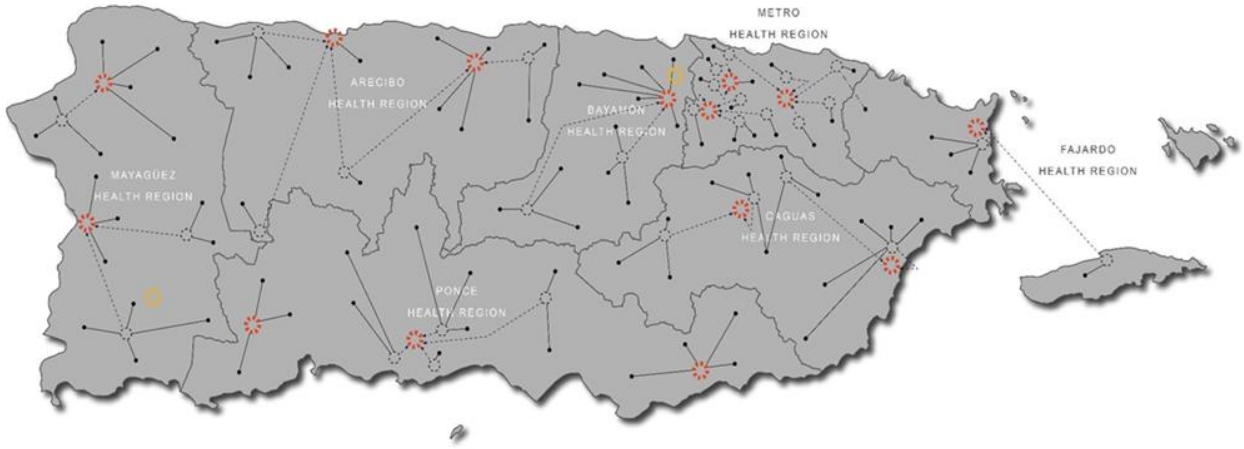
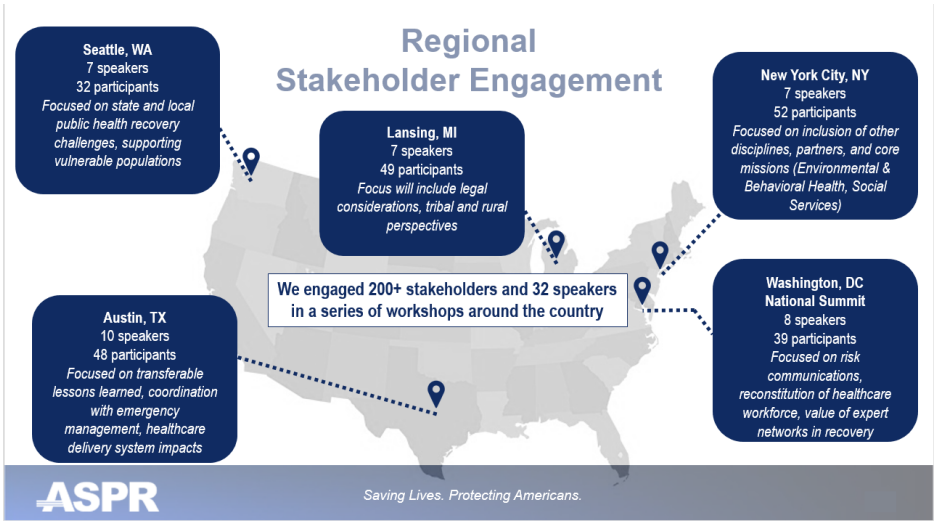


Figure 9. ASPR Recovery National and Regional Engagement for Implementing the National Biodefense Strategy for Bio-incident Recovery



The Recovery program also led the implementation of Goal 5 of the National Biodefense Strategy in FY 2019 through the conduct of a national-level and regional engagement for bio-incident recovery depicted in **Figure 9**. The accomplishment of this engagement was the fulfillment of key objectives in the National Biodefense Strategy by developing draft National Guidance for Bio-incident Recovery that establishes a common knowledge base for how SLTT communities recover from the unique challenges associated with a biological incident (bio-incident). In FY 2020, the Recovery program is rolling out the guidance to coalitions nationwide. The guidance developed will assist states, tribes, territories, and communities recover to restore the community, the economy, and the environment after a bio-incident.

Funding History	
FY 2017	$253,958,000
FY 2018	$264,555,000
FY 2019	$264,555,000
FY 2020 Enacted	$275,555,000
FY 2021 President's Budget	$257,555,000

Budget Request

The FY 2021 President's Budget for the Hospital Preparedness Program is $257,555,000, which is -$18,000,000 below the FY 2020 Enacted level. Within the total, $231,500,000 is provided for HPP formula-based cooperative agreements to states, territories, and freely associated states, the District of Columbia, and three high-risk political subdivisions. This funding will be distributed across all 62 awards. Funds also support TRACIE, ECCC, the Recovery program, CIP, and HPP administration and performance evaluation and oversight. The FY 2021 President's Budget does not include continued funding for the RDHRS pilot projects.

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, 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. In FY 2021, HPP will continue progress towards mirroring existing health care referral patterns, supporting efforts to move beyond jurisdictional boundaries towards interstate regional coordination, and promoting disaster response clinical expertise.

In FY 2021, ASPR will continue to utilize the majority of the PMs first implemented in FY 2017 to evaluate and analyze HPP funding impact. The 2017 PMs 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	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 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 (Outcome)	FY 2018: 50.0 % Target: 40.0 % (Target Exceeded)	55.0 %	55.0 %	Maintain
15a Increase the percent of HCCs that have tested the ability to coordinate among its members during an exercise or event (Developmental)	FY 2018: 98.0 % Target: 80.0 % (Target Exceeded)	100.0 %	100.0 %	Maintain

ASPR Hospital Preparedness Program – Cooperative Agreement Awards by Recipient

(in whole dollars)

State, Locality, Territory	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Alabama	$3,101,457	$3,133,713	$3,133,713	-
Alaska	$1,097,949	$1,163,276	$1,163,276	-
American Samoa	$276,077	$276,229	$276,229	-
Arizona	$4,704,562	$4,469,334	$4,469,334	-
Arkansas	$2,073,408	$2,151,148	$2,151,148	-
California	$23,274,780	$22,111,041	$22,111,041	-
Chicago	$2,742,281	$2,884,681	$2,884,681	-
Colorado	$3,255,651	$3,391,630	$3,391,630	-
Connecticut	$2,241,789	$2,239,494	$2,239,494	-
Delaware	$1,069,426	$1,098,435	$1,098,435	-
Florida	$11,823,573	$11,232,394	$11,232,394	-
Georgia	$7,984,714	$9,054,457	$9,054,457	-
Guam	$344,674	$344,114	$344,114	-
Hawaii	$1,272,454	$1,298,684	$1,298,684	-
Idaho	$1,306,270	$1,398,157	$1,398,157	-
Illinois	$8,808,313	$9,303,292	$9,303,292	-
Indiana	$3,927,515	$3,879,644	$3,879,644	-
Iowa	$2,040,550	$2,053,181	$2,053,181	-
Kansas	$2,002,917	$2,006,517	$2,006,517	-
Kentucky	$2,851,105	$2,879,263	$2,879,263	-
Los Angeles County	$9,155,013	$8,697,262	$8,697,262	-
Louisiana	$2,990,820	$3,021,537	$3,021,537	-
Maine	$1,107,031	$1,182,775	$1,182,775	-
Marshall Islands	$269,480	$271,087	$271,087	-
Maryland	$5,134,799	$5,593,242	$5,593,242	-
Massachusetts	$4,069,878	$3,893,092	$3,893,092	-
Michigan	$5,770,572	$5,493,331	$5,493,331	-
Micronesia	$282,682	$289,083	$289,083	-
Minnesota	$3,376,813	$3,289,000	$3,289,000	-
Mississippi	$2,038,196	$2,054,826	$2,054,826	-
Missouri	$3,636,821	$3,670,013	$3,670,013	-
Montana	$1,090,377	$1,146,062	$1,146,062	-
Nebraska	$1,398,788	$1,447,950	$1,447,950	-
Nevada	$2,593,012	$2,884,946	$2,884,946	-
New Hampshire	$1,098,617	$1,139,558	$1,139,558	-
New Jersey	$5,369,840	$5,101,348	$5,101,348	-
New Mexico	$1,590,617	$1,692,196	$1,692,196	-
New York	$9,864,244	$10,547,466	$10,547,466	-
New York City	$7,501,609	$7,126,529	$7,126,529	-
North Carolina	$6,086,316	$5,960,126	$5,960,126	-

ASPR Hospital Preparedness Program – Cooperative Agreement Awards by Recipient
(in whole dollars)

State, Locality, Territory	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
North Dakota	$1,063,632	$1,085,262	$1,085,262	-
Northern Mariana Islands	$276,615	$280,158	$280,158	-
Ohio	$7,072,358	$6,718,740	$6,718,740	-
Oklahoma	$2,510,199	$2,531,135	$2,531,135	-
Oregon	$2,588,708	$2,663,500	$2,663,500	-
Palau	$256,518	$257,765	$257,765	-
Pennsylvania	$7,728,428	$7,342,007	$7,342,007	-
Puerto Rico	$2,596,212	$2,466,401	$2,466,401	-
Rhode Island	$1,063,672	$1,085,074	$1,085,074	-
South Carolina	$3,139,944	$3,197,531	$3,197,531	-
South Dakota	$1,071,504	$1,103,158	$1,103,158	-
Tennessee	$4,004,671	$3,879,880	$3,879,880	-
Texas	$15,493,193	$14,718,533	$14,718,533	-
Utah	$2,368,945	$2,250,498	$2,250,498	-
Vermont	$1,066,451	$1,091,451	$1,091,451	-
Virgin Islands (US)	$303,699	$300,568	$300,568	-
Virginia	$6,897,199	$7,999,190	$7,999,190	-
Washington	$4,336,358	$4,482,437	$4,482,437	-
Washington, DC	$1,148,960	$1,279,237	$1,279,237	-
West Virginia	$1,404,726	$1,428,115	$1,428,115	-
Wisconsin	$3,416,869	$3,378,264	$3,378,264	-
Wyoming	$1,066,149	$1,090,984	$1,090,984	-
Total Resources	**$231,500,000**	**$231,500,000**	**$231,500,000**	**-**
Note: FY 2020 and FY 2021 amount are estimates				

Summary of Cooperative Agreement Awards
(in whole dollars)

ASPR Hospital Preparedness Program	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Number of Awards	62	62	62
Average Award	$3,733,871	$3,733,871	$3,733,871
Range of Awards	$256,518 - $23,274,780	$257,765 - $22,111,041	$257,765 - $22,111,041

Preparedness and Response Innovation

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	--	--	**15.000**	**+15.000**
FTE	--	--	**6**	**+6**

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

New challenges confront disaster response and require new solutions to ensure our capability and capacity to protect Americans from national security health threats. ASPR's new Preparedness and Response Innovation program will develop, prototype and procure revolutionary health security products, technologies and other innovations that will equip our responders to meet the unique and emerging health needs that result from disasters, natural or manmade. Establishing this program signals the importance of ASPR's mission in developing technologies beyond chemical, biological, radiological and nuclear medical countermeasures and adapting these technologies and practical solutions to ensure the availability of the highest standards of care, when they are needed the most. This activity will place emphasis on revolutionary advancements in health security products, technologies and solutions, specifically to invigorate operations, response, recovery, deployment and dispensing activities. The first two projects focus on portable dialysis technologies and distributed saline production. Technologies such as these have the potential to improve health outcomes dramatically for patients during an event.

ASPR and CMS do a tremendous job to identify and ensure dialysis treatment for end-stage renal disease (ESRD) patients during disasters using emPOWER[28]. Through emPOWER, federal-to-community level partners are able to plan and take action to protect the health of nearly 400,000 outpatient and home-based dialysis patients that live in communities across all states and five territories. In the wakes of Hurricanes Irma and Maria, the emPOWER Program helped ASPR, CMS, and territorial public health officials identify health care and resource gaps for dialysis patients and immediately engage with End-Stage Renal Networks and dialysis providers to ensure continuity of their life-maintaining health care services. While there is a great pipeline established through emPOWER to identify patients and coordinate care, treatment options are limited following disaster events, and individuals on dialysis must be evacuated and provided temporary housing to continue treatments. With these investments, ASPR intends to change this paradigm and advance American Kidney Health. ASPR will ensure people living with kidney failure have access to readily available portable dialysis technologies and access to treatments in any situation. ASPR will develop next-generation portable dialysis units that can provide support to people living with kidney failure in low-resource settings or within their homes, so that they can have access to dialysis with minimal power and from publicly-available water sources, allowing them to stay in their home to receive treatment, or return home sooner following a disaster.

[28] See National Disaster Medical System (NDMS) section for more details on emPOWER program.

During hurricane Maria, ASPR moved approximately 180 dialysis patients using the NDMS, at an approximate cost of $280,000 per patient. Subsequently, more than $1 million per month was paid to sustain, house, transport and treat this population of patients that were relocated from a disaster zone.

The US lost one-third of its production capacity for sterile saline manufacture during hurricane Maria. Additionally, the public is beholden to market influences on, and foreign manufacture of, active pharmaceutical ingredients (API) that make up all the constituents of the medical countermeasures purchased, stored, and distributed within the Strategic National Stockpile. Global markets are struggling to address shortages, especially during times of greatest demand. There has been an increase in health systems purchasing products on the grey market and current production strategies are subject to increased pricing and shortage of this critical life-saving medical supply. The need to shift to distributed, point-of-need manufacture is paramount to ensuring access to limited resources. The ASPR Priority Medicines on Demand program seeks to disrupt the current market influences, production and last-mile distribution paradigms and ensure the availability of saline at point-of-use. This will not only completely disrupt API lockup contracts that have resulted in 1,500 percent or more increases in generic drug prices, but will also develop and validate enabling technologies that will allow drug production to return to US soil.

Funding History	
FY 2017	--
FY 2018	--
FY 2019	--
FY 2020 Enacted	--
FY 2021 President's Budget	$15,000,000

Budget Request

The FY 2021 President's Budget for Preparedness and Response Innovation is $15,000,000, which is +$15,000,000 above the FY 2020 Enacted level. This funding level will support two projects: portable/in-home dialysis care and the manufacture of sterile saline on demand. The ASPR PRI program also aligns with the Secretary's kidney care and Drug Pricing initiatives, as well as guidance called out in M-19-25 "Fiscal Year 2021 Research and Development Budget Priorities." The ASPR PRI program will meet those goals and priorities, including the establishment of the right patient and product baselines to meet the Secretary's goals of improving access to ESRD treatment options, with the eventual goal of having 80 percent of ESRD patients receive dialysis in the home. Additionally, ASPR's Priority Medicines on Demand initiative is directly in line with the Secretary's goal to increase drug availability in the United States.

The initial two projects of the PRI program will multiply the capabilities of ASPR to save lives and protect Americans from 21st century threats. ASPR will no longer have to rely upon extremely costly measures for treating and transporting dialysis patients during disasters. The Priority Medicines on Demand Program will ensure availability of sterile solutions for injection and reduce the long-term costs of sustaining the SNS by eliminating the need to re-purchase expired sterile solution products. Additionally, this will have a significant positive impact on last-mile delivery issues that have plagued ASPR and HHS for years by producing saline at point-of-use. To that end, in the event of a large-scale biological attack, the U.S. federal government has a challenging task: dispensing lifesaving antibiotics and other medicines as quickly as possible. Establishing novel distributed manufacturing platforms that produce MCMs at point-of-need will address the supply chain, staffing challenges and distribution and dispensing issues associated with last-mile delivery.

ASPR Dialysis Care

Portable/In-Home Dialysis Care Prototype Design - $6 million
The PRI program will conduct a review of product requirements and architecture design. This will include conducting R&D on portable dialysis platforms that can create dialysate from potable water sources, and ensure the safety of patients using the technology at home or in a temporary outpatient care facility. The program will fabricate and demonstrate a prototype that extends the capabilities of the next-generation home hemodialysis systems under evaluation by the FDA. This will be achieved by designing advanced features to create the capability of treating multiple patients on a single hemodialysis system.

Priority Medicines on Demand

Sterile Saline Manufacture at Point of Need - $9 million
The PRI program will engineer demonstration units and perform multiple demonstrations, and begin transition activities of prototype units. These will require engineering design demonstration reports, refined architecture reviews, and programmatic risk assessments. The program will also begin validation of sterile saline on-demand technologies, to include the build-out of one modular Current Good Manufacturing Practice (cGMP) facility, establishment of analytical capabilities and cGMP protocol design.

Biomedical Advanced Research and Development Authority

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**561.700**	**561.700**	**561.700**	**--**
Advanced Research and Development (non-add)	*501.700*	*501.700*	*476.700*	*-25.000*
Operations and Management (non-add)	*60.000*	*60.000*	*85.000*	*+25.000*
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

The Biomedical Advanced Research and Development Authority (BARDA) was created as part of ASPR in 2006, when the Public Health Service Act was amended by the Pandemic and All Hazards Preparedness Act. Congress reauthorized the Act in 2013, and again in 2019 as PAHPAIA. BARDA works with both public and private sector partners to support the advanced research, development, regulatory approval and procurement of life-saving medical products—drugs, vaccines, therapeutics diagnostics, and medical devices, known collectively as medical countermeasures (MCMs). As advanced development is both costly and technically challenging, BARDA supports its partners by providing both funding and access to core support services and subject-matter expertise. The resulting MCMs serve as life-saving technologies during public health emergencies involving CBRN threats. Certain qualifying MCMs are stockpile eligible in the SNS through PBS.

BARDA has a proven record of accomplishment, built upon longstanding collaborations with the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (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), and the Director of National Intelligence, these agencies constitute the PHEMCE, a body that sets research and development priorities under a five-year strategy and implementation plan. BARDA's strategy is further elaborated in its own strategic plan. The PHEMCE also facilitates the transition of promising MCMs from the early-stage portfolios of PHEMCE partners into BARDA's advanced-stage portfolio. BARDA also focuses on evaluating, developing, and potentially acquiring commercial products that can be repurposed for MCM uses and developing multipurpose MCMs with commercial potential. These approaches enable more cost-efficient alternatives to stockpiling in the SNS using rotated stock (e.g., vendor managed inventory systems).

Enhancing Public-Private Partnerships to Face National Health Security Threats

BARDA partners with academia, non-governmental organizations, and private sector companies of all

sizes, from large pharma to promising startups.[29] Though the majority of BARDA's partnerships are research and development contracts, BARDA has expanded its use of other transaction authority (OTA). Unlike contracts, OTAs allow for the establishment and management of *portfolios* of candidate MCMs, which may then be modified based on mutual strategic needs. Since 2013, BARDA has awarded seven OTA partnerships spanning its CBRN and pandemic influenza programs, including partnerships with GlaxoSmithKline (established in 2013), Astra Zeneca (established in 2015 then transferred to Pfizer in 2016), Roche and the Medicines Company (both established in 2016), Regeneron (established in 2017), and Genentech and Janssen (both established in 2018). These partnerships allow BARDA to more effectively and efficiently collaborate with each product developer. BARDA exercised its OTA authority to support the research and development of a range of MCMs for such threats as pandemic influenza, multidrug-resistant bacteria, chemical agents, and Ebola, among many other threats. These partnerships allowed BARDA to establish consortiums with the product developers and other innovators researching and developing the next generation of MCMs against these and other threats.

In July 2016, BARDA established the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X), another novel public-private-partnership aimed at promoting innovation in antibacterial research and development by building a portfolio of early-stage candidate drugs, vaccines, and diagnostics. As of January 2020, CARB-X has made awards to 53 different companies. Six projects have entered clinical trials, including:

- Novel vaccines targeting drug-resistant superbugs;
- Next-generation, rapid, point-of-care diagnostics, so that physicians can determine in hours (and not days) if and what antibiotics to prescribe to a patient;
- Antibody-based therapeutics that overcome the ability of bacteria to evolve resistance;
- Phage-based therapies that can be quickly tailored to treat an individual's specific infection; and,
- New classes of antibiotics against which bacteria will have difficulty developing resistance.

This partnership, managed via a grant to Boston University, has led to the establishment of the CARB-X Global Accelerator Network, a network of ten accelerators from six countries that provide business, regulatory, and scientific support to the projects funded by CARB-X.

To encourage private sector involvement, minimize development costs and risks, and accelerate product development and approval, BARDA has established four core services assistance programs that provide nonclinical, clinical, and manufacturing services that address capability gaps of less mature MCM developers. The core services also form a key component of the National Medical Countermeasure Response Infrastructure. The core services are as follows:

- *Centers for Innovation and Advanced Development and Manufacturing (CIADM):* Formed in June 2012, these novel public-private partnerships with industry and academia focus on manufacturing innovation. In addition to supporting MCM development, the CIADMs are also able to meet national surge manufacturing demands for MCMs during public health emergencies. These centers previously supported the 2013 H7N9 avian influenza response, the 2014–2015 Ebola response, and the 2016–2017 Zika response.

- *Fill Finish Manufacturing Network (FFMN):* Established in 2013 to assist developers with final drug product manufacturing, the FFMN provides sterile product formulation and filling capabilities (e.g., vials and syringes) as needed for both product development and emergency responses. Originally comprised of four domestic manufacturing organizations, BARDA recently added two additional contractors with more experience in biologics. Notably, the FFMN supported the production of the experimental Ebola therapeutic ZMapp for the 2014–2015 Ebola response.

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

- *Non-Clinical Studies Network:* Established in 2011, the Non-Clinical Studies Network enables the conduct of key animal studies to support MCM development. Comprised of 23 different laboratories, the network has performed over 128 non-clinical studies under 71 BARDA projects to date. These studies include the development of animal models as needed to support product approval, the evaluation and repurposing of commercial products, and the evaluation of MCMs within the context of an emergency response.
- *Clinical Studies Network (CSN):* Formed in 2014, the CSN provides clinical services to support MCM development and evaluation and to provide surge capacity of clinical capabilities during public health emergencies. Since its inception, the CSN has engaged in six clinical research projects, including supporting the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) vaccine study during the 2014–2015 Ebola response. The CSN also supported the 2016-2017 Zika response by collecting clinical samples to accelerate the development of Zika diagnostics. In FY 2016, the CSN also led the first BARDA-sponsored clinical trial, the BRITE study, to evaluate long-stored vaccine components from the National Pre-pandemic Influenza Vaccine Stockpile; this study showed that the vaccine was still effective, saving millions of dollars in production and re-procurement costs.

Developing Multi-Use Products

The 2010 PHEMCE Review recommended that BARDA focus on more sustainable, multipurpose products possessing both a biothreat and commercial indication as well as platform capabilities, to reduce the time required to respond to an emerging event.

BARDA supports the development of antibiotics that address biothreats such as weaponized anthrax, plague, and tularemia, while also treating high priority community- and healthcare-acquired bacterial infections. Bacterial infections following a CBRN event, or influenza pandemic, are likely to cause significant morbidity and mortality due to secondary infections. To respond to emerging threats, like Ebola, BARDA is supporting the development of platform manufacturing technologies that accelerate the ability to respond to rapidly evolving threats.

BARDA also employs a repurposing strategy for the radiological/nuclear, chemical, and thermal burn programs. The injuries caused by these threats often have treatment solutions with viable commercial markets. Many also have potential cross-threat synergies (e.g., systemic treatments to quell excessive inflammatory responses apply to all three aforementioned portfolios). For example, treatments for neutropenia and thrombocytopenia are used to treat patients for cancer therapy and acute radiation syndrome and skin treatments for diabetic foot ulcers and severe thermal burns have the potential to treat cutaneous radiation injury and chemical burns. The repurposing of commercial products also enables the use of vendor-managed inventories (VMI) as a more cost-effective alternative to stockpiling by leveraging product rotation based on commercial use.

Building a Robust and Formidable MCM Development Pipeline

BARDA, in partnership with industry, has built a robust and formidable pipeline of MCMs in advanced development. These efforts focus on countering the medical consequences of 14 CBRN threats as identified by DHS. These advanced development programs have supported 27 products that have transitioned to support under PBS, 16 of which have been procured for the SNS.

BARDA's efforts have led to the FDA licensure, approval, or clearance of 53 MCMs since 2008, nineteen of which focus on countering CBRN threats (eleven approved under the FDA's Animal Rule), including:

- Raxibacumab anthrax antitoxin (2012)
- HBAT botulinum antitoxin (2013)

- Anthrasil anthrax antitoxin (2015)
- Neupogen to treat myelosuppresive radiation exposure (2015)
- BioThrax vaccine for post-exposure prophylaxis of anthrax (2015)
- ANTHIM anthrax antitoxin (2016)
- VABOMERE to treat complicated urinary tract infections (2017)
- Leukine to treat myelosuppresive radiation exposure (2018)
- TPOXX to treat smallpox disease (2018)
- ZEMDRI to treat complicated urinary tract infections (2018)
- XERAVA to treat complicated intra-abdominal infections (2018)
- RECELL to treat thermal burn wounds (2018)
- Seizalam to treat status epilepticus (2018)
- QMS Plazomicin Assay diagnostic to aid in plazomicin (ZEMDRI) therapy (2018)
- Silverlon dressing to manage mustard-induced vesicant injuries (2019)
- Applied Biosystems anthrax detection kit (2019)
- OraQuick Ebola rapid diagnostic test (2019)
- JYNNEOS smallpox and monkeypox vaccine (2019)
- ERVEBO Ebola vaccine (2019)

BARDA also supported the FDA approval of the Grifols Procleix Zika Virus Assay, the Roche Cobas Zika assay, and Siemens ADVIA Centaur Zika assay. Each of these is a highly sensitive, high-throughput diagnostic for identifying the Zika virus. In FY 2020–2021, BARDA anticipates further FDA approvals for vaccines and therapeutics against Zaire strain of the Ebola virus, as well as biodosimetry devices and biothreat diagnostic devices. The development pipeline remains poised to continue this trend, transitioning CBRN products from advanced research and development to potential acquisition under PBS (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 anthrax portfolio is one of BARDA's most mature portfolios, supporting the development and approval of three anthrax antitoxins (Raxibacumab, ANTHIM, and Anthrasil), licensure of an anthrax vaccine for post-exposure prophylaxis (BioThrax), and the licensure of a new facility to expand domestic vaccine manufacturing capacity. In 2019, the FDA approved the first anthrax diagnostic kit for use in commercial labs during an anthrax event. BARDA is also supporting the development of two next-generation vaccine candidates and the development of laboratory-based and point-of-care assays. One of the next-generation anthrax vaccine candidates has transitioned to PBS and the first procurement of the vaccine occurred in FY 2019.

Smallpox: Smallpox remains a threat of high concern to the U.S. and the international community. BARDA's goal is to ensure adequate vaccine supply for all Americans, including special populations, and to make available at least two different therapeutic agents as recommended by the National Academy of Medicine of the National Academies of Sciences, Engineering, and Medicine. Since 2006, BARDA has supported the development and procurement of smallpox vaccines and antiviral drug candidates with different mechanisms of action.

Under PBS, BARDA supported the late-stage development, procurement, and delivery to the SNS of the smallpox modified vaccinia Ankara (MVA) vaccine for immunocompromised patients. In 2019, the FDA approved the JYNNEOS (MVA) smallpox vaccine to prevent smallpox and monkeypox. JYNNEOS may also be used under EUA for at-risk populations. Additionally, BARDA is supporting development of a freeze-dried formulation of JYNNEOS that has a potentially greater shelf-life and lower stockpiling costs. With support from BARDA, FDA approved TPOXX, an antiviral drug for treating smallpox disease, in

July 2018. Prior to this approval, this MCM was procured and stockpiled in the SNS for potential use under EUA. The development of a second smallpox antiviral drug remains a high priority for advanced research and development and potential procurement.

Broad Spectrum Antimicrobials and Combating Antibiotic-Resistant Bacteria Initiative: Antimicrobial resistance complicates the nation's ability to respond to public health emergencies—in treating primary infections from biothreat agents as well as secondary infections likely to emerge during a public health emergency response. To combat this threat, the United States needs a diverse and vibrant pipeline of antimicrobials to ensure a wide array of treatment options. BARDA's Broad Spectrum Antimicrobials (BSA) program seeks to develop MCMs that counter DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders) and address healthcare- and community-acquired multi-drug resistant pathogens. Since 2010, BARDA has supported the FDA approval of three new antibiotics: VABOMERE (2017), ZEMDRI (2018), and XERAVA (2018). Seven antibiotic candidates are currently in Phase 3 clinical development.

To support a robust early-stage antibacterial pipeline, BARDA and National Institute of Allergy and Infectious Diseases (NIAID) established CARB-X. The goal of CARB-X is to accelerate the development of antibacterial candidates soon after their discovery, transitioning them to Phase 1 clinical testing. As of December 2019, CARB-X has accelerated the efforts of 47 different companies with six projects having advanced to clinical evaluation.

BARDA has also funded antimicrobial resistance diagnostics, focusing on those with both biothreat and routine healthcare utility. This ensures the availability of diagnostics during a biothreat attack with potentially drug-resistant agents. 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.

BARDA will continue to support the advanced research and development of promising antibacterial candidates to address the threat of potentially engineered biothreat pathogens that may be resistant to stockpiled antibiotics.

Viral Hemorrhagic Fever: Viral Hemorrhagic Fevers (VHF), such as those caused by Ebola viruses (Zaire and Sudan) and Marburg virus, are biological threat agents of concern as well as global emerging infectious disease threats. The 2014 outbreak of Ebola in West African countries highlighted the severity of the disease as well as the extreme challenges of providing adequate medical care and preventing disease transmission. With great urgency, the USG launched an immediate, large-scale response in 2014, in which MCMs played a critical role.

To expedite product development against VHFs, BARDA pulled early-stage Ebola MCM candidates into its new Ebola portfolio and fully engaged with industry partners to expedite development of their candidates. In FY 2017, BARDA transitioned four candidates to support under PBS: two therapeutics and two vaccines. Due to these investments, the products are available for 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 the DRC to help the WHO temper the outbreak. BARDA's VHF program also continues to build on NIH's and DoD's long-standing research and development programs into vaccines, therapeutics, and diagnostics.

Ebola Vaccines: In FY 2017, BARDA transitioned two Ebola vaccines against the Zaire strain—one from Merck, one from Janssen/Bavarian Nordic—to PBS for late-stage development and potential procurement. In December 2019, the FDA approved Merck's vaccine, ERBEVO. This vaccine is currently being evaluated in the DRC as part of a clinical trial during the current Ebola response. The

Janssen/Bavarian Nordic vaccine is being used in a clinical trial in Uganda for health care workers and front-line workers.

Ebola Therapeutics: In late FY 2014, BARDA supported the advanced development and manufacture of Mapp Biopharmaceutical's therapeutic monoclonal antibody (ZMapp, produced in tobacco plants) for Ebola Zaire disease. This experimental drug was first used in the 2014-2015 Ebola response under FDA's expanded access ("compassionate use") regimen in West Africa. In FY 2015, a randomized controlled clinical trial began in both West Africa and the U.S. to evaluate the safety and efficacy of all candidate Ebola therapeutics, including ZMapp. In FY 2016, the FDA approved an expanded access protocol for ZMapp, enabling the collection of additional clinical data. BARDA also supported the transition of ZMapp manufacture from a tobacco-based system to a more conventional cell-based system.

BARDA also made advanced research and development investments into other Ebola therapeutics, including another monoclonal antibody therapy and a small molecule antiviral drug candidate with broad-spectrum activity against viral hemorrhagic fever viruses. In FY 2017, BARDA awarded two new contracts under PBS for the late-stage development and potential procurement of two Ebola therapeutics, both of which are being used in the NIH-sponsored clinical trial and a compassionate use protocol as part of the current DRC Ebola response. In 2019, BARDA initiated investments in Ridgeback Biopharmaceutical's monoclonal antibody, originally developed by NIAID/VRC. In the current DRC outbreak, all four candidates were evaluated under a randomized clinical trial, PALM, the results of which showed that the Regeneron monoclonal antibody cocktail, REGN-EB3 and Ridgeback Biopharmaceutical's mAb114 provided efficacy, superior to ZMAPP. These two products are the only therapeutics being used to treat EVD patients in the DRC and will remain a primary focus for BARDA in FY 2020 and 2021.

In FY 2019, BARDA initiated programs to address Marburg virus and Ebola Sudan, both threat agents for which BARDA currently has no MCMs in its portfolio.

Ebola Diagnostics: In FY 2015, BARDA awarded a contract to Orasure Technologies to support development of a test to detect Ebola virus in both suspected individuals and cadavers. The FDA issued two EUAs for this test in July 2015 for use in the 2014-2015 West African Ebola response and the FDA cleared the diagnostic in FY 2019. These tests have been distributed to WHO for use in the current DRC Ebola outbreak.

Biodiagnostics: Since FY 2013, BARDA has supported development of diagnostic technologies to detect infection due to biothreat pathogens, including laboratory and point-of-care diagnostics for anthrax, laboratory diagnostics for botulinum neurotoxin, and point-of-care diagnostics for Ebola virus. In 2016, BARDA prioritized developing Zika-specific assays due to the critical need to test pregnant women. Three of these assays were made available under EUA, and all three have since achieved FDA approval. To further support development of biothreat diagnostics, BARDA is supporting non-clinical studies to identify host signs of infection (biomarkers) and their behavior during the course of disease due *B. anthracis*, *B. pseudomallei*, *B. mallei*, and *Y. pestis*. In FY 2019, the FDA has approved one diagnostic test for detection of anthrax.

Radiological and Nuclear Threats: The radiological/nuclear countermeasures program focuses on developing solutions for all aspects of injury that may result from radiological or nuclear threats. The two major radiological threats addressed are nuclear detonations and radiological dispersal devices (RDD). Radiation exposure injuries are inherently complex and may be combined with other types of injuries such as trauma, blast, and thermal burn within the context of a nuclear detonation. This necessitates a multi-pronged approach to treatment within the logistical challenges of a nuclear response.

To address this need, BARDA has supported the advanced research and development of over 35 product candidates since 2007, over 20 of which have transitioned from NIH's portfolio. This portfolio has included 12 MCM candidates that target various sub-syndromes of acute radiation syndrome, as well as traumatic injury. In FY 2013, BARDA further expanded its portfolio of products to include blood products and treatments for thermal and radiation burns.

BARDA sponsored late-stage development and procurement of three products under PBS: Neupogen, Neulasta, and Leukine. These cytokine products are used commercially to treat neutropenia resulting from cancer chemotherapy. With BARDA's support, all three have achieved FDA approval to treat neutropenia from acute exposure to ionizing radiation. The current stockpile of these MCMs uses a cost-effective VMI strategy within the SNS. These products transitioned to the SNS in FY 2019 with BARDA and the SNS working together under an SNS solicitation that allows for either BARDA or the SNS to purchase additional products to maintain preparedness.

For FY 2019 and beyond, BARDA has identified specific pathways (e.g., coagulation, vascular injury, inflammation) that play essential roles in radiation injury. Repurposing commercially available products based on modulating these pathways, thereby leveraging commercial development efforts, is a central goal of the program. BARDA also continues to collaborate with the CDC to develop pediatric instructions for use of existing MCMs.

Given the importance of blood products during an emergency response, BARDA has been working with the blood industry (including the American Red Cross) and the Office of the Assistant Secretary of Health (OASH) to address existing treatment gaps. Currently, BARDA is supporting the development of next generation blood products (e.g. spray dried plasma) and platforms (e.g., pathogen reduction platforms) that will augment the safety and availability of the blood supply.

Nuclear detonations will also cause severe thermal burns and blast trauma. To address the thermal burns, BARDA takes a comprehensive approach to resolve anticipated treatment bottlenecks resulting from limited treatment capabilities. By developing next-generation treatments that can be used for both routine burn care and during mass casualty incidents, BARDA can simultaneously improve the quality of routine care, reduce costs, and enhance our nation's preparedness posture.

Through BARDA's Thermal Burn program, four different products were awarded PBS contracts: an enzymatic debridement therapy (NexoBrid), an antimicrobial burn and wound dressing (Silverlon), an engineered skin replacement (StrataGraft), and an autograft cell-sparing therapy (ReCell). Silverlon is already FDA-cleared for use and was recently approved to treat burn injuries due to sulfur mustard exposures, and ReCell received FDA approval in 2018; NexoBrid and Stratagraft are currently in Phase 3 clinical trials. In addition, BARDA's portfolio for burn products includes multiple other candidate products in advanced stages of clinical evaluation and development.

For FY 2020 and 2021, the Thermal Burn program will prioritize developing products that address cutaneous radiation injury. BARDA is already evaluating two products and is working with the FDA to develop strategies for expedited product approval. BARDA also plans to develop advanced imaging technologies to assess burn depth and severity, thereby expanding our nation's surgical burn care bandwidth.

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 promising candidates and each has shown biomarker feasibility, transitioned to an advanced stage of product development, and have acceptable instrumentation strategies, often based on existing fielded products. Two candidates were transitioned to PBS in FY 2017, followed by another two candidates in FY 2018. In FY 2020 and 2021, these products will be managed under PBS awards with the goal of supporting FDA clearance.

Chemical Threats: There is a need for improved anticonvulsants that can effectively arrest nerve agent-induced seizures. In September 2013, BARDA awarded a PBS contract to Meridian Medical Technologies (a Pfizer company) to develop and procure midazolam as an anticonvulsant. A 2012 clinical trial, funded in part by BARDA, demonstrated that midazolam can effectively treat status epilepticus, a prolonged type of epileptic seizure. The results of this study, combined with non-clinical studies, enabled the FDA approval of Seizalam in September 2018 for the treatment of status epilepticus. Recognizing Seizalam's potential to arrest seizures resulting from exposure to chemical agents, Seizalam will now be used to replace the expiring diazepam currently in the SNS's CHEMPACK system. Approximately 700,000 multidose vials of midazolam have already been delivered to the SNS.

The most effective way to mitigate the short- and long-term effects of exposure to chemical agents is to reduce exposure through decontamination. To this end, BARDA has supported studies to determine the most efficient way to remove chemical agents from the skin of exposed individuals. Data collected from both in vitro and clinical studies were used to develop scientifically supported guidance for mass-casualty decontamination, first published in 2016 and significantly revised in 2019: the "Primary Response Incident Scene Management" (PRISM) system. An application-based decision aiding tool for first responders was released in 2019 and has received broad acceptance as the primary tool for informing and training first responders

To address chemical burns, BARDA has supported the repurposing of the commercially available burn and wound dressing, Silverlon. In July 2019, Silverlon became the first medical product to achieve FDA approval for treating sulfur mustard exposure.

Rather than develop drugs and indications specific to chemical agents, BARDA's chemical MCM program has instead adopted a strategy of treating the injuries caused by these agents. This strategy enables the repurposing of products with routine clinical utility for the treatment of injuries resulting from chemical agents. One example of this emphasis on repurposing is the development of Alteplase for the treatment of lung injury caused by mustard gas. Currently, there are no MCMs to address inhalation of this threat. Alteplase is currently FDA-approved for the treatment of acute ischemic stroke based on its ability to dissolve blood clots and appears effective at dissolving the fibrin casts that develop in the lungs after exposure to sulfur mustard. Another example of repurposing is BARDA's work with ketamine. Ketamine is FDA-approved for multiple uses and has potential to mitigate the neurological injury due to prolonged nerve agent-induced seizures. BARDA has demonstrated in rat models that ketamine, when given in conjunction with anti-seizure drugs such as midazolam, can further prevent or limit neurological damage.

During FY 2020 and 2021, BARDA will focus on preparing multiple programs for transition to late-stage development and procurement under PBS.

Driving Product Innovation

Under the 21st Century Cures Act, Congress provided BARDA with the 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. In FY 2019, BARDA expanded the accelerator network by adding five partners to increase our geographic coverage across the U.S. BARDA now has 13 accelerators in the network and they were instrumental in bringing over 300 partners together, remotely, via webcasting to participate in BARDA's Industry Day. In FY 2019, BARDA reviewed 245 abstracts under the EZ BAA and awarded 24 contracts under the three impact areas of Early Notification to Act Control and Treat (ENACT), Solving Sepsis, and Other Disruptive Innovations (ODI), all with a significant costs share. DRIVe continues to push the boundaries for how government does business with our stakeholders by increasing the utility of DRIVe Digital Resources that has the potential to be leveraged by the entire BARDA organization. FY 2020 and 2021 funding will continue these efforts and be used to establish the MCIP under the 21st Century Cures Act.

Funding History	
FY 2017	$510,499,000
FY 2018	$536,700,000
FY 2019	$561,700,000
FY 2020 Enacted	$561,700,000
FY 2021 President's Budget	$561,700,000

Budget Request

The FY 2021 President's Budget for Advanced Research and Development is $561,700,000, which is flat with the FY 2020 Enacted level. The Budget request supports the advanced development of the highest priority MCMs against all 14 threats identified by DHS and prioritized in the PHEMCE Strategy and Implementation Plan[30]. Specifically, such funding would support investments in new projects in the following programs:

1. New antiviral therapeutic 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;
7. Novel antibacterial drugs, diagnostics, and vaccines; and,
8. Transition of the CIADMs from an established capacity program to a true capability program.

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 PBS in FY 2016. Funding provided in FY 2021 will support further clinical evaluation of potential intranasal administered, single dose anthrax vaccine, to determine its safety and immunogenicity. Moving forward, BARDA will only invest in anthrax vaccine candidates that offer substantial improvements to concepts of operations for use of the vaccine. This would include those candidates that offer potential protection in a single dose.

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

Smallpox ($15 million): In FY 2011, BARDA supported the late-stage development and procurement of TPOXX (ST-246) under PBS. That program successfully reached pre-EUA status and delivered two million treatment courses to the SNS. Approval of this candidate highlights successful transition from NIAID and DoD funding, to advanced research and development funding, to PBS and delivery to the SNS. FY 2021 funding will support the continued development of a second antiviral candidate against smallpox to meet the HHS goal of having two antiviral products with different mechanisms of action. This would include studies to evaluate efficacy in animal models, manufacturing, and human safety testing. The PHEMCE partners are currently evaluating candidates under research and development and candidates could transition to ARD in FY 2021.

Combating Antibiotic-Resistant Bacteria ($160 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 if 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 and diversify the antibiotics available for a response. 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 2021 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 sustain and expand the scope and scale of investments made by CARB-X, and support programs that graduate out of CARB-X and then 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 built off the previous investments and transitioned additional products to clinical evaluation and furthered the development of diagnostics. The diagnostics are critical to identifying the pathogen and determining antibiotic susceptibility in hours compared to the current four to five days. BARDA anticipates transitioning one or more products to Project BioShield support in FY 2020 and 2021. Three products supported under ARD received FDA approval in 2017 and 2018 and all could be considered for potential PBS support. In FY 2020, BARDA made its first Project BioShield award for late-stage development and potential procurement of an antibiotic to address national security concerns. Funding in FY 2021 will continue to support these efforts focused on gram-negative and complicated, multi-drug resistant bacterial infections and national security concerns of drug resistant biopathogens.

Viral Hemorrhagic Fever ($41 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. In FY 2017, PBS began funding several candidate vaccines and therapeutics with concurrence from the PHEMCE. Ebola Zaire vaccines, therapeutics, and diagnostics, will be further supported under PBS in FY 2020. ARD efforts for FY 2020 and 2021 will focus on vaccines and therapeutics for Ebola Sudan and Marburg viruses; both identified threats to national security by DHS.

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 PBS. 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 2021, BARDA will continue ongoing investments in development 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*. The portfolio also includes antibiotic susceptibility tests that are important for public health and during an event by identifying antibiotic susceptibility of bio-pathogens that adversaries may use.

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 (either 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 2021 funds will continue to support existing candidates to advance to possible transition and support under PBS in FY 2020 and 2021.

Thermal Burns ($30 million): The Thermal Burns portfolio has progressed significantly, with four candidates transitioning to acquisition under PBS. 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. FY 2019 funds supported additional clinical trials for products supported previously under ARD in support of transition to PBS. BARDA is mandated to develop MCMs for "at-risk" populations and the funds will support clinical trials in pediatric populations to support expansion of the label indication. For FY 2021, 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. BARDA has worked collaboratively across the Burn and Chemical program to support multiple indications for Silverlon wound dressing, leading to the first ever FDA approved product for the treatment of sulfur mustard. Funding in FY 2020 and 2021 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 ($10 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 MCMs to create a sustained preparedness posture against CBRN threats. The CSN will be revised in FY 2020 with new awards to further improve the utility of the network. 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 for Ebola Sudan and Marburg also will need to be qualified as new candidate products come into BARDA's pipeline.

Medical Countermeasures Innovation - DRIVe ($35.7 million): FY 2021 funding will maintain existing DRIVe projects. These include:

- Develop innovative approaches to prevent and treat sepsis;
- Support novel technologies to diagnose and identify individuals exposed to infectious disease under the ENACT program; and,
- Incorporate 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 2020 and 2021. 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. FY 2021 funds will also be required to continue support for the MCIP entity to be established in FY 2020.

Centers for Innovation Advanced Development and Manufacturing (CIADMs) ($7 million): It is imperative that funding be provided to support sustainment of the established CIADM capacities. There is momentum to align the DoD ADM and HHS CIADM efforts to support a true capability to respond to emerging infectious diseases and provide for a 'rapid' MCM development and manufacturing response capability when needed during a national emergency. The funds will be used to initiate the transfer of one proven technology, (i.e. a technology that is already being used to support production of vaccines/biologics), into a CIADM. The transferring of such technologies will establish core capabilities so that if a new pathogen is identified, the CIADM could move quickly, utilizing these proven technologies. Examples could include cell expression lines, recombinant vaccine technologies or vaccines technologies such as those used for the recently licensed smallpox vaccine or Ebola vaccine.

Operations and Management ($85 million): FY 2021 funding will support BARDA's crosscutting management and administration activities. Resources are critical to ensure the success of programmatic activities. Additional funding will enhance scientific contract and related support as the overall number and complexity of contracts increase.

Key Outputs and Outcomes Table

Program: Biomedical Advanced Research and Development Authority

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
2.4.13a Increase the number of new licensed medical countermeasures across BARDA programs (Intermediate Outcome)	FY 2019: 7.0 medical countermeasures Target: 3.0 medical countermeasures (Target Exceeded)	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 (Intermediate Outcome)	FY 2019: 5.0 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 2019: 42.0 Target: 11.0 (Target Exceeded)	11.0	11.0	Maintain

Project BioShield

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**735.000**	**735.000**	**535.000**	**-200.000**
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 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. Sixteen of these products have been delivered to the SNS, with additional products to be delivered in FY 2020 and 2021. In 2019, ten of these products achieved FDA approval or licensure, and additional approvals are anticipated in FY 2020 and 2021.

The progress achieved through PBS 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 MCM 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 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, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) and the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) 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 focuses on developing product candidates, when possible, that also have existing or potential commercial uses. For example, products used to treat injuries resulting from radiation during a nuclear blast may also have commercial utility for treating cancer patients or burn victims. Project BioShield allows BARDA to purchase promising experimental products for the SNS that are sufficiently mature for use under an EUA issued by the 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 and, in some instances, in post-approval (e.g., Raxibacumab anthrax antitoxin and

BioThrax anthrax vaccine). Sustainment of companies and products supported under PBS and transitioning to the SNS is a continuing challenge. Now that the SNS is a part of the ASPR organization, BARDA and the SNS are working closely to align budgets and improve communications for transitioning of products. In FY 2019, BARDA and the SNS worked together under an SNS-issued solicitation to support additional procurement of cytokines to maintain preparedness for nuclear threats. FY 2020 and 2021 will see additional examples of this increased collaboration.

Since FY 2005, BARDA has invested in 27 unique MCMs under PBS, sixteen of which have been delivered to the SNS, including:

- Three therapeutics for treatment of inhalational anthrax (Raxibacumab, Anthrasil, and Anthim);
- Biothrax vaccine for the post-exposure prophylaxis of anthrax;
- AV7909, a next generation anthrax vaccine,
- HBAT for the treatment for symptomatic botulism;
- JYNNEOS vaccine for the prevention of smallpox infection in people where replicating smallpox vaccines are contraindicated and monkeypox in healthy adults;
- TPOXX for the treatment of smallpox infection;
- Seizalam for treatment of status epilepticus (a common effect of nerve agents);
- Six countermeasures for the treatment of the effects of radiation exposure (Neupogen, Leukine, Neulasta, Thyroshield, Ca-DTPA and Zn-DTPA); and,
- Silverlon as an antimicrobial wound dressing for the treatment of skin injuries due to chemical and thermal burns.

Of the sixteen countermeasures delivered to the SNS, eleven received FDA approval with support under PBS. BARDA anticipates that several more countermeasures currently supported through Project BioShield will be FDA approved and delivered to the SNS in FY 2020 and 2021.

Based on the successful development of CBRN MCMs in BARDA ARD programs, BARDA will be prepared to acquire up to three new CBRN MCMs under PBS by the end of FY 2021. Since 2014, BARDA has awarded 16 contracts under PBS for late-stage development and potential procurement of MCMs and 27 since the inception of PBS. BARDA will invest significant funds in FY 2020 and 2021 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 EUA. BARDA will balance previous commitments while transitioning promising programs to PBS. BARDA anticipates transition of two to three candidates to PBS in FY 2021. Remaining funds will continue late-stage development and potential procurement of programs previously funded under PBS.

In FY 2020, Congress appropriated $535 million in emergency supplemental funding to the PHSSEF to support procurement of Ebola vaccines, therapeutics and diagnostics. BARDA will use this funding to move forward with procurement of at least one vaccine, one therapeutic and potentially two diagnostics for the Ebola Zaire strain. BARDA will obligate an additional $200 million provided through the FY 2020 PBS appropriations to support additional late-stage development activities to support licensure of the various medical countermeasures. These activities could include phase IV post-marketing requirements or commitments.

BARDA has identified the following promising candidates that have the potential to transition to PBS in FY 2021:

- Additional antimicrobials to treat drug-resistant bio-pathogens;
- Products to address thermal burn injuries and subsyndromes of acute radiation exposure; and,
- Products to address exposure to chemical threats

Funding History	
FY 2017	$508,803,000
FY 2018	$710,000,000
FY 2019	$735,000,000
FY 2020 Enacted	$735,000,000
FY 2021 President's Budget	$535,000.000

Budget Request

The FY 2021 President's Budget for Project BioShield is $535,000,000, which is -$200,000,000 below the FY 2020 Enacted level. The request reflects Congress' forward-funding of procurement of Ebola countermeasures via emergency supplemental funding in FY 2020. The FY 2021 request supports continued development and procurement of next-generation anthrax vaccine, continued procurement of JYNNEOS, and new procurements of new antibacterial drugs, chemical agent medical countermeasures, a new product to temporize burn injury, and a new radiation MCM. The request also supports new intravenous formulations of the 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. The FY 2021 request supports the following eight investments, which reflect the highest priority countermeasures for FY 2021.

1. **New antimicrobial drugs to address biothreat pathogens ($100 million, approximately 25,000 treatment courses of each product).** At least two new antibiotic candidates, presently in the ARD program, may be available to purchase under PBS. 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. Products will be maintained using vendor-managed inventory since there are commercial indications that will support this type of stockpiling.

2. **Sustain development and procurement of next-generation anthrax vaccine ($170 million, three to four million vaccine doses).** In FY 2021, PBS funds will continue procurement of a next generation anthrax vaccine that elicits potential protective immunity in two doses, instead of three required by the current licensed AVA vaccine. This funding is critical to the maintenance of the federal government's preparedness posture against anthrax.

3. **Chemical MCM for nerve agent induced seizures ($40 million, 750,000 doses/autoinjectors).** Diazepam is currently stockpiled for the treatment of nerve agent-induced seizures. Diazepam is nearing its expiry and will need to be replaced. In FY 2013, BARDA supported the late-stage development and procurement of an improved anticonvulsant, midazolam (Seizalam), for the treatment of nerve agent-induced seizures. The FDA approved Seizalam in 2018 and vials for injection have been delivered to the SNS. However, production issues precluded delivery of autoinjectors. Funding will support New Drug Application-enabling studies for an existing adult-dose midazolam autoinjector and development and approval of a pediatric autoinjector as well as procurement of autoinjectors. Funding will also be used to address orphan exclusivity held by the Seizalam sponsor with respect to the seizure indication for midazolam.

4. **Late-stage development and procurement of an intravenous formulation of a smallpox antiviral drug ($20 million, 100,000 treatment courses).** In FY 2011, a PBS contract was awarded for the late-stage development and procurement of a smallpox antiviral drug, TPOXX. This contract has successfully delivered two million treatment courses of tecovirimat to the SNS. The FDA approved TPOXX for the treatment of smallpox in July 2018. FY 2021 funds will support the execution of an existing contract option for the development and procurement of an intravenous formulation of tecovirimat. This formulation would allow for the treatment of severely ill individuals and pediatric patients unable to swallow medication.

5. **Thermal burn product, temporizing matrix ($30 million, 30,000 units).** In FY 2015, BARDA awarded four contracts to address burn injuries resulting from the thermal flux of a nuclear detonation. These products also 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 and 2021 will support existing candidates, clinical studies currently underway and transition of products to address burn conversion and improve sustainability for cadaver skin.

6. **Smallpox vaccine, conversion to lyophilized formulation ($50 million, 2 million doses).** In FY 2017, BARDA procured several lots of IMVAUME smallpox vaccine in bulk form. In FY 2020 and 2021, BARDA expects to convert that product to a lyophilized formulation possessing greater stability and a longer shelf life. This formulation will allow reduce the lifecycle costs of the vaccine. A Phase 3 clinical trial to demonstrate lot-to-lot consistency between the lyophilized formulation and the liquid frozen formulation will be required.

7. **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 PBS (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.

8. **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.

Key Outputs and Outcomes Table

Project BioShield

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
2.4.14b Continue ongoing transition of medical countermeasures into Project BioShield (Intermediate Outcome)	FY 2019: 0.0 Target: 3.0 (Target Not Met)	3.0	3.0	Maintain

Strategic National Stockpile

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**610.000**	**705.000**	**705.000**	**--**
FTE	**225**	**225**	**225**	**--**

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

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)[31] during a public health emergency. It is the largest federally-owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations (FMS),[32] 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 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 percent of the 973 product lines in the SNS are commercially available countermeasures that are purchased through federal supply schedules or simple 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 $8 billion inventory of MCMs. In FY 2019, SNS sustained an inventory accuracy rate

[31] http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm
[32] https://www.phe.gov/Preparedness/support/medicalassistance/Pages/default.aspx#sns

of 99.3 percent and ensured that less than one percent of product was lost due to failure to comply with FDA CGMP practices.

ASPR seeks to maximize the value of the SNS appropriation in collaboration with the 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 four to over ten 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.

In 2019, SNS worked with FDA and DoD to ensure the continued readiness of forward placed Chempack antidotes via SLEP testing, and shared previous practices with DoD regarding requests for exemption to the Drug Supply Chain Security Act requirements for stockpiled medical countermeasures. Working with DoD and FDA, SNS was able to secure a Drug Supply Chain Security Act (DSCSA) exemption for a nerve agent autoinjector (ATNAA) provided by DoD to SNS. This exemption allows SNS to continue to provide this critical nerve agent antidote in our forward placed CHEMPACK containers.

In December 2019, following close work and collaboration to further extend the life of stockpiled antiviral drugs and increase pandemic influenza preparedness without significant additional costs, the FDA reviewed pertinent data and agreed to extend the shelf life for some influenza antivirals for use during emergency responses. This action represents a significant cost avoidance in FY 2020 and beyond, as large volumes of SNS held antivirals approaching final expiration in 2019 and 2020 will remain viable for additional years without replacement. Additional information about these extensions will be shared with state and local jurisdictions as soon as the guidance is finalized.

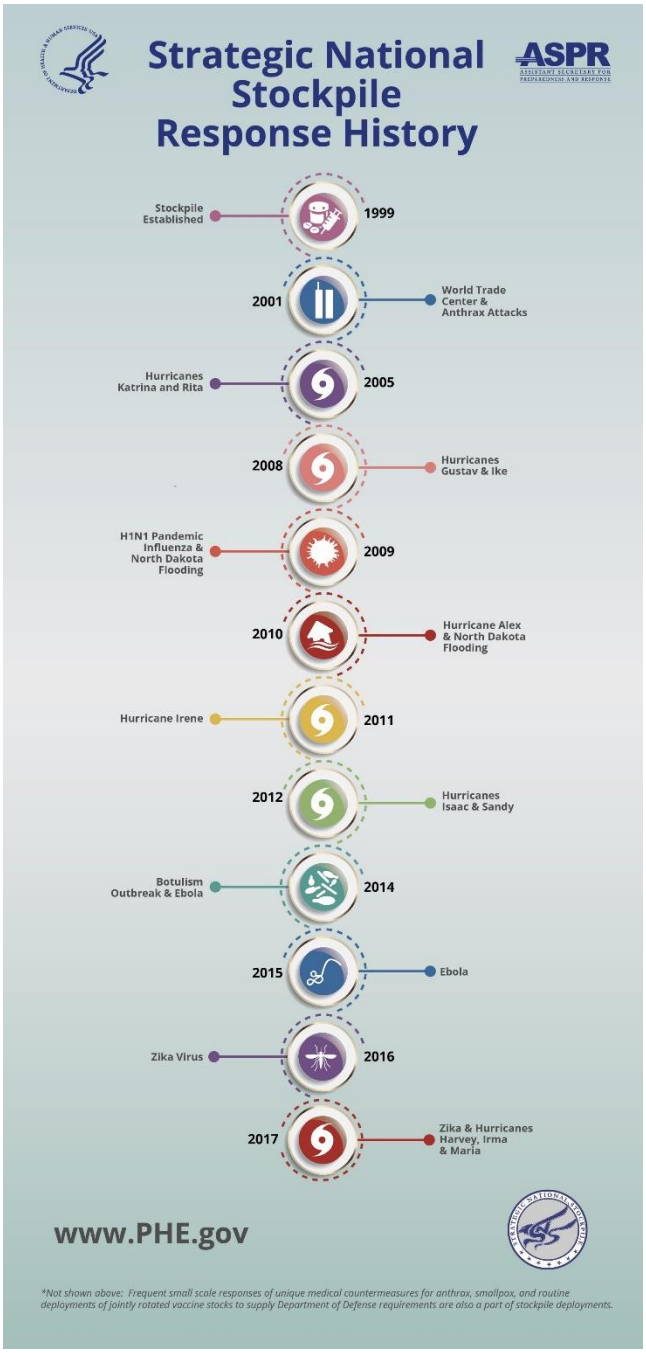
ASPR's robust medical logistics capability can move medical personnel, equipment and supplies across the nation within hours. Ensuring timely delivery of MCMs is critical during an emergency response. The SNS maintains contracts with commercial transportation partners that possess the resources and capabilities 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 can also receive material, both pharmaceutical and non-pharmaceutical, 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, FMS may be requested. Within ASPR, SNS is responsible for deploying and setting up FMS. Once set up, FMS are often run by DMATs deployed by the NDMS.

Following the transition from CDC to ASPR on October 1, 2018, SNS began working to integrate with ASPR's logistics functions. These efforts build on past efficiency measures including the development of a unified pharmacy cache for use by either FMS or DMAT deployment. In May 2019, SNS assumed inventory management responsibility for all NDMS funded materiel. Additionally, seven logisticians funded by NDMS work with SNS to support inventory management of NDMS materiel. Work to fully integrate NDMS materiel into SNS's inventory management systems will continue into FY 2020. Moving all of ASPR's medical materiel to SNS streamlines ASPR logistics operations and better positions ASPR to respond to health threats.

The SNS is capable of rapidly delivering material and support to the site of any response and has regularly demonstrated that ability. In January 2019, SNS deployed tecovirimat and vaccinia immune globulin which was used to successfully treat an unvaccinated lab worker who had been accidentally exposed to vaccinia through a needlestick injury. Additional information about successful first use of tecovirimat for a laboratory-acquired VACV infection can be found in the October 25, 2019, *Morbidity and Mortality Weekly Report (MMWR)*[33]. The successful deployment of tecovirimat and vaccinia immunoglobulin in response to a request from CDC, as well as the work of SNS subject matter experts (SMEs) on the *MMWR* article highlights an important way in which SNS continues to work with CDC after being organizationally transferred to ASPR in FY 2019.



[33] https://www.cdc.gov/mmwr/volumes/68/wr/mm6842a2.htm?s_cid=mm6842a2_w

SNS works closely with state and local jurisdictions to improve their ability to respond to public health emergencies requiring medical countermeasures.

In FY 2019, SNS provided exercise support for eight tabletop exercises and nine full-scale exercises and drills.

Tabletop exercises are a forum used to discuss and validate the timelines for distributing and transferring assets from the SNS to state and local jurisdictions. Additionally, a major goal of tabletop exercises is to sign/update Memorandums of Agreement between ASPR/SNS and the state or local jurisdiction to delineate shared expectations for expected response timelines.

Full-scale exercises are opportunities for states and local jurisdictions to test and validate their response plans to receive, distribute and dispense SNS assets during a public health emergency. During full-scale exercises, states exercise requesting federal assets and demonstrate their ability to work with local jurisdictions to distribute and dispense medical countermeasures using an Anthrax scenario as required by CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement.

SNS staff also participated in Shaken Fury and Crimson Contagion exercises in FY 2019. HHS Shaken Fury brought the whole community, including state and locals, together to evaluate and improve the whole community's ability to establish and implement a coordinated strategy of rapid response and recovery operations for the prioritization and application of accessible resources and capabilities in response to a "no-notice" earthquake incident. Crimson Contagion focused on the whole community response as well as issues around workforce viability; critical infrastructure protection; economic impact; non-pharmaceutical interventions; scarce resource allocation; prioritization of vaccines and other countermeasures; and medical surge operations. Organizations that participated in the Crimson Contagion functional exercise included local, state, and federal departments and agencies, as well as private-sector organizations and NGOs. At least one state from each of HHS' ten regions participated in the exercise; the participating states included Massachusetts (Region 1); New Hampshire (Region 1); Connecticut (Region 1); New York (Region 2); Pennsylvania (Region 3); South Carolina (Region 4); Illinois (Region 5); New Mexico (Region 6); Nebraska (Region 7); Colorado (Region 8); Arizona (Region 9); and Idaho (Region 10). The City of Chicago was also a key participant in the Crimson Contagion functional exercise.

SNS FY 2019 Trainings by the Numbers

2,000+

Learners who completed SNS online training

14

Receive, Stage, and Store Trainings

6

Cold Chain Management Courses

6

Webinars on topics including SNS Formulary Overview; Crisis and Risk Communication; and Temperature Considerations

4

SNS Preparedness Courses at FEMA's Center for Domestic Preparedness

1

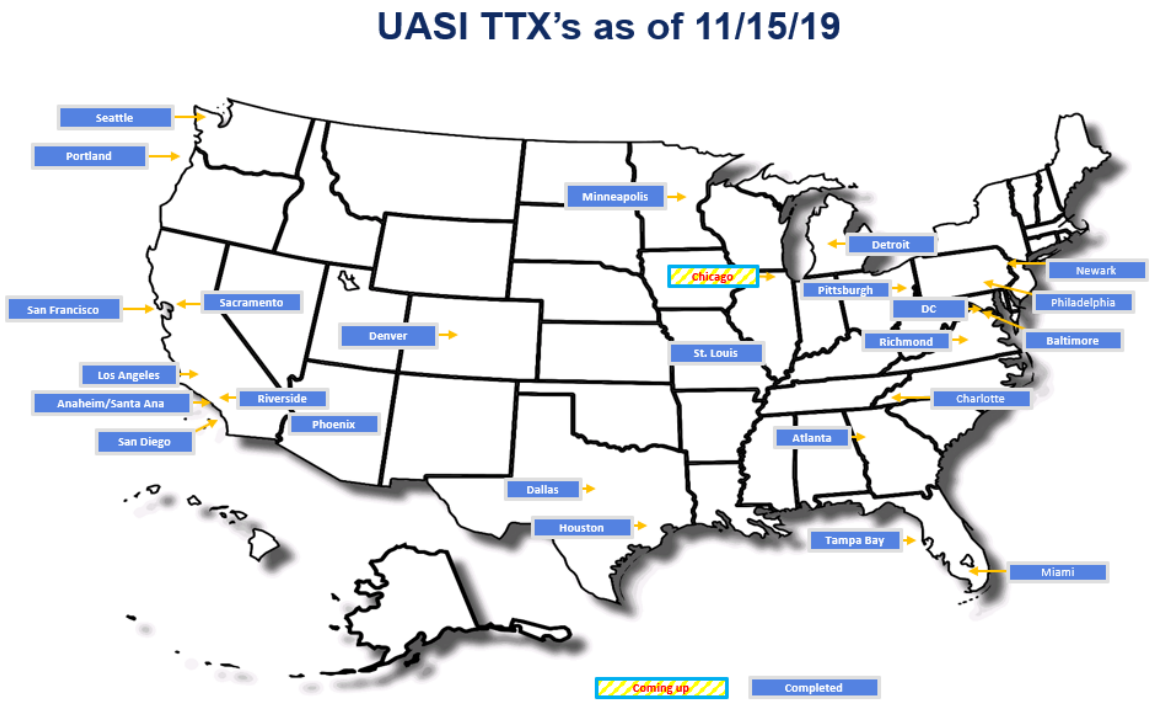
FMS training for external partners

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 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 SNS modeled delivery timelines based on several variables to determine the expected time required to move product from SNS warehouses 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 program representatives met with State and local staff in each of the jurisdictions to further refine delivery timelines and plans. 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 presented 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) with 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. SNS has improved access to MCMs by implementing MOAs with 26 SLTT jurisdictions committing to expedited distribution of MCMs and reducing delivery time from 12 to 24 hours to four to eight hours. 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 eight 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 the jurisdictions shown below.



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.

Improving the resiliency of the SNS by working with industry is a priority. SNS has engaged industry by forming partnerships with major industry trade associations, specifically, the 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 SNS through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to personal protective equipment (PPE);
- Improved public access to MCMs;
- Redundant distribution of MCMs, information, and materiel to ensure that there is no single point of failure during a public health emergency;
- 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 SNS is closely linked to the resiliency of the commercial supply chain. In 2019, SNS continued work with major industry trade associations. In August 2019, SNS hosted 29 industry partners, including HIDA, HSCA, and ISEA, to discuss anticipated challenges and potential opportunities for improved communication, coordination, and continuity between ASPR, SNS, and industry partners prior to and during a public health emergency response and specifically focused on three identified goals:

- Provide progress updates on current collaborative projects between the SNS and industry trade association partners
- Discuss medical supply chain issues focusing on anthrax and Ebola preparedness and response operations
- Determine methods to support emergency communications and collaboration between Emergency Support Function (ESF-8) federal partners and industry trade associations and its members

The meeting helped to

- Identify improvements that could be made to the *SNS Commercial Partner Playbook for an Anthrax Response*, a resource requested by industry partners during previous supply chain mitigation workshops with HIDA.
- Improve a template for information sharing during public health emergencies

This work in 2019 built upon previous work with public-private partnerships. In 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 three 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 can make better decisions on what to purchase, how much to stockpile, and how best to collaborate to protect the supply chain.

SNS has continued to collaborate with CDC to strengthen the nation's ability to respond to public health threats. In FY 2019, SNS collaborated with CDC Regulatory Affairs to enhance anthrax preparedness by ensuring pre-EUAs are in place for imported clindamycin oral capsules. SNS also developed Emergency Use Instructions for ATNAA that are currently undergoing review and are working on a video which will teach SLTT health officials about reconstitution of oral antimicrobial suspensions. Additionally, SNS SMEs serve on the CDC steering committee updating plague clinical guidance and the ACIP committee working on guidelines for Ebola vaccine.

SNS expertise in MCM supply chain optimization and logistics planning is a valued global health resource. In 2019, SNS experts assisted WHO with the design and development of a new humanitarian assistance logistics hub in Dubai, UAE. Using funds from CDC's Center for Global Health in support of the Global Health Security Agenda, SNS sent staff to Nigeria and Sierra Leone to help countries develop national level medical materiel supply chain plans to improve global and U.S. health security. SNS experts supported this international effort through the following activities:

- Trained 105 participants at MCM logistics and planning workshops for plan creation and validations (total includes participants in CDC's Atlanta based Public Health Emergency Manager Fellowship program);
- Executed MCM plan table-top exercises to validate MCM plans for Nigeria and Sierra Leone and Guinea;
- Provided two subject matter experts to support Sierra Leone's full-scale Ebola exercise in June;
- Reviewed six national-level MCM plans for Sierra Leone, Senegal (two drafts), Nigeria, Guinea, and Liberia.

Funding History	
FY 2017	$573,653,000
FY 2018	$610,000,000
FY 2019	$610,000,000
FY 2020 Enacted	$705,000,000
FY 2021 President's Budget	$705,000,000

Budget Request

The FY 2021 President's Budget for the Strategic National Stockpile is $705,000,000, which is flat with the FY 2020 Enacted level. The FY 2021 Budget request prioritizes funding for SNS's smallpox and anthrax portfolios. Investments in products in these portfolios protect Americans by supporting life-saving medical countermeasures for which there is little to no commercial market, including smallpox vaccine and anthrax therapeutics. In addition, ASPR will make investments across a spectrum of high-priority threats. Product procurement in FY 2021 will be guided by the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) and related multiyear prioritization 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 2021 request includes $54 million for procurement of products previously supported through Project BioShield. These products include an anthrax therapeutic and a thermal burn bandage.

Transitioning procurement of products originally funded through Project BioShield, 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.

The FY 2021 request includes $10 million for ASPR's Pediatric Care Disaster initiative. The requested funds will be used to procure fold out rigid temporary shelter systems that will expand deployable capabilities to protect vulnerable populations in large scale responses. These shelter systems will serve as drop in mobile medical facilities permitting a broad scope of medical capabilities in a sterile environment for emergent needs when local capacity is exhausted or inactive, with capacity to treat a number of indications to high levels of severity. This capability would enhance rapid support for the special needs of vulnerable populations, such as fragile infants and pediatric patients who may have limited resistance to infectious disease. The shelter system would also provide a team training module when not in use.

MCMs are only effective during an emergency if they have been securely stored in compliance with CGMP practices. Warehousing and other non-procurement costs ensure that MCMs are securely stored in temperature-controlled environments; that preventative maintenance is performed; and that SLEP and other efficacy testing is performed. In FY 2021, SNS will continue updating and upgrading its warehousing capacity. In 2019 the total value of materiel stored in SNS's warehouses hit $8 billion. Several SNS warehousing contracts are set to expire in FY 2021. The FY 2021 request includes funds necessary to recompete these contracts and award new contracts with requirements for enhanced inventory management, maintenance and deployment capabilities. The new warehousing contracts will reflect SNS's need for increased space and cold chain storage requirements. In FY 2021 SNS anticipates increased warehousing costs. As storage space requirements are updated over time, ASPR expects total warehousing costs to go down. These savings are not expected to be realized in FY 2021.

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 2021 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 2021 by:

- Managing, storing, maintaining, and replacing MCM assets, valued at over $8 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.

Outputs and Outcomes Table: Strategic National Stockpile

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
13.4.5 Number of trained and ready preparedness and response teams available for response to multiple events. (Output)	FY 2019: 20 teams Target: 15 teams (Target Exceeded)	15 teams	15 teams	Maintain
13.4.6 Percentage of inventory accuracies that are attained by using quality inventory management systems. (Outcome)	FY 2019: 99.6 % Target: 97 % (Target Exceeded)	97 %	97 %	Maintain
13.4.7 Maintain the safety and efficacy of medical supplies SNS inventory (Outcome)	FY 2019: 100 percent Target: 100 percent (Baseline)	100 percent	100 percent	Maintain
13.4.8 Maintain the response rate of recall capability (Intermediate Outcome)	FY 2019: 95 % Target: 95 % (Baseline)	95 %	95 %	Maintain

SNS Projected Allocations[1]

	FY 2020 Enacted		FY 2021 President's Budget	
	Projected Level	Percentage of Total Appropriation	Requested	Percentage of Total Appropriation
Total	$705.0M	100%	$705.0M	100%
Product				
Product Total	**$569.1M**		**$569.1M**	
Procurement Total	$350.5M		$391.3M	
Procurement – New[2]	*$161.0M*		*$50.0M*	
Procurement – New (above replenishment)[3]	*$72.7M*	80.7%	*$269.4M*	80.7%
Procurement - Replenishment	*$116.8M*		*$71.9M*	
Sustainment Total[4]	$218.6M		$177.8M	
Warehousing Costs	*$130.0M*		*$145.0M*	
Operations				
SNS Operational Costs	$135.9M	19.3%[5]	$135.9M	19.3%[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 1:1 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 management costs to sustain the $8.0 billion inventory of SNS assets, including storage, transportation, maintenance, and disposal.
[5] This amount supports 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.

Policy and Planning

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**14.877**	**14.877**	**19.877**	**--**
National Biodefense Strategy (non-add)	**--**	**--**	*5.000*	**--**
FTE	**66**	**66**	**71**	**+5**

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, policy and planning activities develop, implement, align, and evaluate the strategies, plans, requirements, and policies that the Assistant Secretary for Preparedness and Response (ASPR) uses to ensure a strong foundation for public health and health care preparedness, response, and recovery activities. Outreach and engagement with mission partners across the whole-of-government ensure that ASPR's operational preparedness and response capabilities coincide with ASPR's priorities, align with broader U.S. Government (USG) policy and planning considerations, are effectively evaluated through data-driven analysis, and that taxpayer-provided resources are effectively allocated based on strategic priorities. To deliver on the mandates of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA), and to save lives, prevent suffering, and increase the resilience of our nation, ASPR:

- Sets strategic direction, in concert with interagency partners, through development, implementation, and evaluation of the National Health Security Strategy (NHSS), the National Biodefense Strategy (NBS), and other national strategy doctrine;
- Develops policies that address public health and emergency medical response issues, empowering ASPR personnel, the HHS, and the American people to decisively respond to any national security incident;
- Generates plans that establish strategic intent and coordinate capabilities so that the nation is prepared to swiftly and effectively respond to 21st century health threats; and,
- Establishes requirements for capabilities and materiel to ensure that ASPR is able to execute its emergency response mission 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, clinicians, responders, and the public—to ensure that strategic goals and deliverables are appropriate, useful, and comprehensive. ASPR provides real-time support to HHS and Public Health and Medical Emergency Support Function 8 (ESF 8) partners during response to national security incidents and public health emergencies through coordination of strategies, policies, and plans to facilitate effective and efficient response in support of States and local jurisdictions. ASPR leverages lessons learned from exercises, incident reviews, risk assessments, and horizon scans to identify gaps, improve on deliverables, and enhance capabilities to meet its mission.

Strategy and Policy Leadership, Coordination, and Evaluation

ASPR oversees a strategic approach to address USG priorities and provides an anticipatory, long-term perspective on national health security to advance preparedness and response initiatives. These efforts ensure coordinated alignment and implementation of key Department of Health and Human Services (HHS), national, and international health security strategies and initiatives across ASPR, HHS, and the federal government. ASPR provides planning, policy analysis, capability assessment, and requirements setting across ASPR programs and initiatives to ensure alignment and optimize capabilities to best help SLTT, interagency, and international partners.

ASPR coordinates and develops national, HHS, and ASPR strategies and policies that directly inform public health and health care preparedness and response capabilities. ASPR leads the quadrennial NHSS. This legislatively mandated document provides a comprehensive strategy to mobilize a whole-of-government approach and leverage the capabilities of the private sector to support SLTT partners in addressing 21st century threats and to prepare for, respond to, and recover from manmade and natural 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 NBS.

ASPR coordinates participation and input into USG, National Security Council (NSC), and HHS policy and strategy initiatives. ASPR collaborates with the NSC on priorities, including the NBS, and supports implementation of the NBS to counter biological threats, reduce risk, prepare for, respond to, and recover from biological incidents. The strategy sets the course for the U.S. to combat the serious bio-threats 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 supports leadership of ESF 8 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 (DLG), 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 leads two legislatively mandated Federal Advisory Committees, the National Biodefense Science Board (NBSB), and the National Advisory Committee on Children and Disasters (NACCD), to provide expert advice and recommendations to the Secretary.

ASPR ensures seamless organizational communication to address emergency issues. For example, informing and promoting a coordinated interagency approach for response to pandemic influenza and other emerging infectious disease threats ensures that policies and capabilities are aligned to save lives and support SLTT response efforts. ASPR analyzes imminent and longer-term public health preparedness and response issues and identifies gaps and challenges in order to establish strategic actions to mitigate national health security threats.

During FY 2020, ASPR is:

- Publishing the 2019-2022 NHSS and Implementation Plan as well as the NHSS Evaluation of Progress for the 2015-2018 quadrennial period and engaging in stakeholder education, implementation, and evaluation activities pursuant to the new NHSS.
- Coordinating implementation of the NBS with other agencies that have responsibilities or capabilities pertaining to biodefense, including the following activities:

  - Providing leadership as Director of the Biodefense Coordination Team (BCT) and assisting the cabinet level Biodefense Steering Committee (BSC) (chaired by the HHS Secretary) in implementation of the strategy;
  - Leading the implementation of the NBS'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 bio-incidents; ensuring biodefense enterprise preparedness to reduce the impacts of bio-incidents; rapidly responding to limit the impacts of bio-incidents; and facilitating recovery to restore the community, the economy, and the environment after a bioincident;
  - Building capacity for management of implementation of the strategy and coordination of interagency participation;
  - Conducting analysis related to biodefense programs, projects, and activities; and,
  - Implementing stakeholder engagement activities to maintain awareness of biodefense activities conducted by federal agencies, relevant interagency entities, and non-federal partners in the broader biodefense enterprise.
- Completing a horizon scan of national health security threats to forecast threats to public health and the healthcare system over the next five to ten years.
- Leading the strategy development and implementation of the Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, bringing together partners across the interagency, private sector, and academia to advance vaccine technology and manufacturing efficiencies.
- Planning and implementing outreach and education to external partners on national health security priorities and specific threat-based risks through multiple mechanisms including stakeholder collaboration events/workshops/presentations, social media and blogs posts, and development of educational materials;
- Coordinating input across HHS Operating and Staff Divisions and represented HHS in the policy development process of the NBS and supported release of the strategy through development and implementation of a strategic communications plan involving stakeholder engagement;
- Coordinating the DLGs for the Departmental response to the 2019 Ebola Virus Disease Outbreak in the Democratic Republic of Congo, closures of ethylene oxide sterilization facilities, the 2019 Crimson Contagion Functional Exercise, and the 2019 Shaken Fury Functional Exercise;
- Completing an assessment of ASPR projects and programs program evaluation needs in order to improve evaluation technical assistance for stakeholders; and,
- Convening two public meetings of the NBSB resulting in recommendations on disaster training competencies for healthcare practitioners and submitted materials to charter the new NACCD.

During FY 2021, ASPR will:

- Continue to coordinate implementation of the NBS with other agencies that have responsibilities or capabilities pertaining to biodefense including by:
  - Continuing to provide leadership of the BCT and assisting the cabinet-level BSC in implementation of the strategy; and,
  - Supporting development of a biodefense assessment and public report, conducting stakeholder engagement, and implementing measures to enhance biodefense.

- Engage in ongoing assessment of the current and evolving threat landscape, including educating new and existing partners to identify and address health security threats in the context of ASPR and national security priority areas;
- Coordinate HHS-wide decision-making on policy issues that impact national health security by convening the DLG to provide situational awareness and inform and advise the HHS Secretary;
- Perform ongoing high quality policy analyses to inform implementation of new and revised requirements resulting from the authorization and appropriations and other legislative processes, executive orders, and new USG priorities;
- Conduct stakeholder outreach and education on national health security risks and NHSS implementation activities;
- 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;
- Develop and implement methodologies to improve data collection and analysis in order to enhance situational awareness specific to health care coalitions and health care preparedness; and,
- Provide strategic advice and recommendations to the HHS Secretary by coordinating, managing, and operating two Federal Advisory Committees, the NBSB and the NACCD. These groups bring together nationally renowned experts in meetings accessible to the public in order to advise the HHS Secretary and the ASPR on, respectively, biodefense and concerns for children in disaster.

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 Public Health Service Act (42 U.S.C. 300hh-10) and guided by the NHSS. ASPR's policy and planning activities establish materiel requirements for medical countermeasures (MCMs) that focus on flexible solutions in response to chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases. These requirements are established in accordance with the Federal Acquisition Regulation, through a framework premised on best practices. Through analysis of alternatives, ASPR focuses on capabilities that can be broadly applicable, to support the needs of all components of the ASPR mission in a fiscally responsible approach to address 21st century health threats, including natural disaster response, CBRN incidents, and emerging infectious diseases that threaten national security.

During 2020, ASPR is:

- Delivering materiel requirements for vesicants, anthrax, smallpox and others;
- Delivering a comprehensive assessment and analysis of the biodefense medical countermeasure industrial base and government enterprise and promulgated recommendations;
- Delivering National Security Objectives to level-set the capabilities targets for the emergency mission of the Department; and,
- Delivering recommendations and implementation strategy for Defense Production Act authorities of the Secretary.

During FY 2021, 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 ESF-8 mission objectives of the National Response Framework; enable 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 MCMs against CBRN threats and emerging infectious diseases; shorten delivery times, provide 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; facilitate improvement in development and acquisition timelines for MCMs.

Funding History	
FY 2017	$14,843,000
FY 2018	$14,877,000
FY 2019 Final	$14,877,000
FY 2020 Enacted	$14,877,000
FY 2021 President's Budget	$19,877,000

Budget Request

The FY 2021 President's Budget for Policy and Planning is $19,877,000, which is $5,000,000 above the FY 2020 Enacted level. The additional $5 million in no-year funding in FY 2021 will support ASPR's government-wide coordination, implementation, and assessment of the NBS.

ASPR will continue to provide policy leadership to address USG, HHS, and ASPR strategic goals. 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 medical emergency preparedness and response, ASPR will lead the implementation and evaluation of the NHSS and support implementation the Global Health Security Strategy.

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 NBSB and NACCD, will gather expert input from the public and non-federal partners. The DLG 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 bio-threats is a critical aspect of our national security. ASPR will continue to implement the NBS, which sets the course for the United States to combat the serious bio-threats our country faces, whether they

arise from natural outbreaks of disease, accidents involving high consequence pathogens, or the actions of terrorists or state actors. 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. ASPR will maintain 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 increase coordination with non-Federal partners, including international organizations.

As noted, the request includes $5 million that will be used to provide needed NBS resources, including staff support, for the management of the BCT and BSC. Funds also will provide data analytic services including collection of data from federal agencies to support implementation of the strategy and analysis and reporting of these data. 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 NBS will strengthen our ability to anticipate, prevent, prepare for, respond to, and recover from biological incidents. This is a critical priority for ASPR and cannot be adequately supported with existing resources.

Key Outputs and Outcomes Table

Policy and Planning[1]

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2020 Target	FY 2021 Target	FY 2021 Target +/-FY 2020 Target
2.4.13 Increase the number of National Health Security Strategy policy tools that support national and health security capabilities (Output)	FY 2020: Result Expected Dec 31, 2020 Target: Set Baseline (Pending)	Set Baseline	FY 2020 Baseline +5% increase in the number of policy tools that support national and health security capabilities	N/A
2.4.15 Increase the percentage of identified ASPR activities designed to implement the National Biodefense Strategy across the entire Biodefense enterprise (Intermediate Outcome)	FY 2020: Result Expected Dec 31, 2020 Target: Set Baseline (Pending)	Set Baseline	Implementation of the FY 2020 actions +75% of the FY 2021 National Biodefense Strategy annual implementation actions assigned to ASPR	N/A
2.4.16 Increase the number of assessments that reduce the risk of biological threats (Intermediate Outcome)	FY 2020: Result Expected Dec 31, 2020 Target: Set Baseline (Pending)	Set Baseline	Baseline +5% increase above baseline in reduced gaps, shortfalls and redundancies	N/A
2.4.17 Increase the number of stakeholder engagement contracts addressing strategic, policy, planning, and requirement-setting issues pertaining to public health and healthcare preparedness and response (Outcome)	FY 2020: Result Expected Dec 31, 2020 Target: Set Baseline (Pending)	Set Baseline	Baseline +5% increase in the number of stakeholder engagements	N/A

[1] The measures in this table replace previous measures for ASPR Policy and Planning

Operations

Budget Summary
(Dollars in Millions)

ASPR	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
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 Assistant Secretary of Preparedness and Response (ASPR) is committed to exemplary stewardship of public resources, the development of a world class workforce, identifying, eliminating, and mitigating risk in all aspects of programmatic and management operations, managing and continually improving performance, and decisive leadership that ensures 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. These funds foster leadership and strategic management, ensuring a collaborative and comprehensive approach to implementing ASPR's goals and strategies. ASPR promotes the Department of Health and Human Services' (HHS) responsibilities for responding to, recovering from, and mitigating the lasting impacts of public health and medical emergencies of all kinds.

Operations activities support management services that enable ASPR to carry out its mission, including oversight of communications with the public and the media; human capital management, and workforce development. ASPR Operations also coordinates technology management and information security; facility operations and administration; travel; legislative affairs; records management; and executive secretariat functions. 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 leverages innovative communication tools and technologies—including social media—to enhance community connectedness and empower individuals to take action before, during, and after public health and medical emergencies.

During FY 2020 and 2021, ASPR continues to modernize the Public Health Emergency (PHE.gov) external cross-agency web site. Using the web site, private industry, state and local government agencies, and community organizations efficiently obtain the information resources and tools they need to prepare, respond, and recover from the health effects of disasters. The public has access to the information needed to make health related decisions before, during, and after disasters and threats.

To enable effective public health emergency responses, Operations activities are multi-faceted and include holistic, nimble, flexible, consistent and innovative acquisition and grants solutions. In support of the acquisition function for ASPR, Operations activities foster procurement, awarding of contracts, grants,

cooperative agreements, and other transaction authority agreements. ASPR's acquisition approach places emphasis on best value to taxpayers through effective and efficient business practices and partnerships. This is accomplished by working with programs early in the acquisition lifecycle in ways that synchronize efforts and efficiencies. ASPR's practices result in meaningful communication, reduced redundancy, and increased efficiency through the streamlining of reviews. For example, ASPR established an acquisition architecture that enables responders to obtain the supplies and services needed when leading the public health and medical response to emergencies under Emergency Support Function (ESF) 8.

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. Through the inclusion of Earned Value Management System and in accordance with the Federal Acquisition Regulation, ASPR audits, provides cost and price analysis, and fosters the development and execution of various acquisition-related training programs for the entire ASPR acquisition community. ASPR grants management function is instrumental in building community resilience through its management support of grants awarded by the Hospital Preparedness Program. Through such grants management supports, responses to emergencies are strengthened, there is resolution of A-133 audit findings, and grant policies improve over time. ASPR continues to use Other Transaction Authorities to enable partnerships with like consortiums to support a portfolio of multiple products on a cost-share basis.

ASPR aligns its financial resources with strategic priorities and conducts annual planning under a multiyear strategy, measuring financial performance, and ensuring course corrections, when needed. ASPR carries out its responsibilities by formulating, monitoring, and evaluating budgets and financial plans to support program activities in ways that assure efficient expenditures. During FY 2019, ASPR Operations submitted to Congress the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget (MYB) report for FY 2018-2022. For HHS PHEMCE partners, including ASPR's Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the Food and Drug Administration, the PHEMCE MYB aligns 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 and Nuclear and emerging infectious disease threats.

ASPR ensures oversight of emergency administration and finance operations that provide Stafford Act expertise, financial tracking, and emergency administrative functions to directly support HHS responders and stakeholders during public health emergencies. When the HHS Incident Management Teams are activated to perform ESF 8 functions under the National Response Function, ASPR's finance function integrates with the Incident Management Team under the structure of the Incident Response Framework. ASPR works closely with the Federal Emergency Management Agency and other response partners to ensure that 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 requests for emergency supplemental appropriations, when needed.

ASPR Operations ensures the accountability and effectiveness of its financial programs and operations through performance management and by establishing, assessing, correcting, and reporting on internal controls, as required by OMB Circulars A-123 and A-11 and consistent with the Department's implementation of Enterprise Risk Management (ERM). This includes tracking, analyzing, and feeding back performance and other data, then using this evidence to promote ongoing improvements, a risk-aware culture, and to create a comprehensive view of risks to drive strategic decisions, and communicate

risk appetite. To this end, ASPR coordinates cross-disciplinary reviews of high impact, high-visibility programs to identify risks and performance challenges that could impede the completion of ASPR's mission, and to develop strategies for ensuring effective and efficient operations.

Funding History	
FY 2017	$30,938,000
FY 2018	$30,938,000
FY 2019	$30,938,000
FY 2020 Enacted	$30,938,000
FY 2021 President's Budget	$30,938,000

Budget Request

The FY 2021 President's Budget for Operations is $30,938,000, which is flat with the FY 2020 Enacted level. The request is integral to achieving ASPR's goals and to the success of ASPR's activities. The request supports continued implementation of acquisition management innovations, long-term fiscal planning, performance management, contributions to HHS Agency Priority Goals, and internal controls. Funds will support the continued development of ASPR's ERM and strategic human capital management initiatives.

ASSISTANT SECRETARY FOR ADMINISTRATION

Cybersecurity

Budget Summary
(Dollars in Millions)

Cybersecurity	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority /1	**57.820**	**57.820**	**67.053**	**+9.233**
FTE	**90**	**133**	**143**	**+10**

1/ FY 2019 – FY 2020 Enacted levels were $58.86 million; levels displayed above reflect 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.

Authorizing Legislation:
FY 2021 Authorization .....Indefinite
Allocation Method .....Direct Federal

Program Description and Accomplishments

The 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. The 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 continues to be a primary target for some of the most advanced cyber criminals in the world. These criminals – intent on stealing protected health information (PHI) and personally identifiable information (PII), profiting from ransomware payouts, or gaining unauthorized access to HHS systems and data for malicious purposes – have posed significant challenges to HHS and its stakeholders. HHS's operational cybersecurity program must be sufficiently flexible and agile to maintain a proactive and advanced security posture, and flexible to quickly pivot and respond to any incidents that occur in the cybersecurity environment.

The Cybersecurity Program implements a comprehensive, enterprise-wide cybersecurity program to protect the critical information with which the Department is entrusted. To accomplish this, HHS provides for 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.

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

In FY 2019:

- HHS managed 7,775 cybersecurity incidents
- HHS conducted 8,711 vulnerability scans (scanning an estimated 2,997,892 targets) preventing 1,090,211 vulnerabilities from being exploited. (9,692 hours, 50 minutes total scan time).
- HHS investigated 61,395 incidents of spam, 2,478 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

HHS seeks to improve information security through key initiatives and focus on improving efficiencies in security tools and deploying enterprise-wide 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 also building the programs and skilled workforce to ensure these technologies meet HHS objectives to protect its mission and information while also facilitating HHS's compliance of federal mandates and guidelines.

Specifically:

I. **Cyber Security Operations (CSO):** CSO implements and manages a wide-range of security services for the Enterprise, and it grows cyber resilience capabilities that align with the Department's implementation of the National Institute of Standards and Technology Cybersecurity Framework (CSF). CSO is comprised of five service capabilities: 1. Computer Security Incident Response Center (CSIRC), 2. Advanced Cyber Defense (ACD), 3. Security Tools and Information Management (STIM), 4. Health Sector Cybersecurity Coordination Center (HC3), and 5.) Trusted Internet Connection. These capabilities work together to track, research, resolve threats and incidents, protect and defend the Department's network perimeter, and collaborate with government and industry partners and stakeholders.

a. Computer Security Incident Response Center (CSIRC)

The CSIRC provides the foundation for cybersecurity at the Department by identifying, verifying, and understanding cyber events in order to respond effectively, develop mitigation strategies, and deliver timely products that address and incorporate stakeholder needs. CSIRC was established in 2008 under the Federal Information Security Management Act (FISMA), which requires each federal civilian agency to establish incident response capabilities, report all incidents to the U.S. Computer Emergency Readiness Team (US-CERT), and designate a primary and secondary point of contact. CSIRC tracks incident notifications originating from multiple sources including, but

not limited to, US-CERT, HHS OpDivs/StaffDivs, and incident response teams (IRTs), HHS computer systems' end-users, and third parties.

All HHS OpDivs/StaffDivs are required to report cybersecurity and privacy-related incidents to CSIRC, who then validates and reports the incidents to US-CERT, thus ensuring FISMA compliance. CSIRC efforts provide HHS users and Incident Response Teams (IRT) across the OpDivs/StaffDivs with 24/7/365 service to ensure that the information transmitted on incidents and reported to DHS is both correct and secure.

The CSIRC provides incident reporting and communication services responding to an average of 767 incidents per month, taking appropriate action and instituting network blocks as appropriate. CSIRC maintains HHS's mission critical operations, blocks malicious sites, filters spoofing emails and spam, trains users through ethical phishing, enables real-time visibility of threat elimination, and protects the health data of hundreds of thousands of Americans. CSIRC's day-to-day operations help the Department and OpDivs/StaffDivs remain prepared for and protected against cyber threats and incidents.

CSIRC centralizes and streamlines Enterprise-level communications through data call tracking and reporting, vulnerability tracking and reporting, and process and procedure documentation on behalf of the Department.

b. Advanced Cyber Defense (ACD)

The ACD branch of CSO provides support across HHS's cybersecurity teams by proactively identifying and researching threats, testing the cybersecurity posture of systems, and searching for malicious activity across the Department. ACD supports the HHS incident response process by providing in-depth analysis and forensic reviews, as well as development of information to share with the Healthcare and Public Health (HPH) sector. ACD provides value to HHS and OpDiv/StaffDiv stakeholders by proactively looking for threats and vulnerabilities that could pose a risk to HHS systems. Specifically, ACD provides the following services:

- Vulnerability Assessment and Penetration Testing
- Spam Mailbox Analysis
- Malware Analysis
- Identifying and reporting websites with malicious content (site takedowns)
- Cybersecurity Research and Forensics investigations and reviews
- Query and script development

c. Enterprise Security Tools and Infrastructure Management (STIM):

HHS OpDivs/StaffDivs have cyber adversaries who regularly target them specifically for the data they collect and store. CSO helps the OpDivs/StaffDivs defend against these threats through the provision and management of cyber tools and technology via the HHS Security Enclaves.

A Security Enclave is a suite of various security tools deployed at the OpDiv/StaffDiv and Trusted Internet Connection Access Provider (TICAP) locations. The STIM capability provides 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. STIM also manages the procurement of enterprise hardware, software, and 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.

STIM will continue to procure enterprise-wide digital investigation technologies to deploy across all OpDivs/StaffDivs. STIM will seek to enhance asset configuration and problem management functions in support of the CSIRC mission. STIM will continue to deploy security tools at OpDiv/StaffDiv internet connections, and continue enterprise deployments of security incident and event management capabilities, firewalls, web proxies, and security analytics.

d. Health Sector Cybersecurity Coordination Center (HC3)

The HC3, in coordination with DHS, communicates cyber threat intelligence and mitigations to the HPH sector, working directly with federal, state, local, tribal, territorial, and private sector partners to improve the sector's overall cybersecurity posture. As part of the Department's fulfillment of the federal cybersecurity information-sharing role within the Cybersecurity Act of 2015, HC3's focus is to support the defense of the HPH sector's information technology infrastructure. This strengthens coordination and information sharing within the sector and cultivates cybersecurity resilience, regardless of organizations' technical capability.

HC3 reaches more than 1,600 organizations and over 3,000 individuals across the HPH sector. HC3 has directly engaged with six key HPH partners, including the National Health Information Sharing and Analysis Center and Health Information Trust Alliance. HC3 closely engages with federal partners including HHS OpDivs/StaffDivs, the intelligence community, the DHS, the VA, and the Defense Health Agency. HC3 delivers intelligence briefings and directly collaborates with a variety of organizations in the public and private sector. HC3 leverages the CSO automated threat analysis platform to collaborate and share Indicators of Compromise (IOCs) with representatives from HHS OpDivs/StaffDivs, federal partners, and the private sector. HC3 and its federal partners have shared over 115,000 IOCs demonstrating the high level of engagement and collaboration across HHS and with external HPH sector partners.

e. Trusted Internet Connection

The TIC program aims to improve the Federal Government's security posture through consolidation of external telecommunication connections and establishment 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.

Investments support engineering and monitoring support costs of the TIC, which will enable the Department to meet its obligations specified in the DHS TIC and Einstein traffic monitoring and intrusion detection program service level agreements.

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

a. 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.

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

Federal Risk and Authorization Management Program authorization program.

c. **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 the Office of Management and Budget reporting while also providing oversight of information security across the Department.

d. **Office of the Secretary Security Services** publishes privacy and information security policy, conducts risk management, compliance, security operations to the Office of the Secretary (OS) and OS Staff Divisions.

e. **Enterprise Privacy** provides HHS-wide privacy governance and advisory support, reduces exposure to privacy risks and mitigates those risks, develops privacy policy and offers training on such policy, and provides privacy incident management support for the department.

Funding History	
FY 2017	$49,820,000
FY 2018	$49,820,000
FY 2019	$57,820,000
FY 2020 Enacted	$57,820,000
FY 2021 President's Budget	$67,053,000

1/ FY 2019 – FY 2020 Enacted levels were $58.86 million; levels displayed above reflect 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 is FISMA, requiring 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 2021 President's Budget for the HHS Cybersecurity Program is $67,053,000, which is an increase of $9,233,000 compared to FY 2020 Enacted. This funding level reflects a realignment of funds totaling $1.04 million from Cybersecurity to ONS in accordance with the memorandum dated October 4, 2012, subject Budget Alignment and Detail of Employees. These funds continue ONS's cyber threat intelligence program, which includes cyber threat intelligence and analysis, technical counterintelligence and technical surveillance countermeasures. This reallocation has occurred annually since the signing of the 2012 memorandum. The request continues to support, sustain, and enhance the Department's security posture and reflects the current landscape of our adversaries seeking to breach our defenses and extract sensitive information. The protection of the HHS mission that delivers healthcare services to tens of millions of American citizens remains a priority. HHS seeks to increase and invest in its protections against cyber threats, such as unauthorized access, denial of service, malicious code, and data automation (artificial intelligence to determine inappropriate usage and insider threats that pose risks to HHS critical functions), services, and data.

Key initiatives HHS is undertaking to improve security include:

- Purchase technology and building OIS programs to improve efficiencies in security tools and deploying enterprise-wise tool solutions to enable HHS's correlation of cyber threat and vulnerability information
- Ensure the availability of a skilled workforce, both internal and external, to ensure these technologies meet HHS objectives to protect its mission and information
- Improve protection of HHS assets and endpoints that process and store information
- Increase situational awareness and response to actions that could exploit or jeopardize HHS information systems.
- Facilitate HHS's compliance against federal mandates and guidelines.

The Budget enables the HHS Cybersecurity Program to continue to provide management and oversight of the Department's Cybersecurity Program and to ensure compliance with the requirements of FISMA. This request helps sustain prior security investments, which were instrumental in enabling the completion of the security engineering and design work for the TIC initiative. The request directly contributed to procuring and implementing efforts at the TIC locations and their ongoing maintenance and operations. It also supports security engineering and funding a suite of Enterprise Security Tools, which will be required to comply with recent guidance requiring the automated reporting of the continuous monitoring of all HHS and OpDiv/StaffDiv IT systems and networks.

Summary of Cybersecurity FY 2019-2021 Funding by Program

(dollars in thousands)

Cybersecurity Program	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
CSIRC	$12,600	$12,600	$12,600	$0
TIC	$2,100	$2,100	$2,100	$0
Enterprise Security Tools	$19,400	$19,400	$25,136	$5,736
FISMA	$23,720	$23,720	$27,217	$3,497
Total	$57,820	$57,820	$67,053	$9,233

1/ FY 2019 – FY 2020 Enacted levels were $58.86 million; levels displayed above reflect 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.

Computer Security Incident Response Center (CSIRC) ($12,600,000): The legacy "CSIRC" program aligns to the CSO CSIRC, ACD, and HC3 narrative capabilities. The request is flat to FY 2020 Enacted, and supports the continued alignment of CSO services across the Department.

Through the CSO capability, the Department has provided proactive cyber hunting capabilities, and cybersecurity situational awareness. CSO has coordinated response across the HPH sector. CSIRC (CSO CSIRC, ACD, and HC3) have also addressed several threat vectors simultaneously by having a central view into all OpDiv/StaffDiv networks. CSO (CSIRC, ACD, and HC3) capabilities proactively minimize attacks across the Department and, in some cases before the attacks escalated

The FY 2021 request continues to invest in cybersecurity technologies. Smartphones, mobile, and cloud computing significantly change the way the Department stores, accesses, and secures data while meeting the protection and accessibility demanded by the public's interest in public health. As threats evolve, become more sophisticated, and technology changes ,investments in consolidated data automation and machine learning (Artificial Intelligence) will enable the Department to evolve and keep pace with those threats.

Trusted Internet Connection (TIC) ($2,100,000): The request is flat with FY 2020 Enacted and allows for ongoing operations support of the TIC.

The TIC program aligns the Department with DHS initiatives to provide greater security in the government's internet connections and facilitate the necessary infrastructure to implement the DHS Einstein initiative for the entire Department. 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 OpDivs/StaffDivs. The TIC provides core capabilities for the Department's Continuous monitoring plan by acting as a single point of aggregation for internet traffic security data collection.

Enterprise Security Tools ($25,136,000): The request is an increase of $5,736 compared to FY 2020 Enacted. This level allows for continued support and enhancement of the Enterprise Security Tools Information Management capabilities and support across the Department.

HHS is the repository for a great deal of sensitive information including bio-defense, the development of pharmaceuticals, and medical information for one hundred million Americans. As a result, HHS information is a target for cyber criminals seeking economic gain, as well as nation states who seek to compromise the security of government information and gain economic, military, or political advantage. As cyber threats continue to evolve through new variations of malicious software used by attackers, HHS will continue to enhance the IT security at the OpDivs/StaffDivs by pursuing and sustaining a number of high impact activities. Enhancing IT security will enable HHS to keep pace, address and correct new and existing security gaps.

This request provides additional solutions to counter malicious software (malware) and other sophisticated computer viruses and worms that continue to plague government computer systems. The request invests in: 1.) Specialized security tools to examine Cloud vulnerability exposure and identify previously unknown IT activity; 2.) Enables the development of a roadmap providing insight into sector cloud activity and dark web engagements (including Cloud Access Security Broker [CASB] solutions); 3.) Consolidating Data Automation and Machine Learning (Artificial Intelligence) applications, activity, and services applied to Department systems and tools; and 4.) Increases the volume and frequency of penetration testing and vulnerability scanning, especially for critical systems such as HHS' high value assets; and enhance HHS' database scanning capabilities to ensure databases in critical systems are tested and secured.

The request also includes funding to support and enable enhancements of the various Departmental CDM tools. The licenses ensure these security activities are implemented fully and consistently at all levels of HHS. An effective Cybersecurity program decreases the number and severity of exploits of sensitive HHS information systems, including compromise of mission critical data. CDM requires Department-wide maintenance and updating of infrastructure to proactively identify and address vulnerabilities before exploitation.

The Budget request renews 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, automated tools for FISMA reporting, security weakness tracking, will provide the support to increase the speed to which the OpDivs implement the technologies

FISMA Program Management ($27,217,000): The request is an increase of $3,497 compared to FY 2020 Enacted. This level allows for continued support of the on-going maintenance of Enterprise Governance, Risk, and Compliance management tools. The tools allow for automated reporting of security performance measures to the DHS. Funds also enable more effective implementation of information security weakness remediation in response to recommendations and findings of various audits and evaluations, including the Department's annual financial statement audits and future GAO and IG audits

as well as strategic and thought leadership and will continue the enhancement of the program's security compliance and annual FISMA program review efforts to more effectively measure the Department and OpDiv/StaffDiv levels of compliance with the requirements of FISMA. The budget request will also invest funds to support increased Phishing events and, deploy specialized training to OpDivs, Escape Rooms and expand Data Guardian programs; identify, provide and promote cybersecurity services that can assist small OpDivs enhance their cybersecurity posture; identify liaisons to work with StaffDiv personnel to better identify and resolve cybersecurity issues.

In addition, the Department will enhance OpDiv/StaffDiv operational IT systems continuous monitoring capability, in order to determine 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 PII Breach Response Team that enable the Department to evaluate OpDiv/StaffDiv breach response assessments to determine the appropriate response to any reported breaches of PII.

Cybersecurity-Outputs and Outcomes Table

Program/Measure	Sum of Most Recent Result	FY 2020 Target	FY 2021 Target	FY 2021 +/- FY 2020
Asset management: Percent (%) of the organization's unclassified network that has implemented a technology solution centrally visible at the enterprise-level to detect and alert on the connection of unauthorized hardware assets. (NIST SP 800-53r4 SI-4 (4)(18), SC-7(10))	FY 2019 Actual: 99.0%	95.0%	95.0%	Maintain
Software Asset management: Number of GFE endpoints covered by a software asset management capability centrally visible at the enterprise-level that is able to detect unauthorized software and alert appropriate security personnel. (NIST SP 800-53r4 CA-7, CM-7(5), RA-5), NIST SP 800-128)	FY 2019 Actual: 72.0%	95.0%	95.0%	Maintain
Authorization management: For each FIPS 199 impact level, what is the number of operational unclassified information systems by organization (i.e. Bureau or Sub-Department Operating Element) categorized at that level? (Organizations with fewer than 5,000 users may report as one unit.) (NIST SP 800-60, NIST 800-53r4 RA-2) 1.1.3. Systems (from 1.1.1. and 1.1.2.) with Security ATO	FY 2019 Actual: 95.0%	100%	100%	Maintain
Privileged Network Access Management: Number of users that are required to authenticate to the network through using a two-factor PIV credential5 or other Identity Assurance Level (IAL) 3/Authenticator Assurance Level (AAL) 3 credential.	FY 2019 Actual: 100%	100%	100%	Maintain
HVA Systems Access Management: Report the number of High Value Asset (HVA) systems8 that require all organizational users (100% privileged and unprivileged) to authenticate through the machine-based or user-based enforcement of a two-factor PIV credential or other IAL3/AAL3 credential. (DHS BOD 18-02, NIST SP 800-63)	FY 2019 Actual: 93.0%	90.0%	90.0%	Maintain

NONRECURRING EXPENSES FUND

Budget Summary
(Dollars in Thousands)

	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Notification #6 Total	$34,000	--	--

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.

In order to execute the mission and adhere to the multitude of mandates, directives, guidance, and executive orders, OIS is engaged in the four initiatives below with outlined accomplishments highlighted in each.

1. HHS Cybersecurity Automation Program (HCAP) (SGRC, CDM, Enterprise Log Management and Cybersecurity Security Information and Event Management)
2. Enterprise Network consolidation and Trusted Internet Connection (TIC) migration to Managed Trusted Internet Protocol Service (MTIPS)
3. Enterprise Packet Capture Solutions Refresh

Initiative 1: HHS Cybersecurity Automation Program (HCAP) Integration (FY 2019 $20.7 million)

Summary Statement:

The Department of Health and Human Services Cybersecurity Automation Program (HCAP) establishes a cybersecurity solution development, governance, leadership, and operational capability delivered by OIS improving cybersecurity visibility, efficiencies and standardization across the Department.

OIS requested and received funds for a continued investment to implement HCAP services leveraging and integrating 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. HCAP will enable sharing and consolidation of data sources and analysis across the agency to produce useable cybersecurity risk management information for the Department.

FY19 HCAP Accomplishments include:

- HCAP Overall:
  - Submitted HCAP Program Charter for executive approval.
  - Established OIS Data Sharing Memorandum of Understanding (MOU) (including department data sets)
  - Elicited, analyzed, and validated requirements for FISMA Tagging (Enabling associating information system assets to the authorized FISMA systems)
  - Created Enterprise Cybersecurity Change Control (ECCC) workflow and draft process.
- CDM:
  - Integrated data across OpDivs to allow cross-OpDivs cybersecurity analysis.
  - Conducted OpDiv assessment workshops (documented "as-Is" states, developed IMS, detailed execution plans)
  - Executed DHS Request for Services (RFS) projects (NAC, Asset Management and Identity and Access Management) respectively.
  - Conducted pilot for whitelisting and NAC to support results of Analysis of Alternatives and requirements towards the DHS Request For Service (RFS)".
  - Developed and piloted the FISMA reporting application (increasing FISMA metrics visibility for FISMA metrics and CAP scores, and deployed to all HHS OpDivs.
- SPLUNK:
  - Full interconnection of HHS data
  - Continued onboarding of data across HHS agencies
  - Bi-directional interconnection of HHS Cybersecurity data sources
  - Augmentation of OpDiv staff to continue maturation for OCIO, OS, IHS
  - Training of HHS Federal Staff
  - Implementation of internal GITLAB to support content sharing
  - Implementation of non-cyber data across HHS agencies
  - Deployment of key monitoring use cases around shared technologies: Cisco, FireEye, Palo Alto Network, BigFix, etc.
  - Automation of FISMA Questions
  - Establishment of Splunk COE for training, cross agency best practices, and lessons learned.
- ARCHER/SGRC:
  - Transitioned to the SGRC Archer Security Operations module from Risk Vision for Incident Handling (October 2019):
    - *Standardizes the Security Operation Center (SOC)*

    - *Enhances HHS's Incident reporting capabilities*
    - *Supports OpDivs with US-CERT reporting and compliance*
  - Streamlined tools across OpDivs (replacing TAF, RMFP, HSDW, Risk Vision and manual /undocumented processes) with a single standardized GRC solution.
  - Developed common language and standardized workflows across 12 Operating Divisions
  - Established a baseline configuration of the Policy for OpDiv utilization (October 2019)

Initiative 2: Enterprise Network consolidation and Trusted Internet Connection (TIC) migration to Managed Trusted Internet Protocol Service (MTIPS)
(FY 2019 $5 million)

Summary Statement:

The Office of Technology Infrastructure and Operations (OPS) and OIS within OCIO are the business owners for the HHS Enterprise Intranet (HHSNet), the Trusted Internet Connection (TIC), and Internet services for HHS. OIS manages government owned infrastructure for the TIC, HHSNet, and Internet services and demonstrates an opportunity for improved operations, security, cost savings and cost predictability for the Department. Additionally, OCIO works with the OpDivs' identified efficiencies migrating to a Managed Trusted Internet Protocol Service (MTIPS).

OIS requested and received funds for a continued investment to identify efficiencies in enterprise security components, fund lifecycle refresh for TIC and Internet security components, support HHS internet requirements and migration cost to MTIPS. These updates strengthened OMB mandated TIC cyber security capabilities. OIS continues to leverage remaining funds for the initiative.

FY19 TIC Accomplishments include:

- Established TIC support of OpDiv applications moving to cloud service providers: Azure, Oracle and AWS.
- Enabled ABQ Palo Alto (PA) state-full mode of operation.
- Completed PA Panorama/PA firewalls upgrade to 8.1.8. This version improves support for zone protection.
- Upgraded Palo Alto Panorama & firewalls to 8.1.9
- Implemented zone protection on DC/ATL/ABQ TICAP PA.
- Created operational dashboards (Threat Anomaly, TIC Anomaly, Nation State Traffic, & Domain Generated Algorithm) leveraging Splunk's MLTK.
- CenturyLink E3A version-2 implemented for all OpDiv's, version-1 was disabled for HHS.
- Purchased and installed CenturyLink DDoS protection.
- Implemented number of VPC instances. Implemented new design to allow applications Internet connectivity to cloud providers, bypassing OpDiv's.
- MTIPS transition associated with a Department wide GSA EIS fair opportunity contract. Expected award mid FY20. Transition kickoff expected shortly after award.

TIC Activity:

Year	Inbound (Avg/Max/Total)	Outbound (Avg/Max/Total)
2019	6.4Gbps/23.95Gbps/13.15PB	3.8Gbps/14Gbps/9.17PB
2018	8425 Mbps/21077 Mbps/33211 TB	4588 Mbps/11428 Mbps/18085 TB
2017	8334 Mbps/20444 Mbps/32853 TB	3953 Mbps/9914 Mbps/15583 TB
2016	8469 Mbps/14926 Mbps/33385 TB	4684 Mbps/15602 Mbps/18464 TB
2015	5128 Mbps/12554 Mbps/20215 TB	2389 Mbps/5564 Mbps/9417 TB
2014	3668 Mbps/8582 Mbps/14459 TB	1474 Mbps/3066 Mbps/5811 TB
2013	2019 Mbps/3942 Mbps/7959 TB	998 Mbps/1889 Mbps/3934 TB

Initiative 3: Enterprise Packet Capture Solutions Refresh
(FY 2019 $5.5 million)

Summary Statement:

A component of the HHS Security Enclave is packet capture technology across the enterprise. This solution extends the capability for cybersecurity operations across the Department. HHS implementation of packet capture technology is vital for the enterprise's overall security posture. The solution requires a timely refresh to continue delivering and enriching indicators of compromise, and proactive security monitoring.

OIS requested and received funds for a continued investment to refresh the Department's Enterprise Packet Capture Solution. The investment in FY19 delivered the Packet Capture Refresh initiative. OIS executed necessary planning and procurement actions for the Packet Capture refresh initiative during the FY19 fiscal year.

FY19 Packet Capture Accomplishments include:

- Executed Stakeholder coordination to identify streamlined and effective refresh initiative.
- Produced a BOM, solicited for award, and executed award.
- Awarded NetWitness Refresh equipment and services Q4 FY20.
- Authorized refresh OpDiv and Security implementation installation schedule.
- Executed Packet Capture refresh schedule Q1 FY20.
- Schedule forecasts completion by end of FY20.

IMMEDIATE OFFICE OF THE SECRETARY

Office of National Security

Budget Summary
(Dollars in Millions)

ONS	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	**8.510**	**8.510**	**8.884**	**+0.374**
FTE	**26**	**37**	**37**	**--**

1/ FY 2019 – FY 2020 Enacted levels were $7.47 million; levels displayed above reflect 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.

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

Program Description and Accomplishments

The Office of National Security (ONS) 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 Coordination Office (FICO). In this capacity, ONS is the HHS point of contact with the Intelligence Community (IC), and is responsible for coordination with the IC and for intelligence and national security support to the Secretary, senior policy makers and consumers of intelligence across the Department. Additionally, ONS is responsible for safeguarding classified national security information across the Department and the appropriate sharing of intelligence, homeland security and law enforcement information externally and internally within HHS among the Operating and Staff Divisions. ONS is headed by the National Security Advisor to the Secretary, who reports directly to the HHS Deputy Secretary. The National Security Advisor to the Secretary serves as the HHS Secretary's Senior Intelligence Official on national security, intelligence and counterintelligence issues, the Senior Designated Official for insider threat issues, and as the Department's Federal Senior Intelligence Coordinator (FSIC). The National Security Advisor has also been delegated original classification authority by the Secretary.

Besides the Immediate Office of the Director, ONS is comprised of three divisions, including the Intelligence and Analysis Division (IAD), the Security and Business Services 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 (national security clearances and Departmental policy on suitability) 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.

More specifically, ONS programs 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), Intelligence Community Directives, 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 IC, 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 and cyber threat intelligence analysts, and special security professionals, to acquire, synthesize, analyze and report on open source and classified information and assess its usefulness in supporting and furthering the HHS mission. ONS utilizes all-source classified and unclassified information from the IC, as well as from Law Enforcement, Homeland Security, 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 threat and cyber threat intelligence issues, including the sharing and safeguarding of national security information.

Funding History	
FY 2017	$7,454,000
FY 2018	$7,419,000
FY 2019	$8,510,000
FY 2020 Enacted	$8,510,000
FY 2021 President's Budget	$8,884,000

1/ FY 2019 – FY 2020 Enacted levels were $7.47 million; levels displayed above reflect 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 2021 President's Budget for ONS is $8,884,000, which reflects an increase of $374,000 above FY 2020 Enacted. This funding level reflects a realignment of funds totaling $1.04 million from PHSSEF Cybersecurity to ONS in accordance with the memorandum dated October 4, 2012, subject Budget Alignment and Detail of Employees. This reallocation has occurred annually since the signing of the 2012 memorandum for the purpose of continuing ONS' cyber threat intelligence program, to include cyber threat intelligence and analysis, technical counterintelligence and technical surveillance countermeasures. The FY 2021 increase of $374,000 will support enhanced national security activities such as Supply Chain Risk Management, Counterintelligence and Insider Threat, Social Media Exploitation, etc. The FY 2021 funding level will otherwise allow ONS to maintain its current FTE and operations.

ONS must maintain its capability to provide timely, appropriately tailored and relevant intelligence, and other strategic (including law enforcement sensitive) information to inform HHS decision-makers and their programs on potential national security threats domestically and abroad. Intelligence/Information is used by HHS to anticipate and warn of emerging threats that may require the department to adjust policy/programs; achieve global health security goals such as those related to the Ebola Epidemic; 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' ability to maintain and work closely with other federal departments and agencies, including law enforcement organizations and the IC, 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. Additionally, ONS must maintain the Department's capability to address 1) supply chain risk management, 2) vetting of foreign national visitors, 3) assessing potential damage to HHS and national security from unauthorized disclosure of classified and/or sensitive information, and 4) addressing potential cyber threats to the Nation's public health and medical infrastructure.

In FY 2019, ONS provided support to all of the Secretary's priority items, including Ebola, intellectual property theft, and the Unaccompanied Children program. The Office of the Chief Information Security Officer, the Office of the Inspector General, the Office of Global Affairs, the Administration for Children and Families, the Food and Drug Administration, National Institutes of Health, the Assistant Secretary for Preparedness and Response, and the Centers for Medicare & Medicaid Services are just some of the 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 security, homeland security and classified programs.

PANDEMIC INFLUENZA

Budget Summary
(Dollars in Millions)

Pandemic Influenza	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Program Level	**260.000**	**260.000**	**310.000**	**+50.000**
Budget Authority (non-add)	*260.000*	*260.000*	*310.000*	*+50.000*
ASPR No-year funding (non-add)	*225.000*	*225.000*	*275.000*	*+50.000*
ASPR Annual Funding (non-add)	*30.991*	*30.991*	*30.991*	--
OGA Annual Funding (non-add)	*4.009*	*4.009*	*4.009*	--
FTE	**5**	**5**	**5**	--

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

Infectious disease models indicate 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 viruses continue to mutate, evolve, and spread globally, infecting humans, wildlife and farm animals, posing evolving threats to public health and to our national health security. During the winter of 2016-2017, China experienced the largest epidemic of avian influenza H7N9 on record since its emergence in 2013. The H7N9 virus had drifted and gained virulence for poultry, prompting the World Health Organization (WHO) to recommend development of a new pandemic influenza vaccine candidate. Although the virus has not gained sustained transmissibility in people and remains endemic within China's borders, about 10 percent of the viruses from human cases have shown markers of resistance to licensed antiviral drugs, restricting therapeutics options for an infection with a case fatality ratio of approximately 40 percent. It is vital that the United States remain vigilant and sustain a robust pandemic preparedness posture against H7N9 and other deadly pathogens, including H5N1 and H5N6.

The public outcry over the repeated spread of Ebola outbreaks in Africa and delayed vaccination during the 2009 H1N1 influenza pandemic in the United States (US), 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 during the next pandemic, the United States Government (USG) must continue to improve MCMs, including vaccines, drugs, diagnostics, and respiratory protection devices, while expanding manufacturing capacity so that MCMs are available when needed. It is also essential that response capabilities are established and sustained to ensure an effective response to emerging pandemics.

Strengthening Pandemic Influenza Preparedness

The US Department of Health and Human Services (HHS) has made significant progress in pandemic preparedness for our nation and internationally. HHS has guided the MCM enterprise through developments recommended in the *2010 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Review* report, along with other reports, including 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* and the *PHEMCE Strategy and Implementation Plan*, which informs development and procurement of medical products to combat pandemics. During 2017, HHS published the *Update of the Pandemic Influenza Plan* to report accomplishments and establish clear priority goals designed to improve pandemic preparedness and response.

The Pandemic Influenza (PI) program has:

- Developed and produced H5N1 and H7N9 vaccine seed strains that allow vaccine production to begin quickly when the need arises;
- Developed and purchased H5N1, H5N6, 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);
- With FDA licensure, developed new influenza vaccines using modern cell- and recombinant-based production technologies to expedite and expand domestic production capacity;
- Supported improved assessment of the relative effectiveness of newly licensed influenza vaccines produced in cell cultures or recombinant platforms as compared to traditional egg-based vaccines;
- 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, tested, and stockpiled new antigen-sparing adjuvants that 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;
- Supported development of new technologies that will help influenza vaccines become available faster than currently possible in response to a pandemic or other public health emergency;
- Conducted clinical trials that provide the necessary evidence 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 two and phase three clinical trials;
- To significantly increase the supply of respirators available during an influenza pandemic, supported the development of technology and processes that promote rapid production of N95 respirators;
- Supported the development and 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, with production, stockpiling 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 worked with partners to improve preparedness at the local, state, and international levels, including:
- Improved technical knowledge and capacity for manufacturing in developing countries in order to increase global pandemic influenza vaccine capacity;
- Conducted surveillance, research, and international collaboration on policies, plans, and training;
- Provided risk communication to improve public understanding of the actions that individuals, businesses, and organizations can take to protect the public from emerging infectious diseases, including those with pandemic potential;
- Supported 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, next-generation ventilators, and medical supplies, including adjuvants and antiviral drugs.

Pandemic Influenza program investments have led and contributed to innovative technologic advancements for MCMs, including the achievements listed below.

Cell-based influenza vaccines: Building on the program's partnership with Novartis (now owned by Seqirus), FDA licensed Flucelvax, the first cell-based influenza vaccine in the US. BARDA's investments in the domestic manufacturing capacity for Flucelvax included supporting a facility in Holly Springs, North Carolina. Production of influenza vaccines in cell culture eliminates the vulnerability of current egg-based pandemic vaccines which depend upon egg supplies, which can be disrupted by a pandemic virus of avian origin that decimates flocks. Cell-based vaccines may reduce the possibility of mutations, potentially impacting vaccine effectiveness. In 2016, FDA extended the indication for Flucelvax (both trivalent and quadrivalent versions), to include persons four years of age and older. With support from BARDA, Seqirus recently achieved manufacturing efficiencies that double the number of pandemic influenza vaccine doses produced, thereby reducing both the cost and time needed to meet production goals during a pandemic. During 2018, this work resulted in Seqirus receiving regulatory approval for a supplemental biological license application (BLA) submission, increasing cell-based vaccine production two-three fold. In 2018, the Pandemic Influenza program also supported efforts to improve fill/finish production processes, allowing more vaccine to be available in a shorter time. Since 2017, the program has worked with Seqirus to support ongoing readiness for pandemics, including developing of seed vaccine virus and bulk antigen production. These efforts are critical to ensuring rapid manufacturing and vaccine production response capability. During FY 2019, the PI program initiated efforts to expand domestic manufacturing capacity for the recombinant influenza vaccine technology. This promotes rapid response capabilities for use during a potential pandemic. These efforts will continue during FY 2020 and 2021.

Recombinant Vaccines: Since 2009, the Pandemic Influenza program has supported the first recombinant-based vaccine for seasonal influenza licensed in the United States. This recombinant vaccine technology supported by BARDA offers the shortest time to first dose delivered in response to an outbreak or pandemic as compared to 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 2015, the Flublok indication was extended from persons between the ages of 18 and 50 to people age 18 years and above. The

Quadrivalent Influenza Virus Vaccine was approved by FDA in the winter of 2016. The PI program is completing a clinical study to assess the safety and antigen-sparing potential of adjuvanted H7N9 recombinant influenza virus vaccine based on the highly pathogenic variants that emerged in China during 2016-2017. This study will enable selection of the optimal vaccine formulation for pandemic response. Initial results reported during FY 2019 indicate the adjuvanted vaccine induces a strong immune response, paving the way for both dose selection as well as future trials to examine other dosing regimens and suitability of other adjuvants. Finally, during 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 coalesce to make more vaccine available to the public sooner in the event of a pandemic, as specified in the HHS Pandemic Plan.

Expanding vaccine capacity with adjuvants: BARDA continues to support advanced development of multiple vaccine adjuvants to achieve dose sparing of antigen, broad immunity across antigenically divergent viruses, and significant long-lasting immunity. Adjuvanted formulations 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. FDA licensed the first adjuvanted pandemic influenza vaccine in the United States, GlaxoSmithKline's Q-PAN H5N1 pandemic vaccine with AS03 adjuvant, in 2013, and subsequently approved the pediatric indication in 2016. In April 2019, Seqirus submitted a BLA for approval of the first cell-based MF59-adjuvanted H5N1 influenza vaccine in the world. This vaccine was produced in cell culture at the Holly Springs, NC facility, with licensure expected in 2020. Domestic production of a cell-based adjuvanted pandemic vaccine constitutes a major advance in pandemic preparedness by contributing at least 150 million doses of pandemic vaccine within six months of an emergency declaration, regardless of the availability of egg supplies. The eventual FDA approval will significantly secure and enhance HHS's ability to respond during a pandemic.

Close collaboration between the Pandemic Influenza and Advanced Research and Development (ARD) programs resulted in the launch of 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 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 vaccines during a pandemic response. Additional studies during 2019 and 2020 will determine the most effective formulation, as well as to test new adjuvants to gather sufficient clinical evidence to support rapid response options in the event of a pandemic.

BARDA continued to support expansion of domestic adjuvant manufacturing capacity in the course of 2019. This effort includes both bulk adjuvant manufacturing as well as fill/finish capability. Additional efforts in 2020 and 2021 will look to further improve and diversify adjuvant manufacturing capacity and fill/finish capability. Once completed, these capabilities will ensure a ready and secure 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 (CIADMs). 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 to develop and manufacture CBRN MCM products from Phase I through FDA approval. Each CIADM has started facilities and is focusing on establishing pandemic influenza response capabilities while refining core services to provide good manufacturing practices to facilitate manufacturing capacity and capability. BARDA's collaboration with the Department of Defense (DoD) continues to re-evaluate both DoD's ADM facility at Ology and the CIADMs.

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. Specifically, the PI program is supporting the optimization of candidate vaccine viruses used in vaccine manufacture to achieve high-production yield, and development of alternative, novel assays for vaccine potency and sterility. Synthetic biology and reverse genetics technologies have expedited candidate vaccine seed strains – including H7N9 seeds – to become available in less than ten days, compared to weeks using classical methods. New sterility assays have shortened this specific testing time from 14 to five days. During 2019, the program 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 2020, the PI program plans to progress these improved release tests towards regulatory approval through a combination of continued contract support and engagements with manufacturers and regulatory authorities.

Expanded domestic influenza vaccine manufacturing surge capacity: Since 2005, BARDA has supported a series of efforts to increase manufacturing capacity and licensure of new manufacturing technologies and process improvements which have coalesced to achieve and exceed the HHS goal of 600 million doses of pre-pandemic bulk antigen in six months. A diversified and expanded seasonal influenza vaccine production base also lowers the risks to the primary infrastructure for a pandemic response. The successful initiatives that BARDA has undertaken have established a sound and robust base for ongoing efforts to improve vaccine delivery, adjuvants and fill/finish capacity to achieve the HHS goal of timely vaccine availability in a pandemic emergency. In 2019, the PI program continued to support this critical infrastructure by funding efforts to maintain access to raw materials for a year-round response to a pandemic, as well as maintaining facility infrastructure. Also, in 2019, the program awarded a contract to Sanofi Pasteur to expand domestic manufacturing capacity for the recombinant based influenza vaccine. This effort is in direct support of the Presidential Executive Order released in 2019: "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health." These efforts, critical to maintaining pandemic influenza production capacity, are planned to continue in 2020 and 2021.

Providing new influenza antiviral drugs to treat critically ill populations: In severe pandemics, hundreds of thousands of people could be hospitalized with severe influenza in the US. In 2015, FDA approved Rapivab (peramivir), developed with BARDA support as a 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 drugs with novel mechanisms of action to reduced risk of viral resistance, expanded treatment windows, and co-administration with other influenza antiviral drugs. Since FY 2017, BARDA used an Other Transaction Authority to make two awards to support development of multiple influenza antiviral drugs. These programs include development of host directed therapeutic products that could be effective in patients hospitalized three or more days after disease onset and also overcome the emergence of resistance during an influenza pandemic or for seasonal influenza. In FY 2019, BARDA continued support for three ongoing pivotal efficacy trial of therapeutic candidates. FY 2020 and 2021 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 Authority (EUA).

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, efforts were 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, BARDA awarded contracts to Cue Health Inc. and Diassess (now Lucira Health) in 2018, 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. These efforts will continue in FY 2020 and 2021 to support submission to FDA for review.

Respiratory Devices and Ventilators: In 2019, FDA approved the Trilogy Evo Ventilator, a next-generation portable ventilator developed by Philips with BARDA support. This game-changing device considered a pipedream just a few years ago, is now available at affordable prices to improve stockpiling and deployment to meet a surge in demand to manage patients of all ages requiring respiratory support in the hospital or at home during a pandemic. BARDA is also supporting efforts at Halyard Health to develop high-speed manufacturing for surge production capability for respiratory protection devices (RPD). In FY 2018, investments were made for early stage development of a reusable elastomeric RPD as alternative to the N95. BARDA has also partnered with Johnson and Johnson, Innovation Labs to support a respiratory device challenge to revolutionize RPDs. Funds provided in FY 2020 and 2021 will continue to support these efforts to develop new RPDs.

Enhancing global pandemic preparedness: Infectious diseases do not respect national borders, making global pandemic preparedness important for protecting the health and wellbeing of the U.S. population and national security. 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), Department of Agriculture (USDA), and Department of Defense (DoD), and other federal departments and agencies, non-governmental organizations, and bilateral and multilateral partners on policy and technical issues surrounding global health security including influenza and other emerging infectious diseases of pandemic potential that can spread into the U.S.

The accomplishments from the HHS/Office of the Secretary International Pandemic Influenza funds have substantially advanced USG global health priorities in countries that are a critical to advancing U.S.

foreign policy goals and support to HHS programs preparing for seasonal influenza epidemics or the next influenza pandemic. Accomplishments include, but are not limited to:

- New procedures for WHO to recommend and facilitate EUA of MCMs 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 12 influenza vaccines in seven countries (Indonesia, Brazil, Romania, Thailand, South Korea, India and Vietnam) and late-stage development of four 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 led 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.
- 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 global health security policy leadership, analysis, and technical support to:

- Develop key WHO tools and reports, including: WHO Pandemic Influenza Risk Management (PIRM) Framework and Implementation Strategy; Pandemic Influenza Severity Assessment (PISA) tool; updated clinical guidance for the use of antiviral agents; generic training modules for case detection; sample collection and management; report on consultations on the effectiveness of live-attenuated influenza vaccine (LAIV); and, WHO Disease Outbreak News.
- Develop and implement the WHO Influenza Vaccine Sustainability Assessments for low and middle-income countries: Indonesia, Mexico, South Africa, Vietnam, Thailand, Serbia, Argentina, Morocco, Brazil, and others.
- Develop 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.
- Facilitate the request from the China-FDA for technical assistance to evaluate submissions from Chinese manufacturers for LAIV and quadrivalent inactivated vaccines.
- Convene, 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.
- Convene high-level stakeholder meetings and action plans for development and updating of National Pandemic Influenza Preparedness Plans (NPIPP).
- 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, USAID, DOS, and WHO.
- Other USG departments and agencies, including the DOS, Office of the U.S. Trade Representative, Department of Commerce, and the U.S. Patent and Trademark 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 the items listed below.

- Coordinated HHS and USG input to, and renewed engagement to promote WHO's new *Global Influenza Strategy 2019-2030* and overall objectives, with special emphasis on continued support for local, regional, and global influenza vaccine manufacturing. From a global estimate of 400 million doses in 2006, to an estimated 6.5 billion doses in 2016 of a pandemic vaccine antigen within nine months of recognition of a novel strain, global capacity remains short of the global requirement for over ten billion doses of a pandemic influenza vaccine.
- Supporting the NSC, by developing and implementing the interagency diplomatic engagement strategy on Influenza/H7N9 sample sharing to identify opportunities and to engage at the technical and diplomatic levels with the Chinese government, especially the Chinese National Health Commission. This includes communicating urgent and critical sample sharing needs with the non-health Chinese ministries involved in the export of virus samples from the China-CDC (e.g. Ministry of Finance and Commerce) to support 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).
- Development of WHO tools, including providing guidance to facilitate and accelerate multi-stakeholder engagement and equitable sharing of samples and benefits, and the *Western Pacific Region Asia Pacific Strategy for Emerging Diseases*.
- 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.
- Advocating for developing countries improving self-sustainability to provide surveillance, detection, and response for influenza and other EID threats affecting their countries and region. OGA has directly supported efforts to leverage global political will to make global health security and influenza initiatives more sustainable (e.g., African Vaccine Manufacturer's Initiative, support to Developing Country Vaccine Manufacturers Network, HHS/WHO Workshops and trainings, cross-sector collaborations between security and health ministries, and facilitating support for IHR core capacity development).
- Prioritizing influenza pandemic preparedness and promoting influenza vaccine confidence through ministerial-level side events and subsequent decisions at the World Health Assembly.
- Establishing and updating national pandemic influenza plans in Africa and other vulnerable regions to support the prioritization of influenza 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, NGOs, and bilateral and multilateral partners on multiple inter-related policy issues for global health security, including:

- Leading policy coordination for key global health security international treaties, agreements, and arrangements addressing challenges related to the implementation of the PIP-FW and the implications of the Nagoya Protocol to pathogen sample and genetic sequence data sharing;
- Developing model tools and documents (e.g., model material transfer agreement, model benefit sharing agreements and model legislation) that could be used by member states during public health emergencies; and,
- Expanding 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 among influenza stakeholders, and consolidated data collection for NPIPP.

Funding History	
FY 2017 /1	$71,831,000
FY 2018	$250,000,000
FY 2019	$260,000,000
FY 2020 Enacted	$260,000,000
FY 2021 President's Budget	$310,000,000

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

Budget Request

The FY 2021 President's Budget for pandemic influenza activities is $310,000,000, which is +$50,000,000 above the FY 2020 Enacted level. Funds will be used to sustain previous investments in critical domestic influenza vaccine manufacturing facility infrastructure, ensure that influenza vaccines can be produced to deploy an effective pandemic response, and maintain overall domestic pandemic readiness. In addition to funding activities that maintain the pandemic influenza preparedness and response capabilities developed over the last decade to achieve pandemic preparedness goals, the funds will also support ongoing efforts to develop near-patient or in-home diagnostics and improved Respiratory Protective Devices (RPDs) 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 robust American workforce for production of MCMs 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.

Of the total funds, $35,000,000 is annual funding, and $275,000,000 million is no-year funding to account for preparedness sustainment costs and continue the advanced research and development of improved vaccines, rapid in-home diagnostics, and RPDs. The request also includes the funds required to maintain pre-pandemic influenza vaccine and adjuvant stockpiles. These stockpiles are essential for rapid response

against an emerging pandemic virus. At this funding level, BARDA will invest in developing and licensing adjuvanted, pre-pandemic vaccines made using more modern, non-egg based platforms to improve the availability of safe and effective vaccines during a pandemic influenza emergency. In addition to investing in currently available vaccines, to make them more widely available, improve production, or improve their use in a pandemic, BARDA will also invest in in vaccine technologies, including adjuvant technologies that will allow vaccines to be made faster, and be more effective, then currently licensed technologies. These vaccines would be transformational to pandemic preparedness and response, but are extremely challenging to develop.

The FY 2021 funding request supports ongoing efforts to develop 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 supporting ongoing efforts to develop 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 2021 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 2021 ($35,000,000)

Vaccine Stockpiling, Storage and Stability Testing ($10,991,000): The request includes funds to continue support of the risk-based stewardship of the NPIVS particularly ongoing stability testing and maintenance of antigens, adjuvants, vaccine ancillary supplies. This testing is required to ensure these critical components are ready to be utilized as soon as needed in the event of an influenza pandemic.

Facilities and Infrastructure Readiness and Sustainment ($4,000,000): This funding will sustain previously funded gains in vaccine fill/finish capacity. 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 2021 funding will allow for continued sustainment of domestic fill-finish capacity for all pandemic vaccine manufacturing platforms.

Improved Influenza Vaccine Advanced Development ($9,000,000): Improving vaccine delivery and efficacy may be achieved in part through improvements in formulation and integration of new and emerging technologies. These funds will support ongoing advanced development efforts to identify optimal vaccine antigen, adjuvant, and delivery formulations, to address some of the most persistent hurdles with vaccine pandemic response capability, including storage, immune response, and administration. This includes formulations for improved stability, particularly with final container vaccine, and technologies that utilize needle-free delivery such as patch/patch-like devices.

Influenza Diagnostics and Respirator Development ($4,000,000): Moving diagnostics closer to the patient and developing improved respirators with enhanced stockpile and utilization capabilities are critical to first line defense against an influenza pandemic. The provided support will allow continued development of diagnostics that move sample collection closer to the home, allowing earlier detection and, subsequently, faster treatment. Funding will also support ongoing efforts to develop improved ventilators that have enhanced capabilities for use in a pandemic.

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 of $4,009,000 is level with the FY 2020 Enacted Budget. 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, prioritizing preparedness for seasonal influenza epidemics, influenza pandemic, and other emerging infectious disease (EID) threats.

Influenza viruses and other EIDs 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 strains and other EID 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 by providing strategic coordination and policy coherence for the Department and within the U.S. Government (USG) on 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: nearly 200 Ministries of Health across the globe; key multilateral and international institutions involved in health security [e.g. the United Nations (World Health Organization [WHO], 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. OGA serves as a critical interface with international health, science, foreign policy and diplomacy, and security partners and programs that address influenza and other global health security threats. Building on lessons learned from influenza preparedness response over the past twenty years, OGA provides essential coordinated diplomatic outreach to bolster global health security, domestic preparedness efforts, and partnerships that are crucial to face the challenges of influenza pandemic threats, and other emerging infectious disease threats of global concern.

In addition, OGA functions as an interlocutor between international public health and domestic public

health. To strengthen U.S. influenza pandemic preparedness efforts, OGA continually coordinates with the White House National Security Council (NSC), 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.
In accord with the *National Security Strategy*, *the National Biodefense Strategy*, the *Global Health Security Strategy*, *Global Health Security Agenda 2024*, 2019 Executive Order (EO) on *Modernizing Influenza Vaccines in the United States*, and the *HHS Strategic Plan*, OGA will bring its technical, policy, and diplomatic expertise to promote policies that include:

- enhancing local, national, regional and global influenza preparedness and response efforts for seasonal influenza and pathogens of epidemic or pandemic potential, including by supporting the implementation of the WHO *Global Influenza Strategy 2019-2030*;
- aligning national influenza preparedness efforts with the goals and strategic objectives of the WHO Global Influenza Strategy 2019-2030, including by, developing or updating national pandemic influenza preparedness plans, creating an enabling environment for the development of better global tools, and considering implementing annual influenza vaccination campaigns for one or more target populations;
- strengthening other nations' commitments to fulfill their obligations under the Pandemic Influenza Preparedness- Framework;
- enhancing influenza surveillance through WHO and partner nations, including by taking steps to eliminate or mitigate delays and disruptions to rapid, systematic, and timely international influenza virus sharing, including seasonal viruses to advance HHS programs and countermeasure development;
- promoting linkages between influenza capabilities and national influenza preparedness and response plans, together with broader IHR and immunization implementation efforts, including through linkages with national action plans for health security;
- strengthening of EID networks to improve risk-communication and promote vaccine confidence/trust to enhance seasonal influenza vaccination;
- working with others governments and relevant stakeholders, including manufacturers and wider private sector entities, to identify gaps in and priorities for sustainable, scalable global influenza vaccine production, supply chains, and distribution networks and to promote sustainability of influenza vaccine manufacturing in developing countries in line with the 2019 EO;
- coordinating all relevant Global Health Security Agenda (GHSA) and Initiative (GHSI)-related activities, including those policies focused on pandemic influenza and biological threats and leading a multilateral working group on sustainable financing for preparedness.

No-year Funding Request for FY 2021 ($275,000,000)

Facilities and Infrastructure Readiness and Sustainment ($102,150,000): Funds will sustain two of the three pillars of domestic influenza vaccine manufacturing capacity: egg-, 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). Without the sustainment of these capabilities, the year-round manufacturing capacity so critical to a pandemic influenza response will be lost. The FY 2021 funding will allow for continued sustainment of domestic manufacturing capacity for egg and cell based manufacturing platforms, including production of pre-pandemic vaccine and adjuvant.

Improved Influenza Vaccine Advanced Development ($169,850,000): At this funding level, BARDA will support expanded manufacturing capacity and subsequent licensure of pre-pandemic vaccine for the third pillar of domestic influenza vaccine manufacturing capacity-recombinant based influenza vaccine. Importantly, this effort will fund trials to support licensure of the pre-pandemic vaccine not just for adults, but also for children, providing maximum utility of the vaccine during a pandemic. This platform offers the potential for a faster time to first dose, and reduced timeline and production risk by not requiring a candidate vaccine virus (CVV), both critical to pandemic influenza response capabilities.

Diagnostics and Respiratory Protection Device Advanced Development ($3,000,000): Funding will be used to continue ongoing activities 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.

ASPR Pandemic Influenza: Key Outputs and Outcomes Table

Measure	**Year and Most Recent Result /** **Target for Recent Result /** **(Summary of Result)**	**FY 2020 Target**	**FY 2021 Target**	**FY 2021 Target** **+/-FY 2020 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 2019: 600.0 million antigen doses Target: 600.0 million antigen doses (Target Met)	600.0 million antigen doses	600.0 million antigen 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 2019: 6.0 programs Target: 2.0 programs (Target Exceeded)	2.0 programs	2.0 programs	Maintain

ASSISTANT SECRETARY FOR HEALTH

U.S. Public Health Service (USPHS)
Homelessness

Budget Summary
(Dollars in Millions)

OASH	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	--	--	10.000	+10.000

Authorizing Legislation:
Authorization ……Public Health Service Act §215
Authorization Status ……Indefinite
Allocation Method ……Direct federal, Contract

Program Description and Accomplishments

Over 550,000 individuals in America experienced at least one night of homelessness in 2018. Of these, at least 200,000 are unsheltered, living on the streets, often suffering from co-existing mental, physical, or substance use disorders. Prolonged homelessness is associated with death rates 3 to 4 times the national average and can lead to more generalized public health threats such as hepatitis A outbreaks and tuberculosis.

The Office of the Assistant Secretary of Health (OASH) supports the Administration's plan to substantially ameliorate the unsheltered homelessness crisis in communities and, separately, unsheltered veteran homelessness, as prioritized by national leadership. The United States Public Health Service Commissioned Corps (Corps), led by the Assistant Secretary for Health (ASH), proposes a public health and medical engagement and deployment strategy coordinated with a broader set of initiatives to address homelessness. This proposal includes necessary planning to iterate specific objectives, challenges, and mission requirements, as well as the public health and medical interventions and services for such a population whose health is marginal or failing, and may harbor infectious threats to themselves and the general population. The initiative would address unsheltered homelessness in some of the cities most impacted; and to be successful, would require significant participation by other federal departments, state and local agencies, and non-profit organizations. A primary objective of the overall program is to provide emergency shelter, while simultaneously providing health screening and treatment, and transition to a more stable shelter and medical home.

The Corps deployment efforts could include initial health assessments, triage, medical stabilization, and care coordination – all of which would be combined with a larger program of human services including housing, nutrition, education, and training.

- The Corps may seek to partner with a non-profit and/or community organization that would provide health care equipment and logistical support, as has been done on previous Corps community engagements under a memorandum of agreement. Engaging with such an organization would be determined by coordination by HUD.

- The estimated scale of operations includes thousands of homeless individuals (including those in family units) over the period of deployment to impacted cities.
- Several weeks could be required for individual client health assessments and initial stabilization, including managing continuity of care over the course of the engagement.
- Following initial assessment, triage, and medical stabilization, the Corps will lead individualized transition plans to assure that all targeted individuals have a medical home and a source of ongoing care, for example, to the Veterans Health Administration (VHA), or Health Resources and Services Administration (HRSA)-funded Health Centers.

The Corps has substantial experience in emergency response, including dealing with homeless and complex populations. This complex mission will include unknown challenges, requiring unprecedented coordination, training, communication, and agility. It is expected that some of this population is suffering from severe mental illness and some of this population may have substance use disorders, and require emergency reversal agents or methadone-assisted treatment (MAT). It is also anticipated that a number will harbor communicable diseases, and will require screening and treatment to prevent further spread.

The Corps is ready and able to accept these challenges, and this mission will be prioritized by the ASH and Corps leadership. The overall goal is to have all targeted individuals, including family units, in a stable medical home for coordinated care and other services required.

The long-term objectives of an integrated program addressing unsheltered homelessness is to reduce the number of chronically homeless individuals and families while simultaneously improving the health, stable living conditions, educational opportunities, and employment of those previously homeless. To achieve this goal, complementary public health and medical interventions will provide comprehensive medical and public health services in order to assess and stabilize acute and chronic illnesses in the overall population served. Interventions would be led by the Corps in collaboration with other federal agencies such as VHA and HRSA, supporting non-governmental organizations (NGOs), and local city/county public health agencies.

A package of services would be provided by the Corps to meet the acute needs of the homeless population, and define a course for chronic management.

Funding History	
FY 2017	--
FY 2018	--
FY 2019	--
FY 2020 Enacted	--
FY 2021 President's Budget	$10,000,000

Budget Request

The FY 2021 President's Budget request is $10,000,000, which is a $10,000,000 increase from the FY 2020 Enacted level. This request will support the development of an integrated program and deployment of Corps officer to address homelessness in impacted cities. Efforts require the following: physical deployment of Corps officers to conduct the initial assessment, triage, and medical stabilization of the target homeless population; and the development of individualized transition plans to assure that all targeted individuals have a medical home and a source of ongoing care.

U.S Public Health Service (USPHS) Commissioned Corps Readiness Training

Budget Summary
(Dollars in Millions)

OASH	FY 2019	FY 2020	FY 2021	
	Final	Enacted	President's Budget	FY 2021 +/- FY 2020
Budget Authority	--	--	1.000	+1.000

Authorizing Legislation:
Authorization …………..………………………………………………………42 U.S.C. § 204a(b)(3)
Authorization Status ..……...…………...……………...……………....………….…..……......Indefinite
Allocation Method ....Direct federal, Cooperative Agreement, Contract

Program Description and Accomplishments

The Office of the Assistant Secretary for Health (OASH) leads development of public health policy recommendations across the Department of Health and Human Services (HHS) and oversees several of the Department's core public health offices – including the Office of the Surgeon General (OSG) and the U.S. Public Health Service Commissioned Corps (Corps). The Assistant Secretary for Health serves as a senior advisor to the HHS Secretary on matters of public health and science and provides leadership to the Corps, a cadre of over 6,300 full-time uniformed officers dedicated to promoting and advancing public health and disease prevention programs. Corps officers serve in a variety of positions throughout HHS and certain non-HHS Federal agencies and programs in areas of disease control and prevention, biomedical research, regulation of food, drugs and medical devices; mental health and substance abuse; sanitation, and health care delivery. As one of America's seven uniformed services, the Corps fills essential public health leadership, clinical and service roles across more than 21 Federal agencies and programs. These include HHS Operating and Staff Divisions (e.g., the Indian Health Service, National Institutes of Health, and the Centers for Disease Control and Prevention) and non-HHS agencies (e.g., Federal Bureau of Prisons, Department of Defense, and Department of Homeland Security).

A critical and essential function for all Corps officers is to deploy at the direction of the Secretary during a public health emergency or other challenge to national biosecurity. Examples of such deployments include natural disasters (hurricanes, wildfires), global infectious disease threats (Ebola in Africa, 2019 Novel Coronavirus), public health threats to individuals and the nation (Southern border deployment for Unaccompanied Children (UACs) and family units in support of the US Coast Guard/Customs and Border Protection), opioid rapid response teams in collaboration with the Department of Justice, and preparedness and response teams for major national events (State of the Union, Boston Marathon, etc.). In the event of a Weapons of Mass Destruction (WMD) incident in the United States, Corps officers would be expected to provide triage, decontamination, and/or care to those injured by nuclear, radiologic, chemical, or biological weapons. In the event of a large military conflict overseas, officers could be responsible for the ongoing care and health of repatriating civilians, or could be "militarized" directly, as has been done historically.

Between 2013 and 2018, Corps officers deployed 7,976 times contributing to 135,587 deployment days to 140 different missions. In 2019, there were 1,409 officers who contributed to 32 missions involving 12,327 days. This equates, on average, to a 40% increase each year for officer deployments.

The United States will continue to experience natural disasters and other emergencies, and there is a

continued risk of a pandemic or intentional threat. To assure that the American people obtain the responses and overall care they expect, training is critical for maintenance of readiness and adequate preparation for future threats. Funding provides one-time training to several hundred officers who will be on the "pointy end" of responses for medical, public health, environmental, and WMD emergencies.

Budget Request

The FY 2021 President's Budget request is $1,000,000, which is a $1,000,000 increase from the FY 2020 Enacted level. This investment will support a readiness and training program.

This funding will enable Corps to build towards readiness and training for all active duty Corps officers. This investment will train 645 Corps officers, a subset of Corps officers who could be called upon to deploy following any natural and man-made disasters The Corps will be on a rotational training cycle for all active-duty Corps officers with the priority focus on those Corps officers supporting rapid deployment units. To provide an effective training, careful management of the officers receiving training by position on the rapid deployment unit or team is essential. CCHQ will focus on leadership, safety and medical positions as a priority, with the training of all officers supporting rapid deployment units receiving the training.

Training aims and outcome

The mobilization of emergency response services is imperative to limiting the public health and medical effects on populations affected by natural and man-made disasters. Title 42, USC § 204a(b)(3) directs the Secretary to ensure that Corps officers are trained, equipped and otherwise prepared to fulfill their public health emergency response roles. In accordance with 42 U.S.C. § 204a(b)(3) , 2,000 Corps officers currently serve on rapid deployment units for the express purposes to respond to urgent or emerging public health needs.

In order to provide timely, appropriate and effective emergency response services, a robust readiness and training program will provide a structured and progressive framework for Corps officers to acquire the knowledge, skills and ability to deploy domestically and internationally to reduce public health risk and ensure national security. The framework will be built upon set core competencies to tie together training, education and professional development programs and will be assessed periodically and expanded or modified as appropriate.

This training will establish core education surrounding officer deployment readiness, individual medical readiness, and public health preparedness which will include, but are not limited to, the following topics:

- Public health and basic infectious disease management;
- Deployment and emergency response activities, to include natural and man-made disasters;
- Incident command and management of mass casualty;
- Basic safety, national health security, force health protection and preventive medicine for field operations; and
- Resiliency, potential behavioral health impacts of deployment and cultural awareness.

CCHQ will leverage collaborative relationships with partners such the National Guard Bureau, the Defense Health Agency, the Assistant Secretary for Preparedness and Response, the Federal Emergency Management Agency's Emergency Management Institute, the Center for Domestic Preparedness and Remote Area Medical to ensure an effective readiness and training program.

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Millions)

Description	FY 2019 Final	FY 2020 Enacted /1	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel compensation:				
Full-time permanent (11.1)	86.774	110.358	115.437	+5.079
Other than full-time permanent (11.3)	8.378	-	-	--
Other personnel compensation (11.5)	4.906	-	-	--
Military personnel (11.7)	9.637	10.219	10.860	+0.641
Special personnel services payments (11.8)	0.016	-	-	--
Subtotal, Personnel Compensation.....	**109.711**	**120.577**	**126.297**	**+5.720**
Civilian benefits (12.1)	29.615	31.283	32.550	+1.267
Military benefits (12.2)	4.653	4.922	5.118	+0.196
Benefits to former personnel (13.0)	0.435	-	-	--
Total Pay Costs.....	**144.414**	**156.782**	**163.965**	**+7.183**
Travel and transportation of persons (21.0)	8.416	9.413	15.976	+6.563
Transportation of things (22.0)	5.366	6.000	7.975	+1.975
Rental payments to GSA (23.1)	6.050	6.350	6.513	+0.163
Rental payments to Others (23.2)	9.379	10.000	11.000	+1.000
Communication, utilities, and misc. charges (23.3)	2.682	2.912	2.913	+0.001
Advisory and assistance services (25.1)	1,010.420	1,056.987	967.455	-89.532
Other services from non-Federal Sources (25.2)	143.524	150.000	150.300	+0.300
Other goods and services from Federal Sources (25.3)	84.885	106.276	106.762	+0.486
Operation and maintenance of facilities (25.4)	14.634	25.255	25.260	+0.005
Research and Development Contracts (25.5)	35.665	40.000	40.000	--
Operation and maintenance of equipment (25.7)	30.292	30.700	32.950	+2.250
Supplies and materials (26.0)	808.794	800.513	752.626	-47.887
Equipment (31.0)	1.543	1.670	3.170	+1.500
Land and Structures (32.0)	34.540	34.600	34.600	--
Grants, subsidies, and contributions (41.0)	284.504	300.000	320.000	+20.000
Insurance claims and indemnities (42.0)	0.250	-	-	--
Total Non-Pay Costs.....	**2,480.944**	**2,580.676**	**2,477.500**	**-103.176**
Total, Budget Authority by Object Class.....	**2,625.358**	**2,737.458**	**2,641.465**	**-95.993**

1/ Excludes supplemental appropriations for procurement of Ebola vaccines, therapeutics, and diagnostics ($535 million).

SALARIES AND EXPENSES

(Dollars in Millions)

Description	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget	FY 2021 +/- FY 2020
Personnel compensation:				
Full-time permanent (11.1)	86.774	110.358	115.437	+5.079
Other than full-time permanent (11.3)	8.378	-	-	
Other personnel compensation (11.5)	4.906	-	-	
Military personnel (11.7)	9.637	10.219	10.860	+0.641
Special personnel services payments (11.8)	0.016	-	-	
Subtotal personnel compensation	**109.711**	**120.577**	**126.297**	**+5.720**
Civilian benefits (12.1)	29.615	31.283	32.550	+1.267
Military benefits (12.2)	4.653	4.922	5.118	+0.196
Benefits to former personnel (13.0)	0.435	-	-	
Total Pay Costs	**144.414**	**156.782**	**163.965**	**+7.183**
Travel and transportation of persons (21.0)	8.416	9.413	15.976	+6.563
Transportation of things (22.0)	5.366	6.000	7.975	+1.975
Rental payments to GSA (23.1)	6.050	6.350	6.513	+0.163
Rental payments to Others (23.2)	9.379	10.000	11.000	+1.000
Communication, utilities, and misc. charges (23.3)	2.682	2.912	2.913	+0.001
Other Contractual Services:				
Advisory and assistance services (25.1)	1,010.420	1,056.987	967.455	-89.532
Other services (25.2)	143.524	150.000	150.300	+0.300
Purchase of goods and services from government accounts (25.3)	84.885	106.276	106.762	+0.486
Operation and maintenance of facilities (25.4)	14.634	25.255	25.260	+0.005
Research and Development Contracts (25.5)	35.665	40.000	40.000	--
Operation and maintenance of equipment (25.7)	30.292	30.700	32.950	+2.250
Subtotal, Other Contractual Services	**1,319.420**	**1,409.218**	**1,322.727**	**-86.491**
Supplies and materials (26.0)	808.794	800.513	752.626	-47.887
Equipment (31.0)	1.543	1.670	3.170	+1.500
Land and Structures (32.0)	34.540	34.600	34.600	--
Grants, subsidies, and contributions (41.0)	284.504	300.000	320.000	+20.000
Insurance claims and indemnities (42.0)	0.250	-	-	--
Total Non-Pay Costs	**2,480.944**	**2,580.676**	**2,477.500**	**(103.176)**
Total Salary and Expense	**2,625.358**	**2,737.458**	**2,641.465**	**(95.993)**
Direct FTE	**958**	**1,012**	**1,039**	**+27**

DETAIL OF FULL-TIME EQUIVALENTS (FTE)

	2019 Actual Civilian	2019 Actual Military	2019 Actual Total	2020 Est. Civilian	2020 Est. Military	2020 Est. Total	2021 Est. Civilian	2021 Est. Military	2021 Est. Total
ASPR	**762**	**75**	**837**	**762**	**75**	**837**	**779**	**75**	**854**
Preparedness and Emergency Operations	81	5	86	81	5	86	85	5	90
National Disaster Medical System.....	61	54	115	61	54	115	63	54	117
Hospital Preparedness Program.....	46	3	49	46	3	49	46	3	49
Medical Reserve Corps.....	5	1	6	5	1	6	5	1	6
Preparedness and Response Innovation...	--	--	--	--	--	--	6	--	6
BARDA.....	154	1	155	154	1	155	154	1	155
Strategic National Stockpile.....	225	--	225	225	--	225	225	--	225
Policy and Planning.....	61	5	66	61	5	66	66	5	71
Operations.....	129	6	135	129	6	135	129	6	135
Cybersecurity	**90**	**--**	**90**	**133**	**--**	**133**	**143**	**--**	**143**
Office of National Security	**24**	**2**	**26**	**35**	**2**	**37**	**35**	**2**	**37**
OGA Pandemic Influenza	**5**	**--**	**5**	**5**	**--**	**5**	**5**	**--**	**5**
PHSSEF FTE Total.....	**881**	**77**	**958**	**935**	**77**	**1,012**	**962**	**77**	**1,039**

DETAIL OF POSITIONS

Public Health and Social Services Emergency Fund	FY 2019 Final	FY 2020 Enacted	FY 2021 President's Budget
Executive level I	--	--	--
Executive level II	1	1	1
Executive level III	--	--	--
Executive level IV	1	1	1
Executive level V	1	1	1
Subtotal Executive Level Positions	3	3	3
Total - Exec. Level Salaries	**582,500**	**590,015**	**597,672**
ES-6	--	--	--
ES-5	--	--	--
ES-4	--	--	--
ES-3	--	--	--
ES-2	1	1	1
ES-1	9	9	9
Subtotal ES positions	10	10	10
Total - ES Salary	**1,866,188**	**1,903,736**	**1,942,059**
GS-15	146	150	152
GS-14	255	265	274
GS-13	226	237	248
GS-12	141	154	158
GS-11	33	38	39
GS-10	8	8	8
GS-9	19	19	19
GS-8	9	9	9
GS-7	19	19	19
GS-6	--	--	--
GS-5	--	--	--
GS-4	--	--	--
GS-3	--	--	--
GS-2	--	--	--
GS-1	--	--	--
Subtotal	856	899	926
Total - GS Salary	**100,876,874**	**105,277,281**	**110,170,047**
Average ES level	1	1	1
Average ES salary	186,619	190,374	194,206
Average GS grade	13	13	13
Average GS salary	117,847	117,105	118,974
Average Special Pay categories			

SUMMARY OF PROPOSED CHANGES TO PERFORMANCE MEASURES

Assistant Secretary for Preparedness and Response					
Unique Identifier	**Change Type**	**Original Measure Wording**	**Proposed Change**	**Reason for Change**	**APP/R Measure**
2.4.11	D/C	Lead and implement national and international strategic plans for public health preparedness and response	It is proposed that 2.4.9, 2.4.11, and measure 12 be replaced with new measures within the budget's policy and planning chapter.	New measures better align with current data collection structures and organization's priorities. For ASPR policy, the new measures (2.4.13, 2.4.15, 2.4.16, 2.4.17) reflect Federal, HHS, ASPR priorities. The new measures are quantitative which lends to improved analysis, trending, and useful feedback to drive improvement.	No
2.4.9	D/C	Increase engagement with stakeholders to disseminate and improve awareness of ASPR strategies for preparedness, response, and recovery	It is proposed that 2.4.9, 2.4.11, and measure 12 be replaced with new measures within the budget's policy and planning chapter.	New measures better align with current data collection structures and organization's priorities. For ASPR policy, the new measures (2.4.13, 2.4.15, 2.4.16, 2.4.17) reflect Federal, HHS, ASPR priorities. The new measures are quantitative which lends to improved analysis, trending, and useful feedback to drive improvement.	No

12	D/C	Expand an evidence base of scientific information about disasters that informs policy decisions	It is proposed that 2.4.9, 2.4.11, and measure 12 be replaced with new measures within the budget's policy and planning chapter.	New measures better align with current data collection structures and organization's priorities. For ASPR policy, the new measures (2.4.13, 2.4.15, 2.4.16, 2.4.17) reflect Federal, HHS, ASPR priorities. The new measures are quantitative which lends to improved analysis, trending, and useful feedback to drive improvement.	No
2.4.13	New Measure for Policy and Planning	N/A	Increase the number of National Health Security Strategy policy tools that support national and health security capabilities (Baseline data to be collected at the end of calendar year 2020 but historical data is being analyzed now)	This is one of the measures to replace measures 2.4.9, 2.4.11, and 12 within the budget's Policy and Planning chapter. This measure would collect baseline documenting the number of gaps closed or reduced through the implementation of tools. This measure is a % increase above baseline. The percent increases in policy tools that support NHSS will be measured.	No
2.4.15	New Measure for Policy and Planning	N/A	Increase the percentage of identified ASPR activities designed to implement the National Biodefense Strategy across the entire Biodefense enterprise (Baseline data to be collected at the end of calendar year 2020 but historical data is being analyzed now)	This is one of the measures to replace measures 2.4.9, 2.4.11, and 12 within the budget's Policy and Planning chapter. This measure would collect the percent of completed NBS annual implementation actions. This tracks implementation actions specifically assigned to ASPR.	No

2.4.16	New Measure for Policy and Planning	N/A	Increase the number of implementation measures and actions that reduce the risk of biological threats in support of the National Biodefense Strategy implementation	This is one of the measures to replace measures 2.4.9, 2.4.11, and 12 within the budget's Policy and Planning chapter. This measure would report the baseline number of identified assessments designed to support implementation of the National Biodefense Strategy. This tracks % increase above baseline.	No
2.4.17	New Measure for Policy and Planning	N/A	Increase the number of stakeholder engagement contacts addressing strategic, policy, planning, and requirement-setting issues pertaining to public health and healthcare preparedness and response	This is one of the measures to replace measures 2.4.9, 2.4.11, and 12 within the budget's Policy and Planning chapter. This is a new version of measure 12 based on changes in programs and data sources. This will be relevant to both NHSS and NBS.	No
2.4.13a	Measure title change	Increase the number of new licensed medical countermeasures within BARDA	The new title is: Increase the number of new licensed medical countermeasures across BARDA programs	The slightly revised title adds clarity to what is being measured. BARDA has many programs. This measure uses data across all BARDA programs.	Yes
2.4.8	D/C	Improve strategic communications effectiveness.	ASPR would like to replace this qualitative measure with a quantitative one but discussions and testing are not finished yet.	New measure(s) are being considered based on updates and improvements to communication strategies.	No
11a	D/C	Ensure deployment of emergency response personnel, consistent with mission timing requirements/objectives	ASPR reviewed this measure and is asking to D/C it because it no longer aligns with the organization as it did prior to the reorganization.	ASPR's advancement and new programs are leading to changes in the performance measures best to report in the budget.	No

1.4	New Developmental Measure for NDPI - will not appear in the budget but added to DAS. This measure is on hold until funding begins.	N/A	Increase and maintain health care professional competency	Within the National Disaster Medical System program, a new pilot for pediatric disaster care was included in the FY20 CJ. Funding and amount are not final. ASPR proposes three new measures to be tested during the start-up phase for this new program. Right now, there is no funding provided for this program, so data collection has not started.	No
1.5	New Developmental Measure for NDPI - will not appear in the budget but added to DAS. This measure is on hold until funding begins.	N/A	Increase regional readiness to care for pediatric patients during disasters	Within the National Disaster Medical System program, a new pilot for pediatric disaster care was included in the FY20 CJ. Funding and amount are not final. ASPR proposes three new measures to be tested during the start-up phase for this new program. Right now, there is no funding provided for this program, so data collection has not started.	No
1.6	New Developmental Measure for NDPI - will not appear in the budget but added to DAS. This measure is on hold until funding begins.	N/A	Increase deployable pediatric response capabilities of the National Disaster Medical System	Within the National Disaster Medical System program, a new pilot for pediatric disaster care was included in the FY20 CJ. Funding and amount are not final. ASPR proposes three new measures to be tested during the start-up phase for this new program. Right now, there is no funding provided for this program, so data collection has not started.	No

13.4.8	New Measure	N/A	13.4.8 Maintain the response rate of recall capability. This measure is a percent as calculated by the average of 12 monthly no-notice response tests over the course of the fiscal year	Two new SNS measures would join the measures transferred from CDC to ASPR last year. This one measures the positive response rate for monthly tests of DSNS recall capability to notify all staff of response activation and receive accurate information on each staff member's readiness to be present within assigned timeframes for their position.	No
13.4.7	New Measure	N/A	13.4.7 Maintain the safety and efficacy of medical supplies SNS inventory. This measure is Maintain the safety and efficacy of medical supplies SNS inventory without failure to comply with Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMP). Reported data: Maintain the monthly test response rate to ensure response within 90 minutes during an emergency	Two new SNS measures would join the measures transferred from CDC to ASPR last year. This one measures the safety and efficacy of medical supplies SNS inventory without loss of product due to failure to comply with FDA current Good Manufacturing Practices.	No

1.3	New Measure for NDMS	N/A	Increase training and resources to address the access and functional needs of at risk individuals who live independently and are impacted by emergencies and disasters	This is the first measure for the emPOWER program. This will be reported in the NDMS budget chapter. 2019 data is being reported (71,061) as baseline in the FY 2021 President's budget. Targets will be set during the 2022 HHS budget phase because this program is relatively young and the data is being analyzed over time before setting targets. Annual increases are expected.	No
11a.1.1	New Developmental Measure so will not appear in the budget and is being tested.	N/A	Increase numbers of products disseminated for addressing the access and functional needs of at-risk individuals in disasters and public health emergencies.	The measure would report the number of electronic “hits” to ASPR webpage products from At-Risk Individuals Branch. Data available through Google Analytics (metric = number of monthly analytics for unique page views for ARI products). Data collection is in progress but there are no plans to transition this measure beyond being a developmental measure at this time.	No
11a.1.2	New Developmental Measure so will not appear in the budget and is being tested.	N/A	Increase numbers of partners trained to address the access and functional needs of at-risk individuals in disasters and public health emergencies.	This measure would report the number of participants completing HHS/ASPR Access and Functional Needs Web-Based Training. Data collection is in progress but there are no plans to transition this measure beyond being a developmental measure at this time.	No

1.4	New Measure for NDMS to replace measure 1.2	N/A	Maintain the percent of NDMS intermittent staff who complete basic, advanced, or specialized training	This measure replaces measure 1.2 in the 2021 President's budget because legislative requiements impacted the measure definition. E.g. supplemental appropriations required specific "specialized" training yet that was not part of the measure definition. So, measure 1.2 is replaced with 1.4. 2019 data is reported in this budget. It is 39.55%.	No
1.2	D/C this measure and replace with measure 1.4. 2019 data will be reported in the FY 2021 President's Budget so there is no gap in reporting.	N/A	Adjust the percent of new NDMS intermittent staff who complete both basic and advanced deployment training.	This measure is being replaced by measure 1.4 in the 2021 President's budget because legislative requiements impacted the measure definition. E.g. supplemental appropriations required specific "specialized" training yet that was not part of the measure definition. 2019 data is reported in this budget for 1.4. The 2019 result is 39.55% which exceeds the target.	No

GOOD ACCOUNTING OBLIGATION IN GOVERNMENT ACT (GAO-IG ACT) REPORT

The information below addresses the requirements of the Good Accounting Obligation in Government Act (GAO-IG Act; Public Law 115-414) to provide a report identifying each public recommendation issued by the Government Accountability Office (GAO) and federal Offices of Inspectors General (OIG) which remains unimplemented for one year or more from the annual budget justification submission date. The recommendations below apply specifically to this division of HHS. Please refer to the General Departmental Management budget justification for more information on the Department's overall progress in implementing GAO and OIG recommendations.

Appendix 1: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-17-187	Public Health Emergencies: HHS Needs to Better Communicate Requirements and Revise Plans for Assessing Impact of Personnel Reassignment	1/9/2017	To help ensure that HHS agencies and offices fully understand the requirements and processes for the temporary reassignment authority, their responsibilities under the authority, and that ASPR is adequately and comprehensively assessing the effect of the authority on public health emergency response and medical surge, the Secretary of HHS should direct ASPR to conduct outreach to HHS agencies and offices that administer programs eligible for the reassignment authority to inform them of their responsibilities and ASPR's expected time frames for reviewing and approving states' and tribes' requests for personnel reassignments, and inform them of their responsibilities and ASPR's expectations for reviewing states' and tribes' after-action reports.	Concur	NA	In Progress	

GAO-13-278	National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals	5/22/2013	To help ensure that HHS is adequately and comprehensively assessing HPP and PHEP awardees' performance and progress in meeting the medical and public health preparedness goals of the cooperative agreements, the Secretary of Health and Human Services should direct ASPR and CDC to develop objective and quantifiable performance targets and incremental milestones that correspond to the new HPP and PHEP performance measures, against which HHS can gauge progress toward the medical and public health preparedness goals of the cooperative agreements and direct technical assistance, as needed.	Concur	NA	Awaiting Disposition	In fiscal year (FY) 2017, ASPR developed a variety of new Hospital Preparedness Program input-, activity-, output-, and outcome-level performance measures at the start of the new project period. The performance measures are detailed in the 2017-2022 Hospital Preparedness Program Performance Measures Implementation Guide. The performance measures remained the same in FY 2018. In FY 2019, HPP released a new Funding Opportunity Announcement (FOA) and began a new five-year project period. While the majority of the performance measures remain the same from the FY 2017 performance measures, there were minor changes to performance measures in FY 2019. Recommend this recommendation be closed. CDC has closed the five-year budget cycle referenced in the latest GAO response and issued a new PHEP five-year cooperative agreement in 2019 that no longer combines program requirements with ASPR's HPP cooperative agreement. CDC also has updated its 15 public health preparedness capabilities and revised its evaluation and performance measurement strategy. During the 2019-2024 performance period, CDC will use a new operational readiness assessment tool to evaluate PHEP recipient progress across all 15 public health preparedness and response capabilities. Currently, CDC’s operational readiness review (ORR) was limited primarily to two capabilities regarding medical countermeasure distribution and dispensing. CDC will conduct a full program review every two years to monitor and assess PHEP recipient progress along a continuum. This operational readiness review (ORR) will evaluate whether recipients have documented progress in achieving a comprehensive set of data elements used to evaluate PHEP program planning and implementation. CDC expects PHEP recipients to make substantial progress toward achieving full operational readiness by the end of the performance period in June 2024.

GAO-13-278	National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals	5/22/2013	To help ensure that HHS is adequately and comprehensively assessing HPP and PHEP awardees' performance and progress in meeting the medical and public health preparedness goals of the cooperative agreements, the Secretary of Health and Human Services should ensure that performance measures and targets remain consistent across the 5-year project cycle and that any future measures be comparable to determine whether awardees are making progress toward meeting short- and long-term medical and public health preparedness goals of the cooperative agreements.	Concur	NA	Awaiting Disposition	ASPR has collected one year of HPP data, which was submitted by HPP recipients in November 2018 and verified in July 2019. HPP will employ a number of methodologies to establish incremental targets for FY 2019 end-of-year reporting. Intended methods may include key informant interviews and an assessment of previous data and information reported by HPP recipients from FY 2017 and FY 2018. The FY 2018 data will be submitted by HPP recipients in fall 2019. Once the data is received and verified, HPP will examine potential performance measures as part of a pilot assessment project to determine targets and benchmarks for HPP performance measures that that will carry over from FY 2017 and FY 2018 to FY 2019. These selected measures will be based on performance measure requirements for all three years of reporting (FY 2017, FY 2018, and FY 2019), applicability to varying unit of analysis, importance and relevance as a key action item in the preparedness and response continuum, and specificity of action. Recommendation will remain open, due to recent modifications of performance measures. CDC has closed the five-year budget cycle referenced in the latest GAO response and issued a new PHEP five-year cooperative agreement in 2019 that no longer combines program requirements with ASPR's HPP cooperative agreement. CDC also has updated its 15 public health preparedness capabilities and revised its evaluation and performance measurement strategy. During the 2019-2024 performance period, CDC will use a new operational readiness assessment tool to evaluate PHEP recipient progress across all 15 public health preparedness and response capabilities. Currently, CDC’s operational readiness review (ORR) is limited primarily to two capabilities regarding medical countermeasure distribution and dispensing. CDC will conduct a full program review every two years to monitor and assess PHEP recipient progress along a continuum. This operational readiness review (ORR) will evaluate whether recipients have documented progress in achieving a comprehensive set of data elements used to evaluate PHEP program planning and implementation. CDC expects PHEP recipients to make substantial progress toward achieving full operational readiness by the end of the performance period in June 2024.

GAO-17-377	Public Health Information Technology: HHS Has Made Little Progress toward Implementing Enhanced Situational Awareness Network Capabilities	9/6/2017	To ensure progress is made toward the implementation of any IT enhancements needed to establish electronic public health situational awareness network capabilities mandated by PAHPRA, the Secretary of HHS should direct the Assistant Secretary for Preparedness and Response to task an integrated project team, made up of an IT project manager and business owner, with including specific actions in the Public Health and Medical Situational Awareness Strategy Implementation Plan for conducting all activities required to establish and operate the network.	Concur	NA	In Progress	
GAO-17-377	Public Health Information Technology: HHS Has Made Little Progress toward Implementing Enhanced Situational Awareness Network Capabilities	9/6/2017	To ensure progress is made toward the implementation of any IT enhancements needed to establish electronic public health situational awareness network capabilities mandated by PAHPRA, the Secretary of HHS should direct the Assistant Secretary for Preparedness and Response to task the integrated project team with developing a project management plan that includes measurable steps--including a timeline of tasks, resource requirements, estimates of costs, and performance metrics--that can be used to guide and monitor HHS's actions to establish the network defined in the plans.	Concur	NA	In Progress	

GAO-17-377	Public Health Information Technology: HHS Has Made Little Progress toward Implementing Enhanced Situational Awareness Network Capabilities	9/6/2017	To ensure progress is made toward the implementation of any IT enhancements needed to establish electronic public health situational awareness network capabilities mandated by PAHPRA, the Secretary of HHS should direct the Assistant Secretary for Preparedness and Response to conduct all IT management and oversight processes related to the establishment of the network in accordance with Enterprise Performance Life Cycle Framework guidance, under the leadership of the HHS CIO.	Concur	NA	In Progress	

Appendix 2: OIG-GAO Open Recommendations							
Report Number	**Report Title**	**Report Date**	**Recommendation Text**	**Concur / Non-Concur**	**Implementation Timeline**	**Implementation Status**	**Implementation Updates and Constraints**
GAO-12-791	Organizational Transformation: Enterprise Architecture Value Needs to Be Measured and Reported	9/26/2012	To enhance federal agencies' ability to realize enterprise architecture benefits, the Secretaries of the Departments of Health and Human Services and Housing and Urban Development should ensure that enterprise architecture outcomes are periodically measured and reported to top agency officials.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-15-431	Telecommunications: Agencies Need Better Controls to Achieve Significant Savings on Mobile Devices and Services	5/21/2015	To help the department effectively manage spending on mobile devices and services, the Secretary of Health and Human Services should ensure procedures to monitor and control spending are established department-wide. Specifically, ensure that (1) procedures include assessing devices for zero, under, and over usage; (2) personnel with authority and responsibility for performing the procedures are identified; and (3) the specific steps to be taken to perform the process are documented.	Concur	2020	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-323	Data Center Consolidation: Agencies Making Progress, but Planned Savings Goals Need to Be Established	3/3/2016	The Secretaries of the Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Housing and Urban Development, the Interior, Labor, State, Transportation, the Treasury, and Veterans Affairs; the Attorney General of the United States; the Administrators of the Environmental Protection Agency, General Services Administration, National Aeronautics and Space Administration, and U.S. Agency for International Development; the Director of the Office of Personnel Management; the Chairman of the Nuclear Regulatory Commission; and the Commissioner of the Social Security Administration should take action to improve progress in the data center optimization areas that we reported as not meeting OMB's established targets, including addressing any identified challenges.	Concur	2020	Awaiting Disposition	This recommendation was based on metrics from M-16-19 which is no longer in effect and has been replaced M-19-19. OCIO has worked closely with OMB to define new metrics and therefore believes this recommendation should be closed.
GAO-16-325	Cloud Computing: Agencies Need to Incorporate Key Practices to Ensure Effective Performance	4/7/2016	To help ensure continued progress in the implementation of effective cloud computing SLAs, the Secretaries of Health and Human Services, Homeland Security, Treasury, and Veterans Affairs should direct appropriate officials to develop SLA guidance and ensure key practices are fully incorporated as the contract and associated SLAs expire.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-468	Information Technology: Federal Agencies Need to	5/25/2016	The Secretary of Health and Human Services should direct the CIO to identify and plan to modernize or replace legacy systems as needed and consistent with	Concur	NA	Awaiting Disposition	OCIO is actively working to

	Address Aging Legacy Systems		OMB's draft guidance, including time frames, activities to be performed, and functions to be replaced or enhanced.				implement the recommendation.
GAO-16-469	Information Technology Reform: Agencies Need to Increase their use of Developmental Practices	9/15/2016	To improve the certification of adequate incremental development, the Secretaries of Defense, Education, Health and Human Services, and the Treasury should direct their CIOs to establish a department policy and process for the certification of major IT investments' adequate use of incremental development, in accordance with OMB's guidance on the implementation of the Federal Information Technology Acquisition Reform Act.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation. We have submitted a draft policy that GAO believes will satisfy the recommendation when it is approved in early 2020.
GAO-16-494	IT Dashboard: Agencies Need to Fully Consider Risks When Rating Their Major Investments	6/2/2016	To better ensure that the Dashboard ratings more accurately reflect risk, the Secretaries of the Departments of Agriculture, Education, Energy, Health and Human Services, the Interior, State, and Veterans Affairs; and the Director of the Office of Personnel Management should direct their CIOs to factor active risks into their IT Dashboard CIO ratings.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-494	IT Dashboard: Agencies Need to Fully Consider Risks When Rating Their Major Investments	6/2/2016	To better ensure that the Dashboard ratings more accurately reflect risk, the Secretary of the Department of Health and Human Services, should direct their CIOs to ensure that their CIO ratings reflect the level of risk facing an investment relative to that investment's ability to accomplish its goals.	Concur	NA	In Progress	OCIO is actively working to implement the recommendation.
GAO-16-511	Information Technology: Agencies Need to Improve Their Application Inventories to Achieve Additional Savings	9/29/2016	To improve federal agencies' efforts to rationalize their portfolio of applications, the heads of the Departments of Agriculture, Commerce, Education, Energy, Health and Human Services, Housing and Urban Development, the Interior, Labor, State, Transportation, the Treasury, and Veterans Affairs; and heads of the Environmental Protection Agency; National Aeronautics and Space Administration; National Science Foundation; Nuclear Regulatory Commission; Office of Personnel Management; Small Business Administration; Social Security Administration; and U.S. Agency for International Development should direct their Chief Information Officers (CIOs) and other responsible officials to improve their inventories by taking steps to fully address the practices we identified as being partially met or not met.	Concur	2020	Awaiting Disposition	OCIO has contacted ASL about closing this recommendation based on the information provided earlier to GAO.
GAO-17-448	Data Center Optimization: Agencies Need to Address Challenges	9/6/2017	The Secretaries of Agriculture, Commerce, Defense, Homeland Security, Energy, HHS, Interior, Labor, State, Transportation, Treasury, and VA; the Attorney General of the United States; the Administrators of EPA, GSA,	Concur	2020	Awaiting Disposition	This recommendation was based on metrics from M-

	and Improve Progress to Achieve Cost Savings Goal		and SBA; the Director of OPM; and the Chairman of NRC should take action to, within existing OMB reporting mechanisms, complete plans describing how the agency will achieve OMB's requirement to implement automated monitoring tools at all agency-owned data centers by the end of fiscal year 2018.				16-19 which is no longer in effect and has been replaced M-19-19. OCIO has worked closely with OMB to define new metrics and therefore believes this recommendation should be closed.
GAO-17-8	IT Workforce: Key Practices Help Ensure Strong Integrated Program Teams; Selected Departments Need to Assess Skill Gaps	11/30/2016	To facilitate the analysis of gaps between current skills and future needs, the development of strategies for filling the gaps, and succession planning, the Secretary of Health and Human Services should require the Chief Information Officer, Chief Human Capital Officer, and other senior managers as appropriate to address the shortfalls in IT workforce planning noted in this report, including the following actions: (1) establish and maintain a workforce planning process inclusive of all staff; (2) develop staffing requirements for all positions; (3) assess staffing needs regularly; (4) assess gaps in competencies and staffing for all components of the workforce; (5) develop strategies and plans to address gaps in competencies and staffing; (6) implement activities that address gaps, including an IT acquisition cadre, if justified and cost-effective; (7) monitor the department's progress in addressing competency and staffing gaps; and (8) report to department leadership on progress in addressing competency and staffing gaps.	Concur	NA	In Progress	OCIO is actively working this recommendation with the Office of Grants and Acquisition Policy and Accountability (OGAPA).
GAO-18-381	Paperwork Reduction Act: Agencies Could Better Leverage Review Processes and Public Outreach to Improve Burden Estimates	8/10/2018	The Secretary of Health and Human Services should review the policies, procedures, and related control activities to ensure that the agency's Paperwork Reduction Act review process is operating effectively.	Concur	NA	In Progress	OCIO is actively working this recommendation.
GAO-18-381	Paperwork Reduction Act: Agencies Could Better Leverage Review Processes and Public Outreach to Improve Burden Estimates	8/10/2018	The Secretary of Health and Human Services should leverage existing consultation with stakeholders and the public to explicitly seek input on the estimated burden imposed by information collections.	Concur	NA	In Progress	OCIO is actively working this recommendation.

GAO-18-42	Information Technology: Agencies Need to Involve Chief Information Officers in Reviewing Billions of Dollars in Acquisitions	1/10/2018	The Secretary of HHS should ensure that IT acquisition plans or strategies are reviewed and approved according to OMB's guidance.	Concur	2020	In Progress	OCIO is actively working this recommendation and has shared information with GAO.
GAO-18-93	Federal Chief Information Officers: Critical Actions Needed to Address Shortcomings and Challenges in Implementing Responsibilities	8/2/2018	The Secretary of Health and Human Services should ensure that the department's IT management policies address the role of the CIO for key responsibilities in the six areas we identified.	Concur	NA	In Progress	OCIO is actively working this recommendation and has shared information with GAO.