



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

Fiscal Year

2022

Public Health and Social Services
Emergency Fund

***Justification of Estimates for
Appropriations Committee***

TABLE OF CONTENTS

Organization Charts 9

 Assistant Secretary for Preparedness and Response..... 9

 Cybersecurity 11

 Office of National Security 12

Introduction and Mission..... 13

Overview of Budget Request 15

Overview of Performance 18

All Purpose Table 23

Appropriations Language 24

 FY 2022 Proposed Appropriations Language 24

 FY 2022 Proposed General Provision 25

 Appropriations Language Analysis 26

Amounts Available For Obligation 27

Summary of Changes 28

Budget Authority by Activity 29

Authorizing Legislation..... 30

Appropriations History..... 31

Appropriations Not Authorized by Law 32

Assistant Secretary for Preparedness and Response..... 33

 Summary of Request..... 33

 Preparedness and Emergency Operations..... 38

 National Disaster Medical System 48

 Medical Reserve Corps..... 65

 Hospital Preparedness Program 71

 Preparedness and Response Innovation..... 109

 Biomedical Advanced Research and Development Authority 111

 Project BioShield 126

 Strategic National Stockpile 132

 Policy and Planning 146

 Operations 153

 Nonrecurring Expenses Fund 156

Assistant Secretary for Administration 157

 Cybersecurity 157

Department of Health and Human Services 168

Public Health and Social Services Emergency Fund

| | |
|---|-----|
| Cyber Incident Response | 168 |
| Immediate Office of the Secretary..... | 172 |
| Office of National Security | 172 |
| Pandemic Influenza..... | 175 |
| Assistant Secretary for Health | 190 |
| Commissioned Corps Readiness Training | 190 |
| U.S Public Health Service Ready Reserve..... | 193 |
| Public Health and Emergency Response Strike Team..... | 196 |
| IDEA Digital Modernization Act | 198 |
| Budget Authority by Object Class | 199 |
| Salaries and Expenses | 200 |
| Detail of Full-Time Equivalent Employment | 201 |
| Detail of Positions | 202 |
| Programs Proposed for Elimination..... | 203 |
| Significant Items in Appropriation Committee Reports..... | 204 |



We are pleased to present the Fiscal Year (FY) 2022 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2022 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 security threats and includes the FY 2022 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 the American people. 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 ASPR's 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). These lifesaving efforts are undertaken in coordination with federal partners across the Public Health Emergency Medical Countermeasures Enterprise.

During FY 2020 and 2021, ASPR worked across the interagency on the fight against the most severe pandemic in a century. As part of ASPR, BARDA supported development, manufacturing, and/or purchase of medical countermeasures to combat COVID-19. Less than one month after the SARS-CoV-2 sequence was shared, BARDA immediately began to leverage existing public-private partnerships to develop vaccines, therapeutics, and diagnostics to address COVID-19. BARDA led early coordination among federal agencies to identify and develop medical countermeasures, and BARDA directly supported seven vaccine candidates including development and manufacturing of Moderna and Johnson & Johnson's Janssen vaccine, and purchase of the Pfizer vaccine; 13 therapeutics, including development of the Regeneron monoclonal antibody therapeutic and purchase of the Eli Lilly and Company therapeutics, as well as the convalescent plasma program; 17 rapidly deployable and other technologies, including next generation technologies to administer vaccines; and 42 diagnostic tests ranging from high-throughput tests for laboratories early in the pandemic to rapid point-of-care and at-home tests; 20 of BARDA-supported COVID-19 tests have received emergency use authorization from the U.S. Food and Drug Administration, and these private sector partners have shipped more than 108 million tests across the country. BARDA also collaborated with the private sector to expand capacity for manufacturing active pharmaceutical ingredients, as well as vaccines and ancillary products such as needles and syringes, purchased the ancillary supplies the SNS needed for vaccine supply kits, and engaged the Centers for Innovation in Advanced Development and Manufacturing for the first time in a pandemic response. In early 2020, BARDA rapidly expanded its broad agency announcements to incorporate COVID-19 medical

countermeasures, refocused its TechWatch program on COVID-19 medical countermeasures to review thousands of submissions, met with hundreds of potential product developers, and pivoted existing agreements with key private sector partners to focus immediately on developing therapeutics and vaccines using flexible platform technologies which BARDA had supported for other potential health security threats. BARDA also provided significant funding and other support to the National Institutes of Health for vaccine and therapeutics clinical trials, as well as for scale-up and manufacturing of new COVID-19 diagnostics. In total, these successful investments continue to yield an enormous benefit to the American people and will be critical to ending the COVID-19 pandemic.

The SNS responded to the COVID-19 pandemic by providing needed supplies such as personal protective equipment (PPE) including masks, gloves, and gowns and working in partnership with the ASPR information management team to develop unprecedented visibility into the globally-constrained supply chain. SNS has also supported the country's vaccination efforts. As of April 8, 2021, SNS has delivered more than 1,279,460 ancillary kits to support the administration of three separate COVID-19 vaccines; the kits support vaccinations for approximately 234 million Americans. Based on the lessons learned during the COVID-19 pandemic, SNS has initiated modernization efforts designed to ensure the SNS has the breadth and depth to respond to any future pandemic or public health emergency and bolster the domestic industrial base for critical pharmaceuticals and medical supplies to reduce America's vulnerabilities and reliance on foreign suppliers and manufacturers.

In addition to responding to other catastrophic incidents such as hurricanes and other natural disasters, ASPR continues to respond to the COVID-19 pandemic with activated National Disaster Medical System (NDMS) personnel. NDMS is supported by a workforce of up to 6,290 authorized intermittent federal employees organized into 69 teams across the country. NDMS teams contain clinical providers and specialized medical service professionals, including physicians, nurses, advance healthcare providers, fatality management professionals, paramedics, veterinarians, and other support staff, such as logisticians and information technology specialists. In the 2020 COVID-19 response, NDMS managed 5,389 deployments which included deploying many personnel multiple times. In numerous locations throughout the nation, NDMS provided hospital augmentation for critical and emergent care facilities critically depleted of resources and subject matter experts to manage medical and mortuary issues for the honorable care of human remains of American citizens that succumbed to this deadly virus. In 2021, NDMS continues to support the COVID-19 response with teams providing behavioral health support to responders and being deployed on testing and vaccination missions across the country.

Years of investment have yielded the ability to provide this surge medical capacity to the unique COVID-19 response; however, more must be done to be able to prepare the nation to be resilient when faced with any public health emergency. To do this, ASPR supports health care coalitions, medical providers, and emergency managers in preparing for incidents that impact medical and public health capabilities. These investments are critical to enabling the requisite federal, state, and local coordination necessary to rise to new challenges.

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 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 other public health emergency, 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. BARDA strategically supports advanced development and acquisition of medical countermeasures that are existing products which 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. These efforts focus on combatting the medical consequences of 18 chemical, biological, radiological and nuclear threats identified by the Department of Homeland Security (DHS). These advanced development programs have supported 28 products that have transitioned from BARDA's advanced research and development program to support under Project BioShield; 18 of these products have been procured for the SNS.

Further, 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. 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 2019, the World Health Organization warned that drug-resistant diseases could cause 10 million deaths each year by 2050 with economic damage as catastrophic as the 2008-2009 global financial crisis, and, by 2030, antimicrobial resistance could force up to 24 million people into extreme poverty. As part of ASPR, BARDA has become a national and global lead in accelerating medical countermeasures to combat antimicrobial resistant infections. In 2016, BARDA co-founded the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program, now the world's largest public-private partnership dedicated to innovation in antibacterial research and development. CARB-X has built a portfolio of early-stage candidate drugs, vaccines, and diagnostics. To date, CARB-X has funded 82 different candidates and currently has 56 active programs for the development of 41 therapeutics, eight vaccines, and seven diagnostics. Seven CARB-X portfolio candidates have entered clinical development, highlighting the success of this program in accelerating early-stage product development to the clinic.

Finally, to improve America's readiness against national disasters, including naturally or man-made disease threats, the SNS, which 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 by ensuring that the policy and planning, technical development, procurement, and then ultimate deployment for these critical materials is done by one, coordinated team. The FY 2022 President's Budget for ASPR is \$3,296,008,000, which is \$521,889,000 above the FY 2021 Enacted level. The Budget provides:

- \$1.6 billion for BARDA, including \$823 million for Advanced Research and Development, and \$770 million for Project BioShield procurements of MCMs;
- \$335 million for pandemic influenza preparedness activities within ASPR and the Office of Global Affairs;
- \$905 million for the SNS to manage and deliver life-saving medical countermeasures during a public health emergency;
- \$292 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;
- \$124 million for public health and medical preparedness and emergency operations, the National Disaster Medical System, and the Civilian Volunteer Medical Reserve Corps;
- \$2 million to sustain the initial investments of Preparedness and Response Innovation (PRI) program; and,
- \$52 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 evolving cyber threat landscape coupled with the rapid proliferation of information assets due to the COVID-19 pandemic, the increased mobility of the HHS workforce, and the need to derive value and intelligence from information assets has forced HHS to redefine its approach to managing and protecting information assets. In April 2020, the Department deployed HHS Protect, a secure data ecosystem for sharing, parsing, housing, and accessing COVID-19 health care information, to inform the federal government's data-driven response to the COVID-19 pandemic. The Cybersecurity program plays a key role in the security and privacy of HHS Protect and its respective sub-component systems, including information stored, processed, and transmitted.

The FY 2022 President's Budget for the HHS Cybersecurity program is \$110,826,000, which is \$53,006,000 above the FY 2021 Enacted level. The Budget supports the advancement of existing, and adoption of new, security technologies to protect the Department's information from the evolving number

and complexity of cyber threats. The Budget continues to support solutions to identify, evaluate, acquire, coordinate, and deploy cybersecurity information and tools across the Department as well as the Health and Public Health sector. The Budget also sustains HHS Protect in order to continue providing critical public health surveillance capabilities.

In addition, the FY 2022 President's Budget includes \$73,290,000 in the PHSSEF for HHS Cyber Incident Response to build greater resilience into information technology systems across HHS by providing resources for Security Operations Center enhancements and increased logging functions.

Office of National Security

The Office of National Security (ONS) 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 increases the Department's security and threat awareness and its ability to respond swiftly and effectively to national and homeland security threats. ONS engages with Federal partners and others to analyze all-source intelligence/information and identify potential threats and vulnerabilities, and it identifies and assesses 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 the Secretary's Senior Intelligence Official. The FY 2022 President's Budget for ONS is \$8,983,000, which is \$473,000 above FY 2021 Enacted.

Secretary's 1% Transfer Authority

The FY 2022 President's Budget proposes to expand the Secretary's one percent transfer authority in Section 204 of the Public Health Service Act such that the PHSSEF appropriation could be increased by up to ten percent instead of three percent. As learned from public health threats such as COVID-19, it is critical for the Department to have the flexibility needed to respond as quickly as possible when such threats arise. An expanded one percent transfer authority would allow the Secretary to transfer more resources to emergency programs funded by the PHSSEF appropriation in order to accelerate critical public health and medical response activities.

Nikki Bratcher-Bowman
Acting Assistant Secretary for Preparedness
and Response

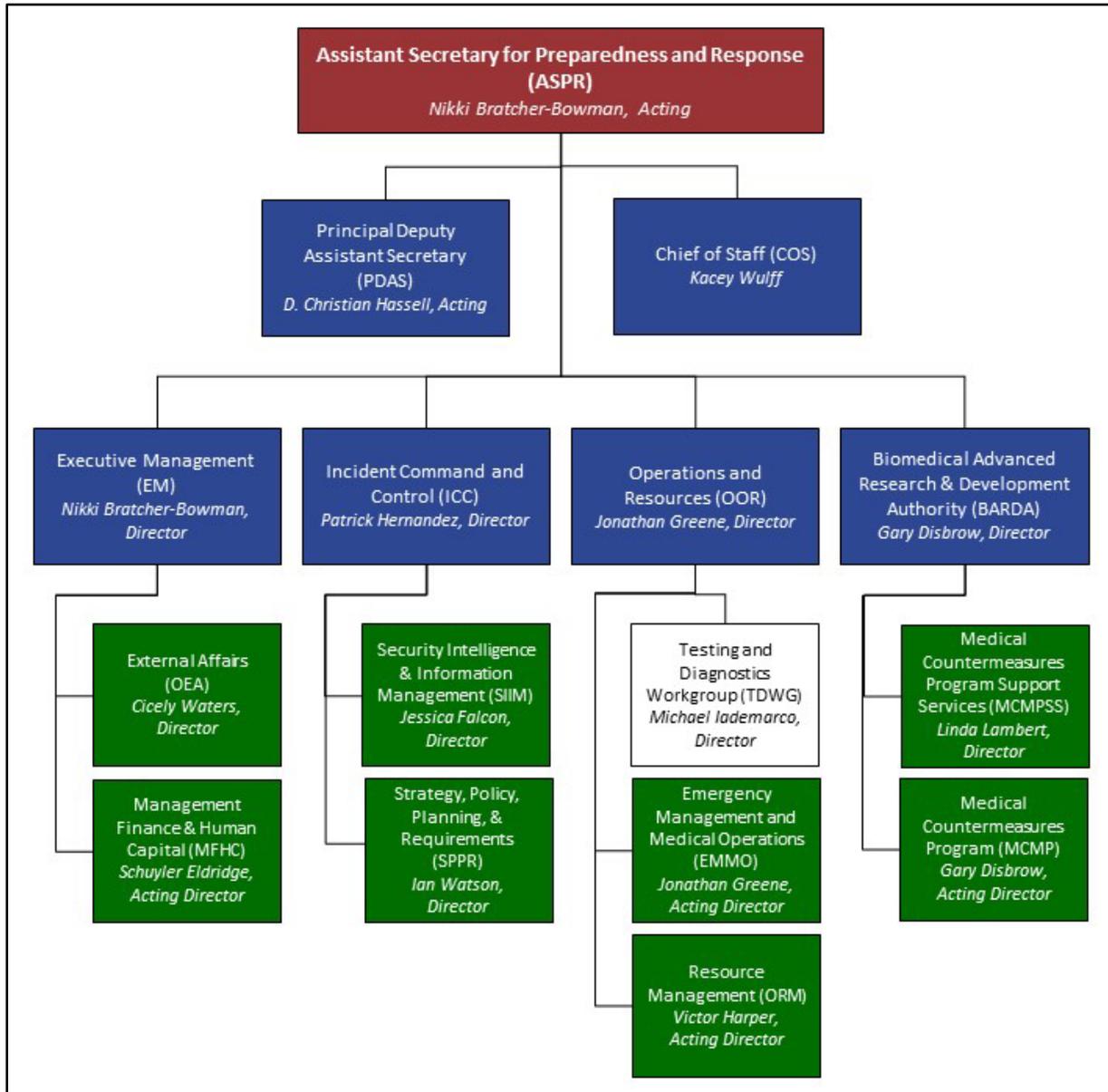
Janet Vogel
HHS Chief Information Security
Officer

Andrea Palm
HHS Deputy Secretary

Michael Schmoyer
National Security Advisor to the
Secretary

ORGANIZATION CHARTS

Assistant Secretary for Preparedness and Response



The Office of the Assistant Secretary for Preparedness and Response is led by Acting Assistant Secretary Nikki Bratcher-Bowman.

The Acting Principal Deputy Assistant Secretary (PDAS), D. Christian Hassell, Deputy Assistant Secretary and Chief of Staff (COS) Kacey Wulff, and Deputy Assistant Secretary and Director of Executive Management Nikki Bratcher-Bowman provide executive support to the Assistant Secretary.

Nikki Bratcher-Bowman, Deputy Assistant Secretary and Director of Executive Management (EM) serves as the executive managing two (2) offices within Executive Management: External Affairs (OEA) led by

Public Health and Social Services Emergency Fund

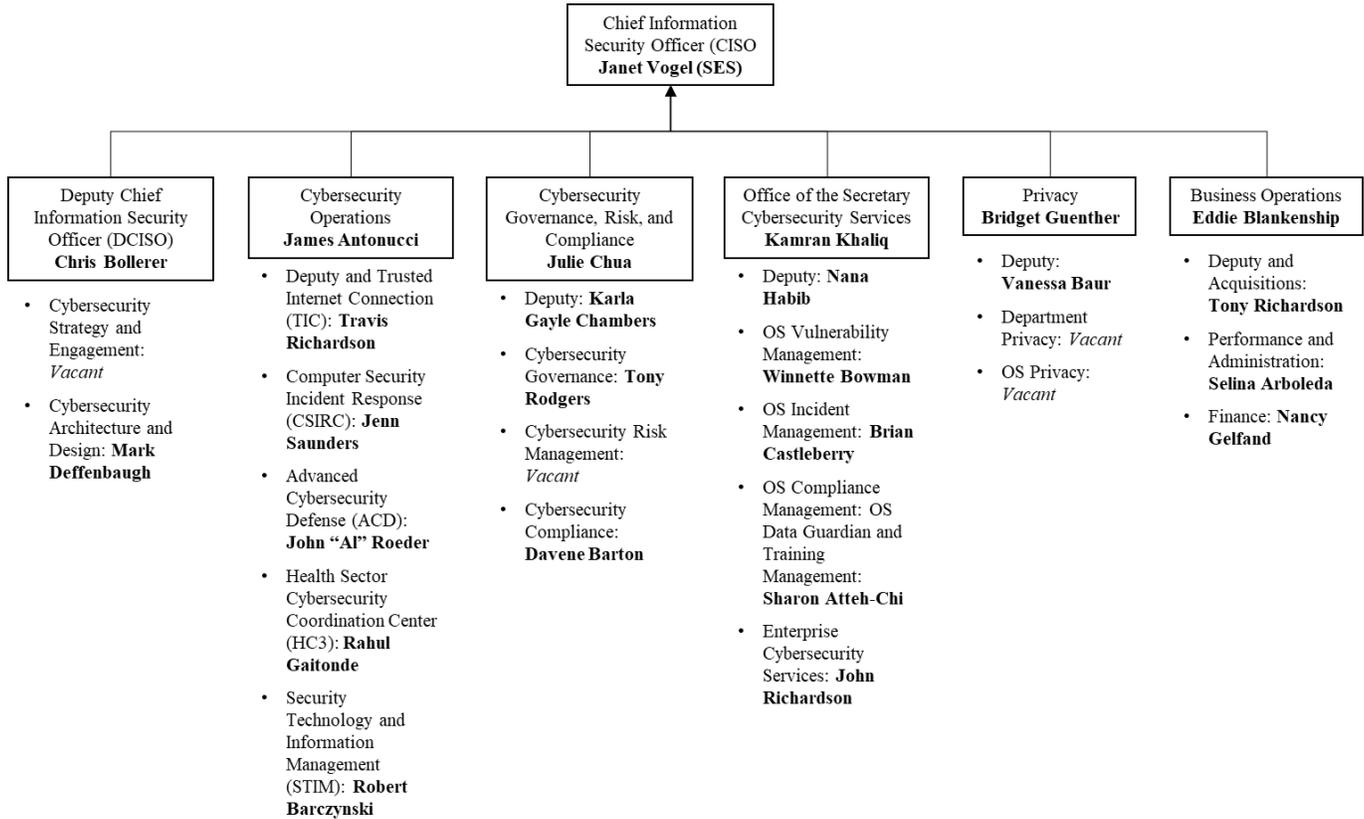
director Cicely Waters and Management Finance and Human Capital (MFHC) led by acting director, Schuyler Eldridge.

Deputy Assistant Secretary Patrick Hernandez serves as the executive managing two (2) offices within Incident Command and Control (ICC): Security, Intelligence, and Information Management (SIIM) led by director Jessica Falcon and Strategy, Policy, Planning, and Requirements (SPPR) led by director Ian Watson.

Deputy Assistant Secretary Jonathan Greene serves as the executive managing two (2) offices within Operations and Resources (OOR) and the Testing and Diagnostics Workgroup (TDWG) led by director Michael Iademarco. The two offices are Emergency Management and Medical Operations (EMMO) led by acting director Jonathan Greene, and Resource Management (ORM) led by acting director Victor Harper.

Deputy Assistant Secretary and Biomedical Advanced Research and Development Authority (BARDA) Director Gary Disbrow serves as the executive managing the two (2) BARDA offices: Medical Countermeasures Program Support Services (MCMPSS) led by director Linda Lambert and the Medical Countermeasures Program (MCMP) led by acting director Gary Disbrow.

Cybersecurity



Office of National Security



FTE Organizational Chart



Security & Business Services

- Division Director - Kimberly Bannister
- Deputy Director
- Communications Specialist
- Management Program Analyst
- Management Program Analyst
- Management Program Analyst
- Intelligence Oper. Specialist (Insider Threat Lead)
- Insider Threat
- Total of 6

Intelligence & Analysis

- Division Director - Alisa Hudgens
- Branch Chief
- Branch Chief
- Branch Chief
- Counterintelligence (CI) Specialist
- CI Specialist
- IAD Program Manager
- Intelligence Operations Specialist (IOS)
- IOS
- IOS
- Senior Advisor for Homeland Sec.
- IOS
- IOS
- IOS
- Cyber Intelligence Specialist
- IOS (Detailed)
- Cyber Intelligence Specialist
- Total 23

Personnel Security

- Division Director: Sonya Sargent Oliver
- Special Security Officer (SSO)
- SCIF Manager
- COMSEC
- Total of 3

Updated 5/21/2021

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 Operating 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) as well as 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 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 both domestically and worldwide.

OVERVIEW OF BUDGET REQUEST

The FY 2022 President's Budget for the Public Health and Social Services Emergency Fund (PHSSEF) is \$3,523,116,000, which is an increase of +\$675,658,000 relative to FY 2021 Enacted. 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;
- Support the Department's counter-intelligence program;
- Support 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 preparedness activities, including funds within the Office of Global Affairs (OGA).

Programmatic Increases (relative to FY 2021):

BARDA Advanced Research and Development (increase of +\$226.680 million, \$823.380 million total): The FY 2022 President's Budget for Advanced Research and Development is \$823,380,000, which is \$226,680,000 above FY 2021 Enacted. The Budget will support existing BARDA Division of Research, Innovation, and Ventures (DRIVE) efforts and expand the portfolio of DRIVE programs to include developing innovative approaches for early identification, prevention, and treatment of sepsis. BARDA will also support novel technologies to empower patients and healthcare workers with information to diagnose and identify individuals exposed to infectious disease under the ENACT program. The FY 2022 Budget will also continue to support the BARDA Accelerator Network, Medical Countermeasures Innovation Partnership (BARDA Ventures program), and efforts to take on new innovation and partnership opportunities to meet constantly evolving health security needs.

The FY 2022 Budget for BARDA supports CARB-X and increases investments for the advanced development of broad-spectrum antimicrobials including vaccines, diagnostics, and novel antibiotic treatments for both complicated and uncomplicated infections. New funding initiatives in FY 2022 will include transitioning one to two CARB-X graduates into the BARDA's advanced development portfolio.

The FY 2022 Budget will also expand funding for vaccines and therapeutics for viral hemorrhagic diseases including Marburg and Sudan viruses (two threats for which no MCMs exist), next generation smallpox therapeutics with increased efficacy and improved safety over currently approved and available drugs, countermeasures against chemical threats to evaluate the efficacy of currently available drugs with commercial indications against a range of chemical threats such as sulfur mustard and nerve agents, and development of next generation therapeutics against botulinum toxin and vaccines against anthrax. The additional funding for these programs will also leverage the experiences learned while fighting the COVID-19 pandemic that highlighted the importance of developing platform technologies that can be rapidly redirected from one threat agent and be deployed to focus on an emerging threat. In addition, BARDA will bolster scientific staff and related support staff and services as the overall number and complexity of contracts increase.

Strategic National Stockpile (SNS) (increase of +\$200 million, \$905 million total): The FY 2022 President's Budget includes \$905 million for the SNS to make meaningful investments across a number of portfolios necessary to ensure readiness for future public health emergencies. The Budget prioritizes funding for pandemic preparedness by making targeted investments in critical medical supplies as well as development and sustainment capabilities to prepare for and respond to pandemics as informed by the COVID-19 response. Additionally, funds would be used to support SNS's ongoing storage and distribution needs, which were expanded and modified to meet the demands of the COVID-19 pandemic.

Pandemic Influenza (increase of +\$48 million, \$335 million total): The FY 2022 President's Budget includes an increase of \$48 million for pandemic influenza preparedness activities to address priorities as outlined in the Executive Order on Modernizing Influenza Vaccines in alignment with the corresponding National Influenza Vaccine Modernization Strategy (2020-2030). Additional funds will be used to advance non-egg based, synthetic influenza vaccine platforms, support efforts to transfer technologies to public-private partnerships to improve influenza pandemic response, and advance alternative influenza vaccine delivery systems. Funds will also be used to sustain previous investments in critical domestic influenza vaccine manufacturing facility infrastructure and support development of improved vaccines in alignment with the Presidential EO, the HHS Influenza Plan Update, and lessons learned from the COVID-19 response.

National Disaster Medical System (NDMS) (increase of +\$28.403 million, \$91.807 million total): NDMS's mission is to augment communities with medical services after a disaster or public health emergency, and to support the Department of Defense (DOD) and Veterans Administration (VA) in cases of a surge in military casualties that could overwhelm their medical systems. ASPR will use an additional \$25 million to meet demands for additional individual and team training to ensure mission readiness, including additional hands-on and online training for new NDMS employees. Additionally, the funds will support the additional workload to onboard new staff, credential the additional 2,600 clinicians, and conduct security background checks. The budget also includes \$6,000,000 to continue the Pediatric Disaster Care program.

Hospital Preparedness Program (HPP) (increase of +\$11.222 million, \$291.777 million total): Within the total, \$240,000,000 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. The remaining funds will support Technical Resources, Assistance Center, and Information Exchange (TRACIE), ASPR Recovery program, Critical Infrastructure Protection (CIP) program, National Emerging Special Pathogens Training and Education Center (NETEC), ten Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs), and HPP administration, performance evaluation, and oversight. HPP will also sustain the four Regional Disaster Health Response System (RDHRS) demonstration sites.

Policy and Planning (increase of +\$5.040 million, \$19.917 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 increased funding will allow ASPR to build on lessons learned from the COVID-19 response through after action reviews that will help us recalibrate existing efforts and anticipate, and prepare for, future emergencies and other events. The additional funds will also build on lessons learned from the COVID pandemic to enhance biodefense.

Operations (increase of \$1.238 million, \$32.176 million total): 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 preparedness, response, and recovery. These funds foster leadership and strategic

management, ensuring a collaborative and comprehensive approach to implementing ASPR's goals and strategies. As acquisition needs grow, ASPR will need to provide additional support to ensure timely and accurate awards. ASPR will also provide additional resources to its financial management mission in order to ensure oversight of ASPR's resources, performance, ERM, and integration to strategic planning. In addition, funding will ensure the effective recruitment and retention of ASPR's human capital assets.

Preparedness and Emergency Operations (increase of +\$0.986 million, \$25.640 million total): The request supports preparedness and response efforts to public health and medical emergencies and a robust Continuity of Operations (COOP) program. This request also continues \$5,000,000 in three-year funding to prepare for, and respond to, National Special Security Events, public health emergencies, and other events that are not eligible for assistance under the Stafford Act.

Medical Reserve Corps (MRC) (increase of +\$0.240 million, \$6.240 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.

Preparedness and Response Innovation (PRI) (increase of +\$0.080 million, \$2.080 million total): The PRI program was established in FY 2021. The request will sustain initial program investments.

Cybersecurity (increase of +\$126.296 million, \$184.116 million total): The Budget includes an increase of \$126 million to strengthen the Department's cybersecurity posture. Additional funds will be used to enhance capabilities for identity management and control, threat hunting, and data loss prevention to ensure the Department's data and networks remain protected from outside threats. Funds will also be used to sustain the HHS Protect data sharing and analytics platform to support data-driven decisions in responding to COVID-19. In addition, funds will be used to mitigate the impacts of the Solar Winds cyberattack across HHS agencies and provide the upgraded capabilities necessary to defend the Department's information systems and network against future cyber threats.

Office of National Security (ONS) (increase of +\$0.473 million, \$8.983 million total): The Budget supports 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 +\$27 million, \$27 million total): The Budget requests \$27 million for the U.S. Public Health Service Commissioned Corps to continue readiness and training programs supported by COVID-19 supplemental appropriations. Funds will be used to: ensure the Corps is fully trained and ready to respond to any number of public health and medical emergencies; support a dedicated strike team of active duty Corps officers to immediately respond to emergent situations; and continue to build and support a ready reserve of Corps officers.

OVERVIEW OF PERFORMANCE

ASPR's Mission

Within the U.S. Department of Health and Human Services (HHS), the Office of the Assistant Secretary for Preparedness and Response (ASPR) leads the country in preparing for, responding to, and recovering from, the adverse health effects of emergencies and disasters by supporting our communities, thus strengthening our health and response systems while 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. ASPR performance provides accountability and transparency by reporting program accomplishments and how well these accomplishments match the programs' goals and objectives. This is done through integration with HHS and ASPR strategic plans, performance, and risk management efforts, reporting results of metrics in budgets and annual performance plans, and contributions to HHS-wide priority goals. ASPR takes a systematic, data-driven, organization-wide approach to performance management and integrates Enterprise Risk Management (ERM) efforts. ASPR focuses resources where there is greatest need then measures the impact of ASPR investments and uses feedback to continually improve.

Among the ways that ASPR aligns financial resources with strategic priorities is through a multiyear strategy to measure financial performance and ensure course corrections. During FY 2019, ASPR submitted to Congress the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget (MYB) report for [FY 2018-2022](#). For HHS PHEMCE partners, including the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), the PHEMCE MYB aligns activities related to 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. During FY 2021 and 2022, ASPR will continue to enhance and update the PHEMCE MYB and other collaborative tools.

Performance Goals

ASPR advances the Administration's priorities through the integration of performance management, risk management, financial management, and strategic planning. ASPR ensures the accountability and effectiveness of its financial programs through risk-based performance management as required by OMB Circulars A-123 and A-11.

ASPR's performance metrics are used to advance effective, efficient, and productive efforts, while promoting accountability. ASPR analyzes performance data to inform data-driven decisions, to gauge meaningful progress towards ASPR and HHS strategic plan objectives, and to identify more effective and efficient progress. ASPR continues to institute significant improvements in performance management, including:

- Create performance metrics that measure the output of ASPR program investments then collect, analyze, and report the impact of programs on a timely basis;
- Contribute to agency priority goals (APG);
- Review performance and risk data then triangulate with other evidence about ASPR programs in order to provide feedback to key audiences to lead improvements;
- Provide ongoing organizational training;
- Support implementation and advancement of the Evidence Act and the Data Act;

- Contribute data for Key Performance Indicators (KPI) to assist monitoring the Covid-19 response; new KPIs are being reported to HHS leadership as part of a Department-wide dashboard;
- Collaborate with colleagues who conduct ASPR's policy and planning activities in order to support, contribute to, and implement performance management efforts and related legislation; and,
- Share best practices and relevant data with colleagues within ASPR and HHS.

Agency Priority Goals (APG)

The Government Performance and Results Modernization Act of 2010 requires agencies to develop and publicly report on APGs. APGs focus the attention of leadership and contributing agencies on the achievement of Departmental priorities where implementation requires active collaboration among more than one Federal agency within the same Department. Agencies identify APGs every two years. APGs target near-term results achievable within approximately 24 months, rely predominately on strong agency execution, and do not require new legislation or additional funding to achieve results. The Department is in the process of identifying new APG areas for the FY 2022-2023 cycle. ASPR looks forward to contributing as this important effort is launched for the new cycle.

During 2018 and 2019, ASPR partnered with the Centers for Disease Control and Prevention to lead the APG on the Health Security APG. When this APG successfully concluded, there were demonstrated increases in the capacity to prevent health threats impacting the United States. During the 2020 and 2021 APG cycle, ASPR contributed to the APG focusing on Kidney Care. In each quarterly report, ASPR provided updates about the procurement/deployment of portable dialysis platforms and continuous renal replacement therapy devices used to address kidney care needs, including those associated with COVID-19.

HHS and ASPR Strategic Planning

The strength of our nation's public health infrastructure is reflected in our ability to quickly mobilize a coordinated response to disasters and emergencies. The needs of American citizens and communities drive strategic planning and setting priorities. This is reflected in how ASPR is implementing their own strategic plan as well and aligning ASPR's programs with the HHS Strategic Plan.

For the 2018-2022 HHS Strategic Plan, ASPR supports 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. During FY 2020, ASPR supported objective 2.2 by reporting the completion of three 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 met the target. In support of HHS Strategic Plan Objective 2.4 during 2020, ASPR increased the number of new licensed MCMs across BARDA programs by two new MCMs, which met the target.

COVID-19 Response

In early February 2020, ASPR entered into the first in a series of expanded public-private partnerships to develop new medical countermeasures. ASPR continues to act with unprecedented speed to initiate and conduct research and development that spurs innovative medical countermeasures. Through these activities, ASPR is part of a whole-of-government response to combat SARS-CoV-2, the virus that causes COVID-19.

ASPR provides vaccines, ventilators, Personal Protective Equipment, the tools for rapid diagnosis, effective therapeutics or antivirals, and other medical countermeasures that save lives. Specific examples of how ASPR contributes to the pandemic response include conducting public health surveillance, epidemiology, and laboratory testing; quarantining individuals who might have been exposed and isolating those who contracted the virus; training health care workers; advancing the development, testing, and availability of new vaccines, therapeutics, and diagnostics; procuring and deploying necessary medical supplies; and providing social services and support to at-risk populations such as older adults, persons with disabilities, American Indians/Alaska Natives, children, and individuals with substance use disorders.

ASPR is tracking and reporting financial, performance, ERM and internal control data about the COVID-19 response through multiple integrated mechanisms. Documentation of inter-agency agreement, property management, inventory management, purchase cards, and travel card procedures are among areas captured this fiscal year. ASPR coordinates control reviews including improper payment assessments. ASPR has established a risk management learning and development program to help train process owners and key staff on managing risk and ensuring appropriate use of process controls.

Pandemic Influenza

Illness caused by influenza and other pathogens, including SARS-CoV-2 (severe acute respiratory syndrome coronavirus), can evolve, spread geographically, and infect large numbers of people quickly. In addition to the annual toll taken by seasonal influenza, hundreds of thousands of people could be hospitalized with influenza in the US during a severe pandemic. ASPR is improving the Nation's seasonal and pandemic influenza prevention and treatment options by a) expanding and maintaining the number of influenza vaccine options and domestic manufacturing capability of those vaccines; b) developing new vaccines with broader protection and faster production time; c) supporting development and broadening indications for influenza therapeutics. This has included licensing of the first two non-egg-based platforms, as well as the first two pre-pandemic influenza vaccines, and an antiviral to treat influenza infection. However, many Americans still die annually from influenza and influenza vaccine efficacy rates fluctuate season to season. Finally, as reinforced by the COVID-19 experience, vaccine production and availability must be faster than current capabilities. In FY 2020, efforts to address these gaps continued in parallel with funding efforts to maintain current capabilities. Specifically, ASPR made awards to significantly expand domestic production of the recombinant influenza vaccine and adjuvant, and address alternative (non-needle/syringe) administration approaches.

During FY 2021 and FY 2022, key components of ASPR's strategy is to further accelerate vaccine production capability, improve vaccine efficacy, and develop formulations that will enable increased vaccine uptake. To do this, ASPR continues to support improvements on current vaccine platforms, such as development of adjuvanted vaccines, as well as development of new, more rapid platforms that may also have better efficacy. Efforts will also be made to identify new therapeutic targets to treat hospitalized patients.

Performance Management Challenges

Tracking and feeding back data are critical to the COVID-19 response. ASPR performance and other data is reported to multiple stakeholders, including HHS and the public in ways that drive ongoing improvements. These data are used to inform decisions at the federal, state, and local levels, including allocation of supplies needed for emergency response. The creation of KPIs and other metrics that track medical countermeasures and SNS activities are one of the ways ASPR is meeting this challenge. Internal

control oversight of the resources being used to address the pandemic will be helpful as investments continue.

The complexity of some areas addressed by ASPR requires clear communication about evidence and performance/risk management data. To promote ongoing improvements as well as implementation of the Evidence Act and the Data Act, data and other evidence must be clearly presented in useful formats when fed back to key audiences. Tools are created and tested to facilitate communication. During FY 2021 and FY 2022, ASPR will continue to modernize the Public Health Emergency ([PHE.gov](https://www.phe.gov)) external cross-agency web site. Using the web site, social media, and other electronic tools, ASPR helps private industry, state and local government agencies, and community organizations obtain the information and resources they need to understand evidence about disease outbreaks, monitor public health situations as they evolve, and deal with natural and other disasters.

ASPR’s SNS manages and delivers life-saving medical countermeasures during emergencies. As the largest federally owned repository of pharmaceuticals, critical medical supplies, and medical equipment available for rapid delivery to support disaster response, the SNS continually improves so that resources are available when needed. But unexpected threats make it hard to predict what to stockpile or how to report performance in ways that drive improvement. To aid in this challenge, ASPR is carefully reviewing what is being measured and how performance data supports data analysis and improvement efforts.



Reporting the Impact of ASPR Programs

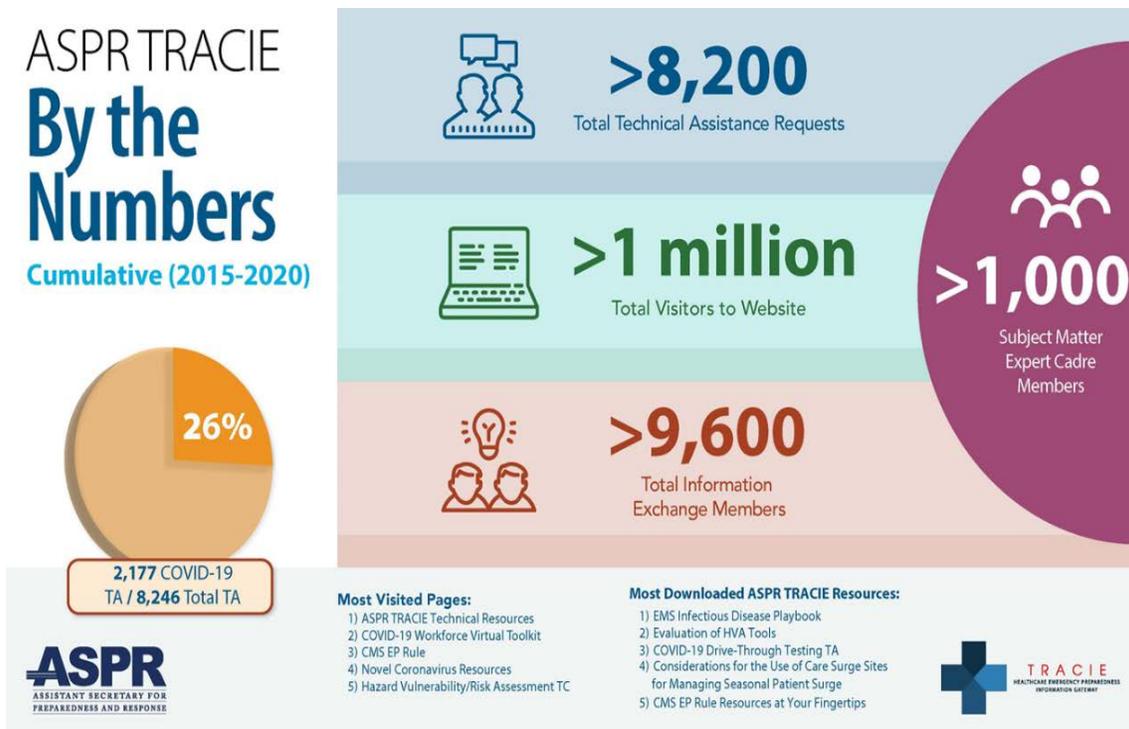
Two examples of ASPR’s impact are provided below to demonstrate how data are aggregated, analyzed, and used to tell a story about the use of federal resources help Americans.

The HHS emPOWER Program (emPOWER) is at the forefront of government innovation. The expanding emPOWER portfolio includes dynamic datasets, mapping tools, comprehensive training programs, and informational resources to support federal and public health authorities and their partners. During FY 2020, emPOWER launched a new publicly accessible, voice-activated artificial intelligence (AI) tool, emPOWER AI, which can be accessed by first responders, Public Health Agencies, emergency managers, health care providers.

During 2020, ASPR’s Technical Resources Assistance Center, and Information Exchange

(TRACIE), enhanced and expanded its technical assistance to state and local communities. TRACIE fills gaps in healthcare system preparedness capabilities by providing timely, innovative ways to share information and promising practices. TRACIE provides evidence-based applications, information, and proven best practices to help healthcare providers, healthcare coalitions, states, and communities build enhanced capacity and improve their knowledge and effectiveness.

Throughout 2020, the ASPR TRACIE Team responded to hundreds of requests for technical assistance while sharing experiences and lessons learned from the field via a variety of products (articles, tip sheets, webinars, and tools). Other 2020 accomplishments include hosting the one millionth visitor to the ASPR TRACIE website, providing nearly 3,000 Technical Assistance responses, achieving overall user satisfaction rating at 99 percent, assistance as a knowledge center for COVID-19 resources, conducting 33 web-based learning opportunities (webinars, short presentations), and increasing TRACIE’s online presence by 23 percent.



Public Health and Social Services Emergency Fund

ALL PURPOSE TABLE

(Dollars in Millions)

| Program | FY 2020 Final | FY 2020 Supplemental Funding /1 | FY 2021 Enacted | FY 2021 Supplemental Funding /2 | FY 2022 President's Budget | FY 2022 +/- FY 2021 Enacted |
|--|------------------|---------------------------------------|--------------------|---------------------------------------|----------------------------------|-----------------------------------|
| Assistant Secretary for Preparedness and Response (ASPR): | | | | | | |
| Preparedness and Emergency Operations..... | 24.654 | 550.000 | 24.654 | | 25.640 | +0.986 |
| <i>National Special Security Events (non-add).....</i> | <i>5.000</i> | | <i>5.000</i> | | <i>5.000</i> | -- |
| National Disaster Medical System..... | 57.404 | | 63.404 | | 91.807 | +28.403 |
| Hospital Preparedness..... | 275.555 | 526.000 | 280.555 | | 291.777 | +11.222 |
| Medical Reserve Corps..... | 6.000 | | 6.000 | 100.000 | 6.240 | +0.240 |
| Preparedness and Response Innovation..... | -- | | 2.000 | | 2.080 | +0.080 |
| Biomedical Advanced Research and Development Authority.. | 561.700 | 18,038.595 | 596.700 | 24,895.000 | 823.380 | +226.680 |
| Project BioShield..... | 735.000 | | 770.000 | | 770.000 | -- |
| Strategic National Stockpile..... | 705.000 | 10,710.000 | 705.000 | 3,250.000 | 905.000 | +200.000 |
| Policy and Planning..... | 14.877 | | 14.877 | | 19.917 | +5.040 |
| Operations..... | 30.938 | | 30.938 | | 32.176 | +1.238 |
| ASPR Pandemic Influenza | | | | | | |
| No-Year Pandemic Influenza..... | 225.000 | | 252.000 | | 300.000 | +48.000 |
| Annual Pandemic Influenza | 27.991 | | 27.991 | | 27.991 | -- |
| Subtotal, ASPR Pandemic Influenza | 252.991 | | 279.991 | | 327.991 | +48.000 |
| Subtotal, ASPR Program Level | 2,664.119 | 29,824.595 | 2,774.119 | 28,245.000 | 3,296.008 | +521.889 |
| Subtotal, ASPR Budget Authority | 2,664.119 | 29,824.595 | 2,774.119 | 28,245.000 | 3,296.008 | +521.889 |
| Other Office of the Secretary: | | | | | | |
| Office of Global Affairs (OGA) Annual Pandemic Influenza.... | 7.009 | | 7.009 | | 7.009 | -- |
| Office of the Chief Information Officer - Cybersecurity..... | 57.820 | 153.575 | 57.820 | | 110.826 | +53.006 |
| HHS-wide Cybersecurity..... | -- | | -- | | 73.290 | +73.290 |
| Office of National Security (ONS)..... | 8.510 | 2.000 | 8.510 | | 8.983 | +0.473 |
| Office of the Assistant Secretary for Health (OASH)..... | -- | 38.700 | -- | | 27.000 | +27.000 |
| Readiness Training..... | -- | 16.700 | -- | | 4.600 | +4.600 |
| Public Health and Emergency Response Strike Team..... | -- | 15.000 | -- | | 8.600 | +8.600 |
| Commissioned Corps Ready Reserve..... | -- | 7.000 | -- | | 13.800 | +13.800 |
| Subtotal, Other Office of the Secretary..... | 73.339 | 194.275 | 73.339 | | 227.108 | +153.769 |
| PHSSEF Total: | | | | | | |
| HHS Pandemic Influenza Budget Authority..... | 260.000 | | 287.000 | | 335.000 | +48.000 |
| No-Year Pandemic Influenza (non-add)..... | 225.000 | | 252.000 | | 300.000 | +48.000 |
| Annual Pandemic Influenza (non-add)..... | 35.000 | | 35.000 | | 35.000 | -- |
| Other Budget Authority..... | 2,477.458 | 197,926.630 | 2,560.458 | 89,418.000 | 3,188.116 | +627.658 |
| Total, PHSSEF Program Level..... | 2,737.458 | 227,945.500 | 2,847.458 | 117,663.000 | 3,523.116 | +675.658 |
| Total, PHSSEF, Budget Authority | 2,737.458 | 227,945.500 | 2,847.458 | 117,663.000 | 3,523.116 | +675.658 |
| NEF | | | | | | |
| ASPR Headquarters Relocation..... | | | | | | |
| FTE | | | | | | |
| ASPR | 847 | 6 | 961 | 90 | 1,134 | +173 |
| OGA | 7 | -- | 11 | -- | 11 | -- |
| OCIO Cybersecurity | 99 | -- | 143 | -- | 143 | -- |
| HHS-wide Cybersecurity | -- | -- | -- | -- | -- | -- |
| ONS | 25 | -- | 37 | -- | 38 | +1 |
| OASH | -- | -- | -- | -- | 62 | +62 |
| Total FTE, PHSSEF | 978 | 6 | 1,152 | 90 | 1,388 | +236 |

1/ Shows supplemental appropriations for COVID-19 response activities, post-transfer and post-reallocation. Excludes supplemental appropriations for procurement of Ebola vaccines, therapeutics, and diagnostics (\$535 million).

2/ This column includes both COVID-19 supplemental funding and mandatory funds appropriated in the American Rescue Plan Act of 2021, P.L. 117-002, post-transfer and post-reallocation.

APPROPRIATIONS LANGUAGE

FY 2022 Proposed Appropriations Language

(Relative to FY 2021 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, [~~\$1,085,458,000~~] *\$1,513,116,000*, of which [~~\$596,700,000~~] *\$823,380,000* shall remain available through September 30, [~~2022~~] *2023*, 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, [~~2023~~] *2024*.

For expenses necessary for procuring security countermeasures (as defined in section 319F–2(c)(1)(B) of the PHS Act), ~~\$770,000,000~~, to remain available until expended.

For expenses necessary to carry out section 319F–2(a) of the PHS Act, [~~\$705,000,000~~] *\$905,000,000*, to remain available until expended.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic, [~~\$287,000,000~~] *\$335,000,000*; of which [~~\$252,000,000~~] *\$300,000,000* 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.

FY 2022 Proposed General Provision

(Relative to FY 2021 Enacted)

SEC. 226. For purposes of any transfer to appropriations under the heading "Department of Health and Human Services—Office of the Secretary—Public Health and Social Services Emergency Fund", section 204 of this Act shall be applied by substituting "10 percent" for "3 percent".

Appropriations Language Analysis

| Language Provision | Explanation |
|---|--|
| <p><i>For purposes of any transfer to appropriations under the heading "Department of Health and Human Services—Office of the Secretary—Public Health and Social Services Emergency Fund", section 204 of this Act shall be applied by substituting "10 percent" for "3 percent".</i></p> | <p>This language expands the Secretary’s one percent transfer authority in Section 204 of the Public Health Service Act such that the PHSSEF appropriation could be increased by up to ten percent instead of three percent.</p> <p>Building on lessons learned from the COVID-19 pandemic response, an expanded Secretary’s one percent transfer authority would provide additional flexibility for the Department during a public health emergency to accelerate critical activities funded by the PHSSEF appropriation.</p> |

AMOUNTS AVAILABLE FOR OBLIGATION

| Detail | FY 2020 Final /1 | FY 2021 Enacted | FY 2022 President's Budget |
|--|-----------------------------|----------------------------|---|
| General Fund Discretionary Appropriation: | | | |
| Appropriation | 2,737,458,000 | 2,847,458,000 | 3,523,116,000 |
| Supplemental (P.L. 116-94) | 535,000,000 | | |
| Supplemental (P.L. 116-123) | 3,400,000,000 | | |
| Supplemental (P.L. 116-127) | 1,000,000,000 | | |
| Supplemental (P.L. 116-136) | 127,274,500,000 | | |
| Supplemental (P.L. 116-139) | 96,566,000,000 | | |
| Supplemental (P.L. 116-260) | | 48,345,000,000 | |
| Subtotal, Adjusted Discretionary Appropriation | 231,512,958,000 | 51,192,458,000 | 3,523,116,000 |
| Transfer of Funds to: ("HRSA Ryan White HIV/AIDS Program") | (90,000,000) | | |
| Transfer of Funds to: ("HRSA Health Care Systems") | (5,000,000) | | |
| Transfer of Funds to: ("HRSA Rural Health") | (180,000,000) | | |
| Transfer of Funds to: ("HHS Office of Inspector General") | (6,000,000) | | |
| Transfer of Funds to: ("Department of Homeland Security") | (289,000,000) | | |
| Transfer of Funds to: ("HRSA Primary Health Care") | (100,000,000) | | |
| Transfer of Funds to: ("HRSA Covered Countermeasure Process Fund") | (612,000) | | |
| Transfer of Funds to: ("IHS Indian Health Services") | | (790,000,000) | |
| Subtotal, Adjusted Discretionary Budget Authority | 230,842,346,000 | 50,402,458,000 | 3,523,116,000 |
| Mandatory Appropriation: | | | |
| American Rescue Plan Act of 2021, P.L. 117-2 | | 70,110,000,000 | |
| Subtotal, Adjusted Mandatory Appropriation | - | 70,110,000,000 | - |
| Unobligated balance, start of year | 695,908,088 | 86,568,725,061 | |
| Unobligated balance, end of year | 86,568,725,061 | | |
| Unobligated balance, lapsing | 30,336,531 | | |
| Unobligated balance transferred to: ("HRSA Covered Countermeasure Process Fund") | (1,665,897) | (4,167,619) | |
| Unobligated balance transferred from: ("NIH Office of the Director") | 31,690,420 | | |
| Unobligated balance transferred from: ("CDC Public Health Preparedness and Response") | 7,847,723 | | |
| Total obligations | 145,046,022,549 | | |

1/ "Excludes the following amounts for reimbursable activities carried out by this account:
2020 \$161,570,106

SUMMARY OF CHANGES

(Dollars in Millions)

| | | | | | | | |
|--|------------------|--------------|----------------------------|--------------|---------------------|-----------------|-------------|
| 2021 Enacted | | | | | | | |
| Total budget authority..... | | | | | | 2,847.458 | |
| 2022 President's Budget | | | | | | | |
| Total estimated budget authority..... | | | | | | 3,523.116 | |
| Net Change..... | | | | | | +675.658 | |
| | FY 2021 Enacted | | FY 2022 President's Budget | | FY 2022 +/- FY 2021 | | |
| | BA | FTE | PB BA | PB FTE | BA | FTE | |
| Increases: | | | | | | | |
| Assistant Secretary for Preparedness and Response | | | | | | | |
| Preparedness and Emergency Operations..... | 24.654 | 86 | 25.640 | 86 | +0.986 | -- | |
| National Disaster Medical System..... | 63.404 | 124 | 91.807 | 148 | +28.403 | +24 | |
| Hospital Preparedness Program..... | 280.555 | 49 | 291.777 | 62 | +11.222 | +13 | |
| Medical Reserve Corps..... | 6.000 | 6 | 6.240 | 12 | +0.240 | +6 | |
| Preparedness and Response Innovation..... | 2.000 | 3 | 2.080 | 3 | +0.080 | -- | |
| Biomedical Advanced Research and Development Authority..... | 596.700 | 222 | 823.380 | 267 | +226.680 | +45 | |
| Strategic National Stockpile..... | 705.000 | 259 | 905.000 | 329 | +200.000 | +70 | |
| Policy and Planning..... | 14.877 | 66 | 19.917 | 81 | +5.040 | +15 | |
| Operations..... | 30.938 | 135 | 32.176 | 135 | +1.238 | -- | |
| Pandemic Influenza..... | 279.991 | 11 | 327.991 | 11 | +48.000 | -- | |
| Office of the Chief Information Officer - Cybersecurity | 57.820 | 143 | 110.826 | 143 | +53.006 | -- | |
| HHS-wide Cybersecurity | -- | -- | 73.290 | -- | +73.290 | -- | |
| Office of National Security | 8.510 | 37 | 8.983 | 38 | +0.473 | +1 | |
| Office of the Assistant Secretary for Health | -- | -- | 27.000 | 62 | +27.000 | +62 | |
| Total Increases..... | 2,070.449 | 1,141 | 2,746.107 | 1,377 | +675.658 | +236 | |
| Net Change..... | | | | | | +675.658 | +236 |

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Millions)

| Activity | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget |
|---|------------------|--------------------|----------------------------------|
| Bioterrorism and Emergency Preparedness | 2,477.458 | 2,560.458 | 3,188.116 |
| Pandemic Influenza | 260.000 | 287.000 | 335.000 |
| Total Budget Authority | 2,737.458 | 2,847.458 | 3,523.116 |
| FTE | 978 | 1,152 | 1,388 |

1/ Excludes supplemental appropriations

AUTHORIZING LEGISLATION

(Dollars in Millions)

| Activity | FY 2021 Amount Authorized | FY 2021 Amount Appropriated | FY 2022 Amount Authorized | FY 2022 President's Budget |
|----------------------------------|---------------------------------|-----------------------------------|---------------------------------|----------------------------------|
| National Disaster Medical System | 57.404 | 63.404 | 57.404 | 91.807 |
| Hospital Preparedness Program | 385.000 | 280.555 | 385.000 | 291.777 |
| Medical Reserve Corps | 11.200 | 6.000 | 11.200 | 6.240 |
| BARDA | 611.700 | 596.700 | 611.700 | 823.380 |
| Project BioShield | 710.000 | 770.000 | 710.000 | 770.000 |
| Strategic National Stockpile | 610.000 | 705.000 | 610.000 | 905.000 |
| Pandemic Influenza | 250.000 | 287.000 | 250.000 | 335.000 |

APPROPRIATIONS HISTORY

(Dollars in millions)

| Details | Budget Estimate to Congress | House Allowance | Senate Allowance | Appropriation |
|---|-----------------------------|-----------------|------------------|---------------|
| FY 2015 | | | | |
| Appropriation | | | 1,389.813 | 1,233.069 |
| Supplemental Appropriation | | | | 733.000 |
| Subtotal | - | - | 1,389.813 | 1,966.069 |
| FY 2016 | | | | |
| Appropriation | 1,909.981 | | | 1,532.958 |
| Supplemental Appropriation (PL 114-223) | | | | 387.000 |
| Transfer to CMS | | | | (75.000) |
| Transfer to HRSA | | | | (66.000) |
| Transfer to OIG | | | | (0.500) |
| Transfer to GAO | | | | (0.500) |
| Subtotal | 1,909.981 | - | - | 1,777.958 |
| FY 2017 | | | | |
| Appropriation | 1,431.117 | 1,631.258 | 1,517.958 | 1,532.958 |
| Transfer to ACF | | | | (3.520) |
| Subtotal | 1,431.117 | 1,631.258 | 1,517.958 | 1,529.438 |
| FY 2018 | | | | |
| Appropriation | 1,662.616 | 1,739.258 | 1,552.958 | 1,953.458 |
| Supplemental Appropriation (PL 115-123) | | | | 162.000 |
| Transfer to HRSA | | | | (60.000) |
| Transfer to SAMHSA | | | | (20.000) |
| Transfer to OIG | | | | (2.000) |
| Subtotal | | | | 2,033.458 |
| FY 2019 | | | | |
| Appropriation | 2,303.877 | 2,046.458 | 2,813.128 | 2,021.458 |
| Transfer from CDC | | | | 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 |
| Supplemental Appropriation (PL 116-123) | | | | 3,400.000 |
| Transfer to OIG | | | | (2.000) |
| Transfer to HRSA | | | | (100.000) |
| Supplemental Appropriation (PL 116-127) | | | | 1,000.000 |
| Supplemental Appropriation (PL 116-136) | | | | 127,274.500 |
| Transfer to HRSA | | | | (275.612) |
| Transfer to DHS | | | | (289.000) |
| Transfer to OIG | | | | (4.000) |
| Supplemental Appropriation (PL 116-139) | | | | 96,566.000 |
| FY 2021 | | | | |
| Appropriation | 2,641.465 | 2,827.458 | 2,913.458 | 2,847.458 |
| Supplemental Appropriation (PL 116-260) | | | | 48,345.000 |
| Transfer to IHS | | | | (790.000) |
| Supplemental Appropriation (PL 117-02) | | | | 70,110.000 |
| FY 2022 | | | | |
| Estimated Appropriation | | | | 3,523.116 |

APPROPRIATIONS NOT AUTHORIZED BY LAW

(Dollars in Millions)

| Program | Last Year of Authorization | Authorization Level | Appropriations in Last Year of Authorization | Appropriations in FY 2021 |
|--|-----------------------------------|----------------------------|---|----------------------------------|
| 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 |

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Summary of Request

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 2,664.119 | 2,774.119 | 3,296.008 | +521.889 |
| FTE | 847 | 961 | 1,134 | +173 |

1/ Totals include ASPR's portion of pandemic influenza funding.

2/ Excludes emergency supplemental appropriations.

The Fiscal Year (FY) 2022 President's Budget for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is \$3,296,008,000, an increase of +\$521,889,000 above FY 2021 Enacted. ASPR's goal for FY 2022 is to build preparedness and achieve new successes in public health emergency management. ASPR has focused proposed resources on addressing preparedness and response capacity gaps and lessons learned in the ongoing COVID-19 pandemic response efforts.

ASPR leads our nation's progress in public health emergency response. Congress statutorily established ASPR after Hurricane Katrina and addressing those weaknesses in emergency management and response 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. ASPR has mobilized this infrastructure and demonstrated its value in the ongoing response to the COVID-19 pandemic.

In addition, ASPR leads policy development, collaboration, and advanced 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 18 chemical, biological, radiological and nuclear threats identified by the Department of Homeland Security (DHS).

These advanced development programs have supported 28 products under Project BioShield; 18 of these products have been procured for the Strategic National Stockpile (SNS), with additional products to be delivered in FY 2021 and 2022. ASPR leveraged existing partnership and projects to quickly react to the threat of COVID-19. Notably, ASPR has supported seven COVID-19 vaccine candidates with the goal of delivering safe and effective vaccines to every American. To that end, ASPR has supported manufacturing in parallel with clinical trials to expedite the traditional vaccine development timeline.

ASPR, 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 18 CBRN threats as identified by DHS. These advanced development programs have supported 28 products that have transitioned to support under PBS, 18 of which have been procured for the SNS. These efforts have led to 59 FDA licensures, approvals, or clearances of MCMs since 2008, 22 of which focus on countering CBRN threats (eleven approved under the FDA's Animal Rule). For FY 2022, ASPR will continue to develop and procure new antiviral therapeutics and vaccines for Ebola Sudan and Marburg viruses, a second antiviral smallpox candidate, new antimicrobial diagnostic devices and drugs, chemical agent MCMs, and a new thermal burns MCM.

The Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) was established in 2016. CARB-X is 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. CARB-X has funded 82 different candidates and currently has 56 active programs for the development of 41 therapeutics, eight vaccines, and seven diagnostics. Seven CARB-X portfolio candidates have entered clinical development, highlighting the success of this program in accelerating early-stage product development to the clinic.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019 requires that a review be conducted 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 to an overall goal of 6,882 personnel. This assumes 69 NDMS response teams (6,290 personnel), Logistics specialists (230 personnel), and Incident Management Team members (362 personnel). There are currently over 3,000 deployable personnel available out of the over 4,000 hired personnel in various stages of completing deployment readiness.

In 2020, due to the aggressive operational tempo for COVID-19 response, and prudent social distancing and travel restrictions, NDMS was not able to conduct the full schedule of in-person trainings, but was still able to create and provide numerous just-in-time online courses to prepare responders for COVID-19 missions. Innovative online training modules were rapidly created to prepare responders to fulfill various COVID mission requirements including – the novel treatment of monoclonal antibodies administration, vaccine administration of countermeasures under Emergency Use Authorizations (EUAs), COVID-19 testing, public health and epidemiological contact tracing, use of new respiratory personnel protective equipment, emergency response under COVID-19 conditions, and several others. In addition, ASPR supported training nearly 1,000 new intermittent responders. ASPR anticipates that the staffing of intermittent response employees will increase toward the target of 6,720 personnel in FY 2021.

The [HHS emPOWER program](#) (emPOWER) 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. Its expanding portfolio of data-driven tools and resources helps public health authorities (PHA) and their community partners protect the health of more than 4.2 million individuals

who live independently and rely on life-maintaining electricity-dependent durable medical and assistive equipment and devices¹ and essential health care services.² ASPR's HHS emPOWER Program provides PHAs and their community partners in all 50 states and 5 territories with mission-critical tools and resources including [dynamic datasets](#), [mapping tools](#), [comprehensive training programs](#), [informational resources](#), and nearly 24/7 real-time technical assistance to protect the health of more than 4.2 million individuals who live independently and rely on life-maintaining electricity-dependent durable medical and assistive equipment and devices and essential health care services. In FY 2020, emPOWER launched an innovative, [award-winning](#) AI tool, [emPOWER AI](#), which puts emPOWER data into the hands of first responders, PHAs, emergency managers, health care providers, and other community partners within seconds, wherever they are. Over 72,000 individuals have used the public [HHS emPOWER Map](#) since 2015 and users nationwide have accessed the [HHS emPOWER REST Service](#) over 360,000 times since 2017 to help communities address the needs of electricity-dependent individuals prior to, during, and after incidents, emergencies, and disasters. In FY 2020, over 11,401 individuals used the Map while their communities supported preparedness and response activities during the COVID-19 pandemic and other disasters.

The Hospital Preparedness Program (HPP) and the other programs that make up the HPP appropriation fulfill ASPR's mission by strengthening health care sector readiness to provide coordinated, life-saving care in the face of emergencies and disasters. These programs provide strong leadership in health care preparedness and response through data-driven insights, proven and innovative practices, ready resources, and strategic partnerships. During the COVID-19 pandemic, HPP's portfolio of initiatives supported health care on the front lines of this unprecedented event – while continuing to manage a broad portfolio of all-hazards health care preparedness programs to mitigate instances of civil unrest, wildfires, and hurricanes across the country. Now more than ever before, it is critically important to continue to invest in HPP's portfolio of programs to enhance the readiness of the nation's health care sector against all hazards.

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). The current monthly web visitation surpasses an average of 16,000 visits per month, with visitor volume reaching over one million in December 2020 (concurrent with the COVID-19 pandemic). The monthly number of technical assistance requests received has increased steadily in the last five years, including a record 569 requests processed in September 2020. ASPR TRACIE has also experienced an increase in requests that are complex and highly specialized, requiring significant time and specific subject matter expertise to complete them. ASPR TRACIE is increasingly seen as a “go to” resource during disasters and in preparation for disasters. ASPR TRACIE has identified [over 10,000 resources](#) to include in the ASPR TRACIE database and developed [over 350 resources](#) to fill identified gaps and information needs.

¹ Electricity-dependent durable medical and assistive equipment and devices include, but are not limited to, ventilators, oxygen concentrators, home dialysis, and electric wheelchairs.

² Essential health care services include outpatient facility dialysis, oxygen tank services, home health care services, and home hospice care services.

Increases above FY 2021:

Biomedical Advanced Research and Development Authority (BARDA)/Advanced Research and Development (ARD): The budget request for Advanced Research and Development is \$823,380,000, which is +\$226,680,000 above FY 2021 Enacted. The budget will expand BARDA innovation efforts through its DRIVe program, the advanced development of broad-spectrum antimicrobials including vaccines, diagnostics, and novel antibiotic treatments, and bolster scientific staff and related support staff and services. The budget will also expand funding for vaccines and therapeutics for viral hemorrhagic diseases, next generation smallpox therapeutics, countermeasures against chemical threats, development of next generation therapeutics against botulinum toxin, and vaccines against anthrax.

Strategic National Stockpile (SNS): The budget requests \$905,000,000 for SNS, which is +\$200,000,000 above FY 2021 Enacted. Building on the COVID-19 response, the request would make meaningful investments across a number of portfolios necessary to ensure readiness for future public health emergencies. Additional funds will also be used to sustain on-going investments in SNS capacity and infrastructure, such as warehousing costs.

Pandemic Influenza (PI): The budget requests \$335,000,000 for Pandemic Influenza activities, which is +\$48,000,000 above FY 2021 Enacted. The request address priorities as outlined in the Executive Order on Modernizing Influenza Vaccines in alignment with the corresponding National Influenza Vaccine Modernization Strategy (2020-2030). Additional funds will be used to advance synthetic influenza vaccine platforms, efforts to transfer technologies to public-private partnerships to improve influenza pandemic response, and alternative influenza vaccine delivery systems.

National Disaster Medical System (NDMS): The budget requests \$91,807,000 for NDMS, which is +\$28,403,000 above FY 2021 Enacted. The request will help to ensure NDMS will be able to meet demands for additional individual and team training to ensure mission readiness, including additional hands-on and online training for new NDMS employees. The budget also includes \$6,000,000 to continue the Pediatric Disaster Care program.

Hospital Preparedness Program (HPP): The budget requests \$291,770,000, which is +\$11,220,000 above FY 2021 Enacted. Within the total, \$240,000,000 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.

Policy and Planning: The budget requests \$19,917,000, which is +\$5,040,000 above FY 2021 Enacted. The request includes +\$5,000,000 to allow ASPR to build on lessons learned from the COVID-19 response through after action reviews to recalibrate existing efforts and anticipate, and prepare for, future emergencies and other events.

Operations: The budget requests \$32,176,000, which is +\$1,238,000 above FY 2021 Enacted. These funds foster leadership and strategic management, ensuring a collaborative and comprehensive approach to implementing ASPR's goals and strategies. As acquisition needs grow, ASPR will need to provide additional support to ensure timely and accurate awards. ASPR will also provide additional resources to its financial management mission in order to ensure oversight of ASPR's resources, performance, ERM, and integration to strategic planning. In addition, funding will ensure the effective recruitment and retention of ASPR's human capital assets.

Public Health and Social Services Emergency Fund

Preparedness and Emergency Operations (PEO): The budget requests \$25,640,000, which is +\$986,000 above FY 2021 Enacted. The FY 2022 request supports preparedness and response efforts for public health and medical emergencies and a robust Continuity of Operations (COOP) program. This request also continues \$5,000,000 in three-year funding to prepare for, and respond to, National Special Security Events, public health emergencies, and other events that are not eligible for assistance under the Stafford Act.

Medical Reserve Corps (MRC): The budget requests \$6,240,000, which is +\$240,000 above FY 2021 Enacted. 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.

Preparedness and Response Innovation (PRI): The budget requests \$2,080,000, which is +\$80,000 above FY 2021 Enacted. The FY 2022 request for PRI will sustain initial FY 2021 program investments.

Preparedness and Emergency Operations

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|--|---------------|-----------------|----------------------------|---------------------|
| Budget Authority | 24.654 | 24.654 | 25.640 | +0.986 |
| <i>National Special Security Events/ Public Health Emergencies (non-add)</i> | 5.000 | 5.000 | 5.000 | -- |
| FTE | 86 | 86 | 86 | -- |

Authorizing Legislation:

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

Program Description and Accomplishments

ASPR strives to respond to events and 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 emergency response events. When ASPR responds to emergencies, it deploys resources (subject matter experts, medical personnel) and supporting logistics (medical caches, lifesaving supplies, and equipment) to disaster areas. During times of relatively minor response activities, or during “peacetime,” ASPR prepares by enhancing 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, information sharing, 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 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 Number 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 Sandy in 2012; Harvey, Irma, and Maria in 2017; Florence, Michael, and Typhoon Yutu in 2018; and Dorian and Typhoon Wutip in 2019. 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 2019 provided support to California for simultaneous wildfires, including the Kincadee fire, throughout the state. In FY 2020, ASPR responded to the earthquakes in Puerto Rico, the California and Oregon wildfire season, and has played an unprecedented role in the response to COVID-19, including the repatriation of American citizens from Wuhan, China. The COVID-19 response activities have carried over into FY 2021 and include support for both therapeutic and vaccine administration, expanding the supply chain for personal protective equipment and other deployable assets, and managing the healthcare surge need to respond to the pandemic. In addition, ASPR supports several of planned annual events including: the President's State of the Union Address; the Peace Officer's Memorial and Independence Day celebrations in Washington, DC; as well as Democratic and Republican National Conventions, Presidential Inaugurations, and Presidential addresses to Congress.

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 and medical response capabilities, the delivery of health care during and after incidents, and the maximizing of emergency response systems to minimize the effects of manmade or natural disasters. 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 personnel, 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 collaborates with FEMA and other interagency partners to maintain and periodically revise a comprehensive national information collection and decision support system entitled 'Lifelines'. This system highlights the interdependencies of different industries, infrastructure resources, and disciplines to better shape national decisions on resource prioritization and the focus of lifesaving efforts.

Additionally, ASPR coordinates the development of HHS contingency plans for chemical, biological, radiological and nuclear (CBRN) threats and other catastrophic incidents, such as the ongoing COVID-19 pandemic, hurricanes, earthquakes, and man-made disasters. In addition to these plans for catastrophic incidents, ASPR has supported several crisis response incidents through the development of National Support Plans and Incident Support Plans for incidents such as COVID-19, 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 National Independence Day Celebration, and the immediate response to public health emergencies. For these special events, ASPR coordinates medical and public health support for both the event and contingency response, averaging the alert and deployment of approximately 500 medical responders per year.

ASPR is also spearheading a major national planning effort to enhance the Nation's ability to quickly dispense medical countermeasures (MCMs) during a public health emergency. The initiative, known as "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 2022, ASPR anticipates the following planning activities:

- Continue to lead the Department's COVID-19 pandemic response planning efforts, as necessary, as well as lead/coordinate inter- and intra-agency revisions to existing pandemic response and recovery plans;
- Update 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;
- Revise the Nuclear-Radiological Annex to Federal Interagency Operational Plan;
- Develop of Medical Critical Infrastructure Disruption Annex;
- Update the Natural Disaster Annex and Earthquake Appendix to ASPR's All-Hazards Plan; and,
- Amend the HHS Continuity of Operations Plan.

ASPR Incident Response Framework

On May 2, 2019, ASPR announced the official release of the HHS ASPR Incident Response Framework (IRF), with an update released in January 2021 that includes lessons learned from the COVID-19 response. 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 response framework was exercised in August 2019 during the Crimson Contagion exercise and has been used in multiple responses since the exercise. For example, it was used for the 2019 Hurricane Dorian response and, more recently, during the 2020 COVID-19 repatriation mission to repatriate American citizens on multiple flights from Wuhan, China and the cruise ship off of the coast of Japan.

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 SOC was at the forefront of the novel coronavirus outbreak in China, providing timely situation reports in December of 2019. The SOC provides uninterrupted surveillance of emerging threats and critical incidents, nationally and internationally, 24 hours a day, seven days a week, 365 days a year. This unique capability ensures that HHS is fully prepared to activate its lead role for ESF-8 and its support role for ESF-6. When activated by FEMA, ASPR representative(s) deploy to the FEMA National Response Coordination Center (NRCC) to serve as HHS's ESF-8 Lead Information Manager. The NRCC program provides a direct link for interagency coordination and information sharing between HHS's Incident Support Team (IST), Information management Section, and Incident Management Team (IMT), and other activated NRCC ESF's and Sections within the NRCC, and FEMA headquarters. The SOC monitors information from Federal, state, localities, territories and tribes (SLTT), private sector, non-profit, and international partners, in order to identify emerging threats to public health in real-time. The SOC analyzes this information, alerts subject matter experts and on-call personnel, and uses multiple methods including text messages, phone calls, and emails to inform decision-makers and enable rapid Federal ESF-8 response.

With the COVID-19 Federal Public Health Emergency (PHE) declaration, this allowed SLTT to request temporary reassignment of personnel from the U.S. Public Health Service (USPHS) Act program-funded work, to roles supporting the public health emergency response. The SOC served as the facilitator and conduit for the COVID-19 Temporary Reassignment process and represented HHS/ASPR and interfaced with SLTT requestors, HHS Disaster Leadership Group (DLG), granting agencies and HHS Senior Leadership. As the SOC received State respiratory ventilator requests, SOC staff extensively documented and tracked State requests through the process. The SOC coordinated and processed 2,638 COVID-19 Temporary Reassignment requests, resulting in the reassignment of the equivalent of 43,045 federal employees to better combat this pandemic.

The SOC serves as the International Health Regulations Focal Point for the United States, facilitating the sharing of information with partner nations and international Agencies. In this capacity the SOC received and transmitted Public Health Emergencies of International Concern (PHEICs), time sensitive contact tracing information, official reports for the novel coronavirus and outbreaks. The correct routing of these messages is vital to public health communications in the United States, and message traffic exceeded 60,000 messages in the first three months of 2020 reaching all-time highs and consistently staying at this level for months.

During the 2020 Puerto Rico Earthquake, SOC quickly sent out alerts and notifications and created briefing materials for leadership to assist in decision-making. Due to the widespread power outages across the island and the impact to three hospitals and multiple dialysis centers, HHS deployed a 10-person team to assess medical shelter set up support at Camp Santiago and five 'Survivor Base Camps,' activated the Emergency Prescription Assistance Program (EPAP), released emPOWER data and coordinated behavioral health counselors where needed. The 2020 hurricane season was record breaking with 30 named storms formed, with 13 becoming hurricanes and six becoming major hurricanes. A record 12 named storms made landfall in the U.S. killing over 400 people and destroying property and

infrastructure totaling in excess of \$41 billion for the season. For these incidents and events, ASPR maintained an operational structure and processes that enabled situational awareness and ensured resources; staffing, planning and information support.

During the USG engagement in humanitarian assistance in the aftermath of the deadly explosion in Beirut (2020 Beirut Explosion Humanitarian Mission, Lebanon), ASPR deployed an advance team to liaise with the Government of Lebanon and forward USG entities. The team assessed and identified four hospitals of concern, identified six main interconnected problems facing the Beirut hospital infrastructure and provided five key recommendations for consideration.

The SOC also coordinates and synchronizes all logistics and resources management activities. These activities include processing thousands of resource requests for personnel and material to ensure requests are promptly tasked to the appropriate resource provider throughout HHS or other Federal Agencies. During FY 2020, the following events were supported by 9,948 deployed personnel and 156 kits/caches totaling 4,490 tons of equipment to include every type of cache and kit.

FY 2022 ASPR SOC anticipated activities include:

- Increasing the resiliency of SOC staffing to enable continued support for current and emergent threats.
- Implementing a standardized SOC certification program to ensure all support personnel are trained and capable to support the SOC's mission;
- Updating the SOC's communications capabilities including IT and communications equipment in the SOC's COOP facility;
- Developing and implementing a SOC Steering Committee to manage corrective actions and to ensure timely execution of improvement initiatives;
- Scoping and developing a plan to obtain and incorporate the necessary technology resources and support structure to transition the SOC's COOP facility from a warm to a hot site;
- Assessing the SOC's programmatic areas and adjusting to align with the Program Support Branch staffing model;
- Implementing a comprehensive SOC augmentee training program; and,
- Building out of SOC augmentee space.

Information Management and Situational Awareness

The ASPR information management program serves as the focal point of information gathering, analysis, and reporting for ASPR during all responses to public health emergencies and national special security events. This program leads the production of various information products (e.g., Senior Leadership Briefs) that support the needs of decision makers at various levels within HHS and other federal agencies. Before, during, and after a disaster, analyzing data and identifying trends over time are key to understanding the event's impact and corresponding need for federal assistance to states and communities. Highly trained personnel use specific analytical tools to make collected data understandable, actionable, and accessible to all those who need it, when they need it. Information management activities also include the integration of quantitative and qualitative information across ASPR and other data streams to support regional and headquarters-based senior decision makers with high quality, real-time data that helps to identify emerging issues, provide decision support, and enhance situational awareness of medical and public health events.

In FY 2022 Information Management activities will include:

- Enhancing data integration and situational awareness to the ASPR regions through the information management personnel assigned to each region who will serve as the support for information sharing and situational awareness in steady state and response operations.
- Expanding analysis, visualization, and integration of data and information from multiple internal and external sources, and enhance near-real time analysis using tools including the Geospatial Information System (GIS)-based GeoHEALTH Platform, Tableau, Operational Data Analysts, and social media analytics.
- Automation and production of response products for notice and no-notice events.
- Development, refinement, and deployment of training and job duty books to ensure consistency in information products and support before, during, and after a response.

Information Technology and Cybersecurity

ASPR's ability to execute its mission is through the dependence on a robust, reliable, and resilient information technology and communications infrastructure. From the audio visual technologies in the Secretary's Operations Center and the communications capabilities in NDMS, to the development of systems like GeoHEALTH, and the SNS Supply Chain Control Tower, or the establishment of an ASPR Common Operating Picture are a few examples of the integrated role of information technology and cybersecurity on ASPR's preparedness and emergency operations capability.

The information and data collected, analyzed, stored, and shared by the all of these systems, applications, and program areas must be protected. The connection of these systems to the internet introduces significant vulnerability and susceptibility to cyber threats compromising the confidentiality, integrity, and availability of critical information during a time of crisis. ASPR works to provide information assurance, risk mitigation and management, and compliance to federal laws such as the Federal Information Security Modernization Act (FISMA) and other directives, standards and policies set for by the department.

Throughout FY 2020 and FY 2021, ASPR has seen a dramatic increase on its dependence of IT systems. Hurricane Dorian, the California Wildfires, and ASPR's engagement supporting the COVID-19 response has developed greater dependence and introduced new IT systems, applications, and platforms to meet the evolving demand and mission requirements.

Operational Intelligence

ASPR established an intelligence function in 2018 to enhance alerting and situational awareness. The intelligence operations mission is to provide ASPR leadership and subordinate elements with accurate, timely, and tailored intelligence information to reduce uncertainty, increase situational awareness, and enhance the planning and execution of risk management and response functions in support of the ASPR mission. Intelligence personnel operate within the appropriate parameters of HHS as a non-Title 50 (NT50) agency and focuses primarily on coordinating NT50 partners and HHS' Office of National Security (ONS) to provide finished intelligence products to ASPR decision makers. Since 2018 and into FY 2021, operational intelligence has supported preparedness and response activities by preparing threat assessments, providing real-time situational awareness reports, and compiling other focused intelligence products to support emergent requirements and responses/deployments.

In FY 2022, ASPR intelligence operations will continue working with HHS and ASPR components to enhance information sharing and provide leadership with holistic threat assessments to healthcare and public health assets. This includes:

- Implementing ASPR's key intelligence requirements to facilitate engagement with the interagency and ensure ASPR maintains proper situational awareness on existing and emerging threats that may impact ASPR operations;
- Integrating intelligence analysis into ASPR activities and products to better inform on the potential impacts to operations; and,
- Compiling and maintaining the ASPR Weekly Readbook and leading monthly ASPR senior leadership threat briefings.

Continuity of Operations Before, During, and After Emergencies

In accordance with presidential and Federal directives, ASPR ensures the continuation of HHS's essential mission, business, and support functions during all hazards. Through management of the Department's Continuity of Operations (COOP) and Continuity of Government (COG) programs, which serve the entire Department, ASPR manages all facets of the HHS continuity program to provide HHS with a consistent and resilient program, integrated into daily operations. Accordingly, ASPR handles the day-to-day operations and implementation of the OS and ASPR Continuity Programs, including maintenance of a continuity facility and maintaining continuity communications systems in a state of constant readiness. Additionally, ASPR drafts and refines the overarching policy, for Secretarial approval, and planning documents to scope and define the HHS unified COOP and COG Programs.

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. HHS has seen increased alternate, contingency, and 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. In FY 2020, ASPR implemented an integrated communications architecture that will provide secure cellular and satellite, along with low side high frequency radio technology, to key HHS and ASPR leadership and regional offices.

ASPR also leads the reviews and evaluations of the various plans, procedures, analyses, and other doctrine that comprise and structure the HHS COOP and COG programs. Most recently, in FY 2018-2020, ASPR's efforts have led to additional cohesion within the HHS program, as seen during the seamless adoption of modified continuity-driven postures in response to COVID-19, while eliminating redundancies, creating efficiencies in information sharing and situational awareness, and addressing gaps in a cost-effective manner. HHS implemented mandatory telework and increased information technology speed and capacity, allowing HHS employees to continue to support all Departmental essential functions without degradation.

On an annual basis, ASPR develops and facilitates several continuity-focused testing, training, and exercise events to strengthen and assess the HHS COOP program. FY 2019 saw ASPR host two

exercises with HHS and ASPR senior leadership to meet the White House's annual continuity exercise and interagency evaluation requirements. FY 2020 saw a shift in the annual structure of interagency continuity exercises due to the COVID-19 pandemic. HHS stepped to the forefront by planning and hosting several internal exercises for ASPR prior to the declaration of the global pandemic. These exercises stressed the infrastructure supporting conduct of daily operations, and prepared ASPR leadership and employees to function in a mostly telework environment.

For FY 2021-2022, the expectation is that the Executive Branch will resume regular annual continuity exercise activities. To that end, ASPR will lead HHS participation in interagency activities scheduled for May 2021 and focused on resuming normal operations. Additionally, ASPR is planning an internal continuity exercise series for HHS, with events tentatively scheduled to occur in October and November 2021 that will focus on cyber-security, electromagnetic pulse disruptions, and other priorities established by HHS and ASPR leadership. FY 2022 will see continuity of operations included within National Level Exercise activities, tentatively scheduled for May or June 2022. Additional milestone accomplishments in FY 2021-2022 are expected to include:

- Administration of continuity planning and program management for ASPR in a manner that continues to allow ASPR HQ and regional leadership and employees to work from multiple alternate locations, using various technologies, to continually perform the mission essential functions and tasks of ASPR without interruption.
- Providing HHS senior leaders with a forum to share situational awareness, deliberate, and make recommendations to the HHS Secretary and the ASPR regarding possible continuity activations and personnel movement or direction, in response to real-world incident responses or exercise scenarios.
- Creation of a multi-year strategy and program management plan for HHS covering CY 2021-2025.
- Continued delivery of the annual HHS-wide continuity exercise series of events with HHS senior leadership, as well as with all HHS continuity personnel.
- Maintaining a fully mission capable alternate site for HHS and ASPR leadership, without any degradation to operational capabilities and to support all command, control, and communications needs following a disruption to normal operations at headquarters location.
- Continued 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, and HHS meets an average of 97.5 percent across the quarters of FY 2021-2022 for all required continuity communications capabilities.
- Review of and update to an impact analysis examining possible impacts and vulnerabilities to the Primary Mission Essential Functions and supporting mission essential functions and tasks for all Operating and Staff Divisions within HHS.
- Creation or further refinement of a business process analysis for each HHS Operating and Staff Division outlining leadership, staff, communications, and facilities needs in order to perform individual mission essential functions.

Personnel Security Operations

The ASPR preparedness and response mission requires the proper security of ASPR assets—locations, systems, and personnel. To protect these assets, it is the responsibility of the ASPR security personnel to manage all national security clearance functions and all personnel on-boarding security functions for

ASPR, including personnel assigned to the NDMS. Currently, ASPR tracks and manages over 500 national security clearances and 100 public trust clearances, maintains a vigorous access control process for all ASPR facilities, and requires the services of a Special Security Officer (SSO) and other Federal Personnel Security Specialists to manage ASPR's classified spaces and its 100 plus granted special accesses.

In FY 2020 alone, ASPR processed more than 2,000 visitor access requests (VARs), 160 new applicant security packages, and 500 security badge requests. Due to increased operations from COVID-19 and the increase of personnel to maintain these operations, the number of personnel security actions and activities has only continued to increase in FY 2021. In FY 2022, personnel security operations are expected to stay at increased levels from FY 2020 and security personnel activities will include the same security process activities, as in previous years, to secure ASPR's assets.

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 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. 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 corrective action plan (CAP) Newsletter to highlight significant lessons learned and/or finalized corrective actions.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$24,654,000 |
| FY 2019 | \$24,654,000 |
| FY 2020 | \$24,654,000 |
| FY 2021 Enacted | \$24,654,000 |
| FY 2022 President’s Budget | \$25,640,000 |

Budget Request

The FY 2022 President’s Budget request for PEO is \$25,640,000, which is \$986,000 above FY 2021 Enacted. The increased funding will offset increasing program and staffing costs. The request will continue current SOC staffing levels to ensure execution of the SOC’s mission essential functions including monitoring and detection and alert and notification, as well as continued implementation of the ASPR Incident Response Framework and situational awareness activities for planning and decision support.

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.

National Disaster Medical System

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|--|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 57.404 | 63.404 | 91.807 | +28.403 |
| <i>Pediatric Disaster Care Program (non-add)</i> | -- | 6.000 | 6.000 | -- |
| FTE | 115 | 124 | 148 | +24 |

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, can request the National Disaster Medical System (NDMS) to help their communities respond, recover, and protect public health. NDMS capabilities, requested through ASPR Regional Administrators, are unique assets able to deliver surge 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 U.S. Department of Health and Human Services (HHS) emPOWER program’s federal health data to identify medically fragile individuals, and pre-emptively take action to protect those most at risk in a public health emergency or disaster.

The NDMS mission is to support communities with medical services during or after a disaster or public health emergency, and to support the DOD and Veterans Affairs (VA) in cases of a surge in military casualties that could overwhelm their medical systems. Since its establishment in 1989, NDMS has responded to over 300 domestic incidents, and two international incidents. NDMS personnel typically hold positions in their own communities across the country, and become temporarily federalized to provide healthcare assistance to communities impacted by 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 healthcare facilities in impacted communities as the request of the state, territorial or tribal government. NDMS responders are the silent heroes in responses. NDMS responders have an option to deploy or not, but they consistently put their lives on hold when the nation calls for their assistance.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019 provides NDMS with additional authorities to strengthen the hiring process and ensure that the NDMS workforce is adequate to meet future operational requirements. For example, PAHPAIA provided authorities to support faster recruitment and hiring of NDMS personnel. Using the hiring authorities in PAHPAIA, ASPR is working to increase its intermittent employee workforce to meet the overall goal of 6,882 personnel. This assumes 69 NDMS response teams (6,290 personnel), logistics specialists (230 personnel), and Incident Management Team members (362 personnel) across three separate and distinct programs. Over 3,000 deployable personnel currently are available out of the over 4,000 hired personnel

in various stages of completing deployment readiness. NDMS teams include clinical providers and specialized medical service professionals, including physicians, nurses, advance healthcare providers, fatality management professionals, paramedics, veterinarians, and other support staff, such as logisticians and information technology technicians. 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 Special Security 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. The revised policy introduced in January 2020 delineates the ASPR intermittent responder physical readiness requirements needed to meet readiness standards. Given the complex and potentially austere response environments, the risk for injury and illness factors into the need for responders to be aware and prepared to deploy safely and effectively.

To promote visibility of hiring challenges going forward, PAHPAIA requires the HHS 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 these issues. With this reporting requirement, Congress will be aware of the existing challenges if/when they occur.

NDMS Training

Disaster medical response is a unique medical discipline that requires specialized training in the unique skills and competencies required for effective disaster medical response. NDMS continues to provide individual and team training to all team members based on roles and team mission requirements. Currently, NDMS trains a minimum of twenty percent of its workforce per annum. Ideally, NDMS seeks to increase this to provide online basic skills refresher training to 100 percent of its deployable personnel and in-person hands-on skills training to 35 percent of deployable members each year. This would achieve reasonable currency in disaster medical skills and proficiency. The unique nature of NDMS team employees as permanent excepted–service federal employees utilized on an episodic intermittent basis means that funding has to be provided to pay for salaries of these intermittent employees when they are activated for training.

In 2020, due to the aggressive operational tempo for the COVID-19 pandemic response, and prudent social distancing and travel restrictions, NDMS was not able to conduct the full schedule of in-person trainings, but was still able to create and provide numerous just-in-time online courses to prepare responders for COVID-19 missions. Innovative online training modules were rapidly created to prepare responders to fulfill various COVID mission requirements including – the novel treatment of monoclonal antibodies administration, vaccine administration of countermeasures under Emergency Use Authorizations (EUs), COVID testing, public health and epidemiological contact tracing, use of new respiratory personnel protective equipment, emergency response under COVID conditions, and several others. Almost 2,000 NDMS employees completed the just-in-time COVID prep training online, over 3,600 completed the newly revised blood-borne pathogen course, and approximately 1,000 NDMS employees combined completed vaccine and other new online COVID-related courses.

NDMS Teams

- ***Disaster Medical Assistance Teams (DMAT):*** The DMATs provide medical care and support during public health and medical emergencies, man-made as well as natural and technological disasters, acts of terrorism, disease outbreaks, and special events including National Special Security Events (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 staff, 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.
- ***Trauma Critical Care Teams (TCCT):*** The TCCT provides 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 TCCT is configured to deploy as a 9-person HMTF, a 10-person HMTF, a 28-person team, and a 48-person team with the capacity to conduct specific trauma related actions. The TCCT is staffed strongly with board-certified and practicing surgical and trauma professionals. In FY 2020, this specialized team was deployed to assist overrun hospitals with COVID-19 patients to manage intensive care units with their specialized skill sets.
- ***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 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 the 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. DMORT team responders are utilized as a bridge of information from the SLTT to the Regions and many times to headquarters to provide subject matter expertise.
- ***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.
- ***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

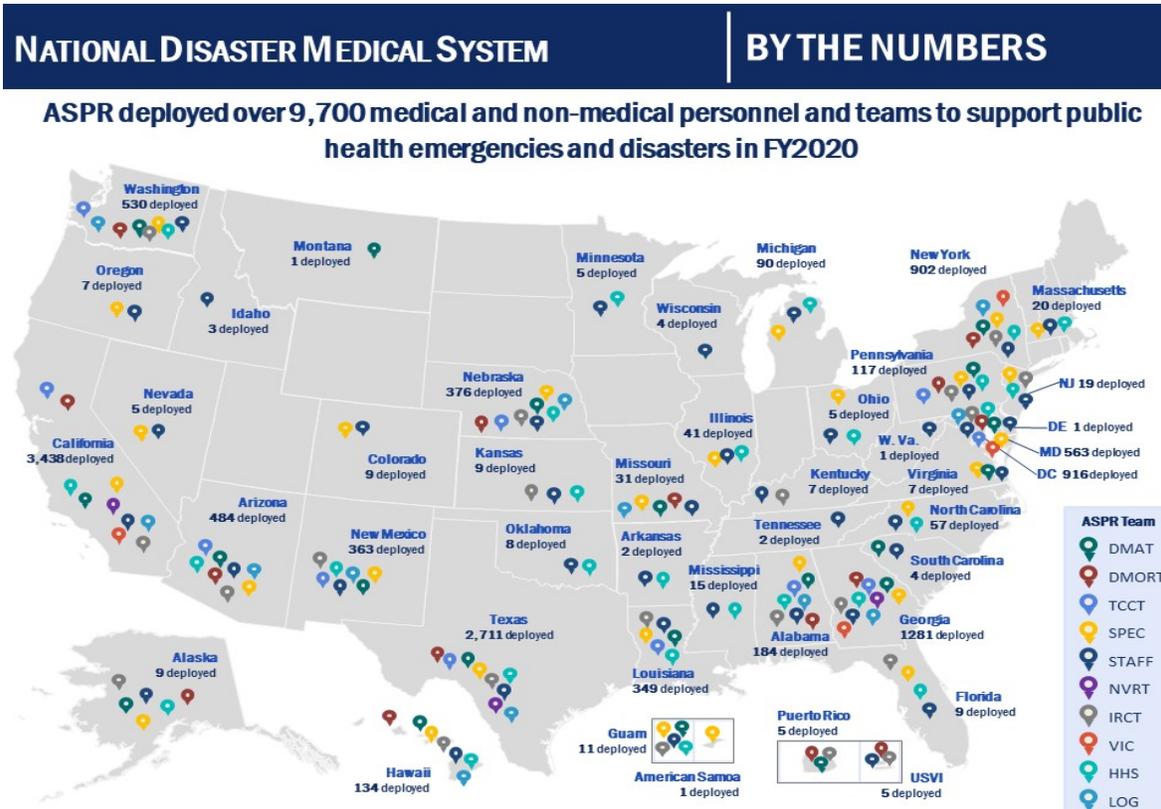
is primarily composed of Veterinarians and Animal Health Technicians to facilitate the stabilization of the service animal populations affected by a disaster and serve a critical role in supporting working animals for NSSEs. The NVRT is a single national team with regional support capability for a more rapid deployment.

In CY 2020, due to the COVID-19 response, NDMS responded to over 5,389 mission sets, which are individual deployments and some personnel deployed multiple times, while deploying 1,106 DMAT, 196 DMORT, 18 VIC, 62 TCCT, 15 NVRT, 85 IMT, and 78 LRAT personnel. The 2020 NDMS missions started with the State of the Union Address (SOTUA), an NSSE, in which NDMS supported the U.S. Capitol Office of the Attending Physician. Within in the next month, NDMS was tasked to a level never before experienced. February 2020 started the avalanche of mission sets that the NDMS program would be involved in for the remainder of 2020. Due to COVID-19, NDMS was deployed for the repatriation of American citizens from China to the United States and then from two cruise ships, one which had docked in Japan. This included supporting multiple locations throughout the country where Americans were being quarantined or required air transport care. In numerous locations across the nation with hospital augmentation for critical and emergent care critically depleted of resources, NDMS subject matter experts assisted SLTT entities in managing medical care and fatalities to ensure the honorable care of human remains of American citizens who lost their lives to this deadly virus. All of these COVID-19 deployments were conducted while simultaneously maintaining a level of support for other emergencies and special events.

NDMS's recent initiatives and accomplishments include:

- From February 2020 to the present, NDMS has deployed to 5,389 COVID-19 international and national deployment mission sets.
- NDMS has commenced a review of training and readiness requirements based on the changing response missions our country and the world faces. NDMS foresees the importance of changing modalities for training and exercises. The program plans to implement these changes over the next few years based on the evidence-based feedback and reports completed.
- Provided support to communities affected by Hurricanes Laura, Zeta, Delta and Sally as well as Oregon wildfires and earthquake in Puerto Rico. Over 4,800 NDMS personnel, U.S. Public Health Service, 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 2020, NDMS teams provided public health and medical support for the following: Supreme Court Justice Ruth Ginsburg and Congressman John Lewis funerals, the SOTUA, the United Nations General Assembly, the Peace Officer's Memorial, and ongoing operations in support of Puerto Rico and the United States Virgin Islands response and recovery efforts.

- NDMS continues with its 2016 initiative of a mobile training platform to its DMATs that allow attendance of the Medical Reserve Corps, 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.



In FY 2021, NDMS continues to support the COVID-19 response with teams providing behavioral health support to responders and being deployed on testing and vaccination missions across the country. NDMS also supported the 2021 Presidential Inauguration in January.

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.

Logistics

ASPR provides the critical logistical support 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 are 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.

Ten new aeromedical caches and a three thousand high acuity bed cache were built, and equipment upgrades were completed on thirty-two caches for DMATs and TCCTs. This brings the total number of NDMS medical caches to 46. In addition, new caches also include portable dialysis units. The addition of these portable units will ensure that the needs of vulnerable populations are met in a timely manner. Lessons learned from the 2017 hurricane season show that 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 U.S. Public Health Service Commissioned Corps, 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 Information and Technology (IT) and telecommunications, transportation, and material management during disaster, incident, emergency or special event. The ASPR LRAT can conduct 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 also trains to achieve competency in resource management and logistics areas associated with the FEMA National Qualification System and National Incident Management System (NIMS).

Following the transition of the SNS from the Centers for Disease Control and Prevention (CDC) to ASPR, NDMS began working with the SNS 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. Work to fully integrate NDMS materiel into SNS's inventory management systems was interrupted by the COVID-19 pandemic in 2020. The SNS expects to complete this work in FY 2021. Moving all ASPR's medical materiel and logistical operations to SNS streamlines ASPR operations and better positions ASPR to respond to health threats.

During FY 2020, the following events and responses were supported by 9,948 deployed personnel and 156 kits/caches totaling 4,490 tons of equipment to include every type of cache and kit:

- Hurricane Dorian response;
- NSSEs, including Elijah Cummins Lying in State, SOTUA, National Independence Day Celebration, John Lewis Lying in State, 2020 Democratic National Convention, 2020 Republican National Convention, 2020 United Nations General Assembly, Ruth Bader Ginsburg Lying in State; and,
- COVID-19 Repatriation Mission, which repatriated approximately one thousand US citizens, and COVID-19 Public Health and Medical Operations.

During FY 2021 thus far, the following events and responses were supported by 2,607 deployed personnel and 225 kits/caches totaling 2,956 tons of equipment:

- Tropical storm and hurricane responses including Laura, Delta, Sally, Zeta, Douglas, Hanna, Isaias, Marco, Gonzalo and response to the Oregon wildfires;
- NSSEs to include the 2021 Presidential Inauguration, and Officer Sicknick Lying in State; and,
- COVID-19 Public Health and Medical Operations.

Field Operations and Response

The success of ASPR is directly related to its ability to facilitate coordinated preparedness activities in each HHS region and to engage with affected state emergency management and public health agencies to determine support and operational requirements during emergencies. One of the fundamental responsibilities is to provide technical assistance, direct support, and interagency and intergovernmental coordination in the earliest phases of evolving regional incidents and emergencies.

Programs responsible for performing these critical functions include:

- Regional Emergency Coordinators (RECs) Program – RECs serve as ASPR’s primary representatives in each of the 10 HHS regions. As members of a regional team led by a Regional Administrator (RA), RECs have the day- to-day responsibility to develop and maintain relationships with SLTT public and private partners to prepare for an effective federal emergency response. During smaller-scale regional response operations, RECs take action to coordinate, activate and deploy regional public health/medical resources. For a larger-scale or complex response, RECs transition responsibility to the designated Federal Health Coordinating Officer (FHCO) who directs deployment of ASPR resources, including NDMS personnel.
- Medical Countermeasures Operations Program (MCOP) – MCOP provides support to regionally assigned Regional Medical Countermeasure Advisors (RMCAs) and serves as a bridge between state and local communities and federal initiatives in medical countermeasure (MCM) planning and operations. These MCM efforts contribute to protecting the health of Americans from 21st century health security threats by examining public health preparedness programs, providing technical assistance on identified areas of improvement, developing plans and policies, researching and implementing promising practices, and developing training and exercises to assist states to improve readiness in preparation for medical countermeasure operations.
- Incident Management Team (IMT) - ASPR’s preparedness and response current structure, processes, and procedures are outlined in ASPR’s Incident Response Framework (IRF). The IRF is the product of after-action findings from 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. The cornerstone of the approach formalized in the IRF is the establishment of the IMT, a single, overarching capability linking the principal components for incident response in a comprehensive and integrated way.

The mission of the IMT is to work with federal and SLTT entities, non-government organizations, and private-sector partners to identify the prioritized needs of the communities affected by all hazards emergencies, identify and coordinate resources to meet those needs, and effectively and efficiently manage HHS/ASPR deployed field resources and capabilities to ensure successful completion of assigned missions.

IMTs are comprised of a combination of the following: 1) experienced and specially trained emergency management professionals; 2) Emergency Support Function (ESF)-8³ public health and medical planners and providers; and 3) regionally based staff who are able to deploy on short notice to support all-hazard incident response activities or who are activated in support of pre-planned special events, as directed by the ASPR or his/her designated representative.

- Special Operations Program – Special Operations provides technical expertise, personnel and operational training to HHS and its federal partners during planned and unplanned events, including under tactical and austere environments. The Special Operations team includes the Tactical Medicine program which provides direct operational medical support and interagency support to include NSSEs and national level medical training. The team engages with interagency planning and response for critical incidents, including Weapons of Mass Destruction incidents. The Special Operations team also provides targeted professional training for IMT personnel to ensure best practices in ESF-8 response.
- Mission Support Program – Mission Support program provides augmentation logistical support for tactical and operational planning for the ASPR in all phases of the emergency management cycle, particularly the Regions and Special Operations teams. The Mission Support program facilitates identifying requirements and derived requirements in support of preparedness and execution of missions. Personnel from the Mission Support program also deploy with the Rapid Response Team (RRT) to support operations on behalf of ASPR in austere environments.
- Special Missions Program – Special Missions provides extensive knowledge and experience working in and around airports, ports and forward operating locations globally. They provide significant expertise in planning, coordinating and executing no notice complex missions while operating in a compressed planning cycle and under very austere conditions. They will lead and provide members for the Rapid Response Team (RRT). The RRT provides a specialized, rapidly deployable mission coordination, planning, medical care and logistics augmentation capability in support of a no notice very significant incident response operation to help save and protect American lives. The integrated team is comprised of members from the Special Missions Program, Mission Support Program, Special Operations Program, NDMS Special Purpose Emergency Augmentation Resource and US Marshals.

Special Programs

- At-Risk Individuals Program – The At-Risk Individuals (ARI) Program is the ASPR lead for response coordination for at-risk populations in disasters. The ARI team coordinates activities across federal agencies to create opportunities, identify gaps, anticipate needs, and provide resources and solutions. The collaborative strength of the ARI team involves longstanding partnerships with HHS agencies

³ https://www.fema.gov/sites/default/files/2020-07/fema_ESF_8_Public-Health-Medical.pdf

and other partners including Department of Transportation (DoT), FEMA, Department of Housing and Urban Development (HUD), United States Department of Agriculture (USDA), U.S. Interagency Council on Homelessness (USICH), VA, and American Red Cross (ARC). Along with leading coordination calls to promote situational awareness and build collaboration across agencies and programs, the ARI team has created journey maps, toolkits (e.g., Maternal-Child Health Toolkit: Develop Emergency Planning Guidance), checklists, and provided technical assistance to various stakeholders to address access and functional needs of at-risk populations nationwide. These activities and tools expand support and mitigate impacts by guiding SLTT leaders, emergency and public health planners and responders, and volunteers in addressing the access and functional needs of at-risk individuals for COVID-19, as well as ensuring ongoing access to essential healthcare and health maintenance services.

- Behavioral Health Program – The Behavioral Health Program is the ASPR lead and subject matter expert for issues related to behavioral health during a disaster, providing technical assistance to federal, state, and local authorities to enhance public health and medical response activities/capabilities, and other topics of interest. The Behavioral Health team develops tools, products and training curricula to enhance and inform the behavioral health elements of public health and emergency response and recovery for planners and responders, as well as establishing and promoting practices across ASPR and the interagency partners that ensure that the needs of people with current behavioral health concerns and those most at risk for adverse behavioral health impacts are met during an incident. The Behavioral Health team coordinates with federal and local resources to ensure behavioral health needs during a disaster are addressed quickly in response and recovery.
- Mass Evacuation Operations – The Mass Evacuation Operations (MEO) team is ASPR’s lead for a key ASPR Strategic Objective of Adaptive Planning and Emergency Repatriation. While the primary focus is to support mass evacuation planning, MEO is ASPR’s subject matter experts for international operations and engagements. Working closely with the Department of State and the HHS Office of Global Affairs, MEO works to ensure ASPR teams have the ability to deploy internationally, if needed, by overseeing pre-deployment requirements (training, passports, etc.). MEO is the ASPR representative to the FEMA International Assistance Framework and the HHS International Deployment Framework. MEO is home for Japan’s Ministry of Health, Labor and Welfare’s (MHLW) liaison to ASPR and works regularly with MHLW to expand their preparedness, response, and MCM development activities between the two countries.

Improving Pediatric Disaster Care

The Pediatric Disaster Care initiative continues to build on progress made since its inception in FY 2019 when the cohort of Pediatric Centers of Excellence pilots funded up to two Pediatric Disaster Care Pediatric Centers of Excellence that addressed 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 is the management of pediatric care related to trauma, infectious diseases including pandemic influenza and other emerging infectious disease, burn, and chemical, biological, radiological and nuclear incidents. The goal is to enhance ASPR’s capacity to provide critical care or surgical care for injured and ill children in the United States.

The Pediatric Centers of Excellence 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 Pediatric Centers of Excellence incorporate lessons learned from the Regional Disaster Health Response System (RDHRS) pilots. In year one (FY 2019), the RDHRS sites shared lessons learned, newly developed specific guidelines, and tools and products that are relevant to the care of pediatric patients. In future years, the Pediatric Disaster Care Pediatric Centers of Excellence 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 two (FY 2020) of the Pediatric Disaster Care Centers of Excellence continued 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 two brought additional challenges with many of the issues focused on COVID-19 response. COVID-19 consumed much of the time of all pediatric practitioners due to the impact on all health providers. The Pediatric Disaster Care Pediatric Centers of Excellence convened conference calls, reviewed literature and provided insight into what pediatric centers were seeing with the pediatric population. They continued to engage in trauma/critical care elements, but this was limited as the need was for the current status of patient care for this special population in 2020.

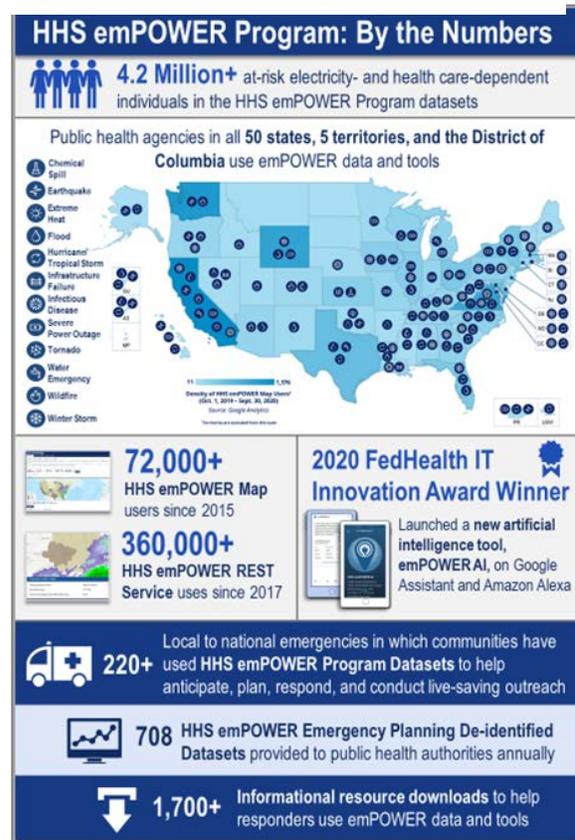
Year three (FY 2021) of the Pediatric Disaster Care Centers of Excellence further expands the pilot program described above by building on lessons learned from previous pilot sites. Funding continues among previously funded pilot sites and will expand to an additional site. The pilots will continue building 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.

HHS emPOWER Program

The [HHS emPOWER Program](#) (emPOWER) 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. This expanding portfolio of data-driven tools and resources helps public health authorities and their community partners protect the health of more than 4.2 million individuals who live independently and rely on life-maintaining electricity-dependent durable medical and assistive equipment and devices⁴ and essential healthcare services.⁵ Using Medicare data, emPOWER provides NDMS, public health authorities, and their partners (e.g., first responders, emergency managers, National Guard, health care providers, health care coalitions, area agencies on aging, public utilities, etc.) with accurate and timely information on at-risk populations to enhance their emergency preparedness, response, recovery, and mitigation activities across 13 emergency support functions⁶ and 13 sectors⁷.

The expanding emPOWER portfolio includes [dynamic datasets](#), [mapping tools](#), [comprehensive training programs](#), [informational resources](#), and nearly 24/7 real-time technical assistance. The program also adopts an agile innovation process to rapidly identify and develop new tools and resources to ensure emergency responders, from headquarters to the front line of response, can readily access and use emPOWER data to support emergency response activities in their communities. For example, in FY 2020, emPOWER launched a new publicly-accessible, voice-activated artificial intelligence (AI) tool, [emPOWER AI](#). This innovative, [award-winning](#) tool leverages [Amazon Alexa](#) and [Google Virtual Assistant](#) technology to put emPOWER data into the hands of first responders, public health authorities, emergency managers, health care providers, and other community partners within seconds, wherever they are. emPOWER AI is a powerful addition to the set of emPOWER tools that make federal health data readily meaningful, consumable, and actionable, helping every community anticipate, plan for, and respond to the needs of electricity- and health care-dependent individuals in their communities.

Figure 1 HHS emPOWER Program: By the Numbers



⁴ Electricity-dependent durable medical and assistive equipment and devices include, but are not limited to, certain cardiac implantable dev-ventilators, oxygen concentrators, home dialysis, and electric wheelchairs.

⁵ Essential health care services include outpatient facility dialysis, home oxygen tank services, home health care services, and home hospice care services.

⁶ The 13 emergency support functions include: Transportation (ESF-1); Communications (ESF-2); Public Works and Engineering (ESF-3); Firefighting (ESF-4); Information and Planning (ESF-5); Mass Care, Emergency Assistance, Temporary Housing, and Human Services (ESF-6); Logistics (ESF-7); Public Health and Medical Services (ESF-8); Search and Rescue (ESF-9); Energy (ESF-12); Public Safety and Security (ESF-13); Cross-Sector Business and Infrastructure (ESF-14), and; External Affairs (ESF-12); Public Safety and Security (ESF-13); Cross-Sector Business and Infrastructure (ESF-14), and; External Affairs (ESF-15).

⁷ The 13 sectors include: Chemical Sector; Communications Sector; Critical Manufacturing Sector; Dams Sector; Emergency Services Sector; Energy Sector; Government Facilities Sector; Healthcare and Public Health Sector; Information Technology Sector; Nuclear Reactors; Materials and Waste Sector; Transportation Systems Sector, and; Water and Wastewater Sector.

From local to national disasters, emPOWER tools and resources, since its inception, have informed over 220 critical emergency response planning, supported life-saving outreach activities, and aided in reconstitution of vital outpatient dialysis, home health, and home oxygen and medical equipment supplier services to health care-dependent individuals. For example, during the 2019 and 2020 wild fire seasons, over 20 California counties used emPOWER data to anticipate, prepare for, and respond to the access and functional needs of at-risk individuals during severe wildfires and public safety power shut offs (PSPS) that resulted in blackouts lasting days and, in some cases, for weeks. The State of California and its counties, as well as others, have integrated emPOWER data into their common operating response platforms to enhance situational awareness and support targeted emergency preparedness and response activities that include, but are not limited to, developing recharging stations, expanding capacity and resources in shelters, and planning to expedite life-saving outreach and evacuation capabilities prior to, during, and after an emergency.

Los Angeles County Strengthens Whole-Community Preparedness and Response with emPOWER



Los Angeles (LA) County, **the largest county in the nation**, is comprised of 88 cities and a diverse population of over 10 million people. Public health emergencies, such as earthquakes, wildfires, flooding, and mudslides, that cause power loss and displacement across the county can be devastating to **thousands of electricity- and health care-dependent individuals**. To protect these at-risk individuals, the LA County Department of Public Health (DPH) **used emPOWER data and tools to support lifesaving response activities during the historic and catastrophic wildfires from 2017 to 2020 as well as established a multi-agency county and city formal protocol** that supports rapid operationalization, integration and multi-agency situational awareness and decision making by county and city public health and emergency management officials and first responders prior to, during and after an emergency or disaster.

The formal protocol and partnership, led by LA DPH, **operationalizes emPOWER data to ensure first responders have the ability to make informed, data-driven lifesaving response decisions within 30 minutes**. LA DPH's innovative use of emPOWER data and tools has **strengthened partnerships, multi-agency training and exercises using the data that have included agency staff and leadership from emergency medical services, fire, police, and public health**. This partnership has created an informed, forward-thinking network dedicated to protecting the health of over 100,000 at-risk community members. Furthermore, LA DPH is planning to expand this readily implementable and repeatable model to more cities within LA County, **strengthening county-to-city level information sharing and data integration**.

In collaboration with emPOWER, LA DPH has also shared its integrated approach to leveraging emPOWER data and tools **by providing peer-to-peer expertise and training to other counties throughout California**. Several counties in the state have now leveraged and integrated LA DPH's best practices and have used the emPOWER data and tools **to support lifesaving outreach and evacuations, establishing shelters and recharging stations and power restoration prioritization during the 2019 wildfires and PSPS events**.

The program has also provided critical data to help a number of other disasters in 2020, which include supporting Puerto Rico response and recovery activities following a 6.4 magnitude earthquake that caused severe and prolonged power outages. [PRDOH](#) used empower data to rapidly identify and conduct outreach to 166 oxygen tank and electricity-dependent at-risk individuals in the impact zone and provided assistance and access to resources to help their recovery. Later in the year, emPOWER data informed preparedness and response activities when New York City and Los Angeles County faced extreme heat, power outages, and wildfires that required rapid activation of response activities to protect the health of over 100,000 at-risk individuals in each jurisdiction. The emPOWER data has also supported state and local emergency responses in Iowa and Oregon.

In FY 2020 11,401 community members nationwide have used the public [HHS emPOWER Map](#), and users have accessed the [HHS emPOWER REST Service](#) over 221,707 times to obtain at-risk data on geographic areas to better understand and target actions to help address the needs of the electricity-dependent populations in their communities. The program provided 708 emPOWER emergency planning

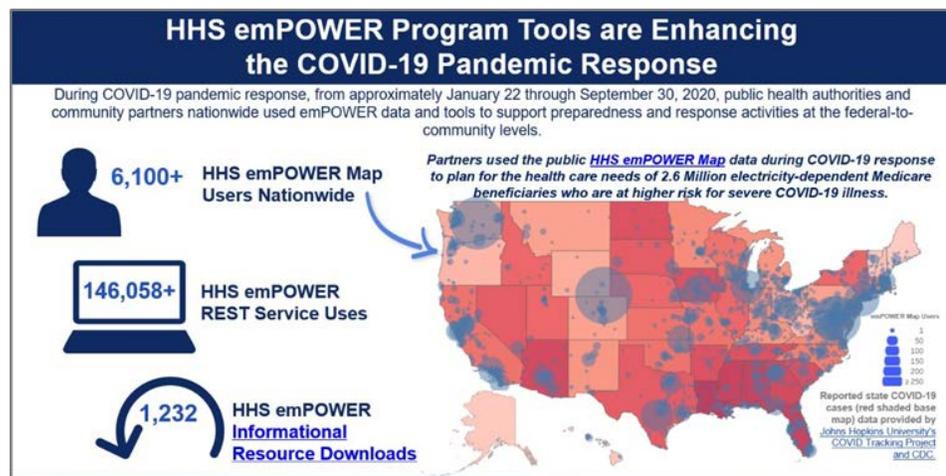
de-identified datasets to 50 states, five territories, who have Medicare beneficiaries, and four major metropolitan areas (i.e., District of Columbia, Chicago, New York City and Los Angeles County) to ensure that they have accurate, monthly updated data to support targeted at-risk preparedness, response, and recovery activities. In FY 2020, partners nationwide, used emPOWER data to inform their COVID-19 response activities as electricity-dependent and healthcare dependent at-risk Medicare beneficiaries were at high risk for severe COVID-19 adverse outcomes and death (Figure 2.). To protect health, Philadelphia Department of Public Health (PDPH), in partnership with the Pennsylvania Department of Health, requested emPOWER data to conduct targeted COVID-19 response outreach activities. [PDPH](#) sent a postcard to all 13,000 identified at-risk individuals that included critical public health and safety messaging (e.g. wear masks, social distance, monitor their health, contact their physicians, etc.) and direct phone numbers for support services (e.g. grocery delivery, aging services, electricity assistance programs, etc.) to help them stay home safely. They also partnered with their home health providers to reinforce messaging and provided informational resources and 1,200 smart thermometers to help them to monitor their health and reduce their risk of potentially exposing their patients to COVID-19.

As the need for data and information on at-risk populations increases, emPOWER continues to build awareness of its current tools and resources, innovate and expand its offerings, maintain consistent communication with its federal and SLTT stakeholders, and provide opportunities

for knowledge sharing from the federal-to-community levels. To address this need, emPOWER initiated development of the [HHS emPOWER Program Platform in FY2020 and officially launched the site in December 2020.](#)

In 2018, ASPR, in partnership with the Centers for Medicare and Medicaid Services, expanded the HHS emPOWER Program to also include the “[emPOWERing State Medicaid and CHIP Data Pilot](#)”. States and territories that volunteer to participate are provided with the knowledge, tools, and technical assistance to develop the analytical framework and capabilities to create complementary emPOWER datasets that provide mission-critical data on electricity- and health care-dependent at-risk children and other adult populations. Five states have successfully implemented pilots, including Florida, North Carolina, Nevada, California, and Oregon, and others are in the process of reviewing the pilots for potential launch in the near future. Most recently, Florida, North Carolina, and Oregon have completed the development of their state emPOWER Medicaid and CHIP datasets, which they used to inform their emergency planning for, and responding to, the needs of at-risk children and other adults during the 2020 hurricane and wildfire seasons. The State of California expedited its pilot launch in 2020 in support of their counties that collectively recognized how critical emPOWER Medicare data was to informing response decision-making and supporting life-saving response activities during the 2017-2019 historic wildfires and PSPS events, as well as that recognized the need for at-risk emPOWER pediatric and other adult data to further advance their understanding and readiness for their state’s evolving threat landscape.

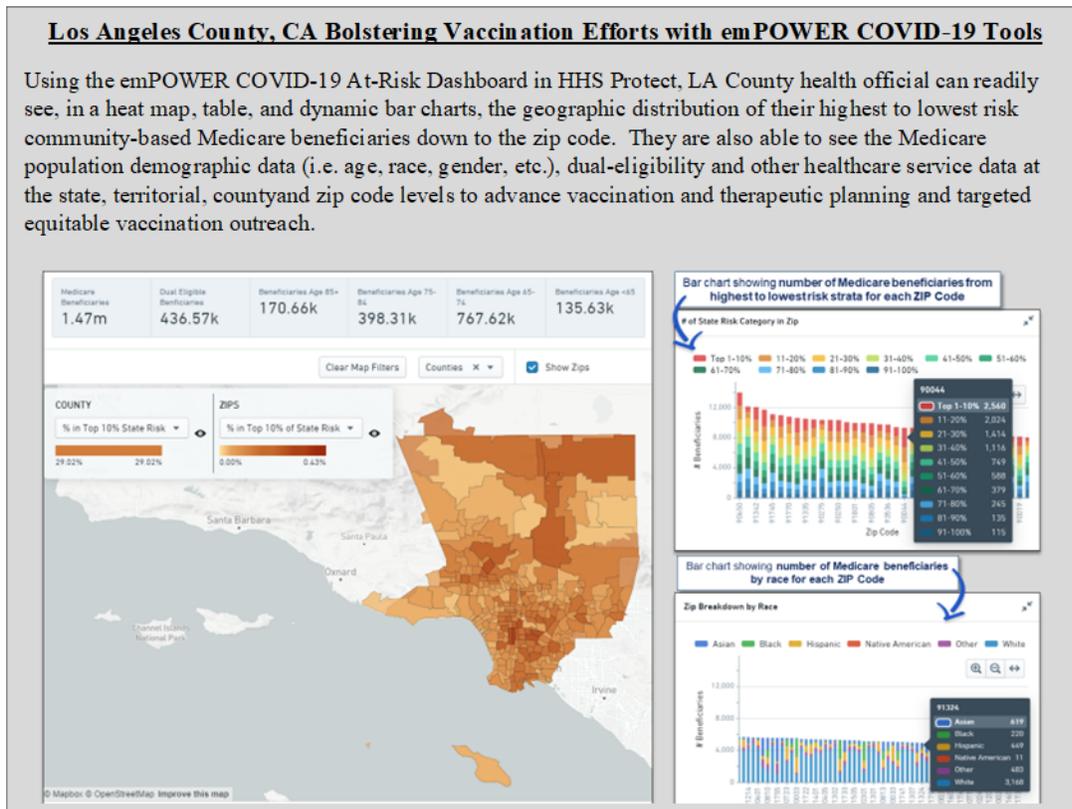
Figure 2. HHS emPOWER Map Use during COVID-19 from January 22 - September 30, 2020



Lastly, as more states and territories participate, requests for technical assistance to support data integration continue and will require additional technical expertise and resources to assess and support planning for future technical integration capabilities and capacities as well.

In FY 2020, the program continued to make progress toward its strategic objectives by exploring new federal data for inclusion in emPOWER tools and launching the new [HHS emPOWER Map](#) with new data export capabilities and mapping functionalities as requested by users across the country. The program will continue to expand engagement of its growing user base to gather feedback and ideas from stakeholders, as well as establish a framework for peer-to-peer technical assistance that can be quickly activated during emergencies or disasters. The program also will continue to assist states and territories developing complementary emPOWER Medicaid and CHIP datasets to further advance community readiness, particularly for at-risk pediatric populations, and, based on funding availability, will begin to assess potential federal technical integration of these additional data sources.

Figure 3. Los Angeles County, CA Bolstering Vaccination Efforts with emPOWER COVID-19 At Risk



Through additional COVID supplemental funding, the HHS emPOWER Program, in FY 2020, initiated development of a new suite of emPOWER COVID-19 At-Risk data and tools that were launched in January 2021. The data and tools were developed to support federal and SLTT COVID-19 response, vaccination planning and outreach, therapeutic planning and recovery public health activities. Leveraging the Center for Medicare & Medicaid Services and Food and Drug Administration’s evidence-based and peer-reviewed risk model that all 62 million Medicare beneficiaries were individually assessed for their risk of COVID-19 hospitalization and/or death in any setting. The comprehensive model integrates comprehensive equity and healthcare factors that includes demographics, socioeconomic, comorbidities, health status indicators and healthcare service utilization. HHS emPOWER is supporting the unified

COVID-19 response by making federal health data accessible to federal and SLTT partners driving national COVID-19 response efforts.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$57,404,000 |
| FY 2019 | \$73,404,000 |
| FY 2020 | \$57,404,000 |
| FY 2021 Enacted | \$63,404,000 |
| FY 2022 President’s Budget | \$91,807,000 |

Budget Request

The FY 2022 President’s Budget for NDMS is \$91,807,000, which is \$28,403,000 above FY 2021 Enacted. The request will support recruitment and training of the NDMS Intermittents program. The President’s Budget also includes \$6,000,000 to continue the Pediatric Disaster Care program.

NDMS Intermittents: The budget includes an additional \$25 million to support efforts to expand the number of NDMS intermittents. A recent review by the Government Accountability Agency (GAO)⁸ stressed the importance of training the NDMS Intermittent workforce and noted the budgetary commitment required for training needed to be prioritized. NDMS began to implement a Direct Hiring Authority to accelerate meeting the goal of 6,290 Intermittents on board and deployment ready. The increase in the NDMS workforce reflects a more than 36 percent increase from current level of staffing. In addition to recruitment, the increase will meet demands for increased individual and team training to ensure mission readiness, including added hands-on and online training for new NDMS employees. The number of intermittents trained is projected to increase by approximately 500 employees annually. Additionally, funds will increase the program’s capacity through full-time personnel and systems to onboard new staff, credential up to 2,600 new clinicians, conduct security background checks and ensure operational support for deployed teams.

NDMS continues to meet its goals for required online training. However, this does not equate to preparedness for disaster medicine deployments. The majority of the current menu of required annual or periodic online training consists mainly of administrative requirements and does not address fundamental skills and competencies required for disaster medicine. Practical disaster medical skills have been traditionally covered by in-person trainings, for which NDMS has not met its targets due to COVID travel restrictions. A transformation of the training mix is needed in order to maximize instruction on those disaster medicine competencies that can appropriately and effectively be taught in online formats. In-person training would still be required for subject matter that is not suitable for online modules; such as tactile use of specialized equipment. Hands-on skills training could be provided to all NDMS personnel on a rotating basis, once every three years. Balancing the combination of effective, interactive online and refresher training in select disaster medicine competencies paired with once-every-three-year hands-on skills training would produce a well-trained, ready national medical response capability.

⁸ Government Accountably Office, 2020. Public Health Preparedness: HHS Should Take Actions to Ensure It Has an Adequate Number of Effectively Trained Emergency Responders. GAO-20-525.

Public Health and Social Services Emergency Fund

Pediatric Disaster Care: The President's Budget includes \$6 million to sustain the Pediatric Disaster Care program. 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.

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)¹ | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 Target |
|--|---|-----------------------|-----------------------|---|
| 1.1 Maintain the percent of new NDMS intermittent staff that complete psychological first aid training (output) | FY 2020: 100% Target: 100 % (Target Met) | 100 % | 100 % | Maintain |
| 1.3 Increase training and resources to address the access and functional needs of electricity and health care service-dependent at-risk individuals who live independently and are impacted by incidents, emergencies, and disasters | FY 2020: 234,802 trained Baseline: 81,720 trained (Baseline) | 88,826 trained | 95,932 trained | Maintain |
| 1.4 Maintain the percent of NDMS intermittent staff who complete basic, advanced, or specialized training (intermediate outcome) | FY 2019: 39.5 % ² Target: 35.0 % (Target Exceeded) | 35.0 % | 35.0 % | Maintain |

¹FY 2020 data in this table result from activities supported by both base and supplemental appropriations.

²No in-person specialized training was conducted in 2020 due to COVID-19 restrictions. Limited in-person specialized training is being conducted during 2021 due to COVID-19 restrictions.

Medical Reserve Corps

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 6.000 | 6.000 | 6.240 | +0.240 |
| FTE | 5 | 6 | 12 | +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 over 200,000 volunteers organized into roughly 800 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 support various steady-state preparedness initiatives. MRC volunteers include medical and public health professionals as well as other community members without healthcare backgrounds who provide support in administrative, logistical, and other capacities. Units bolster community preparedness and emergency response infrastructures by providing supplemental personnel when needed, thereby reducing reliance on state and federal resources. Local health departments sponsor the majority of MRC units, although units are also sponsored by emergency management agencies, local non-profits, and universities.

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

MRC units are very active in their communities and serve as critical medical and public health response assets in the fight against COVID-19. During 2020, MRC units reported 16,535 activities, with volunteers contributing over one million hours of service of which more than 800,000 hours were dedicated to COVID-19 response efforts. As a point of reference, in 2019, the MRC network contributed roughly 300,000 volunteer hours, and in 2018, 270,000 hours. Relative to recent years, volunteers served more than three times the number of hours in 2020 by augmenting local COVID response efforts. There has also been a notable increase in the number of volunteers associated with MRC units. Since the beginning of 2020, the number of volunteers across the MRC network has grown from roughly 175,000 to well over 200,000.

MRC COVID-19 Response

- More than 500 MRC units in 48 states, the District of Columbia, Puerto Rico, American Samoa, and the Northern Mariana Islands have bolstered local emergency response capabilities and

served as critical medical and public health response assets during the COVID-19 pandemic. Beginning in late January 2020 and continuing through the present, MRC units have supported a myriad of response roles and tasks depending on local community need. While response activities vary, common COVID-19 MRC missions include: assisting with community screening and testing operations; medical surge support at long-term care facilities, health care facilities, and alternate care sites; patient case and contact investigations; call center operations; community education and outreach (e.g., assisting elderly and vulnerable community members with well check calls, food distribution, errands, medication pick-up); logistics support (e.g., inventorying, packing, and distributing personal protective equipment); and mass vaccination. During elections, MRC units also reported efforts related to infection control at election polling stations (e.g., ensuring proper sanitation methods, proper use of personal protective equipment (PPE), and maintaining social distancing). In calendar year 2020, MRC units reported approximately:

- 330,000 volunteer hours dedicated to testing;
 - 142,000 volunteer hours dedicated to contact tracing; and,
 - 86,000 volunteer hours dedicated to call center operations.
- Since the first COVID-19 vaccine was authorized for emergency use in the U.S. in December 2020, MRC units have reported increased engagement with COVID-19 vaccination efforts. To date, roughly 400 MRC units in over 40 states and territories are assisting with vaccination efforts in their local communities. Common MRC vaccination roles include patient screening, vaccine administration, monitoring for adverse reactions, exit counseling, behavioral health support, and site operations / administrative support (e.g., vaccine appointment set-up, paperwork and data entry, traffic control). Some MRC units are also working with community partners to offer mobile vaccinations (e.g., vaccinating those who are homebound and unable to travel to a point of dispensing site.)

Examples of local unit efforts related to COVID-19 response include:

- The Rhode Island MRC (West Greenwich, RI) supported a wide variety of COVID-19 missions over the last year. Initially, the unit was called upon to backfill staff at congregate care facilities and nursing homes when resources were stretched thin. Volunteers worked 12-hour shifts through March, April, and May 2020 to bring relief to the staff and professional care to the residents. The unit then began spearheading COVID-19 testing at five fixed-site, seven-day-a-week locations, by providing manpower, logistics support, and ground-up operations control. The unit simultaneously managed state-wide mobile testing responsibilities in communities and locations hardest hit by the COVID-19 pandemic, including congregate care facilities for the housing insecure, domestic violence shelters, and communities where challenges to accessing healthcare are endemic. To date, Rhode Island MRC volunteers administered over 130,000 COVID-19 tests. When vaccines became available, the MRC unit was again called upon and administered vaccinations through 39 MRC-run vaccination clinics.
- The University of Minnesota MRC (Minneapolis, MN) has a dual mission of service to the large university campus community and the local city, county, and state. More than 400 MRC volunteers supported 22 diverse COVID-19 missions since March 2020. High impact COVID-19 deployments include partnering with the Minnesota Department of Health to conduct a large-scale testing event with 82 volunteers providing roughly 4,000 tests; partnership with the campus health service to staff COVID-19 vaccine and contact tracing efforts; and supporting eight Federally Qualified Health Centers with weekly COVID-19 vaccine clinics in hardest hit neighborhoods. Other deployments include providing subject matter expertise to, and conducting case investigations, for the state; phone-based education and outreach to non-English speaking clients at a local community clinic; online grocery outreach for community members in need;

COVID-19 health screenings; assisting with command center support operations and telehealth support for a large health system; and supporting community COVID-19 testing.

- The Middlesex County MRC (East Brunswick, NJ) supported COVID-19 testing operations, including drive-through, walk-up, and mobile clinics. To date, over 35,000 individuals have been tested. Middlesex County MRC volunteers supporting COVID-19 test sites include health professionals (e.g., nurses, physicians, pharmacists, paramedics) and community health volunteers, who perform language translation, oversee patient flow, and assist with data entry. MRC volunteer amateur radio operators provide radio communications between each test site's onsite management element and the county's Emergency Operations Center.
- The Franklin County and Columbus MRC (Columbus, OH) supported a number of efforts, including logistics operations at the local distribution site that works to distribute PPE to facilities such as nursing homes, community clinics, and food banks that may be unable to purchase it through normal channels. MRC volunteers schedule weekly PPE pickups, confer with facilities to validate their needs, and provide operational support at the distribution warehouse. The unit fulfilled 680 unique orders for facilities in need across Franklin County, providing gloves, masks, gowns, thermometers, test kits, and more.
- During the 2020 election season, Virginia MRC volunteers served as Infection Prevention Ambassadors (IPAs) to support safe voting for local, primary, and general elections. Volunteers from 21 of Virginia's 22 units supported local polling sites and precinct officials in May, June, July, and November 2020. Volunteer duties included reminding polling staff and voters to social distance, wear a mask if they were able, and sanitize their hands as needed, in addition to providing guidance on disinfecting high-touch surfaces. IPAs supported early voting and provided pre-election infection prevention education to election officials in some precincts, and supported polling sites on election days. During the November election, Virginia MRC volunteers served more than 6,000 hours.

Weather-Related Events and Natural Disasters

MRC units responded to a number of weather-related events and natural disasters in 2020. Events include, but are not limited to, hurricanes and tropical storms, wildfires, tornadoes, flooding, earthquakes, and heat waves, thunderstorms, and winter storms.

- More than 15 MRC units in Arizona, California, Colorado, Nebraska, Oregon, Utah, and Washington responded to both wildfires and grassland fires by dedicating more than 6,000 service hours. Volunteers most commonly assisted with evacuation and clean air sheltering operations, medical screening and care, veterinary care, and logistics.
- The 2020 Atlantic hurricane season was one of the most active on record. More than 15 MRC units in 10 states responded to hurricanes and tropical storms in their communities. Units — the majority along the Gulf Coast — assisted with evacuation, sheltering, medical needs tracking, COVID-19 screenings for evacuees, veterinary care, and call center operations. For example, multiple Texas MRC units responded to Hurricane Laura. Brazoria County MRC (Alvin, TX) assisted with setting up an evacuation hub for local residents. Denton County MRC (Denton, TX) volunteers provided operations support at a local shelter. The Alamo Area MRC (Brooks City-Base, TX) conducted COVID-19 medical screenings and provided other medical care for evacuees sheltered at local hotels. Harris County MRC (Houston, TX) assisted at the emergency operations center and had volunteers on standby to set up a medical care shelter in the event it was needed. In response to Hurricane Isaias, members of the Capital MRC (Raleigh, NC) set up a

medical shelter for displaced nursing home and home health patients. New Castle County MRC (Newark, DE) volunteers provided medical and behavioral health support in shelters during Tropical Storm Isaias. During Tropical Storm Eta in November 2020, nurse volunteers from the Florida Keys MRC were deployed to area shelters to administer rapid COVID-19 tests and perform medical screening for individuals staying at the shelter.

- After a derecho passed through Iowa and caused widespread power outages, Johnson County MRC (Iowa City, IA) volunteers conducted wellness checks on local community members with special medical needs. Volunteers with the Grundy County MRC (Grundy Center, IA) helped with recovery clean-up efforts.
- MRC units in Texas, Tennessee, Pennsylvania, and South Carolina responded to tornadoes. Volunteers provided emergency veterinary care; emergency operations center, resource center, and logistics support; behavioral health services; and support at a reception center for evacuees.
- A number of MRC units helped respond to floods. For example, in August, Delaware County MRC (Media, PA) supported an evacuee reception center after Tropical Storm Isaias caused major flooding in local communities. Also in August, the Western Tidewater MRC (Suffolk, VA) staffed a disaster shelter at a local church after significant flooding affected the community. And, in May and June, Muskegon County MRC (Muskegon, MI) volunteers assisted local emergency management with damage assessments after severe flooding caused damage to local homes.
- During periods of extreme heat during the summer, many MRC units supported community cooling centers. For example, after a rainstorm left parts of the local community without power in the middle of the summer, the Manalapan MRC/CERT (Manalapan, NJ) opened a cooling station/charging station for affected residents. In July, Brookline MRC (Brookline, MA) volunteers staffed outdoor cooling centers. Also in July, Bucks County MRC (Doylestown, PA) and Philadelphia MRC (Philadelphia, PA) volunteers deployed to several locations to assist with cooling centers.
- During winter weather, MRC units also stepped up to assist. In January and February, Strafford County MRC (Dover, DE) volunteers served more than 250 hours supporting multiple warming centers/shelters in the local community. Multnomah County MRC (Portland, OR) volunteers also provided medical support at warming shelters in response to winter weather.

Communicable Disease Outbreaks

- MRC units across the country provided vaccination support in response to communicable disease outbreaks. In response to hepatitis A, units were particularly focused on high-risk and vulnerable populations, providing vaccination support at a number of community-based outreach clinics. For example, the Pierce County MRC (Tacoma, WA) supported a series of hepatitis A vaccination clinics primarily serving those living homeless across the county. Maricopa County Public Health MRC (Phoenix, AZ) volunteers administered hepatitis A vaccinations at a clinic established to vaccinate at-risk populations during a local outbreak. In response to an exposure at a local restaurant in May 2020, the Southwest Virginia MRC (Bristol, VA) supported a drive-through hepatitis A vaccination clinic for local residents and administered 600 vaccinations in an 8-hour time frame.

Other Local Emergency and Public Health Events

- As firefighters tended to a large, residential structure fire in the community in August 2020, Central Nebraska MRC (Hastings, NE) volunteers provided firefighter rehabilitation support on scene for over six hours, evaluating and checking vitals of responders.
- Members of the Hendricks County MRC (Danville, IN) crisis response team were activated to provide counseling support at a local school after the deaths of two members of the school community.
- Ledge Light Health District MRC (New London, CT) volunteers assisted with potassium iodide distribution events intended for community members who live/work within 10 miles of a nearby nuclear power station. Potassium iodide can help protect the thyroid gland against harmful radioactive iodine in the event of radiological emergencies.
- Volunteers with the Kent County MRC (Smymna, DE), the Sussex County MRC (Georgetown, DE), and the New Castle County MRC (Newark, DE) assisted with distributing and training community members to administer naloxone, a medication that is used to help reverse the effects of an opioid overdose.
- To the extent possible given COVID-19 restrictions, MRC units also participated in non-emergency events throughout the year, including training for emergencies and educating the public about effective responses (e.g., Stop the Bleed, CPR) to emergency events.

Additional MRC Program Activities

At the national level, 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. The program also began a new cooperative agreement with the state of Utah.

- The MRC program introduced a new, three-year cooperative agreement in 2020 titled the “MRC Small Grant Program” that includes two projects — a national-level project (Project A) and a state/territory level project (Project B). The purpose of both of these projects is to continue to build the capabilities of MRC units to respond to and meet their communities’ public health and medical needs in emergencies, as well as to identify and address barriers to the use of MRC units and volunteers. The MRC program made an award to NACCHO under Project A. Under Project B, the MRC program made an award to the state of Utah to support statewide MRC programming, preparedness planning, and response.
- As part of its cooperative agreement with the MRC program, NACCHO announced a series of funding opportunities for MRC units aimed 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.
 - More than 200 MRC units received “2020 Operational Readiness Awards” in early 2020 (totaling over \$1 million);
 - Roughly 30 MRC units received special “COVID-19 Operational Readiness Awards” in fall 2020 (totaling \$160,000);
 - More than 130 MRC units received “2021 Operational Readiness Awards” in early 2021 (totaling over \$1.2 million); and
 - A second round of “2021 MRC Operational Readiness Awards” is now underway to support additional MRC unit preparedness and response capabilities.

Public Health and Social Services Emergency Fund

- The MRC program’s cooperative agreement with the Public Health Foundation provides each of the roughly 800 MRC units with their own MRC-TRAIN account. This allows local MRC unit leaders to assign, track, and manage their volunteers’ trainings such as webinars, on-line presentations, and, when possible, live meetings.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$6,000,000 |
| FY 2019 | \$6,000,000 |
| FY 2020 | \$6,000,000 |
| FY 2021 Enacted | \$6,000,000 |
| FY 2022 President’s Budget | \$6,240,000 |

Budget Request

The FY 2022 President’s Budget request for the civilian volunteer MRC is \$6,240,000, which is +\$240,000 above FY 2021 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, including identifying and sharing training resources for unit leaders and volunteers, best practices in volunteer recruitment and retention, examples for identifying community stakeholders and developing partnerships, and other topics critical to unit leaders. Funding will also continue to support on-going cooperative agreements and for the system used for maintaining unit profiles and activity reporting as well as a means for units to access and track training. The increase in funding will support enhanced existing cooperative agreements and enable additional sub-awards to individual units.

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. Standardized response packages and/or mission sets typically include a recommended set of trainings and other standards that help a unit determine the level of capability that they are able to meet — and thus make it easier for partners to understand what the unit can do in a response. Several mission sets have been developed by NACCHO with support from the MRC program, and many units have found the tools helpful in improving or broadening their unit’s capabilities.

Hospital Preparedness Program

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|--|----------------|-----------------|----------------------------|---------------------|
| Budget Authority | 275.555 | 280.555 | 291.777 | +11.222 |
| <i>HPP Annual Cooperative Agreement (non-add) /1</i> | 231.500 | 231.500 | 240.000 | +8.500 |
| <i>Regional Disaster Health Response System Cooperative Agreement (RDHRS) (non-add)</i> | 7.000 | 8.500 | 7.000 | -1.500 |
| <i>National Special Pathogen System (NSPS) (non-add)</i> | 11.000 | 11.000 | 11.000 | - |
| <i>National Emerging Special Pathogens Training and Education Center (NETEC) (non-add)</i> | 5.000 | 5.000 | 5.000 | - |
| <i>Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs) (non-add)</i> | 6.000 | 6.000 | 6.000 | - |
| <i>Other costs (non-add) /2</i> | 26.055 | 29.555 | 33.777 | +4.222 |
| FTE | 49 | 49 | 62 | +13 |

1/ The Public Health Service (PHS) Act determines the annual 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.

2/ Other costs include HPP cooperative agreement administration, evaluation, and performance management, the Critical Infrastructure Protection (CIP), the Technical Resources Assistance Center and Information Exchange (TRACIE), and the ASPR Recovery program.

Authorizing Legislation:

AuthorizationPublic Health Service Act
Allocation MethodFormula-based cooperative agreement; direct federal/intramural; contracts

Advancing Health Care Emergency Preparedness and Response to Save Lives and Protect Americans

The Office of the Assistant Secretary for Preparedness and Response (ASPR) mission is to save lives and protect Americans from health security threats. The Hospital Preparedness Program (HPP) and the other programs funded under the HPP budget account fulfill this mission by strengthening health care sector readiness to provide coordinated, life-saving care in the face of emergencies and disasters. These programs provide strong leadership in health care preparedness and response through data-driven insights, proven and innovative practices, ready resources, and strategic partnerships. During the COVID-19 pandemic, HPP supported health care on the front lines of this unprecedented event – while continuing to manage a broad portfolio of all-hazards health care preparedness programs to mitigate instances of manmade threats, wildfires, and hurricanes across the country. Now, more than ever before, it is critically important to continue to invest in HPP’s portfolio of programs and activities to enhance the readiness of the nation’s health care sector against all hazards. ASPR has already begun to identify areas to evolve health care preparedness and response, including increasing the agility and adaptability of its resources and services to the field; strengthening its use of data to maintain situational awareness, make decisions, and measure readiness; and deepening its relationship with the private sector.

The programs and activities within the HPP portfolio – ASPR’s Hospital Preparedness Program (HPP), the National Special Pathogen System (NSPS), the Regional Disaster Health Response System (RDHRS), the Technical Resources, Assistance Center, and Information Exchange (TRACIE), the Critical Infrastructure Protection (CIP) Program and ASPR Recovery Program – are essential to creating a health care sector that can rapidly adapt to the evolving threat landscape and effectively respond to disasters when they occur.

This portfolio of programs and activities engages health care stakeholders from all 50 states, U.S. territories, and freely associated states, as well as from across the health care industry – empowering private health care to share ownership in addressing risks and vulnerabilities across the spectrum of disaster care delivery. Additionally, these programs and activities cover the lifecycle of health care preparedness and response, supporting proactive, data-driven preparedness through trainings, data analysis, and assessments; bolstering comprehensive response through technical assistance, targeted funding opportunities, and coordination; and aiding in recovery to ensure that health care systems and communities are equipped for long-term revitalization and that lessons learned are integrated into preparedness strategies for the future.

Figure 1 demonstrates the breadth of these programs and their reach at the national, regional, state, and local level.

Although substantial progress has been made, especially with regard to improved collaboration and coordination across the public and private health care sectors and across local, state, and regional jurisdictions, COVID-19 has demonstrated the significant need for continued investment, collaboration and innovative approaches to maintain and increase momentum on key priorities, which include: 1) increasing patient surge capacity; 2) improving access to specialty medical care; 3) improving health care situational awareness; 4) improving health system readiness; 5) strengthening telehealth capabilities, especially for critical care; and 6) improving patient transport and tracking. As an essential partner to the nation’s health care systems during the COVID-19 pandemic, HPP has identified opportunities to help address these priorities and mitigate gaps, including sustaining regional hubs and training and education resources for special pathogen care that builds on past infrastructure from the Ebola response and increasing funds to the 62 HPP cooperative agreement recipients.

The HPP portfolio supports a comprehensive, national network for health care preparedness and response. The programs and activities within the HPP portfolio are coordinated to address the many, complex facets of the nation’s health care system, creating mechanisms and infrastructure to improve coordination between localities, states, and regions, as well as developing new capabilities (e.g., telemedicine, specialty health care, etc.) specific to key challenges within the modern threat landscape (e.g., highly pathogenic disease; biological/chemical incidents, etc.) HPP works across its portfolio, within ASPR, and with its partners across the United States government and in the private sector to create connection points between these initiatives and work toward the sustainment and advancement of readiness initiatives into a fully developed, highly functioning national system for preparedness and response.

Figure 1. HPP’s Portfolio of Programs and Activities

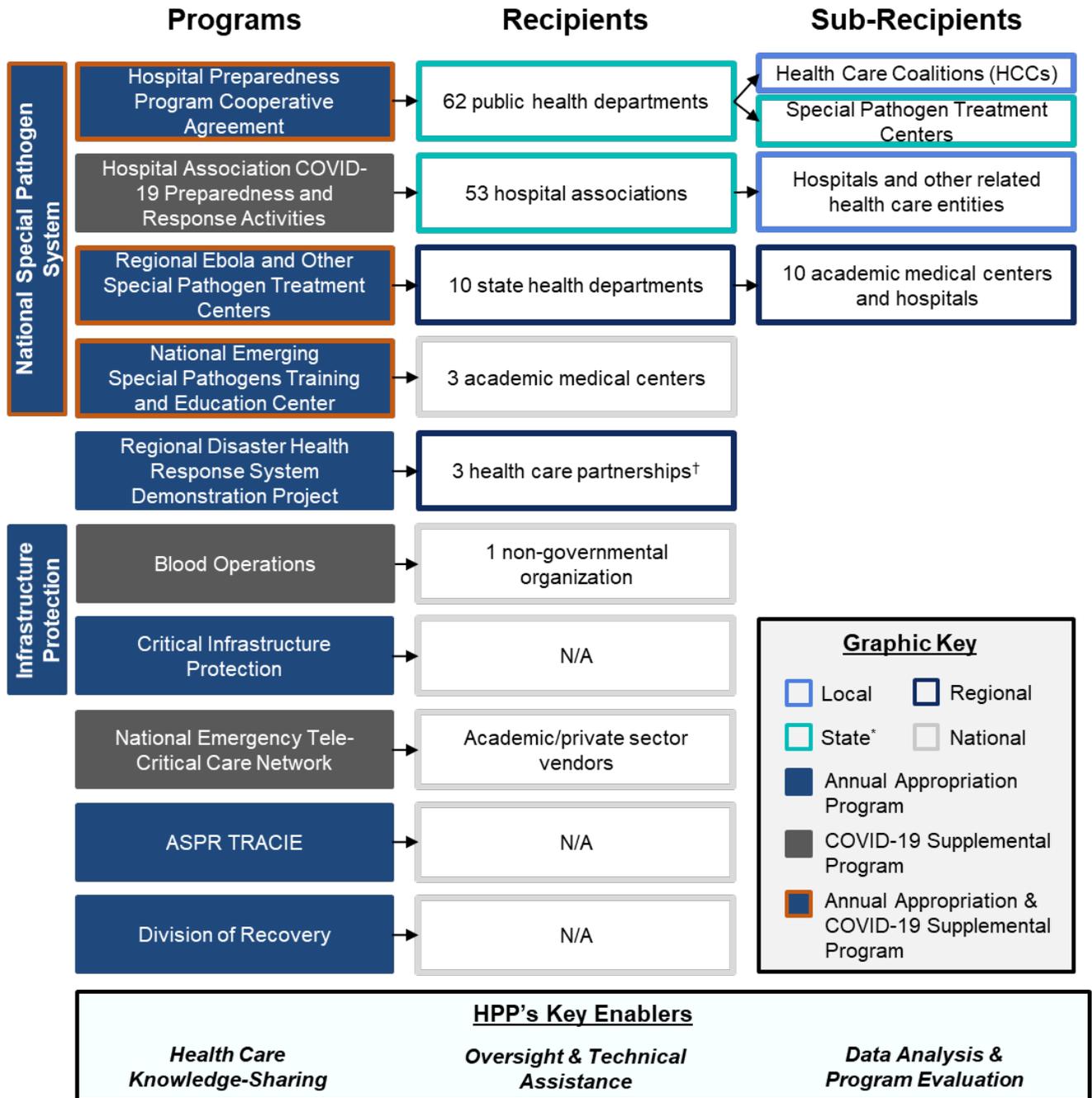


Figure 1. Notes

*Depending on the cooperative agreement/program, state-level recipients may also include states, territories, freely associated states, select metropolitan cities, and other jurisdictions.

[†]Partnerships include at least one hospital, one local health care facility; one political subdivision; one State, and one emergency medical service or emergency management organization. As of April 2021, ASPR funds three health care partnerships through RDHRS; in FY 2021, ASPR will fund a fourth partnership.

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

As the primary source of federal funding for health care system preparedness and response, HPP promotes a consistent national focus to improve patient outcomes during emergencies and to enable rapid health care service resilience and 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 RDHRS demonstration project. During COVID-19, HPP leveraged its strong network of public-private partnerships to provide effective supplemental funding to health care entities on the front lines of the pandemic. These coalitions and partnerships operate and coordinate activities across the local, state, regional, and federal levels to ready health care delivery systems for disasters and emergencies – including developing mechanisms for effective patient movement, communicating situational awareness, and providing resource-sharing. 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 health security threats.

In the past, HPP invested in increasing health care capacity to prepare for and respond to events through improving and coordinating communication, conducting patient tracking, and contributing to information-sharing. In recent years, HPP investments have moved beyond a focus on a single jurisdiction's or individual health care organization's capacity to enhancing a sub-state, state, or region's health care systems' capability to prepare for and respond to emergencies as soon as they occur, decreasing their state or region's reliance on federal medical assets during disasters.

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) – signed into law on June 24, 2019 – amended the Public Health Service Act to reauthorize funding and enhance authority for HPP. 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, managing relevant critical infrastructure protection activities, and requiring HPP to develop an evaluation of the program's evidence-based benchmarks. HPP's programmatic shifts are already well-aligned with these statutory imperatives, which build on existing HPP priorities. For example, in recent years, HPP has continued to expand and diversify the composition of the local, sub-state coalitions it supports; new statutory imperatives provide additional guidance on the types of membership to include.

The *2017-2022 Health Care Preparedness and Response Capabilities*⁹ 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*,¹⁰ *National Preparedness Goal*,¹¹ and the

⁹ *2017-2022 Health Care Preparedness and Response Capabilities*, <https://www.phe.gov/Preparedness/planning/hpp/reports/Documents/2017-2022-healthcare-pr-capabilities.pdf>

¹⁰ National Response Framework, 3rd Edition, June 2016. https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National_Response_Framework3rd.pdf

¹¹ National Preparedness Goal, 2nd Edition, September 2015. https://www.fema.gov/media-library-data/1443799615171-2aae90be55041740f97e8532fc680d40/National_Preparedness_Goal_2nd_Edition.pdf

*National Health Security Strategy and Implementation Plan*¹² 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 June 30, 2020, HPP has seen the following changes in HCC progress toward meeting one hundred percent of each capability:¹³

Changes In HCC Capabilities From FY 2016 to FY 2019

| Capability | FY 2016 | FY 2017 | FY 2018 | FY 2019 |
|---|----------------|----------------|----------------|----------------|
| Foundation for Health Care and Medical Readiness | 77% | 83% | 81% | 88% |
| Health Care and Medical Response Coordination | 67% | 71% | 74% | 88% |
| Continuity of Health Care Service Delivery | 65% | 69% | 68% | 77% |
| Medical Surge | 67% | 71% | 69% | 75% |

From FY 2016 to FY 2019, HCCs improved their progress toward meeting one hundred percent of each capability, with significant improvements in FY 2019 in Health Care and Medical Response and Continuity of Health Care Service Delivery, both of which reached eighty-eight percent.¹⁴

Using Data Insights to Measure Performance, Drive Decision-Making, and Guide Program Priorities

HPP uses performance measures (PMs) to monitor and analyze recipient performance in partnership with ASPR’s health system evaluation program. FY 2022 will be the sixth year in which the PMs will require reporting from HPP recipients, HCCs, territories and freely associated states, and isolated frontier hospitals.^{15,16} Consistent use of PMs fosters better communication of program results and continuous program improvement. The HPP PMs and resulting data enable HPP to: 1) ensure effective stewardship of taxpayer funds; 2) access data for evidence-informed policy decision making; 3) assess national readiness for emergencies affecting health care delivery; 4) promulgate promising practices for health care emergency preparedness and response; 5) communicate program results to elected officials and various internal and external stakeholders, and; 6) continuously learn and make evidence-based improvements to the program.

To measure HPP recipient performance, the various PMs were developed at the input activity, output, and outcome levels. While HPP PMs have historically focused on program activities and their associated outputs, the current PMs additionally target output and outcome measures to meet the information needs of various stakeholders. For example, over half of the PMs are exercise-based, which reduce the reporting burden on recipients, improves collection of actionable data, and permits data validation. Use of mixed reporting requirements to include exercise-based and program performance indicators over the course of

¹² National Health Security Strategy and Implementation Plan 2015-2018, <https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/nhss-ip.pdf>

¹³ The data used here was taken from end-of-year (EOY) performance data from the HPP budget period one (BP1) (July 1, 2019 through June 30, 2020).

¹⁴ Ibid.

¹⁵ For the FY 2019-2023 project period, HPP recognizes the unique challenges and needs of hospitals located in remote and isolated frontier communities. To improve the effectiveness of HPP funding and to reduce the burden on recipients and sub-recipients, ASPR worked with the Health Resources and Services Administration (HRSA) Federal Office of Rural Health Policy to categorize these hospitals and offer modified objectives, activities, and funding requirements

¹⁶ Due to COVID-19, ASPR updated or waived several of the required 28 HPP PM reporting requirements to reduce burden and provide greater flexibility to recipients and sub-recipients actively engaging in the COVID-19 response.

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. During regular data reporting cycles, 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.

During the COVID-19 pandemic, ASPR provided flexibilities to reduce burden on recipients and sub-recipients participating in the active response. Instead of capturing and analyzing data based on exercises, data collected during this period will reflect findings from the COVID-19 response itself.¹⁷

HPP continues to apply rigorous analysis to better understand performance, trends, and new insights about national readiness. This analysis includes internal reviews of the performance measures to assess their effectiveness, but also relies on external evidence-based analysis and stakeholder input to ensure that HPP's strategic direction reflects a health care industry perspective on readiness for contemporary threats.

Health Care Coalitions (HCCs)

Since 2012, HPP's formula-based cooperative agreement program has required its recipients¹⁸ 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. HCCs incentivize diverse, and often competitive, health care organizations with differing priorities and objectives to work together.

¹⁷ HPP recipients also received COVID-19 emergency supplemental funding which will require them to report on PMs specific to the pandemic response. These PMs will provide new insights on real-world execution of preparedness and response capabilities. Additionally, HPP is collecting other data from across its portfolio of programs, including recipients of funding for special pathogen preparedness (see 'National Special Pathogen System' section). These data include measures on real-world COVID-19 response as an allowable "exercise type" to reduce burdens on recipients.

¹⁸ 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.

Rural Maryland HCC Accelerates Information Sharing during the COVID-19 Pandemic

As the rate of hospitalizations increased due to COVID-19, health care facilities in all regions of Maryland, and particularly those in rural areas, began to experience elevated demand for personal protective equipment (PPE). The core members of the Regions I & II Health Care Coalition, which are located across Garrett, Allegany, Washington, and Frederick counties in western Maryland relied heavily on their HCCs for guidance on how to mitigate resource shortfalls and reports that this will continue to be critical in preparing for additional cases of COVID-19.

Comprised of a local health department and acute care hospital in each county as well as emergency management agencies, community health centers, state mental health facilities, long-term care facilities, a community college, and state health agencies, the Regions I & II Health Care Coalition has taken a variety of steps to proactively anticipate reduced capacity to treat COVID-19, including:

- **Tapping into local joint information centers (JIC) and emergency operation centers (EOC)** through conference calls and daily/weekly JIC releases to ensure that all coalition members have situational awareness of the spread of COVID-19 at the county level;
- **Performing weekly check-ins** with coalition members and **compiling their response activities into an HCC situation report**, which is shared with the Maryland Emergency Management Agency (MEMA); and
- **Conducting monthly coalition meetings** to share COVID-19 response updates and provide a platform to raise any unmet resourcing needs.

By activating its coalition response plans, the Regions I & II Health Care Coalition successfully transitioned to operating effectively in a virtual environment, ensuring uninterrupted access to data and information for its core members.

As of June 30, 2020, there are currently 42,128 HCC member organizations participating in 326 HCCs nationwide.¹⁹ ASPR requires that each HCC funded by cooperative agreement recipients include, at minimum, the following core members: two acute care hospitals, public health agencies, emergency medical services (EMS), and emergency management agencies.

The number of HCC members has more than tripled since HPP began focusing on regional health care coordination through HCCs in July 2012. **Figure 2** displays the four core members that each HCC must include and a variety of other partners that ASPR recommends engaging to maximize the potential readiness of the local health care system for disasters and emergencies.

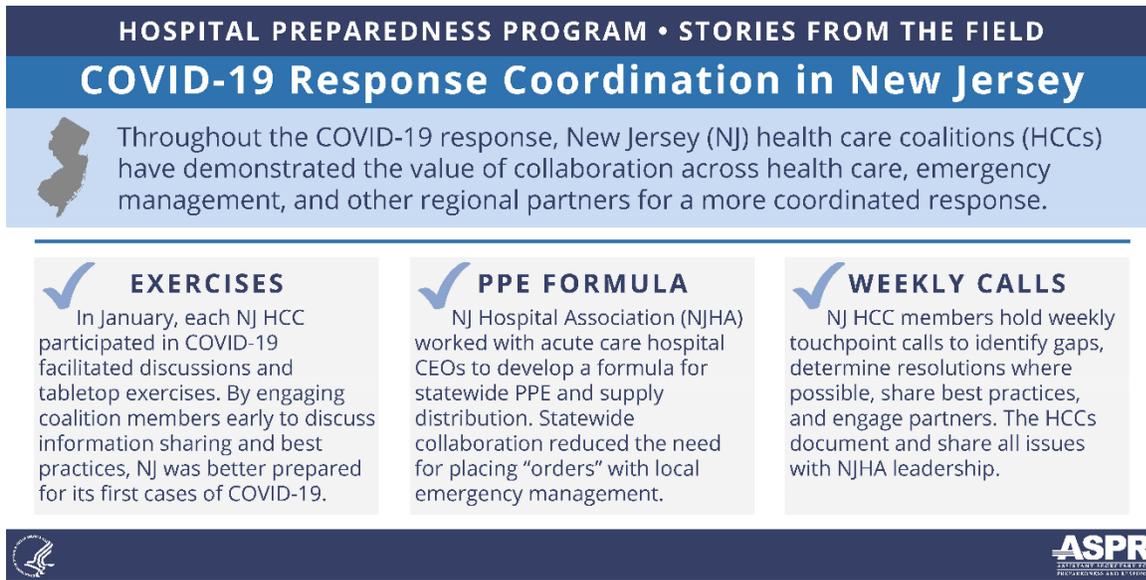
¹⁹ The data used here was taken from end-of-year (EOY) performance data from the HPP budget period 1 (BP1) (July 1, 2019 through June 30, 2020).

Figure 2. Health Care Coalition Membership



Robust HCC membership among the four core members and across multiple other membership categories is critical to building capacity across every component of the health care system and ensuring that preparedness efforts are not siloed. Collaboration across member organizations creates mechanisms for effective information and resource sharing during an emergency. During the COVID-19 response, which required coordination across a multiplicity of health care settings and partners, HCCs’ mechanisms for communication and planning across member types became integral to facilities’ ability to quickly build capacity and address COVID-19 surge. **Figure 3** demonstrates how the New Jersey HCCs were able to effectively coordinate during the COVID-19 response.

Figure 3. COVID-19 Response Coordination in New Jersey



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. In early 2020, the HHS Office of the Inspector General (OIG) published a report which articulates the success of HCCs achieving community preparedness and response, in addition to suggesting ways for further improvement, such as clarified guidance from ASPR on how HCC membership should ensure strategic, comprehensive coverage of communities and identifying new ways to incentive core member participation.²⁰ A complete version of the OIG report can be found on their [website](#).

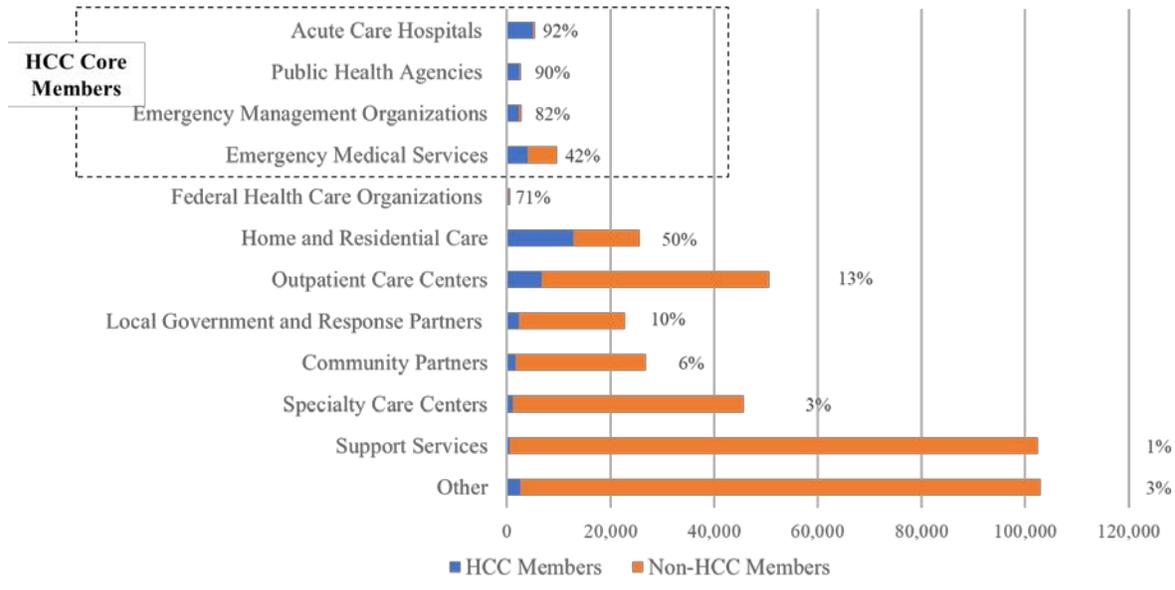
Figure 4 displays the HCC membership diversity and the participation rates by member type as of June 30, 2020. For example, there are currently 5,030 acute care hospitals participating in HCCs, which represents ninety two percent of all U.S. acute care hospitals. Additionally, there are 4,047 EMS agencies participating in HCCs, which represents forty two percent of all U.S. EMS agencies.^{21,22}

²⁰ HHS OIG “Selected Health Care Coalitions Increased Involvement in Whole Community Preparedness But Face Developmental Challenges Following New Requirements in 2017”, July 2020, <https://oig.hhs.gov/oei/reports/oei-04-18-00080.asp>

²¹ The data used here was taken from end-of-year (EOY) performance data from the HPP budget period 1 (BP1) (July 1, 2019 through June 30, 2020).

²² Members comprising the “Other” category include entities such as childcare services, dental clinics, social work services, faith-based organizations, and any other entity that does not align with the other categories.

Figure 4. HCC Membership Diversity and Participation Rates as of June 30, 2020²³



HCCs demonstrate the impact that private health care collaborations and investments in readiness have on the overall success of a community during an emergency. As one building block for a national system for health care preparedness and response, the success of coalition-based partnerships underscores the need for additional efforts designed to incentivize private health care participation in readiness. Informed by these insights, HPP has designed its other initiatives to complement and build upon the HCC model as well as addressing gaps. These other initiatives include regional systems for preparedness and response such as the RDHRS, as well as national assets to provide insights more widely. Together, HCCs and these other HPP initiatives provide resources to health care at every tier (local, state, regional, and national) as part of ASPR’s vision for a comprehensive system for preparedness and response.

Supporting Health Care Leaders during an Emergency Response

In addition to providing HCCs with funding support through the annual HPP cooperative agreement, HPP also enhances HCC preparedness and response capabilities through knowledge transfer, trainings, and sharing of promising practices. Through a partnership with the Federal Emergency Management Agency (FEMA) Center for Domestic Preparedness in Anniston, AL, ASPR provides instruction and practical experience in proven procedures for preparing and responding as an HCC leadership team to community and regional public health emergencies through the Health Care Coalition Response Leadership (HCRL) course. Course participation is fully funded for non-federal attendees. FEMA funds travel, lodging, and meals for HCC participants.

From September 2016 through March 2020, 72 HCCs from 30 states, District of Columbia, Puerto Rico, U.S. Virgin Islands, and six of the U.S. Pacific territories and freely associated states participated in the HCRL course. An additional 12 classes were planned for the remainder of 2020; however, due to COVID-19, only three classes were held. Each HCC that attends the HCRL course may invite up to nine participants, including leaders representing the four core members of HCCs: acute care hospitals, EMS,

²³ To calculate these rates, recipients report the denominators which are the total number of each member type within their jurisdiction.

emergency management agencies, and public health agencies. The three-day course offers insights and lessons learned in establishing an effective HCC framework, conducting HCC planning, and strengthening jurisdictional disaster readiness and 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. When a return to in-person instruction occurs following the COVID-19 pandemic, FEMA and ASPR plan to create a revised HCRL curriculum to include lessons learned from COVID-19 and expand the audience for these courses to better reach a diversity of leaders across the health care and emergency response ecosystem.

In addition to the HCRL course, HPP, FEMA, the National Highway Traffic Safety Administration (NHTSA) Office of EMS, the American Burn Association, the American College of Emergency Physicians, and the American College of Surgeons are developing a “Medical Response to Overwhelming No Notice Mass Trauma” course to improve clinical response to overwhelming, no-notice mass trauma events. The intended audience for this course includes clinical care providers (e.g., trauma surgeons, emergency physicians, EMS), and the curriculum integrates lessons learned from past large-scale events, such as the 2017 Las Vegas mass shooting. While in-person trainings for spring of 2020 were postponed due to COVID-19, a trial version of the course was piloted in November 2019 and the public-private partnership leading the development of the curriculum plans to resume full trainings in the future.

These opportunities demonstrate the potential for HPP to provide trainings, peer-to-peer knowledge sharing, and other mechanisms for information exchange to a wide range of stakeholders (inclusive of and beyond HCCs and other program recipients) across the health care sector. As HPP continues to grow and modernize its portfolio, it will be important for the program to maintain pace with its expansion by creating commensurate trainings and support to health care professionals across the sector to ensure that promising practices are disseminated and implemented appropriately.

Creating the National Special Pathogen System (NSPS)

In the past, public-private partnerships were formed to develop national systems designed to address specific types of clinical care; for example, the national trauma, cardiac, and stroke care system. These systems were designed to create “hub and spoke” models of care to enable health systems across the country to access specialty care and expertise, and to create standards and protocols for treatment of these conditions. These models were used to inform and develop the Regional Ebola Treatment Network (RETN), which similarly leveraged public-private partnerships in order to strengthen health care response capabilities during the Ebola response of 2014-2015. The National Special Pathogen System (NSPS) builds on the Regional Ebola Treatment Network (see **Figure 5** for more detail) to support the urgent preparedness and response needs of hospitals, health systems, and health care providers on the front lines of the COVID-19 pandemic. The NSPS helps prepare these entities to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens, in addition to persons under investigation for such illnesses. While the NSPS has recently demonstrated utility for COVID response efforts, the intent of the NSPS is to create a nationwide systems-based network approach for all special pathogens.

Figure 5. Transforming Ebola Infrastructure to a National Special Pathogen System

| | Regional Ebola Treatment Network | National Special Pathogen System (NSPS) |
|--|--|---|
| RECIPIENTS  | <ul style="list-style-type: none"> The National Ebola Training and Education Center (NETEC) 10 Regional Ebola and Other Special Pathogen Treatment Centers HPP Cooperative Agreement recipients and their state and jurisdiction Ebola Treatment Centers Ebola Assessment Hospitals & Frontline health care facilities | <ul style="list-style-type: none"> NETEC rebranded as the National Emerging Special Pathogens Training and Education Center 10 Regional Ebola and Other Special Pathogen Treatment Centers HPP Cooperative Agreement recipients and their 55 state and jurisdiction Special Pathogen Treatment Centers (formerly Ebola Treatment Centers) Hospital associations in all 50 states, DC, NYC, and Puerto Rico added as a new component |
| SCOPE  | <ul style="list-style-type: none"> Informed by national systems designed to address specific types of clinical care (e.g., the national trauma system) Leveraged public/private partnerships in order to strengthen health care response capabilities for Ebola and other special pathogens at the local, regional, and national level | <ul style="list-style-type: none"> Formalizes a national system and strategy for special pathogens, similar to other national systems designed to address specific types of clinical care (e.g., the national trauma system) Leverages public/private partnerships in order to strengthen health care response capabilities at the local, regional, and national level for any special pathogen, including COVID-19 |

The NSPS is comprised of four different components that complement and build on one another to form the national system: the National Emerging Special Pathogens Training and Education Center (NETEC), ten Regional Ebola and other Special Pathogen Treatment Centers (RESPTCs), 62 Hospital Preparedness Program (HPP) recipients, and 53 hospital associations, which ASPR added as new recipients supported through COVID-19 supplemental funding (see **Figure 6**). More information about the National Special Pathogen System, and the network’s COVID-19 accomplishments and activities supported through emergency COVID-19 supplemental funding can be found in the ‘COVID-19 Supplemental Funding Impacts’ section.

Figure 6. National Special Pathogen System Recipients and Sub-recipients



Even prior to COVID-19, through earlier HHS investments in Ebola and other special pathogens (e.g., H1N1 influenza pandemic, MERS, Nipah Virus), the U.S. health care system achieved significant progress in the development of a regional, tiered network for the treatment of special pathogens:

- In FY 2019, the average time it took an Ebola Treatment Center²⁴ to admit a patient with a special pathogen improved from previous years; that year, admittance for another special pathogen (OSP) patient took 3.5 hours on average (down from ten hours in FY 2017 and well within the 72-hour program goal).
- In FY 2019, eighty-six percent of HPP recipients and their Ebola Treatment Centers (now Special Pathogen Treatment Centers) 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 seventy-six percent of funding recipients in FY 2018 and from forty eight percent of funding recipients after the first year of funding (FY 2015).²⁵

Also in FY 2019, seventy-seven percent of HPP recipients and their Ebola Treatment Centers (now Special Pathogen Treatment Centers) reported that 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. At that time, 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.²⁶ While the COVID-19 pandemic presented many new challenges and uncovered previously unknown gaps in special pathogen preparedness, HPP’s investment in the Regional Ebola Treatment Network equipped recipients with a foundation for a coordinated response to all novel infectious disease – one hundred percent of Ebola Treatment Center²⁷ staff were trained in safely donning and doffing personal protective equipment (PPE) in FY 2019, with the number of individual staff trained in PPE having increased by 2,253 from FY 2016 to FY 2019. Similarly, consistently, over ninety three percent of emergency department staff were trained annually in infection control and safety, with a grand total of 97,858 total trainings having been completed between FY 2015 and FY 2019.²⁸⁻²⁹ While previous achievements related to the Ebola response demonstrate a positive proof of concept for a national system approach to the response to highly pathogenic infectious diseases, gaps and challenges identified during the COVID-19 response highlight the need for the continued evolution of that system.

In addition to tracking recipient accomplishments and improvements in preparedness and response capabilities for special pathogens, previous HPP investments in Ebola and other special pathogen preparedness have also enabled the program to track areas for improvement and continued investment. For example, six out of ten of the Regional Ebola and Other Special Pathogen Treatment Centers reported difficulty with regional collaboration – either in exercising patient movement or reaching entire geographic spread throughout the region³⁰ – which informed HPP’s approach to developing the National Special Pathogen System, including a new emphasis on a nationwide systems-based network approach for

²⁴ Ebola Treatment Centers are now Special Pathogen Treatment Centers; however, data was collected under previous title.

²⁵ FY 2019 HPP Ebola Data, collected from July 1, 2019 – June 30, 2020..

²⁶ Ibid.

²⁷ Ebola Treatment Centers are now Special Pathogen Treatment Centers; however, data was collected under previous title.

²⁸ The same staff members may have been trained each year. Individual staff are only counted once per year.

²⁹ FY 2019 HPP Ebola Data, collected from July 1, 2019 – June 30, 2020.

³⁰ Ibid.

preparedness and response to special pathogens such as COVID-19 similar to other evidence-supported models that improve patient outcomes (e.g., the national trauma system).

National Emerging Special Pathogens Training and Education Center (NETEC)

The National Emerging Special Pathogens Training and Education Center (NETEC) is a critical component of the NSPS. NETEC is a consortium of the three U.S. academic medical centers that safely and successfully treated a confirmed Ebola patient during the 2014 outbreak – 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. Originally, ASPR and the CDC awarded funding to NETEC to help the broader United States health care system prepare for and provide safe and successful care of patients with Ebola Virus Disease. Since then, NETEC has pivoted to support the nation’s health care entities’ preparedness and response for all pathogens of high consequence. The NETEC provides expertise, training, technical assistance, peer review, monitoring, and recognition to the other components of the NSPS, including health care delivery systems in states, territories, and freely associated states, RESPTCs, state- and jurisdiction-based Special Pathogen Treatment Centers, hospital associations, EMS, and other health care entities across the nation.

FIGURE 7. NETEC FY2020 ACHIEVEMENTS

FY 2020 NETEC BY THE NUMBERS
(approx. July 1, 2019 – June 30, 2020)



NETEC³¹ has significantly influenced and improved the overall preparedness and response capabilities for current and future special pathogen events. The consortium 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. A significant NETEC achievement has been the development of an integrated national clinical research network for special pathogens, which was especially important during response to COVID-19, a new special pathogen. This network consists of research sites at each of the ten RESPTCs, supported by centralized resources, including a common rapid response institutional review board, a data repository, a biorepository, research training protocols, and standardized polices. In response to the COVID-19 pandemic, the special pathogen research network successfully initiated a network-wide clinical trial for the investigation of novel medical countermeasures for the treatment of COVID-19 infection in collaboration with the National Institutes of Health (NIH), the Adaptive COVID-

³¹ 2020 NETEC Annual Report https://netec.org/wp-content/uploads/2020/12/NETEC-FY20-Annual-Report_12.2020.pdf

19 Treatment Trial (ACTT). NETEC's special pathogen research network also supported all ten RESPTCs' enrollment in Remdesivir treatment trials for COVID-19.

NETEC has continued to improve national preparedness and response for special pathogen incidents, including during the COVID-19 response. NETEC's key accomplishments for FY 2020 are depicted in **Figure 7**, and include conducting 119 virtual consultations for the COVID-19 response, creating 430 COVID-19 related resources, and 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. During the response, NETEC pivoted to conducting virtual site visits with the ten RESPTCs and other facilities. In addition to pivoting to a virtual format during COVID-19, NETEC also began conducting assessments of long-term care facilities for the first time. These shifts helped NETEC achieve new economies of scale for site visits, informing their overarching strategy to better meet the training and education needs of the entire NSPS and health care sector more broadly. NETEC also plays an important role collaborating with HHS/ASPR Project ECHO COVID-19 Clinical Rounds (refer to 'COVID-19 Supplemental Funding Impacts' for further information). NETEC's COVID-19 webinars complement the COVID-19 Clinical Rounds. During COVID-19 Clinical Rounds, NETEC has provided a depth of expertise in their contributions as speakers and/or panelists. In 2019, PAHPAIA introduced 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.³² NETEC's activities related to improving infection control practices and workforce preparedness against COVID-19 align with those national preparedness goals set forth in PAHPAIA.

NETEC plays a vital role in the National Special Pathogen System, as the consortium is responsible for developing the strategy for a truly national system of care for special pathogens, similar to those used for other medical conditions (e.g., stroke, cardiac care, etc.). To develop the strategy for the National Special Pathogen System, NETEC has engaged 72 stakeholders across the entirety of the health care preparedness and response ecosystem, identifying opportunities to enhance national coordination and developing approaches for mitigating underlying, systemic barriers to special pathogen readiness. As of spring 2021, NETEC is finalizing the strategy and has mobilized teams of experts that will pursue implementation. These activities are vital stepping stones for the National Special Pathogen System, and will ultimately elevate the existing system and bring the nation closer to a stratified system for special pathogen identification, care, and readiness.

While NETEC built on the infrastructure it developed through the Ebola response, COVID-19 demonstrated the need for continued growth of a national body of knowledge on special pathogen care, as well as the need for connected networks to share and advance that knowledge for health care sector implementation. It is vital to continue to invest in NETEC to equip the consortium – and the broader National Special Pathogen System – with the resources it needs to build national capacity for special pathogen care as well as to integrate effectively with other all-hazards systems (e.g., the RDHRS) across the country.

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 both to monitor individuals coming to the U.S. possibly exposed to Ebola or other highly infectious diseases from impacted regions, and also for individuals already within the U.S. exposed to highly infectious diseases. To close this gap, HPP awarded

³² The Public Health Service Act, Sec. 2802(b)

nearly \$20 million in FY 2017 to University of Nebraska Medical Center (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 for up to 30 days. It is the only federally funded entity capable of providing the U.S. government with the services and facility needed to quarantine individuals exposed to Ebola and other highly pathogenic diseases, and to do so within 24 hours. During the COVID-19 response, ASPR's contract with UNMC allowed the federal government to place 22 individuals evacuated from a cruise ship and one individual from Wuhan, China into the TSQC quarantine facility until cleared for release. The nature of the facility allowed UNMC to quickly adapt and use the facility to isolate and care for eight of these individuals who became symptomatic. In addition to utilizing the TSQC facility, ASPR was able to quickly modify the contract to obtain UNMC's services to quarantine, provide basic services to, and monitor 68 individuals evacuated from Wuhan, China and housed at Camp Ashland, an Army National Guard facility near Omaha, Nebraska.

This TSQC facility also 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 such as COVID-19, in both sophisticated and austere environments. In FY 2018, 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 chemical, biological, radiological, and nuclear (CBRN) incidents, training 1,714 NDMS responders over the course of three days. As of September 18, 2019, UNMC trained 359 NDMS and PHS Commission Corps staff and responders, having developed a training curriculum to provide simulated and virtual reality clinical training for health care personnel treating individuals with highly pathogenic diseases. In FY 2019, UNMC began developing additional courses to train NDMS responders on the complexities of preparing and transporting patients with Ebola or similar highly infectious diseases, and how to coordinate the safe transport of the remains of victims who died from Ebola or other highly infectious diseases.

The emergence of COVID-19 in 2020 prompted ASPR to quickly adapt the specific training requirements needed to instruct NDMS and PHS personnel on how to safely care for individuals with or suspected of having COVID-19. On March 16, 2020, ASPR worked with UNMC to develop a Mission Preparation course for individuals to take prior to deployment to COVID-19 hotspot areas. Because travel for training was prohibited during the COVID-19 pandemic, UNMC quickly developed an online training course. As of April 2021, 1,796 NDMS and PHS Commission Corps personnel have registered and 1,248 personnel have completed the course. In 2021, planning has begun to obtain the services of UNMC to train an additional 2,400 NDMS personnel on the appropriate infection control procedures and the use of PPE when treating individuals with COVID-19.

Expanding a Regionalized Approach to Public Health and Medical Preparedness and Response

To address gaps in regional health care delivery during disasters, ASPR developed the Regional Disaster Health Response System (RDHRS): a tiered system that builds upon and unifies existing assets within states and across regions that supports a more coherent, comprehensive, and capable health care disaster response system able to respond health security threats. The RDHRS helps improve disaster readiness capabilities and capacity, increase medical surge capacity, and extend provision specialty care - including trauma, burn and infectious disease, among others - during large-scale disasters or public health emergencies. ASPR currently funds cooperative agreements with three demonstration sites in preparation for building a full nationwide system with RDHRS sites in every HHS region. Current sites include the Region 1 RDHRS, based at Massachusetts General Hospital, the Region 7 Regional Disaster Health Response Ecosystem (RDHRE), based at the University of Nebraska Medical Center, and the Region 8

Mountain Plains RDHRS, based at Denver Health and Hospital Authority. The demonstration sites in Region 1 and Region 7 were initiated in FY 2018, whereas the Region 8 site was initiated in FY 2020. More detailed information about the progress of the first two RDHRS demonstration projects can be found in a [Report to Congress](#), which was released in July 2020.

RDHRS demonstration site core capabilities include building a partnership for disaster health response, aligning plans, policies, and procedures related to clinical excellence in disasters, increasing statewide and regional medical surge capacity, improving statewide and regional situational awareness, developing readiness metrics, and conducting exercises to test capabilities. Importantly, RDHRS sites are not standalone structures. They foster strong partnerships across all levels of government, and existing state, local, tribal, territorial (SLTT), regional, and national assets and structures. As a result, RDHRS work can serve as a unified system across trauma center networks and facilities, burn centers, health care coalitions, EMS systems and networks, and more. In fact, the existing sites each had over 30 partnership agreements and letters of support across their communities to establish their concepts. Sites have additionally already taken action to aid both national and regional preparedness and response and advance solutions to address challenges. Both Region 1 and 7 have enhanced regional operationalization through both actualized and potential models for state- or hospital-hosted deployable medical teams including strategies for creation and long-term sustainability to enhance regional capacity especially in the first 72 hours of response. These programs have aligned with capabilities and structures of federal NDMS teams to foster collaboration potential. Additionally, the demonstration sites 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. Additionally, the demonstration sites created recommendations for readiness metrics that can be used for peer review assessments, monitoring, recognition reporting, and a “Response Ready” designation program for HCCs. Together, each of these programs advances work not only within the demonstration site and region, but also has the potential to impact programs and policies on a nationwide scale.

In Year Two of the program, the Region 1 and Region 7 RDHRS, the two foundational RDHRS pilots, significantly improved clinical collaboration across the private health care sector in their states and have initiated strategies to expand collaboration across their HHS regions while responding to the COVID-19 pandemic. By December 30, 2020, 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. These products include over 50 tools and resources to support training, organization and reporting structures, data collection and information-sharing, telemedicine, state deployable medical teams (DMTs), and the navigation of legal and policy challenges. Now currently in their third year, the two sites are focused on operationalizing partnerships built since their respective site’s initiation, further strengthening their community effectiveness in responding to disasters. Both sites have made progress in facilitating rapid expansion of medical surge capacity, coordination of patient and resource movement, swift involvement of specific clinical specialists integrating into state planning and response, and in further delving into financial incentives for preparedness. During the COVID-19 pandemic, these programs leveraged existing funding and capabilities to support regional response efforts and strengthen relationships within their communities, described in detail below.

The Region 8 Mountain Plains RDHRS, currently beginning their first quarter of their first year, continues to expand the RDHRS model and vision for multi-state, regional emergency preparedness and response partnerships. To date, the Mountain Plains RDHRS is focused on identifying and onboarding

key partners, developing the partnership, and responding to both COVID-19 and other disasters including wildfires. The Mountain Plains RDHRS is currently conducting a gap analysis at a regional level to identify areas of future work, with documentation solicited from partners including health care coalitions, local public health and emergency management agencies, Regional EMS/Trauma Advisory Councils, public-safety answer points, hospital associations, regional American Burn Association (ABA), burn coordinators, and more. Following in the footsteps of Region 1 and Region 7, the Mountain Plains RDHRS is also developing an exercise to leverage the capabilities of health care coalitions and further enhance the implementation of coalition requirements on burn surge. With the addition of this third site, the RDHRS sites have started to show their true potential as a national network. The sites currently work closely at multiple levels to plan, share, and coordinate capabilities while leveraging lessons learned from others to maximize implementation impacts while tailoring solutions for their regions. The current demonstration sites include both urban and rural environments, displaying the unique solutions that best meet their regional needs.

Advancements in the RDHRS demonstration sites 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 demonstration sites have improved all-hazards regional preparedness with a focus on the highly specialized clinical care capabilities related to specific health security threats as well as to specific populations with additional health care needs in disasters. Furthermore, insights generated through the RDHRS demonstration project have informed the development of other programs such as the Pediatric Disaster Care Centers of Excellence, which funded two demonstration sites to enhance the delivery of pediatric clinical care when existing systems are stressed or overwhelmed by enhancing rapid sharing of expertise and assets throughout the state or region. While HPP partially funded this work and does not have programmatic oversight of this initiative (i.e., NDMS provides administrative oversight), RDHRS helped shape the development of the Pediatric Disaster Care Centers of Excellence leveraging lessons learned.

Demonstration sites furthermore made a clear impact during the COVID-19 pandemic response, for which each site leveraged base year funding to demonstrate their fundamental capabilities as an RDHRS responding to a disaster within their region in partnership with their full community. The foundational sites rapidly pivoted to operationalizing concepts developed in Year 1, and the Mountain Plains RDHRS rapidly integrated into partnerships to strengthen response capability and capacity. These successful mobilizations increased engagement of health care delivery and medical expertise in disaster planning and response, immediately augmented their region's disaster medical capabilities, and provided medical expertise patient movement to public health and emergency management leaders. Though the response to COVID-19 has demonstrated that the nation has not fully achieved the cross-state regional health care collaboration necessary to confront large-scale public health and medical emergencies, each site truly leveraged their partnerships to address regional needs and strengthen coordination. Though gaps remain, the RDHRS is well positioned to expand its footprint and mature regional disaster response capacities to meet this need nationwide. As described by the Region 1 RDHRS in their Year Two Annual Report:

“The global pandemic provided an unprecedented opportunity for our team to rapidly pivot from theory to actual mobilization of RDHRS response capabilities in support of our local, state, and regional partners – highlighting the inherent value of an RDHRS to identify and address gaps within coordinated patient care during disasters.”³³

³³ MA/Region 1 Partnership for Regional Disaster Health Response: “Year Two Final Report”

This demonstration initiative should scale to fully address lessons learned from the COVID-19 response and to coordinate effectively with other networks that complement the RDHRS (for example, the National Special Pathogen System) through the depth of knowledge that they provide.

Early lessons from the COVID-19 response suggest that a strong, coordinated, regional approach is warranted to ensure the right services and resources are getting where they need to be in a most efficient and expedited manner. Continued implementation of the RDHRS network will strengthen health care resilience, coordination, existing structures, and preparedness and response capabilities across all levels of government and industry.

Region 1 and Region 7 COVID-19 Response Activities

Region 1 RDHRS (Massachusetts General Hospital)

Ventilator Distribution and Surge Capacity: The Region 1 RDHRS mobilized clinical experts to work with state health authorities to support distribution of over 400 surge ventilators across MA. Additionally, convened citywide hospital group that met daily to optimize ICU and hospital surge capacity across metro Boston hospitals and load-balance the distribution of critically ill COVID-19 patients.

Piloting Novel Response Systems: The Region 1 RDHRS collaborated with Bluestream Health to develop a rapidly deployable, easy to use, HIPAA-compliant telemedicine platform. Piloted the system to provide access to critical care expertise for community hospitals for the treatment of COVID-positive patients.

Region 7 RDHRE

Essential Elements of Information Sharing: The RDHRE Knowledge Center team has been coordinating with local coalitions and the state to develop EEIs and develop a trended EEI dashboard for the state for daily monitoring by health system and public health leaders as well as the governor's office. RDHRE also engaged with the Nebraska Health Information Initiative (our state health information exchange) to align data captured within Knowledge Center to create efficiencies for coalitions and health systems.

Just in Time Training (JITT): RDHRE provided JITT tools to local, state and regional partners for COVID-19 response. These resources were consolidated from other sources and shared throughout the region through knowledge Center, the Nebraska Medicine COVID-19 page, and our Region 7 RDHRE website. RDHRE team members conducted 49 onsite technical visits and provided recommendations to long-term care facilities, meat packing plants and shelters. The Nebraska Medicine resources page is now acknowledged on Up-to-Date, one of the most popular internet-based technical references for medical professionals.

Providing Technical Assistance and Oversight

Across its portfolio of health care readiness programs, HPP provides critical technical assistance, cooperative agreement oversight, and strategic partnership coordination to health care stakeholders (including 130+ cooperative agreement recipients). Throughout the COVID-19 pandemic response, HPP staff played an integral role in quickly releasing funding to recipients, standing up the National Special Pathogen System that engaged existing HPP cooperative agreement recipients and added one completely new recipient pool of hospital associations recipients, to provide support to recipients on the front lines of the response. HPP regional staff provide subject matter expertise across a portfolio of programs, and conduct health care administration, management, policy development, capacity building, and capability development activities to maximize program implementation, performance, and impact. HPP currently coordinates these complex support activities between cooperative agreement recipients and stakeholders through 11 HPP regional staff members assigned across all ten HHS regions (Region Nine has two staff

members). In addition to providing technical assistance to recipients and stakeholders within their region, regional staff are responsible for ensuring compliance with the programmatic aspects of the cooperative agreement (e.g., compliance with statutory, regulatory, accounting, and administration rules). Regional staff also ensure HHS programmatic objectives and requirements are met, supporting recipients and sub-recipients (e.g., HCCs, hospital associations, health care systems, etc.) as they work to improve their performance and enhance capacity for preparedness and response. Regional staff members develop and maintain important relationships that help health care stakeholders and other public and private partners – including other HHS regional staff – effectively respond to disasters. The relationship between recipients and program leadership is a vital component of efficient and effective stewardship of federal funds that are used to enhance and protect the nation’s health care system.

In responding to COVID-19, regional staff’s situational awareness was critical in providing hospital data and operational needs. This included identifying key challenges related to PPE access, hospital bed availability, and the need for rapid distribution of funds to states and hospital associations. Regional staff were critical to the success of numerous other responses across the country occurring simultaneously with the COVID-19 pandemic. During the extreme winter weather event in February 2021, HPP regional staff support was instrumental for Region 6. HPP provided technical assistance to health care coalitions related to the distribution of generators between hospitals, enabling the continuity of patient care. HPP also supported the coordination of individuals to designated warming centers to reduce hospital burden, and worked with Texas utility companies to aid in the return of power to portable O2 plants impacted by the weather event. Overall, regional staff roles as strategic advisors to health care stakeholders and agency representatives to the health care sector expanded as they supported a broad spectrum of cooperative agreement recipients, sub-recipients, and stakeholders throughout the COVID-19 response and various concurrent events, including west coast wildfires, cyberattacks, and annual hurricane and tornado seasons – and regional staff will continue to be essential to HPP’s success.

Providing and Sharing Critical Information to a Nationwide Audience

In addition to providing specialized technical assistance to HPP recipients through its regional staff, HPP also supports the formalized delivery of technical assistance to health care stakeholders nationally. Beginning in FY 2015, the ASPR Technical Resources, Assistance Center, and Information Exchange ([TRACIE](https://asprrtracie.hhs.gov))³⁴ has been enhancing and expanding its technical assistance to state and local communities to enhance their preparedness and response capabilities. Aligned with HPP’s programmatic goals and priorities, ASPR TRACIE 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 8** provides an infographic snapshot of ASPR TRACIE’s impact and reach, capturing data about the number of visitors to the ASPR TRACIE website, number of technical assistance requests received, number of members in its information exchange, and the ASPR TRACIE Listserv reach through March 2021.

The ASPR TRACIE system provides evidence-based applications, information, and proven best practices to help states, health care coalitions and entities, jurisdictions, and communities build enhanced capacity and capability and improve their knowledge and effectiveness. ASPR TRACIE develops and disseminates appropriate, action-oriented technical assistance materials through a coordinated system. Since its launch,

³⁴ ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) Homepage, <https://asprrtracie.hhs.gov>

the ASPR TRACIE website has been available 24/7, 365 days a year, ensuring that stakeholders can readily access and download virtual resources as needs arise.

Since ASPR TRACIE's launch in September 2015, the platform has experienced an exponential increase in use and demand. Initially, web traffic began with a few hundred visitors per month. Currently, monthly web visitation now surpasses an average of 16,000 visits per month, with visitor volume reaching over one million in December 2020 (concurrent with the COVID-19 pandemic). The monthly number of technical assistance (TA) requests received has increased steadily in the last five years, including a record 569 requests processed in September 2020. ASPR TRACIE has also experienced an increase in TA requests that are complex and highly specialized, requiring significant time and specific subject matter expertise to complete them. ASPR TRACIE sees spikes in both TA requests and website visitation statistics during times of declared national emergencies and local disasters. ASPR TRACIE also sees surges in these analytics when offering widely promoted resources (e.g., webinars) and highly anticipated tools and templates – particularly when related to a current or recent incident. ASPR TRACIE is increasingly seen as a “go to” resource during disasters and in preparation for disasters. ASPR TRACIE has identified [over 10,000 resources](#) to include in the ASPR TRACIE database and developed [over 350 resources](#) to fill identified gaps and information needs. Specifically, ASPR TRACIE has provided:

- Consultation with more than 1,000 subject matter experts (SMEs).
- Publication of over 350 [SME-validated resource materials](#).
- Resource pages dedicated to topic areas of particular interest to our stakeholders (e.g., [CMS and Disasters](#), [CBRN](#), [HCCs](#), [Infectious Disease](#), [Mass Violence](#), [Hurricane-Related](#), [Drug Shortages and Scarce Resources](#), -, [Emergency Medical Services](#), [Partners in Medical Surge](#), [COVID-19](#), [COVID-19 Patient Surge and Scarce Resource Allocation](#)).
- Development, SME-reviewed, and continual maintenance of 57 [topic-specific collections](#) of resource materials.
- Development, SME-reviewed, and continual maintenance of 20 COVID-19 specific [resource collections](#) or relevant and timely materials for health care system preparedness, response, and recovery from COVID-19.
- Access to online plans, tools, templates, and trainings.
- Thirteen issues of the newsletter, [The Exchange](#) featuring lessons learned from practitioners in the field.

In direct support of HPP cooperative agreement requirements, ASPR TRACIE has:

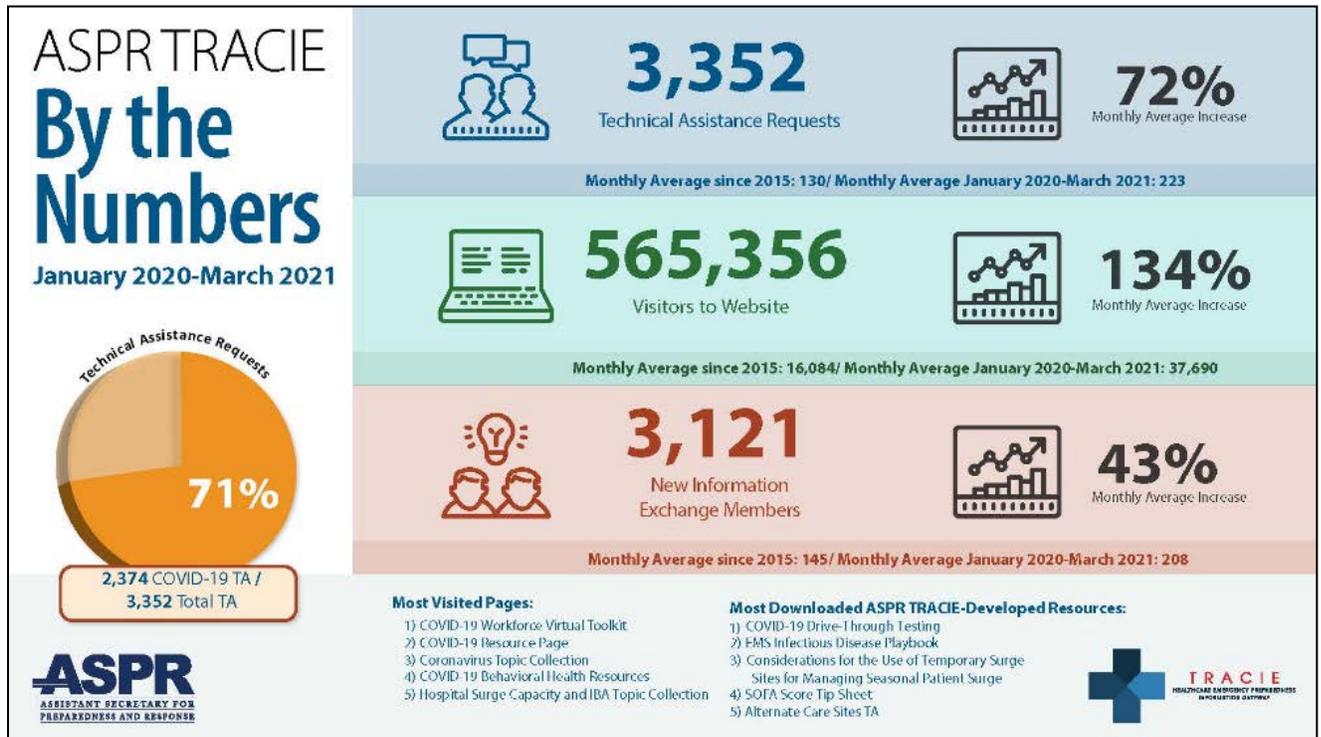
- Conducted national webinars and provided virtual technical assistance to help better inform HPP recipients and their HCCs on several preparedness topics (e.g., HCC- related webinars, HCC Pediatric Surge Annex, Health Care Cybersecurity Response, COVID-19 Impact on Children, Crisis Standards of Care, and Alternate Care Sites).
- Conducted online peer-to-peer engagement and support through the Information Exchange.
- Created tools and templates (e.g., [HCC Burn Care Surge Annex Tabletop Exercise Toolkit](#)).
- Developed resource documents, tip sheets, and illustrative examples of promising practices (e.g., [Health Care System Cybersecurity Readiness and Response Considerations](#), [Health Care Recovery from TX Severe Weather](#), [Health Care Communication Vulnerabilities: Nashville, TN](#), [ASPR TRACIE-developed COVID-19 specific resources](#)).
- Provided technical assistance to numerous HCCs on the surge estimator tool and aggregator.
- Developed a burn care surge tabletop toolkit for health care coalitions.

HPP HCCs are required to develop coalition-level annexes to their base medical surge/trauma mass casualty response plans to manage a large number of casualties with specific needs (e.g., specialty care

for burn, infectious disease, radiation/chemical injuries, etc.) In 2020, at HPP’s direct request to support its cooperative agreement recipients, ASPR TRACIE developed HCC templates for the Pediatric Care Surge Annex, Burn Surge Annex, and Infectious Disease Surge Annex. Tabletop exercise toolkits were also developed for each of these topic areas. ASPR TRACIE is currently developing a Radiation Mass Casualty Events Surge Annex. ASPR TRACIE also provides surge assistance and resources during and after incidents, to be particularly helpful for ASPR and local deployable personnel (e.g., NDMS, Medical Reserve Corps). After fielding numerous calls over the last five years for issues related to Disaster Behavioral Health support for deployed health care personnel, ASPR TRACIE has developed information modules focused on [Disaster Behavioral Health Self Care for Health Care Workers](#) and created [Disaster Behavioral Health Mini Modules to relieve stress for health care workers responding to COVID-19](#).

ASPR TRACIE has focused on developing a robust collection of highly infectious disease resources and materials since its inception in 2014. In preparation for and response to COVID-19, ASPR TRACIE began compiling and sharing [infectious disease resources](#) that would be useful and relevant to health care system preparedness stakeholders in February 2020. In March 2020, at the request of the Health Care Resilience Task Force of the FEMA National Resource Coordination Center, ASPR TRACIE developed a Novel Coronavirus Resource Page, developed 20 COVID-19 specific resource collections, and over 100 COVID-19 related resources. The ASPR TRACIE Novel Coronavirus Resource Page became the coordinating point for health care system preparedness information and resources from the Task Force. Requests for technical assistance and overall visits to the website increased exponentially in 2020 as a result of both COVID-19 and increased national-level use and promotion of ASPR TRACIE. **Figure 8** demonstrates the increased use of ASPR TRACIE between January 2020 and March 2021 above the previously measured baseline.

Figure 8. ASPR TRACIE January 2020-March 2021 Data



Despite increased demand for technical assistance requests and an increased surge in visitors to the website, ASPR TRACIE continues to provide resources and expertise to meet the needs of its stakeholders. ASPR TRACIE is currently experiencing a seventy-two percent increase in the average number of technical assistance requests received per month and a one hundred thirty-four percent increase in the average number of users on the website. In a highly collaborative environment, ASPR TRACIE has created innovative processes for achieving consensus-based approaches for sharing and developing resources that can be easily leveraged and accessed by all those involved in health care preparedness, response, and recovery activities.

As the contemporary threat landscape continues to evolve, ASPR TRACIE must be able to continue to nimbly anticipate and respond to stakeholders’ needs, create meaningful and implementable resources for stakeholders to use before a disaster strikes, and address the just-in-time needs of our stakeholders during and following emergencies ([Select ASPR TRACIE Developed Resources](#)). As the lead curator and convener of national emergency preparedness and response technical assistance resources and expertise, ASPR TRACIE plays an essential role in sustaining health care’s body of knowledge related to readiness and resilience.

Preparing and Protecting Critical Health Care and Public Health Infrastructure

The Healthcare and Public Health (HPH) Sector of critical infrastructure is directly responsible for four of the National Critical Functions:³⁵ providing medical care, supporting community health, maintaining access to medical records, and preparing for and managing health emergencies. These functions are defined by the Department of Homeland Security as “so vital to the United States that their disruption, corruption or dysfunction would have a debilitating effect on security, national economic security, [or] national public health or safety.”³⁶ The nation depends on the continuity of its health care systems, especially during disasters and emergencies. Over ninety-two percent of HPH infrastructure is privately owned and operated,³⁷ with healthcare and public health systems relying on a complex network of staff, supplies, systems, and space to provide care in steady state and during a response. The complex networks of interdependencies and risks often go beyond individual HCCs and their span of control, making it necessary for HPP to drive additional programs dedicated solely to the protection of critical infrastructure.

ASPR’s Critical Infrastructure Protection (CIP) Program complements the work of coalitions and other health care

Figure 9. CIP By the Numbers



³⁵ National Critical Functions (NCFs) are “functions of government and the private sector so vital to the United States that their disruption, corruption, or dysfunction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof.” Cybersecurity and Infrastructure Security Agency (CISA). <https://www.cisa.gov/national-critical-functions>

³⁶ Cybersecurity and Infrastructure Security Agency (CISA). <https://www.cisa.gov/national-critical-functions-set>

³⁷ 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>

readiness programs, by focusing on nationwide risks and mitigation strategies specific to health care critical infrastructure. Under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience, HHS is the Sector-Specific Agency for the HPH sector;³⁸ and additionally, the Public Health Service Act, as amended by PAHPAIA, designates ASPR as the federal authority responsible for managing relevant critical infrastructure protection activities. The CIP program helps to elevate HPP's focus on improving health care situational awareness and creating a coordinated national system for health care preparedness and response through its protection of the nation's health care critical infrastructure to maintain continuity of operations, build capacity, and support medical surge capabilities during a response.

Partnership with the private sector drives the program's work, which creates mechanisms that facilitate the proactive identification and remediation of ongoing and emerging risks facing the HPH through public-private partnership, raising the overall health care system's readiness and resilience. Aligning with its Sector Risk Management Agency (SRMA) responsibilities,³⁹ The CIP Program's core functions include:

1. Facilitating trusted information-sharing between a network of partners.
2. Exercising joint preparedness & response capabilities.
3. Conducting infrastructure analyses to identify and mitigate risks (steady-state and emerging).

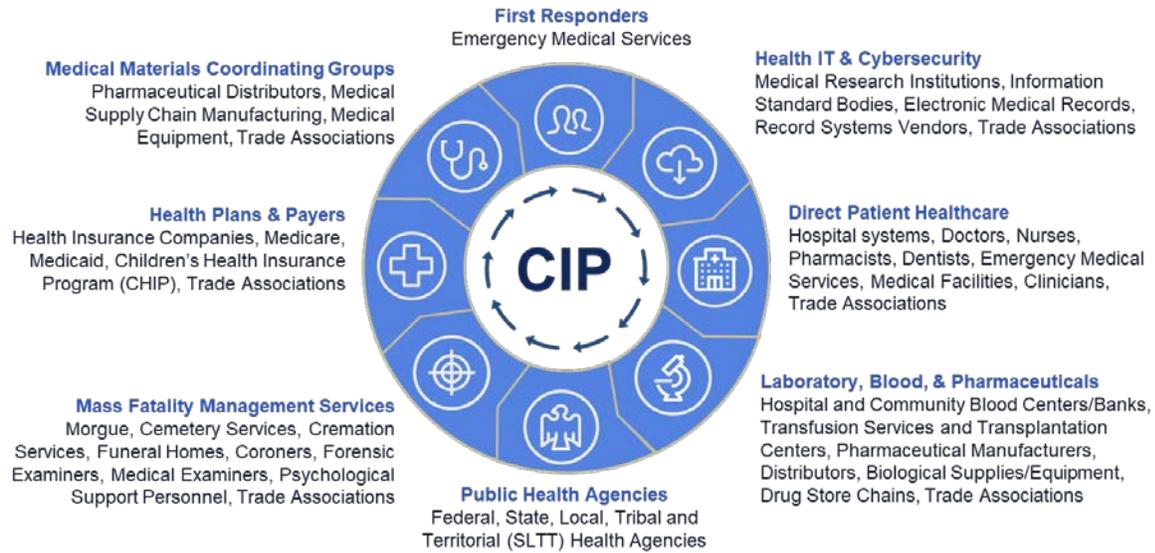
The program operationalizes these functions to further support HHS's goal of promoting the resilience of the nation's health infrastructure by leading a dynamic public-private partnership, drawing from all aspects of the health care sector to manage risk and coordinate effective response to contemporary threats. The CIP program's partnerships include coalition representatives, as well as leadership of national, state, and local leadership of associations and organizations involved in all subsectors of Healthcare and Public Health. In this way, the CIP program's partners can advise on a broad range of topics to support federal-level policy development as well as local level implementation of best practices.

In response to cybersecurity threats, the COVID-19 pandemic, physical threats to health care infrastructure, civil unrest, and hurricanes in FY 2020, the CIP Program facilitated discussions between health care systems, health plans and payers, supply chain partners, and mass fatality management representatives to achieve coordinated responses. **Figure 10** demonstrates the ecosystem of partners the program engages to offer continuous technical expertise and guidance for protecting critical infrastructure. Utilization of these partners allows for an expanded opportunity to leverage resources and expertise within both public and private sector. Through the CIP program's engagement efforts, collaborative preparedness activities include better understanding risk profiles, participating in joint exercises, 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.

³⁸ 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).

³⁹ National Defense Authorization Act for Fiscal Year 2021. [BILLS-116hr6395enr.pdf \(congress.gov\)](#)

Figure 10. CIP's Partnership Vision



Developing Risk-Driven Actions

In FY 2018, the CIP program launched a comprehensive risk assessment tool specific to the needs of the HPH Sector Partnership, including HPP recipients and HCCs. The HPH Sector Risk Identification and Site Criticality (RISC) toolkit expands upon existing risk methodologies to focus more deeply on issues of growing importance to health care facilities, such as continuity of services during extreme weather events and protection against cyber threats. An initiative was funded in FY 2019 to expand the user base of the tool, serving as a nexus for risk management strategic alignment among the public health and health care stakeholder community. Through March 2021, 1,635 unique users have downloaded the RISC Toolkit. The toolkit has been downloaded in all 50 States, the District of Columbia, Puerto Rico, and the US Virgin Islands, with over fifty percent of users working in direct patient care.

As the next phase of enhancement for the RISC Toolkit continues in FY 2021, a web-based tool will enable owners and operators to identify key risks and gaps in capabilities. Enhancements to the tool in FY 2021 also include new types of infrastructure and partners such as manufacturers and distributors. This phase will allow ASPR to collect information on risks to all infrastructure, providing access to relevant risk data to all ASPR Programs, including the Biomedical Advanced Research and Development Authority (BARDA), HPP, and the Strategic National Stockpile (SNS). Access to this data will support data-driven decision-making for ASPR and other federal program managers and related private sector entities, informing resource allocation and strategic capacity-building. Understanding baseline risk to the HPH Sector will allow HHS to understand the success of risk mitigation efforts at the national and local level. Federal and private sector users and stakeholders play an integral role during each phase of development of the toolkit and will provide inputs as the CIP Program explores additional enhancements to incorporate infectious disease and supply chain preparedness modules.

Additionally, the CIP Program also supports the Cybersecurity and Infrastructure Security Agency (CISA) with investigating critical infrastructure vulnerabilities and collecting, consolidating, and adjudicating input from private and public sector partners in order to provide a holistic HPH Sector perspective to these threats. The CIP Program submitted such a deliverable in response to CISA requests for input on position, navigation and timing services in response to Executive Order 13905 on

Strengthening National Resilience through Responsible Use of Position, Navigation, and Timing (PNT) Services. Work on the PNT efforts will continue into and beyond FY 2022, requiring CIP to coordinate across the HPH Sector to develop the necessary content. The CIP Program also provides this function for other Executive Orders and related requirements generated from within the government.

Managing Cyber and Physical Security Risks

The CIP Program, as the HPH Sector Risk Management Agency (SRMA), takes seriously the responsibility to manage cybersecurity risks to the health care sector as defined by various congressional and administrative mandates. In this role, the program works with the private sector as well as SLTT to prepare for and respond to the increasing complicated cyber threat landscape facing the health care system. This collaboration currently consists of over 200 industry and government leaders. Through 15 focused task groups, a multitude of products, resources, and recommendations have been produced by federal and industry cyber specialists for managing various aspects of HPH Sector cyber risk. These resources directly benefit HPP recipients, who can implement nationwide recommendations, in addition to broader health care stakeholders.

As required by the 2019 PAHPAIA amendments to the Public Health Service Act, the CIP Program has worked closely with partners to develop a “strategy for public health preparedness and response to address cybersecurity threats.” This strategy was delivered to Congress in FY 2021 and then implementation began. CIP is leading coordination across HHS of enhanced information-sharing to include webinars, bulletins, and teleconferences to share relevant information on threats, newly-identified vulnerabilities to common software or systems, and ransomware threats. CIP is also leading development of an HHS-wide Cyber Incident Response Plan and Standard Operating Procedures and working with private sector to develop a complementary playbook for public-private sector coordination and information-sharing. A key goal of the work is to seamlessly blend analysis and coordination between the cyber incident and physical impacts that affect the Sector’s ability to perform critical functions.

In the early days of the COVID-19 pandemic, as shops, restaurants, and schools closed, health care infrastructure remained as one of the few places actively open for business—which made those facilities a target for bad actors looking to disrupt their communities. Two individuals motivated by anti-government beliefs targeted a hospital in Kansas and a Navy hospital ship anchored in Los Angeles in March and April 2020. CIP recognized the changing threats to health care and coordinated a partnership between HHS, DHS, the FBI, and the International Association for Healthcare Security and Safety to produce the [Securing the Health Sector Webinar series](#), covering physical and cybersecurity challenges facing health care, medical manufacturing, and research communities, enhancing awareness of emerging threats. The webinars translated new concepts and tactics to thousands of emergency managers, health care practitioners, and preparedness experts.

Promoting Resilient Medical Supply Chains

Hurricane Maria damaged a large portion of the medical product manufacturing facilities in Puerto Rico, creating rippling impacts on the nation’s medical supply industry – and revealing a high number of previously underappreciated supply chain vulnerabilities, which led to significant shortages of medically necessary drugs. During the COVID-19 pandemic, the global supply chain degraded, and health care identified multiple critical materiel needs, underscoring the clear value and a necessity for improved national health care collaboration. In the third year of its cooperative agreement with Healthcare Ready, a nationally recognized Information Sharing and Analysis Center, the CIP Program has established strong relationships with private sector throughout the landscape of the supply chain and built sustainable collaboration practices and resources to address the shortfalls and challenges experienced in such events.

Additionally, through trusted partnerships, the CIP Program has worked with FDA and private sector partnerships to identify root causes of potential impacts to the medical supply chain, including product shortages during disasters, and opportunities to support mitigation to such causes.

During the COVID-19 pandemic, the CIP Program served as a conduit for bringing together expertise and insights of government and private sector partners to support COVID-19 response and vaccine delivery. Contributing to key phases of pandemic response and recovery, the CIP Program team supported a variety of supply chain efforts at HHS and FEMA, including facilitating stakeholder engagements to facilitate medical product distribution, optimization of ancillary kits delivered along with vaccine, and the development of strategies for supply chain resilience. In FY 2021, the CIP Program established a Joint Working Group on COVID-19 Response Coordination, with Task Groups on Vaccine Delivery Acceleration and Supply Chain Resilience.

In FY 2021, the CIP Program solidified a relationship with the DHS CISA exercises program to collaborate on planning and execution of HPH sector entity-specific exercises. Through this partnership, the CIP Program will be able to amplify lessons learned during previous years' all-sector exercises to see how they can be applied at a facility level. Through analysis of exercises at a variety of infrastructure in the sector, including hospitals, academia, and manufacturers, the program will be better able to understand and prioritize risk mitigation needs of the sector.

The CIP Program will utilize the next edition of the National Infrastructure Protection Plan and the SRMA responsibilities as defined in the 2021 NDAA to complete the next iteration of the HPH Sector Specific Plan (SSP), in partnership with Federal and private sector stakeholders. Building on response lessons learned, exercises, and RISC Toolkit user feedback, this SSP will include planned efforts to build a robust articulation of defined risks, threats, and potential mitigation measures. The program will continue to engage with HCCs, industry experts from across the health care sector, law enforcement and intelligence, among others, to enhance activities to prepare for, respond to, and recover from natural hazards and manmade threats. In its work alongside HPP, the CIP Program will align its portfolio of health care preparedness initiatives to support Federal leaders in data-driven decision making and resource allocation, and to contribute to a more secure and resilient health care system.

Looking to the immediate future, the CIP Program is taking on responsibilities of coordinating within HHS to serve together as the SRMA. To be truly successful in building a robust partnership, the CIP Program will work toward carrying out risk analysis activities to include: completion of the RISC tool, analysis of data, and coordination of that data with information collected by other sectors and CISA to create a comprehensive risk picture for the HPH Sector. In the future, the program will also look to re-frame risks in the context of lessons learned from COVID-19, including reliance on more information technology and security as telehealth continues to be utilized. Understanding risk and tailoring ASPR actions, such as direction of grants and development of products and policies, would help bolster activities that can mitigate risk.

Recovering from Disasters and Other Public Health Emergencies

HPP's vision for a comprehensive, truly national system for health care readiness must encompass the entire lifecycle of preparedness and response activities, including strategies for recovery that not only mitigate impacts from a single event, but also integrate lessons learned to improve preparedness for future events. 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 in order to improve health and well-being outcomes for American individuals and families affected by disasters. The policy and doctrinal guidance under the National Disaster Recovery Framework (NDRF) through the

Health and Social Services (HSS) Recovery Support Function serves as a key facet for building recovery capabilities.

When the HSS Recovery Support Function is activated, ASPR 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. ASPR integrates the capabilities of federal and 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, social services, and educational 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.

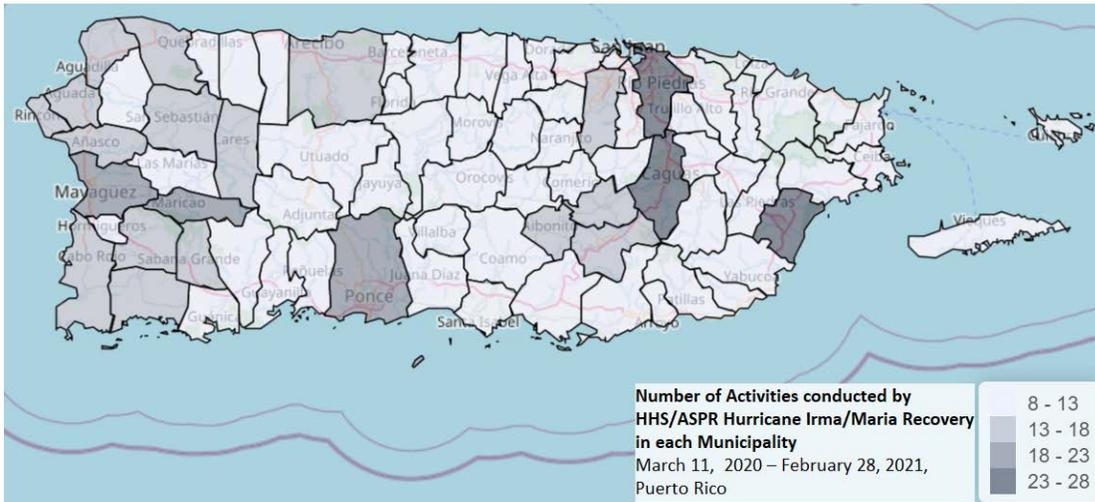
Disasters can create formidable challenges for health care systems to recover, particularly in rural areas where impacts to a single provider can imperil access to health care services for an entire community. Deployed teams coordinate efforts to address those critical gaps so that coalitions —and the communities they serve — can recover.

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.

Starting in CY 2020, through CY 2021, the Recovery Program is separately supporting the states of Louisiana and Oregon with the development of Recovery Needs Assessments for the communities impacted by Hurricane Laura in Louisiana and the Wildfires in Oregon. For both missions, ASPR Recovery Program staff worked with FEMA recovery staff to help local government leaders develop a measurable problem list of recovery challenges and priorities in these communities impacted by natural disasters within the context of an ongoing COVID-19 pandemic. These missions illustrate the value of ASPR's Recovery Program to build and transfer permanent new capabilities to local, state, tribal, or territorial governments to meet health and social services needs in all-hazards disasters, strengthening HCCs and the entire HPP ecosystem and promoting resilient communities for future disaster events. Deployed Recovery Program teams conduct vital work to address underlying capability gaps and fault-lines in the health care system and related key systems that affect health outcomes (such as social services and education systems), generating new insights that add value to HPP's entire portfolio of programs. Through projects targeting those specific gaps, Recovery Program teams improve the capacity of that community's health care system and associated ecosystem to protect lives in future disasters.

Leveraging projects undertaken by ASPR Recovery in Puerto Rico as part of the ongoing Hurricanes Irma and Maria recovery mission, the Puerto Rican health care system was able to capably respond to the January 2020 earthquake sequence, respond as Regional Networks to the COVID-19 pandemic, and aid in the implementation of COVID-19 vaccination throughout the island. These compelling examples demonstrate the efficacy of Recovery operations to develop solutions during response that improve health care and social service systems preparedness for future disasters. As shown in **Figure 11**, the ASPR Recovery Team in Puerto Rico has strengthened the health and social services network in all of the island municipalities, leaving HHS footprint of anything between 8 to 23 capacity and capability building interventions per city.

Figure 11. DHHS ASPR Recovery Footprint in Puerto Rico for Year 2020 Map



During the aftermath of Hurricane Maria, nearly 3,000 Puerto Ricans lost their lives. Of these, deaths directly attributable to the storm’s physical effects number approximately 60, with the remainder of fatalities resulting because of the functional collapse in the health care system. Addressing this critical gap—the capacity of the health care system to continue operations through all-hazards events—has been the most important priority of recovery in Puerto Rico, but not the only contribution to the island. Following the catastrophic effects of Hurricane Maria, the Recovery program partnered with the Puerto Rico Department of Health (PRDOH) 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 7 new “hub and spoke” preparedness regional plans that embody a more effective approach to providing medical access throughout the territory and assisted 52 healthcare facilities in reinforcing their emergency preparedness and response plans. The Health & Social Services recovery in Puerto Rico is currently managing 22 different projects and has also conducted over 158 different interventions aiming to strengthen health care system, build capacity within the social services and behavioral health sectors, strengthen public and environmental health capabilities and aid in the recovery of children, elderly and disabilities and access and functional needs populations.

In late December and January 2020, in the most severe seismic event in Puerto Rico since 1902, an earthquake swarm struck the island, with 11 tremblors greater than magnitude five, and on January 7, 2020 a 6.4 earthquake, with felt shaking intensity of VII (very strong). This was the first major disaster in Puerto Rico since Hurricane Maria, and a progress test for the interventions undertaken by ASPR Recovery in partnership with PRDOH, the HCCs, and other health and social service partners on the island. ASPR worked to support and monitor the “hub and spoke” networks in real time. In the earthquake, three deaths were a direct result of the event, but in stark contrast to Maria, there were no fatalities due to disruptions in the health care environment. The “hub and spoke” networks and other health care sustainability interventions worked; PRDOH and HHS were able to maintain visibility on hospital functioning in real time, and patients were diverted from impacted to operational health care facilities as planned. Systems developed by ASPR Recovery and Puerto Rican health authorities were used to stand up a medical sheltering network and process for vulnerable populations, with active participation from the emergency housing, health, and family services partners; this was Puerto Rico’s first-ever integrated emergency system for medical sheltering and vulnerable population services. The public investment in Puerto Rico’s capacity building for disaster events paid off for earthquake survivors, and as ASPR Recovery continues the coordination of training, capacity building, table top, and functional

exercises for the “hub and spoke” Networks and Regional Implementation in the coming years, additional improvement in the resilience and readiness level of the health care system for major disasters is expected. ASPR Recovery has facilitated technical assistance and exercises in most health care facilities in the island and is in the process of standing up Regional Networks throughout Puerto Rico. With Bayamon as the first Region to successfully complete the functional exercise, ASPR has planned to stand up the health regions that were most impacted by the 2020 Hurricane Season, Mayagüez-Aguadilla and Caguas within the next nine months. Most recently, in 2020’s Hurricane Isaias, 23 island hospitals lost power, with no interruption in health care services, and for the first time in Puerto Rico’s history, real-time visibility on operational impacts to hospitals by the PRDOH, as the systems have built worked as designed.

In FY 2020 and FY 2021, in confronting the COVID-19 pandemic, ASPR initiated health and social services recovery operations in all ten HHS/FEMA Regions, based in the ten regional cities. In late FY 2020 and FY 2021, ASPR began employing these regional recovery operations missions to coordinate federal technical assistance, subject matter expertise, training, and leveraging of grant funding to support states, tribes, and territories to manage long-term pandemic recovery and resilience. Regional-level COVID-19 recovery missions are designed to support HCCs and the entire HPP ecosystem, particularly in the networks that deliver health care and other health and social services. Recovery developed region-specific and COVID-19-specific toolkits and consultations to provide states, territories, tribes, and localities with targeted technical assistance and subject-matter expertise to address local unmet needs. The Recovery Program is currently partnering with state chapters of the National Association of Social Workers to deliver targeted training to social workers in communities nationwide designed to leverage the integrator role played by the social work profession in health care, behavioral health, social services, and education to promote effective community resilience and recovery from the COVID-19 pandemic, completing 11 webinars, which enhanced the clinical skills of 538 Social Workers throughout nation during the second quarter of FY 2021.

To further strengthen community-level COVID-19 recovery efforts, the Recovery Program is building on its FY 2019 engagement through workshops with local communities on bio-incident recovery planning. In FY 2020 and early FY 2021, the Recovery Program has identified key emerging lessons from COVID-19 recovery and fusing that into a new National Guidance for Bio-incident Recovery specific to the challenges faced by local communities grappling with the effects of the pandemic.

At the same time, the COVID-19 experience has also highlighted gaps and challenges which impede success, and principally scalability for recovery operations. To date, the HHS capacity to support long-term disaster recovery has been scaled to support up to two to three concurrent state-level disaster recovery missions and has required Stafford Act funding. However, recent years have illustrated the potential for disaster events exceeding this capacity, and the need for a disaster recovery capability for health and social services that can be scaled to more than three simultaneous state recovery missions. The COVID-19 pandemic event demonstrates that national-level disaster events also occur, and necessitate HHS providing recovery support to states, tribes, and territories across the nation.

COVID-19 Supplemental Funding Impacts

Prior to the COVID-19 pandemic, HPP’s portfolio of health care readiness programs had already contributed toward a foundation of preparedness for all-hazard events, including special pathogens. When the COVID-19 pandemic erupted in the United States, straining the health care system, HPP’s portfolio of programs played a critical role in supporting health care on the front lines of the response, protecting critical infrastructure for the health care sector, and managing simultaneous pandemic and other all-

hazard responses, such as wildfires, cyberattacks, and annual hurricane and tornado seasons. Through infusions of COVID-19 supplemental funding, HPP conducted a host of activities to support preparedness and response against the pandemic and resultant surges. These activities included expanding the National Special Pathogen System, developing platforms for knowledge sharing amongst clinical practitioners, supporting America's blood supply, and standing up the National Emergency Tele-Critical Care Network (NETCCN).

The National Special Pathogen System (NSPS)

As discussed in the section 'Creating the National Special Pathogen System', the NSPS built on infrastructure developed through the Ebola response, creating a nation-wide, systems-based network for all special pathogens, similar to other national systems of care (e.g., the National Trauma System). HPP used emergency COVID-19 supplemental funding to transform the Regional Ebola Treatment Network in order to support the urgent preparedness and response needs of hospitals, health systems, and health care providers on the front lines of the COVID-19 outbreak in order to help prepare them to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens or persons under investigation for such illnesses.

Ultimately, the components of NSPS seamlessly interlock to provide a coordinated national approach to preparing for public health and medical emergencies so that the U.S has a tiered, capable system that coordinates national expertise, regional capabilities, and state and sub-state health care capacity across the public and private sectors in order to drive an effective and safe pandemic response. As the system builds on lessons learned from the Regional Ebola Treatment Network and expands to respond to COVID-19, the National Special Pathogen System will continue to deploy and enhance its capabilities to address continued surge events during the current pandemic – as well as prepare to address potential future special pathogens.

The National Special Pathogen System has already helped to accelerate the nationwide response to COVID-19 (see **Figure 12** for recent NSPS recipient impacts) and will sustain a heightened level of health care preparedness for other public health and medical emergencies so that we are not again faced with the dire consequences of the U.S. private health care sector not being ready to meet the urgent health care needs of a pandemic. Through HPP's funding support and technical assistance, health care systems and providers have greater access to training, consultations, and other educational opportunities. While the NSPS was created through COVID-19 supplemental funding, HPP plans to maintain critical capabilities developed through this system to further enhance the nation's preparedness and response efforts.

Figure 12. NSPS Recipient COVID-19 Impact

| | |
|--|--|
| | <p>National Emerging Special Pathogens Training and Education Center (NETEC): In April of 2020, NETEC began hosting webinars on COVID-19 best practices, response efforts, and guidance for health care providers including those involved in NSPS, such as how to transform normal/positive rooms into negative pressure rooms to care for COVID-19 patients, including pediatric COVID-19 patients.</p> |
| | <p>Regional Ebola and Special Pathogen Treatment Centers (RESPTC): In February of 2020, Washington State’s designated RESPTC, the Providence Sacred Heart Medical Center, applied its expertise as a first responder to the COVID-19 pandemic and hosted 4 COVID-positive passengers from the Diamond Princess cruise ship.</p> |
| | <p>Hospital Associations: In September of 2020, through shared stories and emerging promising practices, hospitals in Missouri began to reflect on COVID-19 and its impact on health care and the community, while looking forward to help prepare for what may yet come. The Missouri Hospital Association released a new report, "Mid-Response Assessment: Missouri Hospitals' Response to the COVID-19 Pandemic," highlighting the clinical and operational lessons learned from the COVID-19 pandemic response among Missouri hospitals. The findings of this report are based on a broad membership survey conducted in July.</p> |
| | <p>Hospital Preparedness Program Recipients: Early in the COVID-19 pandemic, the West Virginia Department of Health and Human Resources launched an information hotline to address questions and concerns from medical providers and the public. In support of West Virginia’s “Operation Save Our Wisdom” vaccination program, this information line has received calls on topics including vaccine registration, vaccination locations, and adverse reactions related to COVID-19 vaccination, as well as general COVID-19 inquiries. West Virginia also launched a COVID-19 Vaccine Information Line to help residents get information on vaccine distribution and availability.</p> |

Supporting Health Care Leaders during COVID-19

During the COVID-19 pandemic response, it was critical to establish mechanisms for clinical providers to rapidly share promising practices for treatment and other response activities. HHS ASPR and Project ECHO (Extension for Community Healthcare Outcomes) rapidly stood up the ‘COVID-19 Clinical Rounds’, a series of sessions designed to provide peer-to-peer, real-time knowledge-sharing regarding challenges and successes in COVID-19 treatment for frontline, primarily pre-hospital and hospital-based clinicians. Project ECHO is an innovative tele-mentoring program designed to create virtual communities of learners by bringing together health care providers and subject matter experts using videoconference technology, brief lecture presentations, and case-based learning, fostering an “all learn, all teach” approach. The COVID-19 Clinical Rounds series is a public-private collaboration among federal agencies and private sector partners including ASPR/HPP, Department of Transportation’s National Highway Transportation Safety Administration Office of EMS, the National Emerging Special Pathogens Training and Education Center (NETEC), professional societies, and hospitals. Each Clinical Rounds session includes brief presentations from experienced expert clinicians complemented by discussion among expert panelists in response to Q&A from participants. Recent session topics include clinician mental health, COVID-19 variants, prolonged ventilation management, and innovative PPE preservation strategies. As of April 2021, 141 sessions have been conducted, engaging 48,169 total participants from all states and over 100 countries. Archived session recordings have been viewed 13,371 times.⁴⁰ Attendees reported that participation in COVID-19 Clinical Rounds resulted in increase in knowledge, and changes in patient care and clinical operations. In November 2020, seventy percent of participants strongly agreed that information provided by COVID-19 Clinical Rounds had helped them provide better

⁴⁰ Data on Clinical Rounds from March 24, 2020 – April 1, 2021. Due to data limitations, total participation over the 141 sessions was measured (these numbers do not reflect the amount of unique participants).

care of their patients, and eighty-nine percent strongly agreed that ‘in the event of a future national or local emergency, they would join COVID-19 Clinical Rounds again’. In addition to the COVID-19 Clinical Rounds, Project ECHO is also conducting a mini-series on Outpatient Therapeutics which provides a deep dive on new and emerging COVID-19 outpatient therapeutics, including monoclonal antibodies. The goal of this mini-series is to equip clinicians with the appropriate knowledge, resources, and tools needed to initiate and scale administration of these therapies and reduce strain on the U.S. health care system. As of April 2021, the HHS/ASPR COVID-19 Outpatient Therapeutics sessions have been viewed a total of 4,910 times.

To address the need and support wide adoption of telemedicine for ambulatory providers, HHS ASPR, Project ECHO and the Public Health Foundation’s TRAIN Learning Network partnered together to create Telemedicine Hack - a ten-week, virtual peer-to-peer learning community. This series includes five tele-ECHO sessions on key topics (e.g., clinical service workflows, documentation, reimbursement) highlighting best practices and case studies from the field. The live sessions concluded on September 23, 2020; however, registrants can access all recordings and materials online at any time. As of April 1, 2021, ten sessions have been conducted, engaging 16,882 total participants through both the live sessions and the recordings. Altogether, 69,961 total participants have attended the COVID-19 Clinical Rounds, the COVID-19 Outpatient Therapeutics sessions, and the Telemedicine Hack.⁴¹

Protecting America’s Blood Supply

America’s blood supply is another essential component of the nation’s critical infrastructure for health care. During the COVID-19 pandemic, HPP collaborated with the American Red Cross to maintain blood operations, enabling hospitals and other health care entities to meet demand for blood and avoid shortages of this lifesaving medical resource. As a result of COVID-19, the American Red Cross grappled with increased costs that threatened the organization’s ability to maintain operations – for example, for supplies and equipment related to infection control during blood donations. HPP’s support contributed to the American Red Cross operating 140,000 blood drives, distributing 3,500,000 units of red blood cells, conducting 2,000,000 COVID-19 antibody tests, and distributing 5,570,000 units of PPE (e.g., masks, face shields, wipes, gloves and disinfectant).

By collaborating with the American Red Cross to meet new challenges and costs incurred by the COVID-19 pandemic, maintain blood supply, and strengthen partnerships between the American Red Cross and health care coalitions supported through HPP, ASPR’s goal for this cooperative agreement is for health care to be able to quickly draw upon a strong blood supply to provide lifesaving treatments for Americans – now and in the future as the United States continues to recover from this pandemic event.

Critical Care Anywhere: National Emergency Tele-Critical Care Network (NETCCN)

The COVID-19 pandemic has created extraordinary stresses related to critical care services within local and regional health systems. While some systems now have telemedicine capabilities for the delivery of ambulatory care and patient-to-doctor communication, tele-critical care (TCC)/acute care telemedicine solutions have remained largely siloed, have limited capability for external communication or coordination, and are not rapidly scalable because they require time-consuming installation of expensive equipment and integration of software solutions with local systems. Many hospitals, particularly those in rural areas, have no access to TCC or other types of specialty telemedicine and face a risk of continuing surges in demand while disadvantaged by limited local expertise and frequent inability to rapidly transfer patients due to issues related to logistics and distance. Traditional physical deployment of subspecialty physicians to support specific needs is not a viable option due to lack of supply and the continuing need

⁴¹ Ibid.

for those physicians to remain in their home locations to continue clinical services. Telemedicine offers the opportunity for specialties such as critical care to be available to support hospitals in need, and potentially other care sites or more traditional deployed teams such as those within NDMS.

In order to address this gap in care for patients most at risk for dying from COVID-19, a coalition has developed the National Emergency Tele-Critical Care Network (NETCCN). The NETCCN was established during the COVID-19 public health emergency and funded by supplemental appropriations. However, it was in development before COVID-19 as an application to be for all-hazards disasters requiring the widespread provision of critical care. The NETCCN is comprised of a cloud-based, low-resource, stand-alone health information management system for the creation and coordination of flexible and extendable “virtual critical care wards.” These wards bring high-quality critical care capability to nearly every bedside, whether in a health care facility, or in an alternate care site such as a field hospital, or in a gymnasium – enabling critical care *anywhere*. The key attribute of a NETCCN architecture is not only the ability to provide virtual surge support forward to the point of need, but the ability to collect and curate data from across this digital ecosystem. The capacity to aggregate and visualize patient data will not only improve medical decision making at the bedside but will also drive patient care algorithms, and support leadership population-health decision making.

The COVID-19 pandemic has emphasized the need for advanced and ubiquitous telemedicine. These capabilities enhance HPP – and ASPR’s – overall mission to create national assets that serve health care and communities locally, at the state level, and across multi-state regions to save lives and protect Americans.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$264,555,000 |
| FY 2019 | \$264,555,000 |
| FY 2020 | \$275,555,000 |
| FY 2021 Enacted | \$280,555,000 |
| FY 2022 President’s Budget | \$291,777,000 |

Budget Request

The FY 2022 President’s Budget request for the Hospital Preparedness Program is \$291,777,000, which is +\$11,222,000 above the FY 2021 Enacted. HPP will use part of these funds to sustain the four RDHRS demonstration sites,⁴² the ten RESPTCs, NETEC, and ASPR TRACIE.

Additionally, HPP will use \$240,000,000 – an increase of \$8,500,000 from the levels of funding allocated for the past two years of the cooperative agreement – to fund the HPP cooperative agreement recipients. This funding will be distributed across the 62 recipients at levels determined by HPP’s statutorily required funding formula. As a result of flat funding in FY 2020 and FY 2021, ASPR has prioritized adding funds to this core program. This additional cooperative agreement funding will meet and sustain capabilities developed during COVID-19 response, support increased coordination activities, and effectively maintain response and recovery efforts. HPP will also support increased technical assistance and oversight to HPP, RDHRS, RESPTC, and NETEC recipients, subrecipients, and health care stakeholders. HPP’s role expanded rapidly during COVID-19, with the addition of new recipients, sub-recipients, and stakeholders.

⁴² Using FY 2021 annual appropriation funding, HPP will establish a fourth RDHRS demonstration site in FY 2021.

HPP supported a broad spectrum of stakeholders throughout the COVID-19 response and various concurrent events, including west coast wildfires, cyberattacks, and annual hurricane and tornado seasons. In FY 2022, HPP will use funds to effectively maintain and strategically serve an expanded recipient pool of health care partners who continue to respond to and recover from surges created by COVID-19 and other incidents.

HPP will use \$33,777,000, an increase of \$4,222,000, for management and administration of the HPP portfolio of readiness programs, including the Recovery Program and the CIP Program. The Recovery Program will use additional funds to develop and deploy a national health and social services recovery mission capability. Additional investments would empower ASPR to staff a long-term disaster recovery support capacity, based in the ten HHS regions with appropriate leadership oversight, to coordinate federal assistance to states, tribes, and territories for recovery from disasters and public health emergencies. This capability includes the resources necessary to coordinate recovery support for public health emergencies which are not declared Stafford Act events. This capability will allow ASPR to respond to other national-level events and a much larger number of simultaneous state-level disasters, capability that was proven to be necessary during COVID-19. Funding would enable ASPR to recruit recovery coordinators to work in the ten regions, supporting states, tribal and territorial governments with disaster and public health emergency recovery requirements, and strengthen a headquarters subject matter expert team to develop and disseminate policy and operational guidance for health and social services recovery. The initiative would specifically build regional-level recovery coalitions, linking federal health and social services programs at the executive level, to broker rapid and effective support to states. This would also permit faster and more cost-effective recovery missions for state-level natural disaster and all-hazards events as well. The initiative is designed to close two critical gaps in HHS recovery mission capacity: the resources to support simultaneous recovery in many states, and the ability to respond to a non-Stafford public health emergency. The initiative would permit the delivery of targeted technical assistance for disaster and public health emergencies to address specific recovery challenges, effectively leverage public and philanthropic resources, and close specific operational gaps and challenges.

Lastly, HPP will use funds to enhance CIP Program activities and mitigate risks to the health care sector. As specified in the National Defense Authorization Act (NDAA), the CIP Program is required by statute to take on new responsibilities as the Sector Risk Management Agency (SRMA) for the Healthcare and Public Health (HPH) sector. In order to fulfill that role, the CIP Program will use funds to enhance their risk management activities, including developing the RISC 2.0, a web-based tool that will allow HPH owners of critical infrastructure to identify and mitigate risks. COVID-19 and other public health emergencies revealed and exacerbated underlying shortfalls in critical infrastructure, such as supply chain vulnerabilities; the CIP Program will leverage FY 2022 funds to mitigate risks at the federal level and support critical infrastructure partners across the private sector.

**ASPR Key Outputs and Outcomes Table
Hospital Preparedness Program**

| Measure | Year and Most Recent Result / Target for Recent Result / (Summary of Result) | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 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: 49.8 % ¹ 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 (Output) | FY 2018: 97.8% ² Target: 80.0 % (Target Exceeded) | 100.0 % | 100.0 % | Maintain |

¹Due to COVID-19 response, the Coalition Surge Test, which informs this measure, has been waived for FY 2019. The latest available data are from FY 2018.

²Due to COVID-19 response, the FY 2019 data reporting deadline was extended to 1/8/2021. Data are expected to be finalized and validated by 2/5/2021.

Public Health and Social Services Emergency Fund

Grant Awards by State
(in whole dollars)

CFDA NUMBER/PROGRAM NAME: 93.899 Hospital Preparedness Program (HPP)

| State, Locality, Territory | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-----------------------------------|----------------------|------------------------|-----------------------------------|----------------------------|
| Alabama | \$ 3,145,268 | \$ 3,145,268 | \$ 3,352,678 | + \$207,410 |
| Alaska | \$ 1,111,466 | \$ 1,111,466 | \$ 1,241,134 | + \$129,668 |
| American Samoa | \$ 279,211 | \$ 279,211 | \$ 283,641 | + \$4,430 |
| Arizona | \$ 4,716,474 | \$ 4,716,474 | \$ 4,729,894 | + \$13,420 |
| Arkansas | \$ 2,099,822 | \$ 2,099,822 | \$ 2,298,630 | + \$198,808 |
| California | \$ 23,171,118 | \$ 23,171,118 | \$ 22,465,160 | - \$705,958 |
| Chicago | \$ 2,818,423 | \$ 2,818,423 | \$ 3,252,117 | + \$433,694 |
| Colorado | \$ 3,281,648 | \$ 3,281,648 | \$ 3,584,461 | + \$302,813 |
| Connecticut | \$ 2,261,523 | \$ 2,261,523 | \$ 2,358,240 | + \$96,717 |
| Delaware | \$ 1,086,723 | \$ 1,086,723 | \$ 1,183,687 | + \$96,964 |
| District of Columbia | \$ 1,187,386 | \$ 1,187,386 | \$ 1,417,404 | + \$230,018 |
| Florida | \$ 11,800,098 | \$ 11,800,098 | \$ 11,319,855 | - \$480,243 |
| Georgia | \$ 7,950,996 | \$ 7,950,996 | \$ 7,033,277 | - \$917,719 |
| Guam | \$ 356,511 | \$ 356,511 | \$ 367,041 | + \$10,530 |
| Hawaii | \$ 1,276,715 | \$ 1,276,715 | \$ 1,365,086 | + \$88,371 |
| Idaho | \$ 1,318,146 | \$ 1,318,146 | \$ 1,467,523 | + \$149,377 |
| Illinois | \$ 8,353,473 | \$ 8,353,473 | \$ 9,241,271 | + \$887,798 |
| Indiana | \$ 3,956,143 | \$ 3,956,143 | \$ 4,095,023 | + \$138,880 |
| Iowa | \$ 2,049,436 | \$ 2,049,436 | \$ 2,152,263 | + \$102,827 |
| Kansas | \$ 2,009,918 | \$ 2,009,918 | \$ 2,060,821 | + \$50,903 |
| Kentucky | \$ 2,803,092 | \$ 2,803,092 | \$ 2,954,813 | + \$151,721 |
| Los Angeles County | \$ 9,142,488 | \$ 9,142,488 | \$ 8,777,493 | - \$364,995 |
| Louisiana | \$ 2,934,248 | \$ 2,934,248 | \$ 3,100,990 | + \$166,742 |
| Maine | \$ 1,122,201 | \$ 1,122,201 | \$ 1,249,871 | + \$127,670 |
| Marshall Islands | \$ 268,164 | \$ 268,164 | \$ 270,830 | + \$2,666 |
| Maryland | \$ 5,297,615 | \$ 5,297,615 | \$ 6,363,498 | + \$1,065,883 |
| Massachusetts | \$ 4,090,461 | \$ 4,090,461 | \$ 4,136,693 | + \$46,232 |
| Michigan | \$ 5,799,153 | \$ 5,799,153 | \$ 5,797,065 | - \$2,088 |
| Micronesia | \$ 283,060 | \$ 283,060 | \$ 289,612 | + \$6,552 |
| Minnesota | \$ 3,399,515 | \$ 3,399,515 | \$ 3,513,195 | + \$113,680 |
| Mississippi | \$ 2,062,902 | \$ 2,062,902 | \$ 2,179,572 | + \$116,670 |
| Missouri | \$ 3,626,688 | \$ 3,626,688 | \$ 3,814,018 | + \$187,330 |
| Montana | \$ 1,099,880 | \$ 1,099,880 | \$ 1,214,234 | + \$114,354 |
| Nebraska | \$ 1,401,496 | \$ 1,401,496 | \$ 1,490,149 | + \$88,653 |
| Nevada | \$ 2,531,286 | \$ 2,531,286 | \$ 2,930,418 | + \$399,132 |
| New Hampshire | \$ 1,106,453 | \$ 1,106,453 | \$ 1,198,839 | + \$92,386 |
| New Jersey | \$ 5,370,096 | \$ 5,370,096 | \$ 5,403,047 | + \$32,951 |
| New Mexico | \$ 1,581,141 | \$ 1,581,141 | \$ 1,744,689 | + \$163,548 |

Public Health and Social Services Emergency Fund

| | | | | |
|--------------------------|----------------|----------------|----------------|---------------|
| New York | \$ 9,895,682 | \$ 9,895,682 | \$ 11,453,105 | + \$1,557,423 |
| New York City | \$ 7,486,901 | \$ 7,486,901 | \$ 7,499,429 | + \$12,528 |
| North Carolina | \$ 6,083,849 | \$ 6,083,849 | \$ 6,153,069 | + \$69,220 |
| North Dakota | \$ 1,071,922 | \$ 1,071,922 | \$ 1,149,321 | + \$77,399 |
| Northern Mariana Islands | \$ 278,796 | \$ 278,796 | \$ 286,534 | + \$7,738 |
| Ohio | \$ 7,059,431 | \$ 7,059,431 | \$ 7,082,951 | + \$23,520 |
| Oklahoma | \$ 2,549,685 | \$ 2,549,685 | \$ 2,679,957 | + \$130,272 |
| Oregon | \$ 2,614,621 | \$ 2,614,621 | \$ 2,823,529 | + \$208,908 |
| Palau | \$ 255,889 | \$ 255,889 | \$ 257,040 | + \$1,151 |
| Pennsylvania | \$ 7,702,626 | \$ 7,702,626 | \$ 7,719,170 | + \$16,544 |
| Puerto Rico | \$ 2,590,019 | \$ 2,590,019 | \$ 2,499,222 | - \$90,797 |
| Rhode Island | \$ 1,071,962 | \$ 1,071,962 | \$ 1,149,415 | + \$77,453 |
| South Carolina | \$ 3,147,824 | \$ 3,147,824 | \$ 3,378,383 | + \$230,559 |
| South Dakota | \$ 1,083,466 | \$ 1,083,466 | \$ 1,176,125 | + \$92,659 |
| Tennessee | \$ 4,013,830 | \$ 4,013,830 | \$ 4,056,260 | + \$42,430 |
| Texas | \$ 15,577,836 | \$ 15,577,836 | \$ 15,541,402 | - \$36,434 |
| Utah | \$ 2,373,046 | \$ 2,373,046 | \$ 2,373,014 | - \$32 |
| Vermont | \$ 1,067,602 | \$ 1,067,602 | \$ 1,139,291 | + \$71,689 |
| Virgin Islands (US) | \$ 305,421 | \$ 305,421 | \$ 309,887 | + \$4,466 |
| Virginia | \$ 6,857,550 | \$ 6,857,550 | \$ 8,642,449 | + \$1,784,899 |
| Washington | \$ 4,367,027 | \$ 4,367,027 | \$ 4,743,095 | + \$376,068 |
| West Virginia | \$ 1,400,530 | \$ 1,400,530 | \$ 1,470,623 | + \$70,093 |
| Wisconsin | \$ 3,417,594 | \$ 3,417,594 | \$ 3,558,652 | + \$141,058 |
| Wyoming | \$ 1,076,454 | \$ 1,076,454 | \$ 1,159,845 | + \$83,391 |
| Total Resources | \$ 231,500,000 | \$ 231,500,000 | \$ 240,000,000 | + \$8,500,000 |

Note: FY 2022 amounts are estimates.

| Grant Awards Tables | | | |
|----------------------------|--------------------------|--------------------------|-----------------------------------|
| Program Name | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget |
| Number of Awards | 62 | 62 | 62 |
| Average Award | \$3,733,871 | \$3,733,871 | \$3,870,968 |
| Range of Awards | \$255,889 - \$23,171,118 | \$255,889 - \$23,171,118 | \$257,240 - \$22,465,160 |

Preparedness and Response Innovation

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|---------------|-----------------|----------------------------|---------------------|
| Budget Authority | -- | 2.000 | 2.080 | +0.080 |
| FTE | -- | 3 | 3 | -- |

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 that confront disaster response require new solutions to ensure the Department’s capability and capacity to protect Americans from national security health threats. Established in FY 2021, ASPR’s Preparedness and Response Innovation (PRI) program seeks to develop, prototype and procure revolutionary health security products, technologies, and innovations that will equip responders to meet the unique and emerging health needs that result from disasters, either natural or manmade.

This program signals the importance of ASPR’s mission to develop technologies beyond chemical, biological, radiological, and nuclear medical countermeasures (MCMs) and adapting those technologies and practical solutions to ensure the availability of the highest standards of care, when they are needed the most. This activity places emphasis on revolutionary advancements in health security products, technologies and solutions, specifically to invigorate operations, response, recovery, deployment and dispensing activities.

PRI funds are directed by Congress and specific to joint US and Israeli cooperative research and development. The FY 2021 appropriation prioritized development of health technologies, to establish a bilateral cooperative program with the Government of Israel for the development of health technologies, including but not limited to the following: artificial intelligence, biofeedback, sensors, monitoring devices, and kidney care. The program was also directed to emphasize collaboratively advancing the use of technology, personalized medicine, and data in relation to aging.

| Funding History | |
|-----------------------------------|--------------------|
| Fiscal Year | Amount |
| FY 2018 | - |
| FY 2019 | - |
| FY 2020 | - |
| FY 2021 Enacted | \$2,000,000 |
| FY 2022 President’s Budget | \$2,080,000 |

Budget Request

The FY 2022 President's Budget request for PRI is \$2,080,000, which is +\$80,000 above FY 2021 Enacted. ASPR will institute a competitive process by which several accelerators attached to academic or clinical research centers will apply for funding, with one award to an accelerator in the US and one accelerator in Israel that will bring in candidate projects for funding in each of the functional areas below. ASPR is directed by Congress to work with Israel on this bilateral project.

Applied (Clinical) Research and Development Projects: The accelerator networks will conduct stakeholder workshops with private companies to establish needs, present novel capabilities, and identify gaps. Resources will support logistics, recruiting, planning, and execution of workshops, and delivery of reports on outcomes. The funds will cover the costs of administration and logistics for recruiting, planning, execution of workshops, funding startup companies, and delivery of reports on outcomes.

Create a Pipeline of Data/Analytics Tools to Enable Transfer of Ownership of Health Records to the Patient, and Establish a New Ecosystem for Healthcare Participation and Drug Discovery: The funds will be used to cover the development of novel data security and analytics platforms that will allow for new ways to secure patient records, enable individuals to own all of their health records in one location and participate in health discovery, and develop new capabilities for phenotypic and multiomic analysis. The funds will cover logistics, recruiting, planning, execution of these data/analytic development efforts, and delivery of software tools and reports on outcomes.

Establish Regulatory Pathways and Safety and Efficacy Summaries: PRI will use funds to continue to fund collaboration between the Food and Drug Administration (FDA) and ASPR for the development of novel evaluation capabilities in the US and Israel that manage the risks in the regulatory environment around novel clinical technologies developed under this initiative. The FDA will work in concert with the Israeli Ministry of Health to establish new evaluation methods and analytical frameworks for combination technologies and combination products, which under normal conditions, undergo an extremely onerous review process. The funds will establish needs, identify gaps and institutionalize new streamlined review processes for these technologies. This covers the cost of administrative logistics, recruiting, planning, execution of joint evaluation efforts, and delivery of reports on outcomes.

Biomedical Advanced Research and Development Authority

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|---|----------------|-----------------|----------------------------|---------------------|
| Budget Authority | 561.700 | 596.700 | 823.380 | +226.680 |
| <i>Advanced Research and Development (non-add)</i> | <i>501.700</i> | <i>364.600</i> | <i>447.380</i> | <i>+82.780</i> |
| <i>DRIVe (non-add)</i> | - | <i>29.100</i> | <i>76.000</i> | <i>+46.900</i> |
| <i>Combating Antimicrobial Resistance (non-add)</i> | - | <i>118.000</i> | <i>180.000</i> | <i>+62.000</i> |
| <i>Operations and Management (non-add)</i> | <i>60.000</i> | <i>85.000</i> | <i>120.000</i> | <i>+35.000</i> |
| FTE | 155 | 222 | 267 | +45 |

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 (PAHPA). Congress reauthorized the Act in 2013, and again in 2019 as the Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2019 (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 – that are 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 eligible to be stockpiled in the Strategic National Stockpile (SNS) through BARDA’s Project BioShield (PBS) program.

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), Food and Drug Administration (FDA), and Department of Defense (DoD). Together with the Department of Homeland Security (DHS), Department of Veterans Affairs (VA), U.S. Department of Agriculture (USDA), and the Director of National Intelligence, these agencies constitute the Public Health Emergency Medical Countermeasures Enterprise (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 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 use rotated stock (e.g., vendor managed inventory systems) of MCM products to enable more cost-efficient alternatives to stockpiling in the SNS.

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 promising startup biotech to large pharmaceutical companies. Though the majority of BARDA's partnerships involve FAR-based research and development contracts, BARDA has expanded its use of other transaction authority (OTA). Unlike FAR-based contracts, OTAs allow for the establishment and management of dynamic *portfolios* of candidate MCMs that may be rebalanced based on mutual strategic needs. Since 2013, this type of partnership has allowed BARDA to more effectively and efficiently collaborate with product developers and establish consortia with other innovators researching and developing the next generation of MCMs against such threats as pandemic influenza, multidrug-resistant bacteria, chemical agents, and Ebola, among many other threats.

In July 2016, BARDA established the Combating Antibiotic Resistant Bacteria Biopharmaceutical 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 April 1, 2021, CARB-X has funded 82 different candidates and currently has 56 active programs for the development of 41 therapeutics, eight vaccines, and seven diagnostics. To date, seven CARB-X portfolio candidates have entered clinical development, highlighting the success of this program in accelerating early-stage product development to the clinic.

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 for all 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 in 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 also contribute to national surge manufacturing demands for MCMs during public health emergencies. These centers previously supported the 2013 H7N9 avian influenza response, the 2014–2016 Ebola response, the 2016–2017 Zika response, and are currently supporting the COVID-19 pandemic 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 partnered with two additional contractors with more experience in biologics. Notably, the FFMN supported the production of the experimental Ebola therapeutic ZMapp for the 2014–2016 Ebola response and is supporting the ongoing COVID-19 pandemic response.
- *Nonclinical Development Network*: Established in 2011, the Nonclinical Development Network provides broad capabilities and capacity for testing MCMs addressing CBRN threats, pandemic influenza, and emerging infectious diseases. Directed by BARDA's programmatic priorities, the network of laboratories assures the availability of robust animal models of disease, key reagents, and supportive assays required to advance priority MCMs, particularly those pursuing approval or licensure under the Animal Rule. Comprised of 22 laboratory partners, the network has performed over 200 nonclinical studies under 98 BARDA projects to date. During 2020, the Nonclinical Development Network accelerated the development of small and large animal models and supportive assays for SARS-CoV-2 infection and provided testing capacity for vaccine candidates and therapeutics to address COVID-19 indications.
- *Clinical Studies Network (CSN)*: Formed in 2014 and revised in 2020, the CSN provides clinical

development services to support MCM development and evaluation and to provide surge capacity of clinical trial capabilities during public health emergencies. Since its inception, the CSN has engaged in nine clinical research projects, including supporting the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) vaccine study during the 2014–2016 Ebola response and conducting a 2017-2018 Phase 2 safety and immunogenicity study of a novel influenza H7 vaccine. The CSN supported the 2016-2017 Zika response by collecting clinical samples to accelerate the development of Zika diagnostics, and led the first BARDA-sponsored clinical trial, the BRITE study, to evaluate long-stored influenza H5 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. More recently, the CSN conducted clinical trials of an investigational anthrax vaccine in the elderly (FY 2017-2018), and a Phase 1 pharmacokinetic study of sublingual atropine as a MCM for nerve agent toxicity (FY 2019-2020). Starting in FY 2020 and continuing through FY 2021, the CSN is supporting the Federal COVID-19 Response to rapidly design, implement, and analyze COVID-19 MCM clinical trials.

Developing Multi-Use Products

The 2010 PHEMCE Review recommended that BARDA focus on more sustainable, multipurpose products possessing both a biothreat and a commercial indication as well as platform capabilities to reduce the time required to respond to an emerging event. The following activities are examples of BARDA's commitment to developing and repurposing multi-use MCMs:

- Development of antibiotics that address biothreats such as weaponized anthrax, plague, and tularemia, while also treating high priority community- and healthcare-acquired bacterial infections.
- Development of platform discovery and manufacturing technologies that accelerate the ability to rapidly respond to evolving threats.
- Repurposing of existing treatments for injuries caused by radiological/nuclear and chemical threats as well as thermal burns. The injuries caused by these threats often have treatment solutions with viable commercial markets. The repurposing of commercial products also enables the use of vendor-managed inventories (VMI) as a more cost-effective alternative to product stockpiling by leveraging product rotation based on commercial use.
- Development of new MCMs and evaluation of approved drugs to prevent and/or treat the pathophysiological consequences of CBRN threat agents rather than directly targeting the agent itself. Examples include the following: 1) treatment of seizures due to nerve agent exposure, 2) lung and skin injuries due to chemical exposure, 3) numerous injuries due to acute radiation exposure, and 4) a range of blast and burn injuries resulting from a nuclear detonation.
- Execution of a strategy to “treat the injury, not the threat” for the development of agnostic technologies and MCMs capable of preventing and treating injuries and illnesses associated with biological threats (i.e., bacterial and viral) when the threat is not known. Such capabilities, which may include broad-acting MCMs capable of targeting a range of bacterial and viral threat agents and pathogen-independent approaches such as host-direct immune modulators, have the benefit of being used effectively to counter a newly emerged and rapidly spreading disease agent when the identity of that agent is unknown.

Developing a layered suite of technologies, platforms, approaches, and MCMs that can be rapidly deployed is critical to effectively respond to previously unidentified threats that will certainly continue to pose a threat to national health security.

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 18 CBRN threats as identified by DHS. These advanced development programs have supported 28 products that have transitioned to support under PBS, 18 of which have been procured for the SNS. BARDA's efforts have led to 59 FDA licensures, approvals, or clearances of MCMs since 2008, 22 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 myelosuppressive radiation exposure (2015)
- Neulasta to treat myelosuppressive radiation exposure (2015)
- BioThrax vaccine for post-exposure prophylaxis of anthrax (2015)
- ANTHIM anthrax antitoxin (2016)
- Roche Cobas Liat *C. diff* diagnostic (2017)
- VABOMERE to treat complicated urinary tract infections (2017)
- Leukine to treat myelosuppressive 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)

The importance and innovative impact of numerous MCMs under development at BARDA are also reflected by the Breakthrough Designation granted by the FDA. Since 2018, the following products have received the Breakthrough Designation under the 21st Century Cures Act:

- StrataGraft, a full-thickness off-the-shelf skin substitute for burn injuries by Stratatech
- DeepView, which uses machine learning algorithms, for burn depth imaging by SpectralMD
- NovoSorb (BTM), a temporizing wound coverage covering for expansive burn injuries by PolyNovo
- INMAZEB (formerly EB3), a cocktail of three monoclonal antibodies as a therapeutic for Ebola Zaire by Regeneron
- EBANGA (formerly mAb114), a single monoclonal antibody therapeutic for Ebola Zaire by Ridgeback

Anthrax: In response to the emphasis DHS has placed on anthrax as a national security threat, HHS has invested nearly \$3 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 licensure of a new facility to expand domestic vaccine manufacturing capacity. One of the next-generation anthrax vaccine candidates has transitioned to PBS and has now completed enrollment of a Phase 3 clinical trial. The first procurement of the vaccine, for potential use under EUA, occurred in FY 2019.

Smallpox: Smallpox remains a threat of high concern to both the domestic and 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 modified vaccinia Ankara (MVA) smallpox vaccine for immunocompromised patients. In 2019, the FDA approved the JYNNEOS (MVA) smallpox vaccine to prevent smallpox and monkeypox. BARDA is supporting procurement of frozen liquid vaccine doses in parallel with the development of a freeze-dried formulation of JYNNEOS that may have a longer shelf-life and lower stockpiling costs. With support from BARDA, FDA approved TPOXX, an antiviral drug to treat smallpox disease, in July 2018. BARDA is continuing to support intravenous and pediatric formulations to make TPOXX more broadly available. BARDA is also continuing to support TEMBEXA (formerly brincidofovir) and Chimerix has initiated rolling submission of its NDAs for the oral and suspension formulations of TEMBEXA. To further increase the likelihood of developing a second therapeutic for smallpox while also diversifying the product classes of candidates, BARDA awarded a contract to Biofactura in 2019 to support development of their monoclonal antibody cocktail.

Broad Spectrum Antimicrobials and Combating Antibiotic-Resistant Bacteria Initiative:

Antimicrobial resistance complicates the Nation's ability to respond to public health emergencies, specifically the treatment of primary infections from biothreat agents as well as secondary infections likely to emerge during a public health emergency response. BARDA's Broad Spectrum Antimicrobials (BSA) program is developing MCMs that counter DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders) and that address healthcare- and community-acquired multi-drug resistant pathogens. Seven antibiotic candidates in the BSA portfolio are currently in Phase 3 clinical development. BARDA is also supporting the late-stage development and procurement under PBS of a promising novel antibiotic (Paratek's Nuzyra) for the treatment of both anthrax and community-acquired bacterial pneumonia. To support a robust early-stage antibacterial pipeline, BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) established CARB-X in 2016. 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 August 2020, CARB-X has supported the development of 82 novel candidates with seven projects having advanced to clinical stage development.

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. BARDA has supported and FDA has licensed or cleared vaccines, therapeutics, and diagnostics that have been deployed to the Democratic Republic of the Congo (DRC) to help the World Health Organization temper the 2018 Ebola outbreak as well as the more recent 2020 and 2021 outbreaks in the DRC and Guinea.

In December 2019, the FDA licensed Merck's Ebola vaccine, ERVEBO. Approximately 300,000 doses of ERVEBO have been used in the DRC and surrounding countries. Since licensure of ERVEBO by the FDA in 2019, BARDA initiated procurement of the vaccine to ensure domestic preparedness for future Ebola outbreaks. The Janssen Ebola vaccine, which was approved by European regulators, has been used

in a clinical trial in the DRC and Rwanda, just outside of the 2018 outbreak zone, for healthcare and other front-line workers.

Regeneron's EB3 (now known as INMAZEB) Ebola therapeutic and Ridgeback's mAb114 (now known as EBANGA) Ebola therapeutic were licensed by the FDA in late CY 2020, and all work for both products is now being supported by BARDA. BARDA recently initiated procurement of 50,000 treatment courses of INMAZEB to be delivered to the SNS. BARDA is also working with Ridgeback to develop a scaleup plan that will allow manufacturing and eventual procurement of EBANGA for the SNS. Both products have been used in the 2021 Ebola outbreaks in the DRC and Guinea.

In FY 2019, BARDA initiated programs to address Marburg virus and Ebola Sudan, both threat agents for which BARDA currently has no approved MCMs in its portfolio. BARDA is currently investing in two different vaccine candidates for Marburg virus and one candidate for Ebola Sudan. On the therapeutics side, BARDA is supporting a single monoclonal antibody candidate for treatment of Marburg and a two monoclonal antibody cocktail that targets Sudan, Ebola, and the related Bundibugyo viruses.

Biodosimetry and Bidiagnostics: 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. BARDA initially supported the development of eleven 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 has acceptable instrumentation strategies, often based on existing fielded products. Two candidates were transitioned from ARD to PBS in FY 2017, followed by another two candidates in FY 2018. In FY 2021 and FY 2022, product verification, validation, regulatory filing, and production preparation for these products are being managed under PBS awards with the goal of supporting FDA 510(k) clearance. In FY 2021 and FY 2022, as verification testing is completed, product validation progresses, and with extensive interaction and feedback from FDA, BARDA will further downselect its biodosimetry portfolio with continued support for candidates that achieve promising results.

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. BARDA supported nonclinical studies to identify host signs of infection (biomarkers) or bacterial toxins and their behavior during the course of disease for *Bacillus anthracis*, *Burkholderia pseudomallei*, *Burkholderia mallei*, and *Yersinia pestis*. In FY 2019, the FDA cleared the Applied Biosystems anthrax detection test, which was the first BARDA supported molecular diagnostic test for detection of anthrax. In addition, BARDA awarded a contract in FY 2015 to Orasure Technologies to support development of a test to detect Ebola virus in both suspected patients and cadavers. The FDA issued two EUAs for this test in July 2015 for use in the 2014-2015 West Africa Ebola response and the FDA cleared the diagnostic in FY 2019. These tests were distributed to the WHO and are being used in DRC and Guinea.

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. To address this threat, 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, blood products, and treatments for thermal and radiation burns.

Acute Radiation Syndrome and Blood Programs: BARDA has identified specific pathways (e.g., coagulation, vascular injury, inflammation) that play essential roles in radiation injury and trauma. Repurposing commercially available products that modulate these pathways, thereby leveraging commercial development efforts, is a central goal of the program. Commercial products to treat thrombocytopenia are being developed to treat the thrombocytopenic component of acute radiation syndrome as well as being investigated for their potential role in addressing vascular injury. Given the importance of blood products during an emergency response, BARDA will continue to develop its blood portfolio as well as other therapeutics for trauma. Currently, BARDA is supporting the development of next generation blood products (e.g. spray dried plasma and lyophilized platelet products) and platforms (e.g., pathogen reduction platforms and ex vivo platelet manufacturing) that will augment the safety and availability of the blood supply.

Thermal Burns: Nuclear detonations will also cause severe thermal burns and blast trauma. Since FY 2013, in an effort to address the large-scale threat of burn mass casualty, BARDA has taken a comprehensive approach to identify and resolve anticipated bottlenecks resulting from limited treatment capabilities and inefficiencies. By developing next-generation treatments that not only address these bottlenecks but also can be integrated into routine burn care, BARDA has built a robust and sustainable preparedness for mass casualty incidents. With this strategy, BARDA can simultaneously improve the quality of routine care, reduce costs, and maintain a user base that is skilled in the new technology products while also enhancing our nation's preparedness posture. Some of BARDA's accomplishments include the following:

- Spectral MD DeepView burn depth imaging and machine learning algorithms program entered into a second contract in FY 2018 and was granted Breakthrough Designation by the FDA.
- StrataGraft full-thickness off-the-shelf skin substitute and the NovoSorb temporizing wound coverage were also granted Breakthrough Designation by the FDA.
- Avita's RECELL Spray-On Skin™ Cells received 510(k) clearance for the treatment of acute thermal burn wounds in 2018.
- Philips Lumify ultrasound technology for detection of lung injuries was granted 510(k) clearance in FY 2021, within the first year of its contract. BARDA is also supporting Philips to use machine learning to develop algorithms to differentiate bacterial and viral pneumonias, including COVID-19.

All of these products address the need for better triage and provide temporary coverage in expansive burns, thereby expanding our nation's surgical burn care bandwidth. In FY 2020, the Burn program expanded two new sub-portfolios focusing on the following: 1) initial care for mechanical trauma and combined injuries, and 2) burn wound healing and surgery reduction.

Chemical Threats: BARDA's Chemical MCM Program has also adopted a strategy of treating the injuries caused by chemical agents rather than developing drugs and indications specific to individual agents. This strategy enables the repurposing of products with routine clinical utility for the treatment of injuries resulting from chemical agents, a strategy that will ensure the rapid availability of MCMs at the time and place of need. One example of this emphasis on repurposing is the development of Alteplase for the treatment of lung injury caused by sulfur mustard. Alteplase is 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 airways after exposure to sulfur mustard. Another example is the development of drugs for refractory status epilepticus (seizure) that can also mitigate the neurological injury due to prolonged nerve agent-induced seizures.

As part of the emphasis on developing treatments for the effects of chemical exposure, BARDA in FY 2019 began to invest in organ-on-chip technologies to identify novel pathways of chemical injury.

These technologies will lead to an improved understanding of the pathophysiology of toxicant injury and the identification of clinically available treatments that are candidates for repurposing as chemical MCMs. The organ-on-chip systems can also be used as preliminary efficacy screens for MCM candidates, saving both time and animals in pre-clinical development. In FY 2021, the BARDA Chemical MCM Program partnered with BARDA's Division of Research, Innovation, and Ventures (DRIVE) to launch the ReDIRECT program that is partnering with innovators to repurpose commonly available therapeutics to treat conditions resulting from exposure to chemical agents. As of April 2021, the ReDIRECT program has awarded two contracts: 1) to MediciNova for the testing of MN-166 (ibudilast) as a potential treatment for acute lung injury and acute respiratory distress syndrome (ARDS) resulting from exposure to chlorine, and 2) to FirstString Research to evaluate the therapeutic potential of aCT1 eye drops, a synthetic peptide that has been shown to promote wound healing, for treatment of sulfur mustard corneal injury. ReDIRECT will accelerate the development of these and future candidates through preclinical development and then transition the most promising candidates into the BARDA Chemical MCM Program portfolio for advanced clinical development.

Driving Product Innovation: In FY 2018, BARDA established the Division of Research, Innovation and Ventures (DRIVE). Since then, DRIVE has made significant progress in developing new technologies for health security that can address multiple threats simultaneously and respond quickly to an emerging or unexpected need by innovating at the intersection of business, technology, and science. DRIVE has developed an end-to-end approach to innovation by incorporating a greater flexibility to pivot, adapt, and respond to new and emerging threats with novel technologies and capabilities and an emphasis on speed. In FY 2022, DRIVE will continue to invest in its core programs and actively identify new and emerging needs for investment and formalize new funding mechanisms to drive innovation, such as the Medical Countermeasures Innovation Partnership that focuses on needs such as preventing and responding to future pandemics.

The ENACT (Early Notification to Act, Control, and Treat) Program is focused on empowering patients and healthcare workers with real-time information to take control of early diagnosis and treatment. ENACT has developed 12 sensing technologies and advanced data analytics algorithms to provide early and actionable health information to individuals, such as pre-symptomatic detection of a viral infection like flu or COVID-19. Three ENACT-supported technologies utilizing wearable physiological monitors have proven highly relevant for COVID-19 and are currently supported by DRIVE to aid in the response.

The Solving Sepsis Program has begun developing new classes of MCMs to address sepsis, which can result from almost any infection, including COVID-19. The program made 11 awards, including those to develop host-based diagnostics that can predict, identify and prognosticate sepsis outcomes. In addition, the program has examined, in partnership with the Center for Medicare and Medicaid Services (CMS), the patient and economic burden of sepsis among Medicare beneficiaries.

The Beyond the Needle Program, started in FY 2021 as part of the COVID-19 response, has made six awards focused on developing and validating new vaccine and drug delivery technologies. The goal of these technologies, which include microneedle skin patches, solid-dose vaccines, and oral formulations, is to enable significantly simpler vaccine administration that doesn't rely on needles and syringes across a range of medical countermeasures, including COVID-19 and flu vaccines. Availability of these technologies in the future would transform the ability to quickly vaccinate an entire population or deliver critical drugs to diverse populations, including rural and underserved settings. It would also improve supply chain resilience by providing orthogonality in manufacturing and fill-finish capabilities to typical vial and syringe/needle processes.

Driving Process Innovation: DRIVE continues to push the boundaries for how government does business with its stakeholders by establishing and utilizing the customer-friendly, rapid contracting

mechanism, called the EZ Broad Agency Announcement (EZ-BAA), which was designed to make awards in under 30 days. DRIVE also established the DRIVE Digital Resources team, which has automated many of BARDA's administrative and reporting processes and has scaled up these tools across BARDA in FY 2020 and FY 2021. The BARDA Accelerator Network, a network of 13 health technology accelerators across the country, enables BARDA to engage with a broad entrepreneur and innovation ecosystem to source new technologies, inspire a generation of startups to focus on health security priorities, and provide market intelligence to BARDA. In FY 2020 and 2021, the Accelerator Network helped DRIVE identify many new early-stage startups for investment, provided market intelligence reports for anti-fungal therapies and next-generation ventilation technologies, and convened stakeholder roundtables of clinicians, patients, and others on current and future efforts. The Accelerator Network will continue to provide these services into FY 2022. In FY 2020, DRIVE also piloted a new approach to start new funding programs through a process called DRIVE Start. Under DRIVE Start, new ways to engage the entrepreneurial community will be adapted with prizes, challenges, and other innovative ways to quickly deploy capital to the most successful partners. This is designed so that BARDA can be more agile in responding to emerging threats and needs.

BARDA Ventures: Under the 21st Century Cures Act, Congress provided BARDA with the authority to invest in a Medical Countermeasures Innovation Partner (MCIP) to use venture capital practices in the development of products, tools, and technologies to address 21st-century health security threats. In response, BARDA Ventures was officially launched in FY 2021, marking the first time HHS will use such a mechanism. The primary goals of BARDA Ventures are the following: (1) leverage private investment with public funding to amplify impact, (2) have greater control and influence on the development of critical health security products, and (3) maximize taxpayer value by recycling returns from successful ventures for new investments. In FY 2021 and FY 2022, it is expected that BARDA will continue to ramp up funding to the Ventures partnership and expand its portfolio of investments.

COVID-19 Response: During FY 2020 and 2021, ASPR worked across the interagency on the fight against the most severe pandemic in a century. As part of ASPR, BARDA supported development, manufacturing, and/or purchase of medical countermeasures to combat COVID-19. Less than one month after the SARS-CoV-2 sequence was shared, BARDA immediately began to leverage existing public-private partnerships to develop vaccines, therapeutics, and diagnostics to address COVID-19. BARDA led early coordination among federal agencies to identify and develop medical countermeasures, and BARDA directly supported development and manufacturing of seven vaccine candidates including Moderna and Johnson & Johnson's Janssen vaccine and purchase of the Pfizer vaccine; 13 therapeutics, including development of the Regeneron monoclonal antibody therapeutic and purchase of the Eli Lilly and Company therapeutics, as well as the convalescent plasma program; 17 rapidly deployable and other technologies, including next generation technologies to administer vaccines; and 42 diagnostic tests ranging from high-throughput tests for laboratories early in the pandemic to rapid point-of-care and at-home tests; 20 of BARDA-supported COVID-19 tests have received emergency use authorization from the U.S. Food and Drug Administration, and these private sector partners have shipped more than 108 million tests across the country.

BARDA also collaborated with the private sector to expand capacity for manufacturing active pharmaceutical ingredients, as well as vaccines and ancillary products such as needles and syringes, purchased the ancillary supplies the SNS needed for vaccine supply kits, and engaged the Centers for Innovation in Advanced Development and Manufacturing for the first time in a pandemic response. In early 2020, BARDA rapidly expanded its broad agency announcements to incorporate COVID-19 medical countermeasures, refocused its TechWatch program on COVID-19 medical countermeasures to review thousands of submissions, met with hundreds of potential product developers, and pivoted existing agreements with key private sector partners to focus immediately on developing therapeutics and vaccines using flexible platform technologies which BARDA had supported for other potential health security

threats. BARDA also provided significant funding and other support to the National Institutes of Health for vaccine and therapeutics clinical trials, as well as for scale-up and manufacturing of new COVID-19 diagnostics. In total, these successful investments continue to yield an enormous benefit to the American people and will be critical to ending the COVID-19 pandemic.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$536,700,000 |
| FY 2019 | \$561,700,000 |
| FY 2020 | \$561,700,000 |
| FY 2021 Enacted | \$596,700,000 |
| FY 2022 President’s Budget | \$823,380,000 |

Budget Request

The FY 2022 President’s Budget for Advanced Research and Development is \$823,380,000, which is +\$226,680,000 above FY 2021 Enacted. The additional funds are being requested to support numerous program areas, including: the Division of Research, Innovation, and Ventures (DRIVE) and its Medical Countermeasures Innovation Partner (MCIP), which will provide equity funding for research and development of innovative and disruptive healthcare technologies, and BARDA’s Broad Spectrum Antimicrobials Program to expand its portfolio of next generation antibacterial candidates addressing the global threat of antimicrobial resistance and to continue its support of an Accelerator to support early stage development of novel antimicrobial therapies.

Additional program areas that will be expanded with the increased funding include: vaccines and therapeutics for viral hemorrhagic diseases, including Marburg and Sudan viruses (two threats for which no MCMs exist); next generation smallpox therapeutics with increased efficacy and improved safety over currently approved and available drugs; countermeasures against chemical threats to evaluate the efficacy of currently available drugs with commercial indications against a range of chemical threats such as sulfur mustard and nerve agents; and development of next generation therapeutics against botulinum toxin and vaccines against anthrax. The additional funding for these programs will also leverage the experiences learned by BARDA over the past 16 months while fighting the COVID-19 pandemic that highlighted the importance of developing platform technologies that can be rapidly redirected from one threat agent and be deployed to focus on an emerging threat.

Lastly, additional funds requested will support an increase in Management and Administration to ensure that BARDA has the required staffing to address its current threat space while it continues to respond to the ongoing COVID-19 pandemic.

The Budget request supports the advanced development of the highest priority MCMs against all 18 threats identified by DHS and prioritized in the PHEMCE Strategy and Implementation Plan⁴³.

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. Next generation botulinum antitoxin;
4. New antidotes for treatment of injuries induced by chemical agents (for example, mustard gas exposure and chlorine gas);
5. Diagnostic devices to confirm infection with biological agents and identify an effective antibiotic sooner, some of which will be suitable for use in point-of-care and near patient settings;

⁴³ <https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx>

6. Innovations for advanced, portable extracorporeal membrane oxygenation (ECMO) devices;
7. Innovations in early stage MCM research and development focusing on sepsis, wearable diagnostics, and distributed manufacturing technologies;
8. New candidate products to address the pathologies caused by radiological or nuclear events, including thermal burns;
9. New diagnostic devices to help reduce the emergence of antimicrobial resistant bacteria by identifying the appropriate treatment sooner;
10. Multi-tissue human microphysiological models ("body-on-a-chip") that incorporate immune system models for screening of vaccines and therapeutics;
11. Novel patient triage technologies, including phone apps, for rapid patient assessment and information sharing within first responder and hospital networks;
12. Novel host-based therapeutic approaches that are agnostic to pathogen and address severe forms of disease and sepsis;
13. Novel host-based diagnostic approaches to address disease severity and identify health deterioration in a number of clinical settings (pre-hospital, hospital, post-discharge);
14. Novel antibacterial drugs, diagnostics, and vaccines;
15. Patient behavior modification approaches as an MCM; and
16. Diagnostic technologies suitable for use in limited testing resource settings, such as nursing homes, temporary treatment centers, tribal clinics, and even homes, by minimally trained personnel.

Anthrax (\$10 million): FY 2022 funding will support assessment of delivery approaches that may enable a next-generation anthrax vaccine that can provide protection after a single dose. 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.

Anthrax Antitoxins (\$1 million): FY 2022 funding will support ongoing analytical studies designed to evaluate extended stability of existing anthrax antitoxins.

Combating Antibiotic-Resistant Bacteria (\$180 million): The FY 2022 request includes an additional \$62 million to support CARB-X and the advanced development of broad-spectrum antimicrobials, including vaccines, diagnostics, and novel antibiotic treatments for both complicated and uncomplicated infections. Additional funds will sustain and expand the scope and scale of CARB-X to ensure the early stage pipeline remains robust and delivers MCMs that are attractive for subsequent advanced development funding from BARDA as well as other organizations. New funding initiatives in FY 2022 will include transitioning one to two CARB-X graduates into the BARDA's advanced development portfolio. ARD funding will also support continued progress across the broad-spectrum antimicrobial portfolio. All funded efforts are focused on the development of next generation therapeutics that address the growing incidence of antimicrobial resistance and the potential threat of a bioterrorism event.

Botulinum antitoxins (\$10 million): FY 2022 funding will support the continued development of a 2nd generation botulinum antitoxin, including down-selection of candidate antibodies against botulinum neurotoxin serotypes A-G and proof-of-concept efficacy studies.

Chemical (\$80 million): FY 2022 funding will be used to continue development of animal and organ-on-chip models to support evaluation of candidate products as well as to support the ARD of products, including those identified through ReDIRECT. These funds will help address gaps in preparedness for multiple chemical threats, such as chlorine, opioids, 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 and non-pharmaceutical strategies aimed at treating the life-threatening effects of opioid-induced respiratory depression.

Acute Radiation Syndrome (\$80 million): FY 2022 funds will be used to continue support for all the existing candidates that continue to perform well, further develop vascular injury treatments, and begin to develop a portfolio to address inflammation that will likely have applicability across several threat areas, including emerging infectious diseases. Also, there are several cross-threat areas for joint development between programs, such as the use of antibiotics in the context of radiation injury, combined injury caused by radiation and thermal burns, and acute lung injury (such as pneumonitis and subsequent fibrosis) for both radiation injury and chemical injury.

Biodosimetry and Biothreat Diagnostics (\$50 million): In FY 2022, BARDA will continue ongoing investments for development and studies to identify biomarkers of infection as well as the dynamics of those biomarkers during the disease process in preparation for diagnostics development. Initiation of formal development programs for additional biothreat diagnostics is envisioned for FY 2022. The portfolio also includes the following: 1) antibiotic susceptibility tests that are critically important for public health as well as for potential bioterrorism events; 2) tests that distinguish viruses from bacteria in FY 2022; and 3) anthrax diagnostics candidates that are sufficiently mature to achieve FDA clearance.

Thermal Burns (\$50 million): In FY 2022, BARDA 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.

Smallpox Therapeutics (\$25 million): FY 2022 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 that could transition to ARD in FY 2022.

Viral Hemorrhagic Fever (\$130 million): FY 2022 funding will focus on vaccines and therapeutics for Sudan ebolavirus and Marburg viruses. BARDA will continue to develop vaccine candidates for both viruses into Phase 2 clinical development. The funding will also support continued development of the first Sudan and Marburg therapeutics in BARDA's portfolio and further expansion of the portfolio to include additional candidates.

Clinical Network and Nonclinical Studies Network (\$11.3 million): The Clinical Studies Network (CSN) will continue the development of clinical protocols for evaluation and testing in FDA-regulated trials. These studies will broaden the current indications of MCMs to create a sustained preparedness posture against CBRN threats. The CSN was revised in FY 2020 with new awards to further improve the utility of the network. The Nonclinical Studies Network will continue the development of animal models that are essential to support licensure or approval of CBRN MCMs that require supportive data for FDA approval under the Animal Rule. Further work is critical in evaluating MCM candidates' efficacy for acute radiation syndrome (ARS) sub-syndromes including gastrointestinal, skin, and pulmonary injury. Viral hemorrhagic fever models for Ebola Sudan and Marburg also will need to be qualified as new candidate products come into BARDA's pipeline.

DRIVE and the Medical Countermeasures Innovation Partner (MCIP) - DRIVE (\$76 million): FY 2022 funding will maintain existing DRIVE efforts and expand the portfolio of programs. These include the following:

Public Health and Social Services Emergency Fund

- Develop innovative approaches for early identification, prevention, and treatment of sepsis;
- Support novel technologies to empower patients and healthcare workers with information to diagnose and identify individuals exposed to infectious disease under the ENACT program; and,
- Continue to support the BARDA Accelerator Network, MCIP (BARDA Ventures program), and efforts to take on new innovation and partnership opportunities to meet constantly evolving health security needs.

The requested funding will build an end-to-end innovation solution within BARDA. This includes maintaining the Accelerator Network that has been instrumental in providing market intelligence to BARDA as well as continuing support of BARDA Ventures, the MCIP entity, to continue to utilize equity-based financing to invest on behalf of BARDA and the USG. At current FY 2021 funding levels of \$10 million, it is anticipated that a minimum of three to five investments will be initiated in FY 2022. With the additional funds requested for FY 2022, Ventures could make 7-10 investments, with significantly reduced risk as is typical with more diverse investment portfolios. DRIVE Start will provide funding support to new program starts, challenges, prizes, and new ideas to ensure that DRIVE continues to innovate and operate at the leading edge of technology. In FY 2022, it is also expected that many of the investments made in Solving Sepsis and ENACT projects will be positioned for commercialization, enabling dramatic, positive impacts on the healthcare system and the ability to detect and respond to health emergencies, whether caused by CBRN threats, pandemic influenza, or emerging infectious diseases.

Management and Administration (\$120 million): The Budget includes an additional \$35 million for BARDA's management and administration costs. These funds provide support to BARDA's programs for Advance Research and Development, Project BioShield, and Pandemic Influenza. The BARDA organization has grown significantly over the years as a result of increasing workload. Funding will be used to bolster scientific staff and related support staff, including contracting officers and contracting specialists, as the overall number and complexity of contracts increase. Funds will support staffing for federal personnel, contractors, awards for acquisition of services, central costs, travel, and training. Funds also will be used for related services and oversight provided by ASPR to support BARDA's mission. These functions include information technology, data analysis and modeling, such as the activities carried out and products provided by the Visualization Hub, acquisition policy including Earned Value Management (EVM) analysis and contract close outs, MCM requirements planning and coordination, grants management, financial planning, analysis and oversight, personnel security and security assessments for facilities under BARDA contracts, policy leadership, scientific and medical subject matter expertise for coordination with other agencies, and other necessary expenses. This amount also includes BARDA's contribution to the Public Health Service Evaluation Set-Aside assessed by HHS pursuant to section 241 of the Public Health Service Act.

In FY 2020-2021, BARDA funded information technology and subject matter expertise staffing contracts using COVID-19 supplemental appropriations. The functions are permanent capabilities necessary for BARDA through the COVID-19 response and beyond. It is critical that these capabilities be maintained going forward to ensure that BARDA has adequate staffing and manpower to address current CBRN threat requirements while simultaneously responding to the COVID-19 pandemic and preparing for the next public health emergency response. In addition, the IT capabilities that BARDA has established over the course of the COVID-19 response have been critical for the collection and analysis of enormous data sets essential for both program management and strategic decision making, capabilities that must be maintained going forward to be prepared for future responses.

In response to the HHS Inspector General's report, HHS's Office of the Assistant Secretary for Financial Resources is undertaking an internal review of the use of advanced research and development funding from the Public Health and Social Services Emergency Fund (PHSSEF) for fiscal years 2015 through

Public Health and Social Services Emergency Fund

2019 to identify any potential Anti-deficiency Act violations. HHS also hired an outside accounting firm which is auditing ASPR's use of funds for administrative services. Both reviews are estimated to be completed by the summer of 2021. The PHSSEF supports a variety a public health emergency preparedness and response needs, including associated administrative costs, and its annual appropriation authorizes the use of funds "...for expenses necessary to support advanced research and development pursuant to section 319L of the PHS [Public Health Service] Act and other administrative expenses of the Biomedical Advanced Research and Development Authority...".

Key Outputs and Outcomes Table

Biomedical Advanced Research and Development Authority

| Measure | Year and Most Recent Result / Target for Recent Result / (Summary of Result)¹ | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 Target |
|---|---|---------------------------|---------------------------|---|
| 2.4.13a Increase the number of new licensed medical countermeasures across BARDA programs (Intermediate Outcome) | FY 2020: 3 medical countermeasures Target: 3 medical countermeasures (Target Met) | 3 medical countermeasures | 3 medical countermeasures | Maintain |
| 2.4.13b Increase the number of new countermeasures eligible for consideration by FDA for Emergency Use Authorization (Intermediate Outcome) | FY 2020: 1 medical countermeasures Target: 2 medical countermeasures (Target Not Met) | 2 medical countermeasures | 2 medical countermeasures | Maintain |
| 2.4.14a Increase the technical assistance provided by BARDA to medical countermeasure manufacturers (Intermediate Outcome) | FY 2020: 16 manufacturers Target: 11 manufacturers (Target Exceeded) | 11 manufacturers | 11 manufacturers | Maintain |

¹FY 2020 data in this table result from activities supported by both base and supplemental appropriations.

Project BioShield

Budget Summary (Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 735.000 | 770.000 | 770.000 | -- |
| 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 ongoing COVID-19 pandemic, and those caused by intentionally engineered CBRN threats 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 28 products that are critical to prepare for and treat the effects of these threats. Eighteen of these products have been delivered to the SNS or procured as Vendor Management Inventory (VMI), with additional products to be delivered in FY 2022 and FY 2023. As of April 2021, 18 of these products achieved FDA approval or licensure, and additional approvals are anticipated in FY 2021 and FY 2022. 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 has 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, while next generation antibiotics capable of treating infections following an anthrax attack can also be used for treating patients hospitalized with community-acquired pneumonia. PBS allows BARDA to purchase and maintain in the SNS promising products that are sufficiently mature for use under an Emergency Use Authorization (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. PBS 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 anthrax vaccine). Sustainment

of companies and products supported under PBS and transitioning to the SNS is a continuing challenge. 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. In FY 2020, BARDA and SNS leveraged an existing BARDA contract to procure additional doses of an approved smallpox therapeutic to offset expiry of existing inventory and maintain preparedness.

Since FY 2005, BARDA has invested in 28 unique MCMs under PBS, 18 of which have been delivered to the SNS or procured as VMI, including the following:

- 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);
- Nexobrid and RECELL for the treatment of injuries due to thermal burns;
- Silverlon as an antimicrobial wound dressing for the treatment of skin injuries due to chemical and thermal burns; and,
- ERVEBO vaccine for prevention of Ebola Zaire disease.

Based on the successful development of CBRN MCMs in BARDA ARD programs, BARDA will be prepared to support the advanced development and/or procurement of up to six new CBRN MCMs under PBS by the end of FY 2022. Since 2014, BARDA has awarded 18 contracts under PBS for late-stage development and procurement of MCMs and 28 since the inception of PBS. BARDA will invest significant funds in FY 2022 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 2022. 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 used this funding to procure one vaccine, one therapeutic, and potentially two diagnostics for the Ebola Zaire strain. BARDA also obligated an additional \$200 million provided through the FY 2020 PBS appropriations to support late-stage development activities for licensure of the various medical countermeasures. These activities could include phase IV post-marketing requirements or commitments.

The following promising candidates have the potential to transition to PBS in FY 2022:

- Additional antimicrobials to treat drug-resistant pathogens;
- Products to address thermal burn injuries;
- Products to address acute radiation exposure;
- Products to address exposure to chemical threats; and,
- Antibody cocktail therapeutic for Marburg Virus.

| Funding History | |
|----------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$710,000,000 |
| FY 2019 | \$735,000,000 |
| FY 2020 | \$735,000,000 |
| FY 2021 Enacted | \$770,000,000 |
| FY 2022 President's Budget | \$770,000,000 |

Budget Request

The FY 2022 President's Budget for Project BioShield is \$770,000,000, which is flat with FY 2021 Enacted. Relative to the FY 2021 Enacted level, BARDA prioritized increasing funding for promising novel technologies in its ARD program as it assesses potential pathogens responsible for a future public health pandemic. The FY 2022 request supports continued development and procurement of a next-generation anthrax vaccine, therapeutics for Sudan and Marburg viruses, continued procurement of JYNNEOS, and procurements of new antibacterial drugs, medical countermeasures to treat chemical injuries, a new product to temporize burn injury, and a new MCM to treat the effects of radiation exposure. 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 the following:

- Phase 3 clinical studies for biothreat indications;
- Pivotal non-clinical studies for biothreat indications; 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 2022 request supports the following eight investments, which reflect the highest priority countermeasures for FY 2022:

1. **New antimicrobial drugs to address biothreat pathogens (\$150 million, approximately 10,000 treatment courses of each product)**

In FY 2022, PBS funds will continue to be used to procure NUZYRA and one new antibiotic candidate that is presently in the ARD program and will transition to a PBS contract. The inclusion of NUZYRA and a second antibiotic candidate will enhance the USG's posture to respond to public health emergencies and will provide added spectrum of activity against one or more biothreats or high-priority public health pathogens that are drug resistant. Products may be maintained using vendor-managed inventory or delivered to the SNS.

2. **Chemical MCM for nerve agent induced seizures (\$50 million, 300,000 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. In FY 2021, BARDA will publish a second RFP to support New Drug Application-enabling studies for an existing adult-dose midazolam autoinjector and development and approval of a pediatric autoinjector as well as to begin procurement of autoinjectors. FY 2022 funding will be used to continue the modernization of the SNS CHEMPACK program by

supporting the NDA submission and initial procurement of improved autoinjectors for other vital nerve agent MCMs.

3. Late-stage development and procurement of smallpox antivirals (\$100 million, approximately 300,000 treatment courses)

In FY 2011, a PBS contract was awarded for the late-stage development and procurement of a smallpox antiviral drug, TPOXX, which was approved by the FDA in 2018 for the treatment of smallpox. The 2011 contract and a follow up PBS contract awarded in 2019 have now supported production and delivery of over two million treatment courses of TPOXX to the SNS. BARDA anticipates that a second antiviral will be approved in 2021. FY 2022 funds will support continued development and procurement of alternate formulations of TPOXX (IV and pediatric) and late-stage development and procurement of two formulations (oral and suspension) of a newly approved smallpox antiviral. This strategy builds on prior success with TPOXX by broadening USG capability to treat the majority of patients (oral formulation), those who cannot swallow (IV formulation), and patients under the age of 18 (pediatric formulation) while also supporting development and procurement of a second antiviral to avoid a single point of failure in the supply chain and provide healthcare providers with multiple options for therapeutic intervention.

4. Thermal burn products (\$5 million, 8,080 units)

In FY 2021, to build robust burn care preparedness, BARDA plans to procure allograft (cadaver) skin via vendor managed inventory (VMI) and integrate into the standard of burn care network. In addition, the PBS program with Stratatech is expected to receive BLA which clears the way to initiate procurement of the full-thickness artificial skin substitute (StrataGraft). A small amount of funding will supplement the previously funded procurement that will start in FY 2022. This additional procurement would bolster the VMI to establish a new level of national preparedness for mitigating burn injuries. In addition, BARDA intends to transition at least one ARD product to PBS that addresses burn imaging or conversion.

5. Smallpox vaccine, conversion to lyophilized formulation (\$110 million, 5 million doses)

In FY 2017, BARDA procured several lots of Bavarian Nordic's IMVAUME smallpox vaccine, now referred to as JYNNEOS, in bulk form. In FY 2022, BARDA expects to convert that product to a lyophilized formulation that possesses greater stability and a longer shelf life, and to procure additional vaccine in the liquid formulation if needed. The lyophilized formulation will reduce the lifecycle costs of the vaccine. FY 2022 funding will allow the manufacturer to progress towards the lyophilized formulation and the USG to procure up to 5 million doses of JYNNEOS to improve smallpox vaccine preparedness for special populations.

6. Therapies for acute ionizing radiation exposure (\$160 million, 46,667 treatment courses)

Exposure to acute ionizing radiation can induce thrombocytopenia as part of the damage to the hematopoietic system. In January 2021, Amgen's Nplate received FDA approval for treatment of thrombocytopenia due to acute radiation syndrome and is ready for inclusion in the SNS. Available funding will be used to procure treatment courses and initiate vendor managed inventory.

7. Biodosimetry for acute ionizing radiation (\$45 million)

Funds will support late-stage activities for multiple devices to detect ionizing radiation that are both point-of-care (field use) and high-throughput laboratory-based devices.

8. **Filovirus therapeutics (\$150 million)**

In December 2020, Ridgeback Biotherapeutics' Ebanga (formerly “mAb114”) became the second FDA-approved therapeutic for Ebola. The product was approved by the FDA in rapid response to positive clinical trial data that demonstrated Ebanga’s superiority over ZMapp. Prior to 2018, ZMapp was widely considered standard of care for patients with disease caused by the Zaire species of Ebola. BARDA anticipates supporting GMP scale-up to enable procurement of Ebanga for the SNS by 2025. FY 2022 funding will also support continued late-stage development of a therapeutic for the Sudan species of Ebola and advancement of a therapeutic for Marburg virus to PBS, including pivotal efficacy and pharmacokinetic studies and manufacturing validation.

**ASPR Key Outputs and Outcomes Table
Project BioShield**

| Measure | Year and Most Recent Result / Target for Recent Result / (Summary of Result) | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 Target |
|--|---|-----------------------|-----------------------|---|
| 2.4.14c Increase the number of medical countermeasures supported under Project BioShield ¹ (Outcome) | FY 2021: Result Expected Dec 31, 2021 Target: Set Baseline (Pending) | Baseline+ | Baseline + | N/A |

¹ This measure replaces 2.4.14b and provides a cumulative count of the PBS medical countermeasures

Strategic National Stockpile

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 705.000 | 705.000 | 905.000 | +200.000 |
| FTE | 225 | 259 | 329 | +70 |

Authorizing Legislation:

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

Program Description and Accomplishments

The Strategic National Stockpile (SNS) manages and delivers life-saving medical countermeasures (MCM)⁴⁴ during a public health emergency. It is the largest federally-owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations (FMS),⁴⁵ 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.

In the spring of 2020, recognizing the challenges SNS faced at the beginning of the COVID-19 response, SNS initiated modernization efforts designed to:

- Ensure the SNS has the breadth and depth to meet any future pandemic or public health emergency.
- Bolster the U.S. industrial base for critical pharmaceuticals and medical supplies.
- Reduce America’s vulnerabilities and reliance on foreign suppliers and manufacturers.

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.

⁴⁴<http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm>

⁴⁵<https://www.phe.gov/Preparedness/support/medicalassistance/Pages/default.aspx#sns>

The majority of SNS appropriated funding is directed to procurement and maintenance of the stockpiled holdings of medical countermeasures. Investments in the maintenance of stockpiled supplies include storage, quality control, compliance, transportation, security, and day-to-day management of the \$12.1 billion inventory of MCMs. In FY 2019, SNS sustained an inventory accuracy rate of 99.3 percent and ensured that less than one percent of product was lost due to failure to comply with [FDA CGMP](#) practices. In FY 2020, due to COVID-19 related travel restrictions, SNS suspended physical inventories. SNS plans to resume physical inventories in FY 2021 once travel restrictions are lifted.

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.

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, to be packaged or kitted rapidly to address unique response requirements.

The proven SNS logistics capability seamlessly supports ASPR's mission to save lives and protect Americans from 21st-century health threats. Historically, the SNS has deployed personnel to respond to public health emergencies. These staff supported response efforts in a variety of ways. Within ASPR, SNS is responsible for deploying and providing technical assistance to SLTT jurisdictions setting up FMS. FMS are often requested in response to natural disasters, but were also deployed to provide surge hospital capacity during the COVID-19 response. Once set up, FMS are often run by National Disaster Medical System (NDMS) Disaster Medical Assistance Teams (DMATs). The logistical expertise of SNS

responders allow 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. In addition to support for FMS, in the aftermath of Hurricane Maria, SNS, drawing on its strength in medical logistics, expanded its support of the response by establishing warehousing and distribution capability as was required in Puerto Rico.

With COVID-19 related travel restrictions in 2020, SNS challenged itself to come up with solutions about how to provide training and support remotely. These efforts led to the development of just-in-time training to assist SLTT jurisdictions assembling FMS, eliminating the need for a team to travel during the pandemic.

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 was interrupted by the COVID-19 pandemic in 2020. SNS expects to complete this work in FY 2021. 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 2020 the COVID-19 pandemic rapidly spread around the world. The SNS began supporting the federal response to COVID-19 on January 30, 2020. During the early stages of the response, SNS primarily supported the repatriation mission deploying resupply support to deployed federal responders staffing the Incident Management Teams (IMTs) located at various military installations around the country.

In early March, SNS began distributing PPE to the 62 PHEP jurisdictions, which included all 50 states, four large metro areas and eight territories and islands. HHS

SNS COVID-19 Support by the Numbers*

180+

Private industry partners
engaged for medical supply
chain & delivery

4,380+

Trucks transporting supplies

640+

Flights transporting supplies

16,800+

Tons of cargo shipped

200+

Staff working the response

*As of 3/18/2021

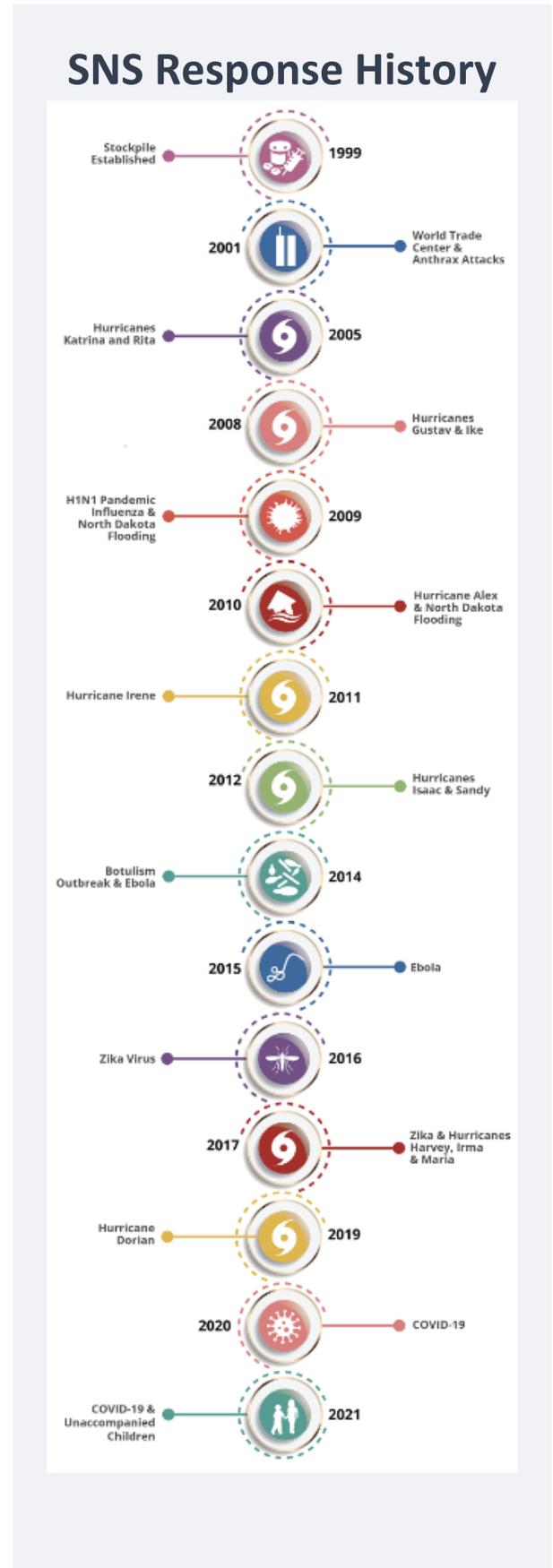
leadership determined the distribution strategy, which was based on a pro rata allocation that is proportional to the population size of each jurisdiction; baseline population data was the 2010 Census. Allocations from SNS included N95 respirators, face masks, face shields, gowns, gloves, and coveralls.

The first shipments of PPE to a jurisdiction began on March 1, 2020 with the initial request from Washington State, leading to a large PPE push to Washington, followed by two shipments to Rhode Island. The pro rata push to the 62 jurisdictions was initiated on March 9, 2020; followed by near simultaneous coordination for additional shipments to areas of high intensity. Ultimately, all 62 jurisdictions received 100 percent of their allocations, including high intensity shipments along with their first 25 percent allocation. The final deployment of the final 25 percent began on March 26, 2020. Over the course of six weeks, SNS deployed 90 percent of all its personal protective equipment (PPE) to help frontline healthcare workers across the United States.

Early in the response, the integration of NDMS materiel into the SNS was tested when SNS was called upon to support the initial establishment, resupply, and demobilization of the largest deployment of IMTs and U.S. Public Health Service and NDMS teams simultaneously.

In addition to PPE, SNS deployed thousands of ventilators to help treat critically ill patients and all 32 of SNS's Federal Medical Stations to provide surge capacity in areas around the country where hospitals ran out of beds.

As the COVID-19 pandemic continues to evolve and response efforts turn to focus on accelerating an aggressive national COVID-19 vaccination strategy, the collaboration between the SNS and McKesson Corporation to assemble and distribute vaccine ancillary supply kits remains a critical piece to the overall federal COVID-19 response efforts. As of April 8, 2021, approximately 1,279,462 ancillary kits have been delivered nationwide to support the administration of three separate COVID-19 vaccines



authorized by the U.S. Food and Drug Administration (FDA) for emergency use. These kits support vaccinations for approximately 234 million Americans.

Ancillary kitting operations and distribution efforts continue to move forward at an expedited pace as COVID-19 vaccine availability and supply progressively increase and further clinical evaluation and testing reveal new vaccine administration and shipping requirements for current and future COVID-19 vaccines. In January, ancillary kitting requirements and operations shifted in response to an FDA label update to the Pfizer-BioNTech COVID-19 vaccine that now recognizes six, rather than five, doses per vial based on draw technique and use of low dead volume syringes and needles. The change in the number of doses increased the requirements for ancillary supplies, including the needles and syringes necessary to support vaccine administration.

In response, SNS and McKesson quickly deconstructed already assembled kits to reconfigure and introduce a new and larger combined ancillary supply kit configuration – the super Pfizer mega kit (SPMK) – to meet the new requirement. Production began on January 11, 2021 and the new SPMKs began shipping to administration sites on January 19, 2021. The team successfully completed kit reconstruction and rebuild on February 18, 2021. The SPMK includes low dead volume syringes and needles to allow for the six doses.

In the early days of the pandemic, SNS did not hold sufficient PPE to meet demand from SLTT jurisdictions. Recognizing the need to improve SNS’s ability to respond to pandemics, unprecedented efforts began to build SNS’s inventory of PPE and ventilators to ensure that the SNS can meet 90 days of need for pandemic response.

SNS has made significant progress towards meeting these goals while taking care to not disrupt the commercial market for PPE. Progress towards meeting these goals is shown in the table below as of April 9, 2021.

| Item | Deployable Quantity | Goal | Status |
|-----------------------------------|---------------------|---------------|------------------------------|
| N95 Respirators | 358 million | 300 million | Met |
| Masks(Surgical/Procedural) | 273 million | 400 million | Not Met – Increased Holdings |
| Eye/Face Shields | 19.5 million | 18 million | Met |
| Gowns/Coveralls | 2.9 million | 265 million | Not Met |
| Gloves | 311 million | 4,500 million | Not Met - Increased Holdings |
| Ventilators | 154,000 | 152,000 | Met |

In addition to these stockpiling goals, SNS is working to improve its operational capacity in several ways, including by:

Establishing a distributor working model:

- The SNS is adjusting its contracting for certain services so that supplies can go directly from distributors to areas in need rather than bringing all products into SNS warehouses before they are then delivered to state, tribal, territorial, and local jurisdictions.

Refining the SNS strategy and structure:

- Work is underway to modernize the types and quantities of products and supplies the SNS needs to hold and how these needs are determined.

Expanding the supply chain control tower:

- This data-driven initiative will provide greater visibility on supplies from manufacturing to end user; and,
- It will give a comprehensive picture of inventory across all levels: from hospitals to states to SNS and FEMA to commercial suppliers. The supply chain control tower will inform decision making and help balance supply and demand.

Expanding domestic manufacturing:

- Significant capital investment is underway to ensure the United States can produce what it needs with a significant reduction in the reliance on foreign suppliers. A strong domestic industrial base for critical medical supplies will ensure the United States is prepared for any public health challenge.

In addition to ongoing work to respond to the COVID-19 pandemic, in March 2021, SNS demonstrated its ability to simultaneously respond to multiple events when it began sending NDMS caches and other medical materiel in support of responding to the influx of unaccompanied children crossing the southern border.

SNS also responds to small events requiring the deployment of MCMs not readily available on the commercial market. 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)*⁴⁶. 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.

SNS works closely with state and local jurisdictions to improve their ability to respond to public health emergencies requiring medical countermeasures. While the COVID-19 pandemic forced the cancellation of SNS's planned in-person training after February 2020, SNS worked to address the training needs of staff at the federal, state, and local levels through web-based and virtual training opportunities.

Prior to widespread travel restrictions in FY 2020, SNS provided training to 307 partners through:

- SNS Operations Course at FEMA's Center for Disaster Preparedness;
- Receive, Stage, Store courses for three jurisdictions; and,
- SNS Workshop and SNS Regional Emergency Coordinator Workshop.

In addition to these in person trainings, SNS provided:

- Virtual training accessed by 1,946 people on a range of topics including SNS Overview; Mass Dispensing; and Closed point of dispensing training;

⁴⁶ https://www.cdc.gov/mmwr/volumes/68/wr/mm6842a2.htm?s_cid=mm6842a2_w

- Web-based FMS training for 913 participants. This training is available in both English and Spanish; and,
- Six webinars viewed by 289 people on topics including introduction to the SNS; crisis and risk communication; temperature consideration; FMS; navigating the pharmaceutical supply chain; and extending the expiration dates of expired doxycycline.

SNS partnered with the American Association for Respiratory Care (AARC) to develop SNS-held ventilator training for state, local, tribal, and territorial (SLTT) respiratory therapists and other healthcare clinicians. The SNS/AARC ventilator training provides necessary resources for the respiratory therapist to prepare for mechanically ventilating patient populations during a large-scale public health emergency or pandemic event. The AARC will host three live webinars, virtual training events in 2021 via Zoom. The training content includes Scarce Resource Allocation, Mass Respiratory Failure, Strategic National Stockpile: Ventilator Allocation, Storage and Maintenance Activities, and SNS Ventilators Performance Characteristics: Matching Patient Need to Device Capability. As of April 8, 2021, the first two webinars provided training to 327 registered participants. Once all live webinars are completed, an audio recording of the instructional webinar will be posted to the AARC SNS webpage for respiratory therapist to access for just-in-time training or clinical resources.

In addition to the live webinars, SNS partnered with the AARC to develop 15 SNS-held ventilator demonstration videos. Each video offers a video demonstration on how to set-up and start mechanically ventilating a patient. The videos are housed on the AARC SNS webpage⁴⁷.

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

⁴⁷ <https://www.aarc.org/resources/clinical-resources/strategic-national-stockpile-ventilator-training-program/>

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 is critical for both public health preparedness and responses to real-world events. SNS is focused on working with the highest risk urban areas – defined by the Department of Homeland Security as Urban Area Security Initiative (UASIs) – with defined delivery timelines based on evolved capabilities to execute a full 60-day anthrax response, including prophylaxis and treatment of large numbers of people. As part of this process, leading logistics experts for the 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 plan for receipt and distribution of SNS product more realistically 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 as of November 15, 2019. While work in this area was put on hold in light of the COVID-19 pandemic in 2020, SNS will reengage with jurisdictions on these issues and incorporating lessons learned during the pandemic to inform future planning.

UASI TTX's as of 11/15/19



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.

In 2020, SNS built upon work previously done with industry to respond to the COVID-19 pandemic by partnering with Strategic Marketplace Initiative (SMI). SMI is a group of medical distributors and providers committed to driving meaningful improvements in supply chain agility, efficiency, and resilience. The goals of this group include:

- Developing and all around understanding of the medical supply chain and how SNS supports during periods of high demand;
- Developing sourcing strategies of on-shore or on-continent procurement when possible; diversification strategies to reduce reliance on single points of failure;
- Developing resiliency plans that include more than just building large inventories; and understanding the potential impacts to annual operations from an incident such as COVID-19.

SNS's successful partnership with medical distributors during the COVID-19 pandemic would not have been possible without previous engagements with industry partners. Prior to the COVID-19 pandemic, SNS 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; and,
- 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; and,
- Improve a template for information sharing during public health emergencies.

These 2019 efforts 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.

While in person meetings were cancelled in 2020, prior to the pandemic, SNS 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 the Antidote Treatment Nerve Agent Autoinjector (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 Advisory Committee on Immunization Practices (ACIP) working on guidelines for Ebola vaccine.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$610,000,000 |
| FY 2019 | \$610,000,000 |
| FY 2020 | \$705,000,000 |
| FY 2021 Enacted | \$705,000,000 |
| FY 2022 President’s Budget | \$905,000,000 |

Budget Request

The FY 2022 President’s Budget for the SNS is \$905,000,000, which is \$200,000,000 above FY 2021 Enacted. With these funds SNS would build on COVID-19 lessons learned and make meaningful investments across a number of portfolios necessary to ensure readiness for future public health emergencies.

In the short-term, SNS expects to utilize COVID-19 supplemental appropriations to continue supporting: the ongoing COVID-19 response and make incremental progress on modernization efforts, including procuring and maintaining PPE and other materiel necessary to respond to the COVID-19 pandemic; services enabling expanded pandemic response capabilities, including ventilator maintenance and warehousing; the Supply Chain Control Tower (SCCT), a tool that helps SNS understand the supply chain better and make better decisions about where to send supplies during a public health emergency; and distributor contracts that support distributors shipping product directly to areas in need, rather than to SNS warehouses to be shipped out to SLTT jurisdictions. Additional funds in FY 2022 will help support these COVID-19 sustainment needs once supplemental funds are expended.

For longer term sustainment, additional funds in FY 2022 will be used to support on-going investments in expanded SNS capacity and infrastructure. 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 2022, SNS will be required to recompute three warehouse contracts. Due to reconditioning and other costs frontloaded into warehouse contracts, the cost for these three warehouses is expected to be several times higher in FY 2022 than their annual maintenance costs in subsequent years. Additionally, while short-term investments to ensure adequate warehousing for products may be funded through remaining COVID-19 supplemental appropriations, the additional funds requested are necessary to begin the steady-state needs of SNS warehousing and product storage.

The request also prioritizes funding for pandemic preparedness by making targeted investments in pandemic influenza and ancillary supplies in addition to SNS’s storage and distribution capacity. Additional funds requested in this budget would be used to support pandemic readiness gaps, including antivirals necessary to treat pandemic influenza, ancillary medical supplies necessary to administer medicine and facilitate the treatment of patients during a public health emergency, and storage and distribution capacity without which SNS is unable to safely store or distribute any medical materiel.

Additionally, SNS plans to make a significant investment in antibiotics. Antibiotics are a key component of the SNS given that they can be used not only in the anthrax portfolio (where they are typically categorized) but also to close preparedness gaps against other threats. SNS also plans to prioritize funding for MCMs necessary to respond to a chemical incident in FY 2022.

Product procurement in FY 2022 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. Priorities identified in this budget request may shift pending additional guidance from PHEMCE.

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. In FY 2021, in response to the COVID-19 pandemic, SNS adjusted course to provide additional online and remote learning opportunities. Using lessons learned during the pandemic, ASPR will maintain training and exercise support in FY 2022 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, requested funds will ensure SNS assets are available and ready for use to protect America from 21st century health security threats in FY 2022 by:

- Managing, storing, maintaining, and replacing MCM assets, valued at over \$12.1 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.

**Key Outputs and Outcomes Table
Strategic National Stockpile**

| Measure | Year and Most Recent Result / Target for Recent Result / (Summary of Result) ¹ | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 Target |
|--|---|----------------|----------------|----------------------------------|
| 13.4.5 Number of trained and ready preparedness and response teams available for response to multiple events. (Output) | FY 2020: 20 teams ² Target: 15 teams (Target Exceeded) | N/A | N/A | N/A |
| 13.4.6 Percentage of inventory accuracies that are attained by using quality inventory management systems. (Outcome) | FY 2019 99.6% ³ Target: 97% (Target Exceeded) | 97% | 97% | Maintain |
| 13.4.7 Maintain the safety and efficacy of medical supplies SNS inventory (Outcome) | FY 2020: 100% Target: 100% (Target Met) | 100% | 100% | Maintain |
| 13.4.8 Maintain the response rate of recall capability (Intermediate Outcome) | FY 2020: 99.9% ⁴ Target: 95% (Target Exceeded) | 95% | 95% | Maintain |

¹FY 2020 data in this table result from activities supported by both base and supplemental appropriations.

²This measure was last taken in January 2020, at which point SNS had 20 deployable teams. Due to COVID-19 related travel restrictions, SNS disbanded its deployable teams in February 2020. SNS does not have any plans to rebuild deployable teams at this time and seeks to retire this measure.

³Due to COVID-19 related travel restrictions, SNS did not perform physical inventories in FY 2020. SNS plans to reinstate physical inventories as soon as it is safe to do so, but expects that there may be data deficiencies in FY 2021.

⁴ Data collection for this measure was suspended from February – May 2020 due to the COVID-19 response.

Public Health and Social Services Emergency Fund

SNS Projected Allocations¹

| | FY 2021 Enacted | | FY 2022 President's Budget | |
|--|-----------------|-----------------------------------|----------------------------|-----------------------------------|
| | Requested | Percentage of Total Appropriation | Requested | Percentage of Total Appropriation |
| Total | \$705.0M | 100% | \$905.0M | 100% |
| Product | | | | |
| Product Total | \$587.9M | | \$784.4M | |
| Procurement Total | \$420.8M | | \$570.9M | |
| <i>Procurement – New²</i> | <i>\$79.0M</i> | | <i>\$0M</i> | |
| <i>Procurement – New (above replenishment)³</i> | <i>\$189.1M</i> | 83.4% | <i>\$142.5M</i> | 86.7% |
| <i>Procurement – Replenishment</i> | <i>\$152.7M</i> | | <i>\$428.4M</i> | |
| Sustainment Total ⁴ | \$167.1M | | \$213.5M | |
| <i>Warehousing Costs</i> | <i>\$159.4M</i> | | <i>\$173.4M</i> | |
| Operations | | | | |
| SNS Operational Costs ⁵ | \$117.1M | 16.6% | \$120.6M | 13.3% |

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 \$12.1 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 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|---------------|-----------------|----------------------------|---------------------|
| Budget Authority | 14.877 | 14.877 | 19.917 | +5.040 |
| FTE | 66 | 66 | 81 | +15 |

Authorizing Legislation:

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

Program Description

The Office of the Assistant Secretary for Preparedness and Response (ASPR) creates the strategic foundation for public health and health care preparedness, response, and recovery. Within ASPR, policy and planning activities develop, evaluate, align, and implement the strategies, plans, requirements, and policies that the ASPR uses to save lives and protect Americans from 21st century health threats. ASPR translates national-level strategies, policies, and plans into strategic-operational level long-range guidance to ensure that operational preparedness and response capabilities align with broader policy and planning considerations.

ASPR provides recommendations that enable the Department of Health and Human Services (HHS) Secretary to provide the best available public health and medical advice across the full spectrum of national health security concerns to the President, the National Security Council (NSC), and other national leaders. ASPR policy and planning activities also lead operational planning and requirements generation efforts, in coordination with a broad cross section of public health preparedness stakeholders.

Within ASPR policy and planning activities, there are four areas of focus for the policy and planning lifecycle: strategic development, policy analysis and evaluation, implementation planning, and operational requirements.

ASPR policy and planning activities provide 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 state, local, tribal, and territorial (SLTT) jurisdictions.

National Health Security Strategy (NHSS)

ASPR policy and planning activities lead the statutorily required quadrennial NHSS, which is the primary policy vehicle for advancing public health and health care emergency capabilities and represents HHS’s prospective approach for achieving national health security. The NHSS offers an assessment of current and emerging health security threats and discusses challenges, opportunities, and gaps in public health and medical capabilities and infrastructure. The current 2019-2022 NHSS provides a comprehensive strategy to support SLTT partners to address 21st century health threats and advances key initiatives such as building regional disaster health response capabilities and advancing innovative development of medical countermeasures. The NHSS provides actions to improve readiness and adapt operational

capabilities to protect the nation from the health effects of emerging and pandemic infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. The document integrates the national security, homeland security, and health security sectors and aligns with national doctrine such as the National Security Strategy, the National Defense Strategy, and the National Biodefense Strategy (NBS).

Recent accomplishments include:

- Developed the “National Health Security Threat Landscape: Reassessing Health Security Threats in a Pandemic Environment” analysis document which discusses specific risks identified during the COVID-19 pandemic and informs NHSS implementation and education of key stakeholders; and
- Engaged with SLTT stakeholders through a learning session at the National Association of County and City Health Officials (NACCHO) 2021 Preparedness Summit. The session provided an overview of the NHSS and threat landscape, discussed priorities and strategies for adapting to COVID-19 and other evolving threats, and solicited SLTT perspectives on strengthening and adapting response and recovery capabilities.

National Biodefense Strategy

ASPR collaborates with the NSC on NBS priorities and supports NBS implementation to counter biological threats, reduce risk, and prepare for, respond to, and recover from biological incidents. The NBS 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. The Strategy underpins our efforts to strengthen biodefense and sets up a process to assess our capabilities and to prioritize biodefense resources and actions across the Government. Through the strategy, the USG is comprehensively evaluating biodefense needs and monitoring implementation of actions on an ongoing basis.

In support of implementing the NBS, ASPR, together with other Federal Departments and Agencies, established the Biodefense Coordination Team (BCT). ASPR ensured assignment of personnel to the BCT, developed an annual request for information, data collection mechanism, and analytic approach, conducted stakeholder engagement, and completed a Biodefense Assessment and a Public Report. A second Biodefense Assessment and Public Report are in the final stages of development. Continued implementation of the strategy will improve U.S. capabilities to ensure that the nation is prepared for biological incidents, including pandemics like COVID-19.

Recent accomplishments include:

- Developed an annual request for information and built a data collection and analysis tool;
- Conducted stakeholder engagement, including a meeting of the Biodefense Steering Committee in September 2020;
- Completed one Biodefense Assessment, with a second Assessment in the final stages of clearance; and
- Completed and released a Public Report on how to protect the American people from biological threats; a second report is in development.

Biosafety, Biosecurity, and Global Health Security Policy Development

The policies governing biosafety and biosecurity need to be coordinated across the USG as well as within HHS. Research involving biological agents can inform public health and medical preparedness efforts, however, this research may also entail biosafety and biosecurity risks. Therefore, the risks and benefits of

biological research must be evaluated, both in the context of recent domestic biosafety incidents and to keep pace with new technological developments, in order to determine which types of studies should go forward and under what conditions. Policy and planning leads several efforts to provide research oversight and also develops and contributes to the implementation of policies meant to ensure biosafety and biosecurity across HHS and the USG.

- Lead the HHS Biosafety and Biosecurity Coordinating Council (BBCC), which provides a focused forum for coordinating and collaborating biosafety and biosecurity activities across the Department of Health and Human Services;
- Lead an interagency working group to review the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*;
- Review and guide HHS funding decisions on proposed potential pandemic pathogen research through implementation of the *HHS Framework for Potential Pandemic Pathogen Care and Oversight (P3CO)*; and
- Lead development and implementation of Backward Contamination components of the National Strategy for Planetary Protection.

Recent accomplishments include:

- Issued a Federal Register Notice to solicit stakeholder input pertaining to the potential need for updating the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* and addressed the concerns of synthetic DNA providers, a critical component of our bioeconomy.

ASPR also supports several activities to achieve global health security.

- Serve as USG Senior Official for the Global Health Security Initiative (GHSI), including providing some technical expertise leading the Rad/Nuc Working Group.
- Function as the national approval authority for reporting public health events of international concern (PHEIC) to the World Health Organization (WHO), with OGA and the HHS Secretary's Operation Center (SOC) provide 24/7 operational support for reporting.
- Serve as HHS Liaison to DOS on global health initiatives including the Biological Weapons Convention, the UN Security Council Resolution 1540, and the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction.

National Influenza Modernization Strategy (NIVMS)

As required by the Executive Order (EO) 13887, a National Influenza Vaccine Task Force (Task Force), co-chaired by HHS and the Department of Defense (DoD), was established to develop and implement a strategy to promote the use of more agile and scalable vaccine manufacturing technologies and to accelerate development of vaccines that protect against many or all influenza viruses. The Task Force developed a ten-year NIVMS that was delivered to the President and transitioned to the implementation phase. The NIVMS articulates a common national vision and provides a strategic framework for the USG and its partners to respond more quickly and effectively to future influenza pandemics and, simultaneously, strengthen our response to seasonal influenza. ASPR led interagency coordination for development of the NIVMS, and continues to lead the effort. This leadership includes coordination of Task Force activities, working with the interagency and external stakeholders on developing a public facing plan to support the strategy, and providing an annual report summarizing progress made to the White House/NSC.

National Advisory Councils

ASPR leads the statutorily required National Biodefense Science Board (NBSB), National Advisory Committee on Children and Disasters (NACCD), National Advisory Committees on Seniors and Disasters (NACSD), and National Advisory Committee on Individuals with Disabilities and Disaster (NACIDD). The latter groups are uniquely positioned to examine the disproportionate impact of COVID-19 on those specific populations. These groups bring together nationally renowned experts—as well as ex-officio members from pertinent federal departments and agencies—in meetings accessible to the public to advise the HHS Secretary and the ASPR on, respectively, biodefense and the concerns of children, individuals with disability, and seniors in disasters and public health emergencies. ASPR is also responsible for annually updating Congress on cross-agency coordination for these advisory committees. In FY 2021, ASPR chartered the newly formed NACSD and NACIDD; completed the member recruitment for the NACCD, and held NBSB working group and public meetings to produce recommendations on clinical disaster response training and medical countermeasure research and development goals.

Policy, Planning, and Evaluation Coordination

ASPR coordinates participation and input into USG, NSC, and HHS policy and strategy initiatives and provides real-time technical assistance, decision analysis, and policy support to leadership of ESF 8 and of 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 providing HHS-unified policy recommendations to the HHS Secretary through coordination of the Disaster Leadership Group (DLG), managing White House policy engagements to ensure appropriate representation and coordination of ASPR's equities in preparedness and response policy actions, and tracking ASPR-wide implementation of Executive Orders related to COVID-19.

ASPR promotes a coordinated interagency approach for response to pandemic influenza and other emerging infectious disease threats and 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 to establish strategic actions to mitigate national health security threats. This includes engagement in National Mitigation Framework Leadership Group and National Mitigation Investment Strategy activities to ensure that public health and healthcare issues are integrated into national mitigation efforts.

ASPR provides subject matter expertise, guidance, and direct technical assistance to key ASPR programs and initiatives to promote consistent and effective evaluation of agency programs, goals, outputs, and outcomes. In FY 2021, ASPR is conducting data collection, benchmark and measure development, and analysis and evaluation on the Hospital Preparedness Program and Ebola A and B supplemental awards. ASPR's program evaluation efforts:

- Develop purpose-driven performance measures that follow leading practices and standards that support the agency to communicate outcomes to senior government stakeholders and the public, empower program managers, and incentivize program implementers;
- Align performance measures to organizational and program goals and evaluates progress towards stated goals and targets;
- Analyze data, identifying findings and conclusions to support decision-making;
- Conduct data quality assurance activities and introduces data quality procedures into agency data collection efforts;

- Monitor burden on recipients and implementers across programs; and,
- Support the agency to conduct program data reviews that design solutions to operational problems.

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 and guided by the NHSS. ASPR's policy and planning activities establish materiel requirements for medical countermeasures that focus on flexible solutions in response to CBRN threats and emerging infectious diseases. These requirements are established in accordance with the Federal Acquisition Regulation, through a framework focusing 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.

In addition to the activities described above, during FY 2022, ASPR will:

- Draft the NHSS Evaluation of Progress for the 2019 to 2022 quadrennial period;
- Draft the NHSS and NHSS Implementation Plan for the 2023 to 2026 quadrennial period;
- Advance 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 implementation of the NBS with other agencies that have biodefense responsibilities or capabilities, including the following activities;
- Provide strategic advice and recommendations to the HHS Secretary and the ASPR on biodefense and the concerns of children, individuals with disability, and seniors in disasters by coordinating, managing, and operating four Federal Advisory Committees, the NBSB, NACCD, NACIDD, and NACSD;
- Evaluate key ASPR programs and initiatives, such as the Hospital Preparedness Program, to identify gaps, improve program performance, and meet Evidence Act and other USG, Departmental, and Agency goals;
- 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;
- 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;
- Deliver materiel and capability-based requirements for COVID pandemic, anthrax, smallpox nuclear threats, and hurricanes;
- Deliver a strategy for modernizing the SNS for 21st century pandemic threats, comprehensive PHEMCE strategy and implementation plan for sustaining the MCM enterprise, and a biodefense industrial MCM base policy for the ASPR partnership with the private sector for MCM development and provision;
- Promulgate a final Health Resources and Priorities Allocation System regulation and business processes for Defense Production Act authorities of the Secretary;
- Lead the development of three frameworks to guide sample return missions to off-world bodies: a Risk Assessment Framework, a Mission Approval Framework, and a Return Procedures Framework. These frameworks will fulfill objectives of the National Strategy for Planetary Protection;

Public Health and Social Services Emergency Fund

- Implement the Laboratory Biological Incident Reporting Survey for all HHS biological laboratory staff;
- Lead the interagency to determine whether, and if so how the 2010 HHS *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* will be updated; and,
- Continue to implement the HHS Framework for Potential Pandemic Pathogen Care and Oversight (P3CO) to guide HHS funding decisions on proposed research that is reasonably anticipated to create, transfer, or use potential pandemic pathogens resulting from the enhancement of a pathogen’s transmissibility or virulence in humans.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$14,877,000 |
| FY 2019 | \$14,877,000 |
| FY 2020 | \$14,877,000 |
| FY 2021 Enacted | \$14,877,000 |
| FY 2022 President’s Budget | \$19,917,000 |

Budget Request

The FY 2022 President’s Budget request for Policy and Planning is \$19,917,000, which is +\$5,040,000 above FY 2021 Enacted. Funds will allow ASPR to continue providing policy leadership to address USG, HHS, and ASPR strategic goals. ASPR will develop strategic, crisis action, 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.

The \$5 million increase will allow ASPR to build on lessons learned from the COVID-19 response through after action reviews that will help recalibrate existing efforts and anticipate, and prepare for, future emergencies and other events. These reviews will access lessons learned from stakeholder as well as from ASPR itself. The additional funds will also build on lessons learned from the COVID pandemic to enhance biodefense. ASPR will enhance collaboration with federal agencies and other stakeholders and support efforts to implement the NBS to improve our long-term capability to advance biodefense, and increase our ability to prevent, prepare for, respond to, recover from, and mitigate the risk of bioincidents.

Key Outputs and Outcomes Table
Policy and Planning

| Measure | Year and Most Recent Result / Target for Recent Result / (Summary of Result) | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 Target |
|---|---|---|---|---|
| 2.4.13 Increase the number of National Health Security Strategy policy tools that support national and health security capabilities (Output) | FY 2020: 40 policy tools Target: 40 policy tools ¹ (Baseline) | 42 policy tools ² | 46 policy tools ³ | +4 policy tools |
| 2.4.16 Increase the number of implementation measures and actions that reduce the risk of biological threats in support of the National Biodefense Strategy implementation (Intermediate Outcome) | FY 2020: 6 actions Target: 6 actions (Baseline) | 9 actions | 12 actions | +3 actions |
| 2.4.17 Increase the number of stakeholder engagement contacts addressing strategic, policy, planning, and requirement-setting issues pertaining to public health and healthcare preparedness and response (Outcome) | FY 2020: 29.0 stakeholder engagement contacts Target: 29.0 stakeholder engagement contacts (Baseline) | 34.0 stakeholder engagement contacts ⁴ | 39.0 stakeholder engagement contacts ⁵ | +5 stakeholder engagement contacts |
| 2.4.18 Increase the number of identified ASPR activities designed to implement the National Biodefense Strategy across the entire Biodefense enterprise (Output) | FY 2020: 8 activities Target: 8 activities (Baseline) | 9 activities | Prior Result + 10% | N/A |

¹ Baseline is the number of NHSS policy tools that support national health security capabilities

² Two above the FY 2020 baseline developed in support of national health security capabilities

³ Four above the FY 2021 result

⁴ 5% increase above baseline in the number of stakeholder engagement contacts

⁵ 10% increase in the number of stakeholder engagements contacts

Operations

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 30.938 | 30.938 | 32.176 | +1.238 |
| FTE | 135 | 135 | 135 | - |

Authorizing Legislation:

AuthorizationPublic 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 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 Operations provides oversight and support in management of the organization and programs for public health preparedness and response. ASPR Operations also supports acquisitions and grants policy, strategy development, interagency coordination and tools and training in support of ASPR’s mission.

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, financial management and workforce development. ASPR Operations also ensures coordination for technology management and information security, facilities, 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 worked to expand its workforces to meet the demands of the COVID-19 pandemic by processing over 1,052 hiring selections, including 754 National Disaster Medical System intermittent hires.

ASPR leverages innovative communication tools and technologies—including social media, to enhance community connectedness, engage ASPR’s stakeholders and take action before, during, and after public health and medical emergencies. During FY 2021 and FY 2022, ASPR will transition its current website

(phe.gov) to a modernized site (aspr.hhs.gov) with a new look and feel that is optimized for mobile devices. This website is the primary platform ASPR uses for sharing information internally and externally. Using the new site, private industry, state and local government agencies, and community organizations will be able to efficiently obtain the information resources and tools they need to prepare, respond, and recover from the health effects of disasters. The public will also have 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 through policy development and oversight. 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 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 2020, 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 BARDA and SNS, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA), 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, 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 (FEMA) 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 at 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) and the Foundations for Evidence-Based Policymaking Act of 2018 ("*Evidence Act*"), This includes tracking, analyzing, and feeding back performance and other data, then using this evidence to promote ongoing improvements and contributions to the Annual Performance Report, the Annual Financial Report, and Annual Performance Goals. ASPR’s advancement of a risk-aware culture promotes a comprehensive view of risks in ways that 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. Performance and ERM outputs and feedback are integrated into both ASPR and HHS’ Strategic Plans and linked to federal priority goals.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$30,938,000 |
| FY 2019 | \$30,938,000 |
| FY 2020 | \$30,938,000 |
| FY 2021 Enacted | \$30,938,000 |
| FY 2022 President’s Budget | \$32,176,000 |

Budget Request

The FY 2022 President’s Budget for Operations is \$32,176,000, which is +\$1,238,000 above FY 2021 Enacted. Funding at this level allows for continued support of ASPR’s growing programs for preparedness and response. 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 further support the continued development of ASPR’s ERM and strategic human capital management initiatives.

The Budget includes an additional \$1.2 million to support increased costs associated with the commitment to exemplary stewardship of public resources, the development of a world class workforce, the identification, elimination, and mitigation of risks in all aspects of programmatic and management operations, the management and continual improvement of performance and impact reporting, and decisive leadership that ensures the nation’s health security.

Nonrecurring Expenses Fund

Budget Summary
(Dollars in Thousands)

| ASPR | FY 2020 ² | FY 2021 ³ | FY 2022 ⁴ |
|---------------------------------|----------------------|----------------------|----------------------|
| Notification¹ | 22,749 | | |

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. Since 2019, ASPR has received \$22.75 million, which has been obligated to the ASPR Headquarters buildout. A detailed description of this important project follows. ASPR also received a smaller amount of funding for IT projects in FY2017; a description of this is also below.

FY2020: ASPR Headquarters (\$22,749,000)

While the exact departure date is still being negotiated due to COVID-19, ASPR will eventually be required to move out of its current leased headquarters, the O’Neill Building. NEF funding from FY 2020 is being used to support the build-out/renovation/construction of commercially leased office space for replacement headquarter space. The new space will include approximately 142,000 useable square feet (USF), workstations and offices for 815 staff (Federal employees and contractors), multiple conference rooms, a multi-room conference center and other administrative spaces. Overall, this critical funding will allow ASPR to house its headquarters staff in modern, functional office space and to meet the many challenges of its disaster response mission.

GSA awarded the design contract in October 2020; GSA is expected to begin the design process in May of 2021. That process should take approximately 1 year. Construction would then begin in June 2022 and take approximately 18 months. Occupancy would be possible in January 2024.

FY2017: IT Projects (\$320,000)

This funding was used to initiate Phase II of the NextGen Project. NextGen Phase II is to develop an Enterprise Wide IT Architecture Framework (People, Process and Technology) for ASPR. The NextGen IT project seeks to develop common organizational, process, and technology framework and IT Architecture across all ASPR program offices in order to improve ASPR’s return on IT investments, facilitate leveraging of cross organizational collaborations, and reduce cost through alternative IT delivery methods and elimination of redundancies.

¹ Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use
² Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on July 20, 2020.
³ Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2020.
⁴ HHS has not yet notified for FY 2022.

ASSISTANT SECRETARY FOR ADMINISTRATION

Cybersecurity

Budget Summary (Dollars in Millions)

| Cybersecurity | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|----------------------------|---------------|-----------------|----------------------------|---------------------|
| Budget Authority /1 | 57.820 | 57.820 | 110.826 | +53.006 |
| FTE | 99 | 143 | 143 | -- |

1/ FY 2020 and FY 2021 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 AuthorizationIndefinite
Allocation MethodDirect 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 Department 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.

The HHS Cybersecurity Program is mandated, in whole or in part, by increasing federal mandates requiring the Department to implement a comprehensive cybersecurity program. In FY 2018, the cybersecurity program was responsible for compliance with 65 legislative mandates. In FY 2021, identified mandates increased to over 100 including the President’s Executive Order (EO) on *Improving the Nation’s Cybersecurity*, published on May 12, 2021. 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.

HHS continues to be a primary target for some of the most advanced cyber criminals in the world. The cybersecurity threat landscape continues to evolve at a rapid pace with a heightened focus on the Healthcare and Public Health (HPH) sector as a prime target for bad actors. The criminal intent is stealing protected health information (PHI) and personally identifiable information (PII). Criminals desire to profit from ransomware payouts or gaining unauthorized access to HHS systems and data for malicious purposes. The unprecedented volume of activity over the last several years and in most recent months due to the global health pandemic poses significant challenges to the Cybersecurity Program’s mission.

OCIO 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:

- Establishing cybersecurity strategies
- Implementing and enhancing specific cybersecurity capabilities
- Engaging in HHS-wide security collaboration activities
- Increasing information sharing, and awareness of sector specific threats
- Cultivating cybersecurity partnerships in both the public and private sectors

HHS continues to increase its protections against cyber threats, which pose great risk to HHS' critical functions and services, in addition to the confidentiality, integrity, and availability of HHS data. These threats include unauthorized access, denial of service, malicious code, inappropriate usage, and insider threat.

In FY 2020, the Cybersecurity Program:

- Managed 6,522 cybersecurity incidents;
- Conducted 9,662 vulnerability scans, an increase of 951 over FY 2019 (scanning an estimated 3,938,580 targets), preventing 1,256,421 vulnerabilities from being exploited, an increase of 166,210 over FY 2019 (9,713 hours of scan time);
- Investigated 57,570 incidents of spam, 1,679 of which were malicious and, if gone unchecked, could have compromised HHS data;
- Hosted weekly HPH sector threat intelligence briefings and supported the OIG in 123 victim notifications and 190 vulnerability HPH sector notifications; and
- Reviewed 113,292 websites and reported 33,364 malicious websites for takedown.

These metrics are consistent with previous years, demonstrating a continual threat to the department; it remains critical that HHS continue to operate a robust program to meet today's cybersecurity needs while ensuring HHS meets the needs of an ever-changing threat landscape.

COVID-19 Response

In response to COVID-19, HHS adopted new security technologies with the focus on an enhanced-heightened security framework to protect HHS from increased cyber threats and ensure network operability. COVID-19 supplemental funding directly supports the security and privacy of those technologies ensuring these systems are secure, protect privacy and transparency, and enable secure data sharing with integrity to combat the COVID-19 pandemic. In support of the pandemic response, HHS developed and deployed an ecosystem of key technologies that include HHS Protect, HHS Vision, HHS Cares, and HHS Transform to provide insight to decision-makers. The Cybersecurity Program plays a key role in the security and privacy of these systems and the information stored, processed, and transmitted.

- **HHS Protect.** At the onset of the pandemic, the Centers for Disease Control and Prevention (CDC) transferred a pilot project that aggregated health care system data to OCIO. As a team, OCIO took the CDC proof of concept, integrated eight commercial technologies, and launched HHS Protect within five days. OCIO added cloud-based tools to identity and access management, secure file transfer capabilities, mapping technology, supervised machine learning tools, data parsing, curation, and sharing tools with time-series-based immutability, and leading edge data analytics capabilities to create a public health surveillance capability to create visibility into the COVID-19 pandemic. HHS Protect is the largest move to commercial cloud capabilities in the history of HHS.

- **HHS Vision.** Vision is an enterprise-grade artificial intelligence capability that uses supervised machine learning and the four billion data elements in HHS Protect to empower decision makers with predictions and impact assessments. HHS Vision exemplifies the use of emerging technology on cloud-based data.
- **HHS Cares.** Another strategic system HHS developed is HHS Cares. Cares builds on HHS Protect by incorporating economic data to illustrate the impact of the pandemic on industries and communities across the United States. This gives policy makers the ability to understand how the economic environment is shifting based on the impact of the pandemic. Furthermore, Cares allows HHS to look at the long-term impact of economic decline on regions across the United States through the health lens.
- **HHS Transform.** Oracle donated a set of open source software tools to help HHS combat COVID-19. OCIO used human-centered design to create HHS Transform and digitize processes that were historically paper-based. Patients record the way their body responds to a therapeutic and any potential vaccine in HHS Transform, and it creates the connectivity with the legacy health infrastructure including hospitals, minute clinics, and pharmacies. This is done to ensure that, logistically, the individual can plan to receive their vaccine and care they need. Identifying volunteers for the largest clinical trial effort and vaccinating 330 million Americans is no easy task. Creating the technical capability to make this happen is necessary for the health and safety of the nation and requires human-centered design and partnership across operational divisions. This also gives HHS the ability to take the data in HHS Protect and HHS Cares, the tools and capabilities of HHS Vision, and the infrastructure and connectivity of HHS Transform to redefine how research grants are funded, how data is shared, and how the nation manages the COVID-19 pandemic.

Hardening HHS Cybersecurity Posture

In the last year, the HHS Cybersecurity Program successfully defended against waves of cyber-attacks. In March of 2020, HHS experienced a large-scale distributed denial-of-service (DDOS) attack and similar threats in the weeks that followed. The HHS Cybersecurity team successfully defended more than 1.8 billion events during an 18-hour period. The Cybersecurity Program thwarted these attacks without a disruption in service while 95% of HHS' workforce teleworked. HHS also partnered with the National Security Agency (NSA) and the Department of Homeland Security (DHS) to improve the Department's cybersecurity posture in real time as the events continued to unfold.

In partnership with HHS agencies, OCIO streamlined collaboration during the cyber events and preparation for maximum telework. This partnership was a key factor that allowed OCIO to successfully navigate challenging issues during the COVID-19 pandemic. Investments made in the HHS IT infrastructure ensured network access and availability for the majority of the HHS workforce to transition to working remotely during the pandemic. Despite the impact to the workforce, and in response to the heightened threat environment, HHS continued to bolster its cybersecurity posture.

The program anticipates increased sophistication in phishing, malware, and ransomware campaigns as the adversaries learn from current successes. As tools, techniques, and procedures develop and evolve, cyber programs must be responsive and adaptive to stay ahead of adversarial innovation. It is critical that cybersecurity investment provides focus on timely and proactive detection of previously unseen approaches by malicious actors.

Cybersecurity, privacy, and end-of-life legacy systems remain the top three IT challenges facing HHS. The program has seen:

- Growing sophistication of cyber-attacks, requiring more technical abilities to better prevent, defend and mitigate threats;
- Increased data exposure because of increased cloud migration and access by authorized and bad actors;
- Increased phishing and spear-phishing attempts based on current trends; and
- New threat vectors introduced by a more distributed workforce using unapproved tools and technologies while working remotely.

HHS Cybersecurity Program

The Cybersecurity Program 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 enable the department to improve HHS's correlation of cyber threat and vulnerability information. This activity allows for better situational awareness and response to events potentially exploiting or jeopardizing critical HHS information. Additionally, the Cybersecurity Program seeks to improve protection of HHS assets and endpoints that process and store the information. These efforts include not only procuring technology, but also building programs and skilled workforce to ensure technologies meet HHS objectives, protect information, and facilitate compliance with federal mandates and guidelines.

- 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. 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:
 - 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 (TIC).

- a. **The 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 Modernization 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 544 incidents per month and taking appropriate action and instituting network blocks as appropriate. CSIRC maintains HHS's mission critical operations, blocks malicious sites, filters spoofing emails and spam, and trains users through ethical phishing. In FY 2020, CSIRC conducted 273 ethical phishing exercises across the HHS enterprise while achieving a phishing resistance rate of 95%. These activities enable real-time visibility of threat elimination and protect the health data of hundreds of thousands of Americans. CSIRC's day-to-day operations help the Department 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 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 agencies have cyber adversaries who regularly target them specifically for the data they collect and store. CSO helps the agencies 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 Agency and TIC access points. 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 agencies. 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 Agency internet connections and continue enterprise deployments of security incident and event management capabilities, firewalls, web proxies, and security analytics.

d. The 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 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 agencies, the intelligence community, DHS, Department of Veterans Affairs, 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 agencies, federal partners, and the private sector. HC3 and its federal partners have shared over 24,152 IOCs and 36 analyst products, demonstrating the high level of engagement and collaboration across HHS and with external HPH sector partners.

e. Trusted Internet Connection (TIC)

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. In FY 2020, TIC provided over 16 petabytes of inbound HHS internet traffic.

The TIC program improves HHS's information security posture and incident response capability through reduction in the number of, and consolidation of, external connections, while providing enhanced monitoring and situational awareness of external network connections. The TIC program supports engineering and monitoring support costs for the TIC, enabling the Department to meet its obligations specified in the DHS TIC and Einstein traffic monitoring and intrusion detection program service level agreements.

II. Federal Information Security Modernization Act (FISMA) Program Management: 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 HHS in support of effective risk-based decision-making. This includes the deployment of DHS' Continuous Diagnostics and Mitigation (CDM) program, which

deploys security tools and technologies throughout the Department to support near real-time risk identification and remediation. Additionally, the Federal Risk and Authorization Management Program (FedRAMP) undertakes the sponsorship and continuous monitoring of cloud-based technologies that enable HHS to meet its mission with more cost-effective, scalable solutions.

- 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 and conducts risk management, compliance, and security operations for 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 | |
|----------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$49,820,000 |
| FY 2019 | \$57,820,000 |
| FY 2020 | \$57,820,000 |
| FY 2021 Enacted | \$57,820,000 |
| FY 2022 President’s Budget | \$110,826,000 |

1/ FY 2019 – FY 2021 levels reflect a realignment of \$1.04 million to the Office of National Security.

Budget Request

The FY 2022 President’s Budget for the HHS Cybersecurity Program is \$110,826,000, which is an increase of \$53,006,000 above FY 2021 Enacted. The request continues support and sustainment of the Department’s security posture by increasing investments in protections against cyberthreats, 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 the Cybersecurity Program desires to execute to improve security include:

- Innovating technology and building cybersecurity resources to improve efficiencies in security tools, machine learning, and automation;
- Deploying enterprise-wide tool solutions to enable HHS’s correlation of cyber threat and vulnerability information;
- Ensuring the availability of a skilled cybersecurity workforce, utilizing innovations to meet HHS objectives to protect its mission and information;
- Improving protection of HHS assets and endpoints that process and store information;

Public Health and Social Services Emergency Fund

- Increasing situational awareness and response to actions that could exploit or jeopardize HHS information systems; and
- Facilitating HHS’s compliance against federal mandates and guidelines.

**Summary of Cybersecurity FY 2020-2022
Funding by Program**

(dollars in thousands)

| Cybersecurity Program | FY 2020 Final ^{1/} | FY 2021 Enacted | FY 2022 President’s Budget | FY 2022 +/- FY 2021 |
|----------------------------------|-----------------------------|-----------------|----------------------------|---------------------|
| CSIRC | \$11.560 | \$11.560 | \$11.560 | \$0 |
| TIC | \$2.100 | \$2.100 | \$26.793 | \$24.693 |
| Enterprise Security Tools | \$19.400 | \$19.400 | \$47.394 | \$27.994 |
| FISMA | \$24.760 | \$24.760 | \$25.079 | \$319 |
| Total | \$57.820 | \$57.820 | \$110.826 | \$53.006 |

^{1/} FY 2020 and FY 2021 levels reflect a realignment of \$1.04 million to the Office of National Security.

Computer Security Incident Response Center (CSIRC) (\$11,560,000): The request is flat to FY 2021 Enacted funding. Funding to this program aligns to continued alignment of CSO services across the Department. CSIRC includes CSO, ACD, and HC3 narrative capabilities. 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, ACD, and HC3 capabilities proactively minimize attacks across the Department, in some cases, before the attacks escalate. CSIRC, ACD, and HC3 address several threat vectors simultaneously by having a central view into all HHS agency networks.

HHS must invest in expanding cybersecurity technologies and an evolving remote workforce to stay ahead of challenges. Smartphones, mobile, VPN, 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 and become more sophisticated and technology changes, investments in consolidated data automation, proactive threat hunting capabilities, and machine learning (artificial intelligence) will enable the Department to evolve and keep pace with those threats.

Trusted Internet Connection (TIC) (\$26,793,000): The request is an increase of \$24,693,000 to FY 2021 Enacted funding and supports enhancements and ongoing support of the TIC. Funding for this program aligns with continued operations of a heightened security framework in response to the COVID-19 cyberattacks, using new security technologies to reduce HHS’ attack surface. 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.

The increase supports TIC-compliant managed security services to secure HHS’ data, networks, and boundaries while providing visibility into HHS’ data and IT traffic transport, including cloud communications. The Department’s TIC/DHS initiative supports greater security in the government’s internet connections and facilitates the necessary infrastructure to implement the DHS Einstein initiative for the entire Department.

- \$9 million for expansion and upgrades to HHS circuits;

Public Health and Social Services Emergency Fund

- \$5 million for refresh of end of life infrastructure;
- \$5 million to reinforce and mature network monitoring solutions; and
- \$6 million for additional capabilities and support resources to merge functionalities of TIC NOC and CSO SOC.

Enterprise Security Tools (\$47,394,000): The request is an increase of \$27,994,000 above FY 2021 Enacted. Funding to this program aligns with Enterprise Security Tools Information Management capabilities and support across the Department. Funding supports 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, and security weakness tracking. Funding will also provide the support to increase the speed at which the OpDivs implement the technologies.

The increase supports partial operations and maintenance of a series of strategic information systems developed and implemented in response to COVID-19. These systems must remain secure, ensure privacy, protect transparency, and enable data sharing with integrity to combat COVID-19 and support future pandemic response efforts.

- \$21.9 million for the continuing execution and delivery of the HHS COVID-19 ecosystem including platform licenses and data integration support services for HHS Protect; and
- \$6.1 million for the Microsoft E5 licenses upgrade across OS for added security and capabilities.

FISMA Program Management (\$25,079,000): The request provides an increase of \$319,000 above FY 2021 Enacted. Funding to this program aligns with continued on-going maintenance of enterprise governance, risk, and compliance management activity and solutions. The increase supports movement toward 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, and strategic and thought leadership. Funds will continue the enhancement of the program's security compliance and annual FISMA program review efforts to effectively measure the Department and OpDiv/StaffDiv levels of compliance with FIMS requirements.

Funding through the FISMA Program Management supports the Cybersecurity Program's workforce. As cyber threats continue to multiply and become more complex, the need for enhanced controls and threat management strategies continues to grow. The evolving cyber threat landscape coupled with the rapid proliferation of information assets, the increased mobility of the HHS workforce, and the need to derive value and intelligence from information assets, have forced HHS to redefine its approach to managing and protecting information assets. A mature cybersecurity workforce – equipped with the appropriate training, education, and skill sets – is vital to managing the evolving threats to these information assets and adequately implementing the controls necessary for protecting HHS's information assets. Although OCIO has the capacity to drive secure resolutions to many of these challenges, ongoing stakeholder engagement is a critical success factor that will ensure these solutions are lasting and continue to strengthen HHS's risk posture.

The Cybersecurity Program continues OpDiv/StaffDiv operational IT systems continuous monitoring capabilities. These capabilities determine compliance with Department policy and standards, including quarterly evaluation of security weakness Plans of Action and Milestones (POA&M), Privacy Impact

Public Health and Social Services Emergency Fund

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. Flat commitment to FISMA program management impacts the ability to sustain mission critical cyber and privacy operations, increases risk to health information (PHI) and personally identifiable information (PII) disclosures, reduces protective measures associated with ransomware pay-outs, and exposes HHS systems and data at a higher cyber risk for malicious attacks.

Cybersecurity-Outputs and Outcomes Table

| Program/Measure | Sum of Most Recent Result | FY 2021 Target | FY2022 Target | FY2022 Target +/- FY2021 |
|---|----------------------------------|-----------------------|----------------------|---------------------------------|
| 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 2020 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 2020 Actual: 74.0% | 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 2020 Actual: 98.0% | 100% | 100% | Maintain |
| Privileged Network Access Management: Number of users that are required to authenticate to the network through using a two-factor PIV credential ⁵ or other Identity Assurance Level (IAL) 3/Authenticator Assurance Level (AAL) 3 credential. | FY 2020 Actual: 100% | 100% | 100% | Maintain |
| HVA Systems Access Management: Report the number of High Value Asset (HVA) systems ⁸ 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 2020 Actual: 96.0% | 90.0% | 90.0% | Maintain |

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Cyber Incident Response

Budget Summary
(Dollars in Millions)

| | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | -- | -- | 73.290 | +73.290 |
| FTE | -- | -- | -- | -- |

Authorizing Legislation:

FY 2021 AuthorizationIndefinite
 Allocation MethodDirect Federal

Program Description

The rapid rate of change in how HHS as an enterprise utilizes IT, including mobile, cloud services, operational technology (OT) and the Internet of Things (IoT), continues to increase in the number of new vulnerabilities and our exposure to threats. SolarWinds Orion products are currently being exploited by malicious actors. This tactic permits an attacker to gain access to network traffic management systems. The compromise of SolarWinds’ Orion Network Management Products poses serious risks to the security of HHS networks. There is evidence that the threat actor that inserted the SolarWinds backdoor also made it possible for other threat actors to utilize initial access vectors to gain entry to other functions and software products unrelated to the SolarWinds Orion platform.

The ways in which HHS harnesses technology is changing rapidly. Driven by the need to leverage mobile and cloud-based tools and technologies due to greater efficiency, resilience, and cost-effectiveness, HHS’ portfolio of IT solutions continues to expand. The abundance and landscape of cybersecurity threats also continues to expand, as exemplified by three high-profile cybersecurity events witnessed in the first four months of calendar year 2021 alone. The SolarWinds, Microsoft, and Pulse Connect Secure events highlighted the need for HHS to respond to vulnerabilities quickly, and put in place greater, more proactive cybersecurity protections.

In response to these events, HHS must continue to hunt for the tactics, techniques, and procedures (TTPs) as well as indicators of compromise (IOCs). HHS must conduct system memory, host storage, network and cloud forensic analyses, and hunt activities in an effort to identify IOCs or other evidence of threat actor activity all in support of the actions directed by the Cybersecurity and Infrastructure Security Agency (CISA) advisory, “*Advanced Persistent Threat Compromise of Government Agencies, Critical Infrastructure, and Private Sector Organizations*” as well as associated mandatory Emergency Directives. HHS must rebuild hosts monitored by the SolarWinds Orion monitoring software using trusted sources and take actions to remediate post-exploitation attacks that extract service account credential hashes from Active Directory for offline cracking. This technique, called kerberoasting, is a common, pervasive attack that exploits a combination of weak encryption and poor service account password hygiene,. HHS will continue to work with our partners to monitor for active exploitation associated with these vulnerabilities including engaging with a 3rd party with experience eradicating APTs from enterprise networks. Recent

cyber-attacks, including the Microsoft Exchange server incident and the Pulse Connect Secure have led us to perform additional research related to internal and external threat hunting to improve the likelihood of problem identification and increased speed to remediation.

As important as the Department’s response to these events is, it is equally important that HHS must bolster its already strong cybersecurity program, understanding that the events like SolarWinds and Pulse Connect Secure are not isolated incidents. HHS must stand ready for the next attack in an ever-expanding threat landscape.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | -- |
| FY 2019 | -- |
| FY 2020 | -- |
| FY 2021 Enacted | -- |
| FY 2022 President’s Budget | \$73,290,000 |

Budget Request

The Government-wide FY 2022 discretionary request identified a cyber reserve of \$750 million. The FY 2022 President’s Budget allocates these resources to nine agencies that were significantly impacted by the SolarWinds incident, one of which is HHS. The purpose of the funding is to address immediate response needs and does not focus on wholesale replacement of IT systems at this time. The funding request targets critical cybersecurity needs at these nine agencies which prioritizes basic cybersecurity enhancements, including Security Operations Center (SOC) enhancements and increased logging functions.

The FY 2022 President’s Budget includes \$73,290,000 for HHS Cyber Incident Response. Funds will be allocated across HHS Agencies to address identified needs to build greater resilience into Agency and Departmental IT systems. The FY 2022 request includes \$68,159,236 for SOC enhancements and \$5,130,764 for increased logging functions. These resources are necessary to swiftly address vulnerabilities exposed by the recent cyber-attacks and to put in place greater, more proactive cybersecurity protections.

SOC Enhancements

To increase the effectiveness of threat intelligence, behavior profiling and analytics – all focused on improving HHS’ detection of cybersecurity threats – HHS will enhance capabilities for a comprehensive, unified Security Operations Center (SOC). Enhancements include centralizing and maturing key capabilities such as Security Information and Event Management (SIEM), incident analysis, digital forensics, event investigation, and threat hunting. These capabilities will be bolstered by increased adversarial eradication, event tracking, and integration with third-party technologies.

Security monitoring functions must not only be maintained; they must evolve to ensure that relevant events are being captured; correlation rules, dashboards, contextual data (such as threat intelligence, or vulnerability data) are configured and maintained; and useful alerts are being generated, reviewed and managed across the enterprise.

Each of the three cybersecurity events witnessed in the first four months of 2021 – SolarWinds, Microsoft and Pulse Secure Connect – show, at least in part, vulnerabilities in cybersecurity supply chain risk

management (C-SCRM). The *National Security Presidential Directive 54, Homeland Security Presidential Directive 23*, and *Defense Authorization Act 254* have made supply chain risk management (SCRM) a national priority and HHS will invest in the expansion of SCRM and C-SCRM to build an expanded risk-based awareness of both service providers and technology suppliers, including Tier 1 (direct) and Tier 2 (secondary).

HHS will develop access to new sources of information and increase the analytic capacity to understand and assess intent and capability. HHS will also implement new processes to identify suspect or high-risk vendors, products, software, and services that pose a risk to HHS and/or national security. HHS will operationalize SCRM and processes consistent with industry best practices to safeguard the technology and services that are procured and deployed across the enterprise. New tools and technologies will be procured and developed to provide automatic updates to threat information and risk mitigations, enable rapid detection and automatic response to threats, and increase agility through artificial intelligence machine learning; thereby, enhancing the enterprise security infrastructure. Asset upgrades to include servers, switches, software, appliances, and or endpoints are required for incident remediation and will reduce supplier or third-party vulnerabilities and increase the level of protection across HHS' networks, systems, and data from future attacks and compromise.

HHS will enhance threat intelligence across an enterprise Threat Intelligence Platform (TIP), an emerging technology supporting organizations as they consume and then act on cyber intelligence. Threat intelligence is evidence-based knowledge about a threat that can be used to inform decisions regarding the response to that threat. HHS will transition from a reliance on external intelligence sources to an enterprise bi-directional intelligence-based TIP with observations from within the HHS environment. The result is elevated cyber maturity and improved resilience against attackers. In order to successfully defend against the multitude of Advanced Persistent Threats (APT) HHS faces, consuming external and internal threat intelligence data has become an increasingly important aspect of cybersecurity. To process all of this internal and external data and have it result in actionable intelligence, an enterprise TIP must be employed. The HHS TIP will be the central management repository for all external and internal intelligence that will provide the mechanism to act upon this intelligence by:

- 1) Collecting intelligence from multiple sources in multiple formats and automatically enriching the intelligence;
- 2) Correlating intelligence and help determine which sources are the most effective;
- 3) Categorizing intelligence to help perform analytics on threats, recognize tactics, techniques, and procedures (TTPs), and understanding relationships through modeling and visualizations;
- 4) Integrating the intelligence with workflow processes to further enrich existing data;
- 5) Providing actions by supporting various integrations via Application Program Interfaces (APIs), bidirectional feeds, and email notifications; and
- 6) Supporting the sharing of intelligence among trusted communities

With the increase in remote work and migration of applications and data to cloud services, the perimeter and boundaries of our network that have been effective in the past no longer provide comprehensive protection we need to secure HHS' networks, systems, and the data with which the Department is entrusted. HHS' assets – both digital and human - are increasingly located outside of the enterprise, forcing HHS to adapt and change the way it has traditionally applied security controls, which may lack the necessary flexibility. Instead of the traditional approach, HHS will focus on Zero Trust (ZT) and invest in a cybersecurity mesh model, a modern security approach that deploys controls where they are needed the most, in a manner that is composable, scalable, flexible, and resilient.

HHS will design and implement an IT security infrastructure that does not focus on building a single perimeter around all devices or nodes across the network, but instead establish smaller, individual perimeters around access points. A cybersecurity mesh enables tools to interoperate by providing foundational security services such as a distributed identity fabric, security analytics, intelligence, automation, and triggers, as well as centralized policy management and orchestration. To ensure real-time identification, including location and operational status, of all access points, the Department will invest in an enterprise asset management solution. This will provide insights into critical systems, networks, and information across the infrastructure that must be protected to mitigate supply chain risks and adversaries. HHS will also focus on containerization with the implementation of container instrumentation platforms to facilitate actively rolling infrastructures in lieu of traditional servers that require patches, network isolation, and active configuration to mitigate security risks and vulnerabilities.

Logging

Logging capabilities are critical in determining the breadth of a cybersecurity event and provide unparalleled assistance to HHS' research and forensics capabilities. HHS will enhance logging capabilities in support of adversarial eradication. For example, the Office of Inspector General (OIG) and FDA will bolster logging capabilities to include Splunk Enterprise Security (ES), indexing, and engineering support services to deliver security content and event-monitoring capabilities, including security-specific queries, visualizations and dashboards, and case management, workflow, and incident response capabilities. HHS will also analyze data through expanded use of current capabilities using artificial intelligence and supervised machine learning.

IMMEDIATE OFFICE OF THE SECRETARY

Office of National Security

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | 8.510 | 8.510 | 8.983 | +0.473 |
| FTE | 25 | 37 | 38 | +1 |

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 Director, who reports directly to the HHS Deputy Secretary. The Director 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 Director 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 (SBSD) 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 intelligence analysis 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 leadership of OpDiv/StaffDivs 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 | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$7,419,000 |
| FY 2019 | \$7,470,000 |
| FY 2020 | \$8,510,000 |
| FY 2021 Enacted | \$8,510,000 |
| FY 2022 President’s Budget | \$8,983,000 |

Budget Request

The FY 2022 Request for ONS is \$8,983,000 which reflects an increase of \$473,000 above FY2020 Enacted. The FY 2022 increase of \$473,000 will support enhanced national security activities such as a counterintelligence view of Supply Chain Risk Management (SCRM-CI). SCRM-CI is a critical area of national interest, and especially to the Department. ONS needs additional staff and associated resources to meet the increasing requirements for SCRM-CI in order to protect the Department and our national security. For example, Executive Order 14017 involves a government-wide enhancement of SCRM requirements along with several long-term tasks. This increased emphasis for SCRM will in turn increase the emphasis and requirements for the SCRM-CI aspect that ONS adds to larger SCRM efforts. To properly handle these SCRM-CI matters of the Department and meet the ongoing requirements of statutes, E.O.s and regulations, ONS requests resources for one (1) additional FTE and associated administrative costs.

ONS must also be able to maintain its capability to provide timely, appropriately tailored and relevant intelligence, and other strategic (including law enforcement sensitive) information to inform HHS decision-makers and their programs on potential national security threats domestically and abroad. Intelligence/Information is used by HHS to anticipate and warn of emerging threats that may require the department to adjust policy/programs; achieve global health security goals such as those related to the COVID-19 pandemic and 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.

PANDEMIC INFLUENZA

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|---------------------------------------|------------------|--------------------|----------------------------------|------------------------|
| Program Level | 260.000 | 287.000 | 335.000 | +48.000 |
| <i>Budget Authority (non-add)</i> | <i>260.000</i> | <i>287.000</i> | <i>335.000</i> | <i>+48.000</i> |
| <i>ASPR No-year funding (non-add)</i> | <i>225.000</i> | <i>252.000</i> | <i>300.000</i> | <i>+48.000</i> |
| <i>ASPR Annual Funding (non-add)</i> | <i>27.991</i> | <i>27.991</i> | <i>27.991</i> | - |
| <i>OGA Annual Funding (non-add)</i> | <i>7.009</i> | <i>7.009</i> | <i>7.009</i> | - |
| FTE | 11 | 11 | 11 | - |

Authorizing Legislation:

AuthorizationPublic Health Service Act, Sec. 319L; Sec. 2811 42 U.S.C. 247d-7e, 300hh-10
 Authorization Status.....Indefinite
 Allocation MethodDirect 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 ten percent of the viruses from human cases have shown markers of resistance to approved 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 influenza viruses. Finally, the recent identification of the “G4” influenza A/H1N1 as a circulating virus with potential to cause a global pandemic clearly demonstrates the threat continues to exist and evolve, underscoring the need for continued development of better, faster medical countermeasures (MCM).

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.

The response to the SARS-CoV-2 virus has shown us how important it is to be prepared to address pathogens with pandemic potential well in advance of any potential outbreak. To address the COVID-19 pandemic, the USG has needed extensive resources to ensure the development of vaccines, therapeutics, diagnostics and other medical supplies while providing relief funding to sustain the economy, demonstrating the importance of annually appropriated funding to prepare the nation for pandemic influenza. Tools developed to address the pandemic influenza threat proved invaluable in the COVID-19 response: access to bulk and final container fill/finish capability, and platform technologies for more rapid production are just two examples. The COVID-19 response also validates known gaps in capabilities: time to production of first dose, immediate access to large scale manufacturing capability, rapid diagnostics, and therapeutics for severely ill individuals. These lessons learned, coupled with the Executive Order to modernize influenza vaccines and the 2017 Update to the HHS Pandemic Influenza Plan will continue to guide and shape the BARDA Pandemic Influenza portfolio.

Strengthening Pandemic Influenza Preparedness

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. Finally, on September 19, 2019, the Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health was signed.

The Pandemic Influenza (PI) program has:

- Built dual-purpose infrastructure and capabilities that were utilized to support the COVID-19 response;
- Developed a standard process to rapidly develop vaccine banks for different production platforms. As a result, multiple influenza virus vaccine seed stocks are readily available for rapid vaccine production as the need arises, including against H5N1, H5N6, and H7N9;
- 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 seasonal and pandemic 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;

Public Health and Social Services Emergency Fund

- 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, H5N8, 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 approved influenza antiviral drugs these candidates have shown activity against oseltamivir-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;
- 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;
- Worked with partners to improve preparedness at the local, state, and international levels
- 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;
- Increased stockpiling of vaccines, next-generation ventilators, and medical supplies, including adjuvants and antiviral drugs; and,
- Through capacity expansion and support of adjuvant production, enabled development of additional seasonal influenza vaccine products.

PI 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. ASPR’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-to-three-fold. In 2018, the PI 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. As a result of this partnership, in February of 2020, Seqirus licensed the first ever adjuvanted, cell-based influenza vaccine to protect against influenza A H5N1 sub-type.

Recombinant Vaccines: Since 2009, the PI program has supported the first recombinant based- vaccine for seasonal influenza licensed in the US. 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. 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: ASPR 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 US, 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, with domestic manufacturing capability at Holly Springs, NC, and approval was obtained in 2020. Furthermore, an HHS Vendor Managed Inventory of MF59 adjuvant was established in partnership with Seqirus to include rotation of MF59 adjuvant inventory. 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. Technology transfer of GSK's AS03 adjuvant production to a US domestic location is complete and includes drug substance production, fill/finish, and packaging for distribution. These licensed capabilities significantly secure and enhance HHS's ability to support surge production and respond during a pandemic.

Close collaboration between the PI 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 ten 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 is providing important clinical evidence to optimize vaccination strategies using stockpiled influenza vaccines during a pandemic response. Additional studies initiated 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.

Innovation in Advanced Development and Manufacturing: In June 2012, ASPR entered into novel public-private partnerships with industry and academia to establish three Centers for Innovation in Advanced Development and Manufacturing (CIADMs). ASPR 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 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. In 2020 that Holly Springs facility was licensed to produce pre-pandemic vaccines, adding on to previously obtained facility approvals to produce seasonal influenza vaccine.

Expedited Vaccine Availability: Under the Influenza Vaccine Manufacturing Improvement initiative led by ASPR 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. In 2020, 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 2021, 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. Sanofi Pasteur is currently validating an increased fill volume of pandemic flu vaccine in multi-dose vials, which will allow more vaccine doses to be distributed faster in the event of a pandemic. 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.” Stage two of this effort was funded during 2020 with funding for expansion of adjuvant production capacity. These efforts, critical to maintaining pandemic influenza production capacity, are planned to continue in FY 2021 and FY 2022.

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 novel antiviral products with unique mechanisms of action that could be effective in overcoming the emergence of resistance during an influenza pandemic or for seasonal influenza. In FY 2020, BARDA continued support for three ongoing pivotal efficacy trial of therapeutic candidates. FY 2021 and FY 2022 funds will continue to support ongoing and new programs to develop novel influenza antiviral drugs and other therapeutics.

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 develop new technologies such as home use molecular tests, medical devices including wearables, and advanced intelligent network-based technologies. These technologies 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.

In FY 2020, leveraging the prior investment in developing home use Flu diagnostics, both Cue Health and Lucira achieved Emergency Use Authorization and delivered diagnostics tests in support of the SARS-CoV-2 Public Health Emergency (PHE). Though the PHE will delay Cue’s Flu FDA 510K filing since clinical studies were paused due to exposure risk of medical personnel, the significant technical advances in Cue’s product development and manufacturing capacity will accelerate market availability when the studies can be re-initiated. In FY 2020 BARDA also invested in network-based public health surveillance tools to better track disease outbreaks. In FY 2020, as part of the COVID-19 response, BARDA invested in 13 combination multiplexed COVID-19+Flu A/B diagnostic tests, 9 of which are molecular tests and two of these are have home-use potential, if authorized by FDA, improving the nation’s preparedness for

co-circulating influenza and SARS-CoV-2. In FY 2022, BARDA will focus on FDA clearance and market release of home use molecular tests, along with leveraging new home use appropriate products accelerated by the massive investment the USG made in diagnostic technologies in FY 2020.

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 is now available to improve stockpiling and deployment to meet a surge in demand and enable management of patients of all ages requiring respiratory support in either the hospital or at home during a pandemic. BARDA has also supported 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 development of a reusable elastomeric RPD as alternative to disposable N95s. The importance of domestically produced reusable RPDs was highlighted during the 2020 pandemic. Applied Research Associates completed development of their prototype device, which is expected to achieve NIOSH approval in FY 2021 and begin market entry in FY 2022. BARDA has also partnered with Johnson and Johnson, Innovation Labs to support a respiratory device challenge to revolutionize RPDs.

Enhancing global pandemic preparedness: As an interlocutor between international public health and domestic public health, to strengthen U.S. influenza pandemic preparedness efforts, the Office of Global Affairs (OGA) continually coordinates across HHS divisions, including the Centers for Disease Control and Prevention, The Food and Drug Administration, and the National Institutes of Health, across the Federal Government, including the White House National Security Council (NSC), the Departments of State (DOS), Agriculture, and Defense, and other Federal departments and agencies, as well as non-governmental organizations, and bilateral and multilateral partners on policy and technical issues related to global health security and pandemic preparedness.

The accomplishments from the HHS/Office of the Secretary International Pandemic Influenza funds have substantially advanced USG global health priorities in countries that are critical to advancing U.S. foreign policy goals and support to HHS programs preparing for seasonal influenza epidemics or the next influenza pandemic. Significant accomplishments include:

- 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.
- Strengthening 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.
- Worked with Brazil and other international partners, expanded the scope of global conversations around influenza preparedness at the level of the World Health Assembly to include both seasonal and pandemic influenza preparedness, drafting and leading successful negotiations and adoption of a formal influenza preparedness decision.
- Promoted adaptation of influenza pandemic preparedness resources and tools for the global COVID-19 response.
- Supported 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).
- Supported development of tools by WHO, 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*.
- Advocated for developing countries improving self-sustainability to provide surveillance, detection, and response for influenza, and other emerging infectious disease (EID) threats affecting their countries and region. OGA 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-sectoral collaborations between security and health ministries, and facilitating support for IHR core capacity development.)
- Prioritized influenza pandemic preparedness and promoted influenza vaccine confidence through ministerial-level side events and subsequent decisions at the World Health Assembly, such as the Influenza Preparedness decision led by the U.S.
- Established and updated national pandemic influenza plans in Africa and other vulnerable regions to support the prioritization of influenza at the national level.
- Supported the implementation of influenza vaccination programs in at-risk populations in low and middle income countries through the Partnership for Influenza Vaccination Introduction.
- Engaged internationally around the release of the September 2019 Executive Order on *Modernizing the Influenza Vaccines in the United States*, and supporting the *National Influenza Vaccine Modernization Strategy* in the areas requiring engagement with international partners.
- Led the global discussion to promote the rapid, systematic, and timely international influenza virus sharing, including seasonal viruses.
- Led U.S. engagement in the Global Health Security Initiative (GHSI) (G7 countries, Mexico, the European Commission, and WHO) to coordinate international preparedness

- efforts to address pandemic influenza, emerging infectious diseases with pandemic potential, and CBRN threats.
- Led U.S. engagement within the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza (NAPAPI) as the Executive Secretariat to promote greater cross-border health security in the region, leveraging the partnership for the COVID-19 response and addressing key issues like supply chain of critical medical products (e.g., PPE).
 - Provided global health security policy leadership, analysis, and technical support to:
 - Develop key WHO tools and reports, including: WHO Pandemic Influenza Risk Management 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 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, a multi-ministerial meeting of the five global WHO National Influenza Collaborating Centers in Beijing, to review programmatic challenges and find solutions for rapid sharing of influenza viruses of pandemic potential.
 - Convene a 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.
 - Lead 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. Also develop model tools and documents that could be used by Member States during public health emergencies.
 - Expand 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.
 - As the Executive Secretariat of the Global Health Security (GHSI) Medical Countermeasures Task Force, develop a tool to facilitate the international deployment of medical countermeasures during an international public health emergency, including pandemic influenza, which is currently with WHO for final review, clearance, and publication.
 - As the Executive Secretariat of the North American Plan for Animal and Pandemic Influenza (NAPAPI), foster close technical collaboration and information exchange among the United States, Canada, and Mexico to address issues of supply chain, cross-border measures, sample sharing, etc. that have been of critical importance during the COVID-19 pandemic.

Public Health and Social Services Emergency Fund

- Support Mexico’s Secretary of Health to strengthen Mexico’s public health emergency preparedness, response, and recovery programs to address pandemic influenza and other threats as well as supporting the establishment of Mexico’s new National Center for Health Emergencies.
- As Executive Secretariat of the GHSI Pandemic Influenza Working Group (PIWG), led coordination of a workshop held to discuss challenges to implementation of non-pharmaceutical interventions during an influenza pandemic, especially with respect to public communications.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | \$250,000,000 |
| FY 2019 | \$260,000,000 |
| FY 2020 | \$260,000,000 |
| FY 2021 Enacted | \$287,000,000 |
| FY 2022 President’s Budget | \$335,000,000 |

Budget Request

The FY 2022 President’s Budget for pandemic influenza activities is \$335,000,000, which is \$48,000,000 above FY 2021 Enacted. The increased funding will support addressing priorities as outlined in the Executive Order (EO) on Modernizing Influenza Vaccines in alignment with the corresponding National Influenza Vaccine Modernization Strategy (2020-2030). Specifically, additional funds will be used to support the advanced development of non-egg based influenza vaccines and associated technologies by investing in: synthetic vaccine platforms; efforts to transfer technologies to public-private partnerships to improve pandemic response; and alternative vaccine delivery systems. Funds will be used to sustain previous investments in critical domestic influenza vaccine manufacturing facility infrastructure, and support development of improved vaccines in alignment with the Presidential EO, the HHS Influenza Plan Update, and lessons learned from the COVID-19 response.

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 while also supporting technologies to improve, and ultimately transform, the approach to pandemic readiness and response. Finally, funds will be utilized to support early efficacy trials of new influenza therapeutics. 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 focus on approaches that have a faster response time, a more flexible manufacturing platform, and are developed using public-private partnerships that will drive a sustainable end product.

Of the total funds, \$35,000,000 is annual funding, and \$300,000,000 million is no-year funding to account for preparedness sustainment costs and continue the advanced research and development of improved vaccines, therapeutics, and rapid in-home diagnostics. The request also includes the funds required to maintain 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 vaccine technologies, including antigen and adjuvant technologies that will allow vaccines to be made faster, and be more effective, than currently licensed technologies. These vaccines would be transformational to pandemic preparedness and response, but are extremely challenging to develop.

The FY 2022 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. These strategic investments will close important gaps by enabling early detection of emerging influenza viruses, as well as preventing transmission. The FY 2022 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 2022 (\$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 influenza virus antigens and adjuvants. 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.

Influenza Diagnostics Advanced Development (\$17,000,000): BARDA will take advantage of the COVID-19 related investment in diagnostics to move molecular tests as well as tests made using newer technologies closer to the home. This will allow earlier detection and, subsequently, faster treatment, which is a critical first step to a pandemic response.

OGA International Influenza Activities (\$7,009,000): The FY 2022 President's Budget for the Office of Global Affairs is \$7,009,000, which is flat with FY 2021 Enacted. 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 pandemics, pandemic preparedness more broadly, and other emerging infectious disease (EID) threats.

Influenza viruses and other pathogens with pandemic potential (e.g., SARS-CoV-2) continue to mutate, evolve, and infect animals and humans, posing continued significant threats to global public health and to the U.S. As COVID-19 has demonstrated, the world is unprepared for a pandemic. Not only is influenza preparedness critical because experts maintain that influenza remains the pathogen of highest probability for causing a severe pandemic in the future, but past influenza preparedness efforts and key USG and global influenza experts greatly assisted in the domestic and international response to COVID-19, also caused by a respiratory virus. These preparedness efforts must be continued and supported in the event of an influenza 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. Our actions in the face of these pandemic threats require a holistic approach to health involving multiple sectors and disciplines, including human, animal, and environmental health. 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 rest of the U.S. Government (USG), utilizing its expertise 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, including on international issues that impact or may be impacted by U.S. domestic considerations. 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. Working to strengthen U.S. health security through USG-wide and international engagement, 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 and response over the past twenty years, and playing a key role in U.S. coordination with the international public health community in the global COVID-19 response, OGA provides essential policy development support and coordinated diplomatic outreach to bolster global health security, domestic preparedness and response efforts, and partnerships that are crucial to face the challenges of influenza pandemic threats, and other emerging infectious disease threats of global concern.

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, National Strategy for the COVID-19 Response and Pandemic Preparedness and associated EOs, 2021 National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness, 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;
- Supporting efforts to document and rapidly apply emerging scientific, technological, public health, and international coordination lessons from the COVID-19 pandemic response to advance global preparedness for influenza and other respiratory disease pandemics.
- Enhancing influenza surveillance through WHO and partner nations,
- Working with domestic and international partners to ensure the rapid, systematic, and timely international influenza virus sharing, including seasonal viruses by promoting international policies that enable such sharing and taking steps to eliminate or mitigate delays and disruptions to virus sharing to advance HHS programs and countermeasure development;

Public Health and Social Services Emergency Fund

- Promoting linkages between influenza capabilities and national influenza preparedness and response plans, together with broader IHR, strengthening of health systems, 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 other 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;
- Collaborating with domestic and international partners to identify and address challenges to the global supply chain for critical pandemic response products, such as personal protective equipment and medical countermeasures, in support of the development and implementation of the Pandemic Supply Chain Resilience Strategy as called for under the 2021 EO A *Sustainable Public Health Supply Chain*;
- Coordinating all relevant Global Health Security Agenda (GHSA) and Global Health Security Initiative (GHSI)-related activities, including those policies focused on pandemic influenza and biological threats and providing leadership for White House and multilateral initiatives for sustainable financing for preparedness;
- Coordinating all relevant North American Plan for Animal and Pandemic Influenza (NAPAPI) activities, focusing on lessons learned from the COVID-19 pandemic experience and addressing critical issues like supply chain;
- Supporting the development and implementation of policy frameworks, coordinating HHS-wide response to public health and medical emergencies with a domestic-international interface; and
- Continuing 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 GHSA, including collaborations with domestic and international partners to support the development and strengthening of IHR core capacities.

No-Year Funding Request for FY 2022 (\$300,000,000)

Facilities and Infrastructure Readiness and Sustainment (\$99,000,000): Funds will sustain one of the pillars of domestic influenza vaccine manufacturing capacity: 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 this capability, the year-round manufacturing capacity so critical to a pandemic influenza response will be lost. The FY 2022 funding will allow for continued sustainment of domestic manufacturing capacity for cell based manufacturing platforms, including production of pre-pandemic vaccine and adjuvant. A key lesson from the COVID-19 response has been the need not just to have available manufacturing space/capacity, but also the need to have trained personnel with ongoing experience in large-scale cGMP manufacturing. Funds will be used to develop and maintain this capability, with a focus on producing products in public-private partnership facilities that use technologies, including platform technologies such as mRNA, that can be rapidly shifted to support influenza vaccine production as needed.

Influenza Therapeutics Advanced Development (\$45,000,000): The COVID-19 pandemic response has shown the importance of having therapeutics that prevent progression to severe disease, as well as therapeutics that can treat severely ill individuals. In FY 2022, BARDA will initiate a Phase II type trial to assess efficacy of at least one influenza vaccine therapeutic that can treat severely ill individuals.

Improved Influenza Vaccine Advanced Development (\$146,000,000): The Presidential Executive Order, as well as the COVID-19 pandemic, validated previously identified risks associated with a pandemic response. The response also validated certain assumptions around preferred vaccine characteristics. The Budget includes an additional \$48 million to address these current pandemic influenza response gaps and enable BARDA to support four key initiatives:

1. More flexible, rapid platforms with smaller manufacturing footprints to allow a shorter time from sequence to first dose ready for vaccination coupled with ability to rapidly scale up and out.
2. Alternative, self-administrable delivery device to allow easier, rapid large-scale vaccinations without the need for person-to-person contact
3. Development of adjuvants, devices, or other approaches/technologies that allow vaccine efficacy after a single dose instead of the current two-dose regimen)
4. Development of new approaches/techniques that will allow better protection/efficacy.

Successful completion of these efforts, which will benefit greatly from the current COVID-19 investments, will represent the next generational jump in fulfilling pandemic influenza response capabilities. Further, these efforts will also directly support an enhanced response to other emerging infectious diseases.

Influenza Diagnostics Advanced Development (\$10,000,000): 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.

**Key Outputs and Outcomes Table
ASPR Pandemic Influenza**

| Measure | Year and Most Recent Result / Target for Recent Result / (Summary of Result) | FY 2021 Target | FY 2022 Target | FY 2022 Target +/-FY 2021 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 2020: 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 2020: 2.0 programs Target: 2.0 programs (Target Met) | 2.0 programs | 2.0 programs | Maintain |

ASSISTANT SECRETARY FOR HEALTH

Commissioned Corps Readiness Training

Budget Summary
(Dollars in Millions)

| USPHS Commissioned Corps Readiness Training | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|---|---------------|-----------------|----------------------------|---------------------|
| Budget Authority | -- | -- | 4.600 | +4.600 |
| FTE | -- | -- | 2 | +2 |

Authorizing Legislation:

Authorization.....42 U.S.C. § 204a(b)(3)
 Authorization Status.....Indefinite
 Allocation Method.....FTE, Contracts

Program Description and Accomplishments

The Office of the Assistant Secretary for Health (OASH) leads the development of the 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 (USPHS) Commissioned 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 6,000 full-time uniformed officers dedicated to promoting and advancing public health and disease prevention programs. USPHS Commissioned 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 USPHS Commissioned 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 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 USPHS Commissioned 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, earthquakes, tsunamis, wildfires, etc.), global infectious disease threats (Ebola Virus Disease, Zika Virus Disease, COVID-19, etc.), urgent public health needs (opioid overdose epidemic, disaster case management, etc.), and health and medical support for National Special Security Events (the State of the Union, Boston Marathon, Independence Day Celebration, etc.). In the event of a Weapons of Mass Destruction (WMD) incident in the United States, USPHS Commissioned 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, USPHS Commissioned Corps 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 to 2020 Corps officers deployed 9,629 times, contributing 197,561 deployments days to 154 different missions. As of April 16, 2021, The Corps has deployed over ½ of all officers in support of

COVID-19; the highest historic deployment of officers to date. 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, readiness and deployment preparation trainings are critical for maintenance of readiness and adequate preparation for future threats. The mission of the Readiness and Training program, located at Commissioned Corps Headquarters (CCHQ), is to provide a sustainable training delivery model that prepares *all* (Active and Ready Reserve) USPHS Commissioned Corps officers to respond to public health and medical emergencies, urgent public health needs and special national security events in a timely manner. To carry out this mission, Readiness and Training program functions to ensure that USPHS Commissioned Corps officers are appropriately trained and ready to deploy in a timely, appropriate manner in advance of the Nation’s need.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | -- |
| FY 2019 | -- |
| FY 2020 | -- |
| FY 2021 Enacted | -- |
| FY 2022 President’s Budget | \$4,600,000 |

Budget Request

The FY 2022 President’s Budget for CC Readiness Training is \$4,600,000, which is \$4,600,000 above FY 2021 Enacted.

The FY 2022 budget request will ensure the continuation of training programs developed and implemented by CCHQ in FY 2021 utilizing COVID-19 supplemental funding. In FY 2021, with the support of COVID-19 supplemental funds, CCHQ anticipates providing the required training per 42 U.S.C. 204a focused on readiness and deployment preparedness training to approximately 1500 officers. To ensure continuation of training operations, the FY 2022 budget request will provide training capability for an additional 1500 officer trainings. The requested funding supports administration, delivery of training (including travel), and training development (contracts, training purchases of commercially available offerings).

Training Aims and Outcomes:

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 USPHS Commissioned Corps officers are trained, equipped, and otherwise prepared to fulfill their public health emergency response roles.

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 USPHS Commissioned 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, simulation exercise, and professional development programs and will be assessed periodically and expanded or modified as appropriate.

Public Health and Social Services Emergency Fund

This training will establish core education surrounding USPHS Commissioned Corps 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 its current 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.

U.S Public Health Service Ready Reserve

Budget Summary
(Dollars in Millions)

| ASPR | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|------------------|--------------------|----------------------------------|------------------------|
| Budget Authority | -- | -- | 13.800 | +13.800 |
| FTE | -- | -- | 20 | +20 |

Authorizing Legislation:

Authorization.....H.R. 748, the Coronavirus Aid, Relief, and Economic Security (CARES) Act Title XVII
 Authorization Status.....Indefinite
 Allocation Method.....FTE, Contracts

Program Description and Accomplishments

The Assistant Secretary for Health (ASH) oversees the Department’s key public health offices and programs, ten regional health offices across the nation, and the Office of the Surgeon General (OSG) and Commissioned Corps of the U.S. Public Health Service (Corps). Commissioned Corps Headquarters (CCHQ) is responsible for all functions regarding personnel, administration, medical, readiness, deployment operations, and policy for both the active duty and reserve components. The U.S. Public Health Service (USPHS) Reserve (Ready Reserve), a cornerstone of the Modernization Plan for the Corps, will have a profound positive impact on the public health capabilities of the Federal government and the Nation.

The ASH serves as a senior advisor to the Secretary of Health on matters of public health and science. As the administrator of the USPHS, the ASH also oversees the Corps, providing it with strategic and policy direction. The Corps is a cadre of over 6,000 full-time uniformed officers dedicated to promoting and advancing public health and disease prevention programs. As one of America's eight uniformed services, the Corps fills essential public health leadership, clinical and service roles across more than 21 Federal agencies and programs. These include Health and Human Services (HHS) Operating and Staff Divisions (e.g., the Indian Health Service, National Institutes of Health, and the Centers for Disease Control) and non-HHS agencies (e.g., Federal Bureau of Prisons (BOP), Department of Defense and Department of Homeland Security).

Corps officers maintain readiness to deploy and respond to public health crises, disease outbreaks, and humanitarian missions. In recent years, requests for deployment of Corps Officers have expanded considerably. Deployments of Corps officers have increased significantly; with an average increase of 47% every year over the past 7 years and PHS Reservists will focus on the much needed clinical skills and specialties required for disaster response. Between 2013 and 2020, Corps officers were deployed 9,629 times, contributing to 197,561 deployments days for 154 different missions. As of April 16, 2021, the Corps has deployed two-thirds of all officers in support of COVID-19 with 429,425 deployment days, the highest historic deployment of officers to date.

The deployment of active duty officers however, can create a gap in agency workforce and the Ready Reserve ensures that PHS has the surge resources to meet the demand of multiple missions by maintaining a sufficient supply of health professionals available for deployment without jeopardizing the

ongoing service-to-underserved-and-vulnerable-population missions. The Ready Reserve also offers an opportunity to serve for clinical and public health professionals who cannot commit to a full-time active duty position in the Corps.

On March 27, 2020, the President signed H.R. 748, the Coronavirus Aid, Relief, and Economic Security (CARES) Act into law. This historic legislation provided the necessary legislative changes to reinstate/implement the Ready Reserve Corps as well as the initial funding to build the infrastructure for the program and begin the recruitment and training of an initial cohort. It is anticipated that around 200 Ready Reserve officers will be commissioned by the end of FY 2021. The CARES Act also made several technical fixes that will allow for implementation of the Ready Reserve, such as providing appropriate statutory authority for consistent pay and benefits and issuance of retired pay. In accordance with the statute, the USPHS Reserve shall:

- a) be available and ready for involuntary calls to active duty during national emergencies and public health crises, similar to the uniformed service reserve personnel;
- b) be available for backfilling critical positions left vacant during deployment of active Commissioned Corps members as well as for deployment to respond to public health emergencies, both foreign and domestic;
- c) be available for service assignment in isolated, hardship and medically underserved communities to improve access to health services; and
- d) participate in routine training to meet the general and specific needs of the Commissioned Corps.

All USPHS Ready Reserve officers are part-time officers; paid when placed on active duty (such as training or deployment). Reservists are required to train (“drill”) for a minimum of 2 weekends/month (on average) and 14 days/year for annual training. Reservists are placed on active duty for deployment or for training for drill weekends. Based on critical specialized skill sets, reservists can also be placed on active duty (temporary/part-time) to support personnel shortages in HHS/or non-HHS agencies; e.g. the Indian Health Service or other hard to fill positions. The Ready Reserve ensures the USPHS has trained, ready and equipped surge capacity to respond to any public health emergency. Recruitment is focused for high-demand, already-trained clinical professionals. When not activated, Reservists work in their respective civilian jobs.

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | -- |
| FY 2019 | -- |
| FY 2020 | -- |
| FY 2021 Enacted | -- |
| FY 2022 President’s Budget | \$13,800,000 |

Budget Request

The FY 2022 President’s Budget for Ready Reserve is \$13,800,000, which is the initial request for this activity.

The FY 2022 Budget provides the funding required to continue building the Ready Reserve by recruiting an additional 250 ready reserve officers in FY 2022 for a total force of 450 Ready Reserve officers by the end of FY 2022. Additionally, the Budget supports CCHQ in the hiring of additional FTEs to support the

Public Health and Social Services Emergency Fund

management, systems and infrastructure required to support the PHS Ready Reserve force. The FY 2022 Budget ensures that the Ready Reserve can meet its statutory requirement, support the officers brought on in FY 2021, and expand and recruit additional officers as planned.

The FY 2022 Budget supports the priority set forth to modernize the Commissioned Corps and employ it as an agent of change for those with the highest acute and/or chronic public health needs, and provides greater depth and flexibility to the Corps by creating an option to retain high-demand, already-trained clinical professionals (medical officers and dentists) that have the highest separation rates from the Regular Corps and fulfilling the need to have additional Commissioned Corps personnel available on short notice (similar to the uniformed service's reserve program) as the Ready Reserve is 'activated' or called to duty to assist Regular Corps personnel to meet both routine public health and emergency response missions. The increased number of deployments in support of COVID-19, is a striking reminder of the Corps mission to respond to regional, national, and global public health emergencies. The Ready Reserves ensures that the Corps has surge resources to meet its mission in support of the Nation.

Public Health and Emergency Response Strike Team

Budget Summary
(Dollars in Millions)

| | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|-------------------------|--------------------------|----------------------------|---|--------------------------------|
| Budget Authority | -- | -- | 8.600 | +8.600 |
| FTE | -- | -- | 44 | +44 |

Program Description and Accomplishments

The Assistant Secretary for Health (ASH) oversees the Department’s key public health offices and programs, the ten regional health offices across the nation, and the Office of the Surgeon General (OSG) and the U.S. Public Health Service Commissioned Corps (Corps). Commissioned Corps Headquarters (CCHQ) is responsible for all functions regarding personnel, administration, medical, training, readiness, deployment operations, and policy for both the active duty and ready reserve.

The Public Health and Emergency Response Strike Team (PHERST) is comprised of a small, select cadre of full-time active duty Corps Officers trained, prepared and ready to immediately respond in order to assess critical requirements in emergent situations; e.g. outbreaks, domestic events or natural disasters. PHERST will complement the PHS Ready Reserve as an active duty strike team available at the request of the President or the Secretary to deploy immediately. Dedicated 100% to public health emergency response, PHERST officer’s primary function is as first responders. Managed and hired by USPHS Headquarters/Office of Surgeon General, PHERST officers are full-time active duty officers “first on the ground teams”, which means they do not require agency supervisory approval and can be immediately deployed. The PHERST will be on standby; ready to deploy within 8 hours of national emergency declarations. When not deployed, the PHERST officers are assigned full-time to various agencies such as the Indian Health Service, Bureau of Prisons, and/or Immigrations and Customs Enforcement to fill short-term staffing gaps. As a skilled and flexible asset and when not deployed, the PHERST officers may be assigned to agencies who serve, hard to fill locations such as rural, remote or underserved communities.

In recent years, response demand cues have expanded considerably. In total, between 2013 and 2020, Corps officers deployed 9,629 times, contributing 197,561 deployments days to 154 different missions. The Corps has deployed over two-thirds of the officers in support of COVID-19, the highest historic deployment of officers to date. The United States will continue to experience natural disasters and other emergencies, and there is a continued risk of a pandemic or intentional threat.

In FY 2020, \$7 million in COVID-19 supplemental funding supported the establishment of the PHERST and the initial build of infrastructure, management and manpower requirements to adequately recruit and train the initial PHERST cohort. It is anticipated that around 20 PHERST officers will be on-board by the end of FY 2021.

Public Health and Social Services Emergency Fund

| Funding History | |
|-----------------------------------|---------------|
| Fiscal Year | Amount |
| FY 2018 | -- |
| FY 2019 | -- |
| FY 2020 | -- |
| FY 2021 Enacted | -- |
| FY 2022 President's Budget | \$8,600,000 |

Budget Request

The FY 2022 President's Budget request for PHERST is \$8,600,000, which is the initial request for this activity. The FY 2022 budget enables CCHQ to recruit an additional 40 PHERST officers and fund management, training and overhead. The FY 2022 budget sustains and builds upon the infrastructure required to support PHS officers assigned to PHERST and ensure the Corps has the resources to meet its mission for regional, national, and global public health emergency responses and ensure the Corps can rapidly respond to urgent and/or emergency public health requirements with highly trained professional staff.

The Corps has made significant strides in improving the nation's pandemic preparedness as part of HHS' overarching strategy to address new challenges, however, there are still challenges to be met. The FY 2022 Budget continues the funding of a swiftly deployable PHERST. Enhanced response time reduces stress on the system and allows officers to get ahead of the disaster. These officers will also be able to deploy for extended durations, if needed; thereby ensuring continuity of care and minimizing the information loss that occurs when rotating personnel during a deployment.

IDEA DIGITAL MODERNIZATION ACT

Modernization of the Public-Facing Digital Services – 21st Century Integrated Digital Experience Act

The 21st Century Integrated Digital Experience Act (IDEA) was signed into law on Dec. 20, 2018. It requires data-driven, user-centric website and digital services modernization, website consolidation, and website design consistency in all Executive Agencies. Departments across the federal landscape are working to implement innovative digital communications approaches to increase efficiency and create more effective relationships with their intended audiences. The American public expects instant and impactful communications – desired, trusted content available when they want it, where they want it, and in the format they want it. If the consumer is not satisfied they move on and our opportunity for impact is lost.

Modernization Efforts

In FY 2019 HHS engaged Department leadership and developed a Digital Communications Strategy that aligns with the requirements of IDEA. In FY 20, HHS Digital Communications Leaders began implementation of the Strategy in alignment with IDEA, beginning to align budgets to modernization requirements.

As the result of a comprehensive review of costs associated with website development, maintenance, and their measures of effectiveness, HHS will prioritize:

- modernization needs of websites, including providing unique digital communications services, and
- continue developing estimated costs and impact measures for achieving IDEA.

Over the next four years HHS will continue to implement IDEA by focusing extensively on a user-centric, Digital First approach to both external and internal communications and developing performance standards. HHS will focus on training, hiring, and tools that drive the communication culture change necessary to successfully implement IDEA.

Over the next year, HHS Agencies and Offices will work together to continue to implement IDEA and the HHS Digital Communications Strategy across all communications products and platforms.

BUDGET AUTHORITY BY OBJECT CLASS

| Description | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|--|-------------------|--------------------|----------------------------------|------------------------|
| <u>Personnel compensation:</u> | | | | |
| Full-time permanent (11.1) | 94.435 | 135.080 | 149.959 | +14.879 |
| Other than full-time permanent (11.3) | 8.147 | - | - | -- |
| Other personnel compensation (11.5) | 7.410 | 0.087 | 0.091 | +0.003 |
| Military personnel (11.7) | 12.582 | 12.526 | 24.500 | +11.974 |
| Special personnel services payments (11.8) | 0.089 | - | - | -- |
| Subtotal, Personnel Compensation..... | +122.663 | +147.693 | +174.550 | +26.857 |
| Civilian benefits (12.1) | 35.616 | 39.421 | 41.622 | +2.200 |
| Military benefits (12.2) | 1.238 | 5.070 | 8.491 | +3.421 |
| Benefits to former personnel (13.0) | 0.088 | - | - | -- |
| Total Pay Costs..... | 159.604 | 192.184 | 224.662 | 32.478 |
| Travel and transportation of persons (21.0) | 5.366 | 6.520 | 9.670 | +3.150 |
| Transportation of things (22.0) | 6.195 | 7.003 | 9.053 | +2.050 |
| Rental payments to GSA (23.1) | 7.037 | 7.341 | 8.356 | +1.015 |
| Rental payments to Others (23.2) | 9.425 | 11.000 | 12.000 | +1.000 |
| Communication, utilities, and misc. charges (23.3) | 3.495 | 3.432 | 3.640 | +0.208 |
| Printing and reproduction (24.0) | 0.100 | 0.108 | 0.208 | +0.100 |
| <u>Other Contractual Services:</u> | - | - | - | |
| Advisory and assistance services (25.1) | 1,116.930 | 1,122.570 | 1,605.676 | +483.107 |
| Other services (25.2) | 145.019 | 153.494 | 208.059 | +54.566 |
| Purchase of goods and services from government accounts (25.3) | 96.717 | 101.513 | 103.472 | +1.959 |
| Operation and maintenance of facilities (25.4) | 1.818 | 5.351 | 5.358 | +0.007 |
| Research and Development Contracts (25.5) | 60.197 | 75.000 | 75.000 | -- |
| Medical care (25.6) | - | 0.043 | 0.043 | +0.000 |
| Operation and maintenance of equipment (25.7) | 43.044 | 39.870 | 40.290 | +0.420 |
| Subtotal, Other Contractual Services..... | +1,463.724 | +1,497.841 | +2,037.899 | +540.058 |
| Supplies and materials (26.0) | 798.074 | 795.328 | 811.566 | +16.238 |
| Equipment (31.0) | 3.192 | 3.602 | 53.062 | +49.460 |
| Land and Structures (32.0) | 1.177 | 2.500 | 2.500 | -- |
| Investments and Loans (33.0) | - | - | - | -- |
| Grants, subsidies, and contributions (41.0) | 279.693 | 320.000 | 350.000 | +30.000 |
| Insurance claims and indemnities (42.0) | 0.375 | 0.600 | 0.500 | -0.100 |
| Interest and dividends (43.0) | - | - | - | -- |
| Refunds (44.0) | - | - | - | -- |
| Total Non-Pay Costs..... | +2,577.853 | +2,655.274 | +3,298.454 | +643.180 |
| Total, Budget Authority by Object Class..... | +2,737.457 | +2,847.458 | +3,523.116 | +675.658 |

SALARIES AND EXPENSES

| Description | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget | FY 2022 +/- FY 2021 |
|--|-------------------|--------------------|----------------------------------|------------------------|
| Personnel compensation: | | | | |
| Full-time permanent (11.1)..... | 94.435 | 135.080 | 149.959 | +14.879 |
| Other than full-time permanent (11.3)..... | 8.147 | -- | -- | -- |
| Other personnel compensation (11.5)..... | 7.410 | 0.087 | 0.091 | +0.003 |
| Military personnel (11.7)..... | 12.582 | 12.526 | 24.500 | +11.974 |
| Special personnel services payments (11.8)..... | 0.089 | -- | -- | -- |
| Subtotal personnel compensation..... | +122.663 | +147.693 | +174.550 | +26.857 |
| Civilian benefits (12.1)..... | 35.616 | 39.421 | 41.622 | +2.200 |
| Military benefits (12.2)..... | 1.238 | 5.070 | 8.491 | +3.421 |
| Benefits to former personnel (13.0)..... | 0.088 | -- | -- | -- |
| Total Pay Costs..... | +159.604 | +192.184 | +224.662 | +32.478 |
| Travel and transportation of persons (21.0)..... | 5.366 | 6.520 | 9.670 | +3.150 |
| Transportation of things (22.0)..... | 6.195 | 7.003 | 9.053 | +2.050 |
| Rental payments to GSA (23.1)..... | 7.037 | 7.341 | 8.356 | +1.015 |
| Rental payments to Others (23.2)..... | 9.425 | 11.000 | 12.000 | +1.000 |
| Communication, utilities, and misc. charges (23.3)..... | 3.495 | 3.432 | 3.640 | +0.208 |
| Printing and reproduction (24.0)..... | 0.100 | 0.108 | 0.208 | +0.100 |
| Other Contractual Services: | | | | |
| Advisory and assistance services (25.1)..... | 1,116.930 | 1,122.570 | 1,605.676 | +483.107 |
| Other services (25.2)..... | 145.019 | 153.494 | 208.060 | +54.566 |
| Purchase of goods and services from government accounts (25.3) | 96.717 | 101.513 | 103.472 | +1.959 |
| Operation and maintenance of facilities (25.4)..... | 1.818 | 5.351 | 5.359 | +0.008 |
| Research and Development Contracts (25.5)..... | 60.197 | 75.000 | 75.000 | -- |
| Medical care (25.6)..... | -- | 0.043 | 0.043 | +0.000 |
| Operation and maintenance of equipment (25.7)..... | 43.044 | 39.870 | 40.290 | +0.420 |
| Subtotal, Other Contractual Services..... | +1,463.724 | +1,497.841 | +2,037.900 | +540.059 |
| Supplies and materials (26.0)..... | 798.074 | 795.328 | 811.566 | +16.238 |
| Equipment (31.0)..... | 3.192 | 3.602 | 53.061 | +49.459 |
| Land and Structures (32.0)..... | 1.177 | 2.500 | 2.500 | -- |
| Grants, subsidies, and contributions (41.0)..... | 279.693 | 320.000 | 350.000 | +30.000 |
| Insurance claims and indemnities (42.0)..... | 0.375 | 0.600 | 0.500 | -0.100 |
| Total Non-Pay Costs..... | +2,577.853 | +2,655.274 | +3,298.454 | +643.180 |
| Total Salary and Expense..... | +2,737.457 | +2,847.458 | +3,523.116 | +675.658 |
| Direct FTE..... | 978 | 1,152 | 1,388 | +236 |

DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT

| | 2020 | 2020 | 2020 | 2021 | 2021 | 2021 | 2022 | 2022 | 2022 |
|---|--------------------|--------------------|-----------------|------------------|------------------|---------------|------------------|------------------|---------------|
| | Actual Civilian | Actual Military | Actual Total | Est. Civilian | Est. Military | Est. Total | Est. Civilian | Est. Military | Est. Total |
| ASPR | 749 | 98 | 847 | 858 | 103 | 961 | 1,009 | 125 | 1,134 |
| Preparedness and Emergency Operations | 74 | 12 | 86 | 74 | 12 | 86 | 71 | 15 | 86 |
| National Disaster Medical System..... | 77 | 38 | 115 | 86 | 38 | 124 | 100 | 48 | 148 |
| Hospital Preparedness..... | 38 | 11 | 49 | 38 | 11 | 49 | 50 | 12 | 62 |
| Medical Reserve Corps..... | 5 | -- | 5 | 6 | -- | 6 | 12 | -- | 12 |
| Preparedness and Response Innovation... | -- | -- | -- | 3 | -- | 3 | 3 | -- | 3 |
| BARDA..... | 149 | 6 | 155 | 216 | 6 | 222 | 260 | 7 | 267 |
| Pandemic Influenza | 11 | -- | 11 | 11 | -- | 11 | 11 | -- | 11 |
| Strategic National Stockpile..... | 211 | 14 | 225 | 240 | 19 | 259 | 304 | 25 | 329 |
| Operations | 123 | 12 | 135 | 123 | 12 | 135 | 123 | 12 | 135 |
| Policy and Planning..... | 61 | 5 | 66 | 61 | 5 | 66 | 75 | 6 | 81 |
| Cybersecurity | 99 | -- | 99 | 143 | -- | 143 | 143 | -- | 143 |
| Office of National Security | 23 | 2 | 25 | 35 | 2 | 37 | 36 | 2 | 38 |
| OGA Pandemic Influenza | 7 | -- | 7 | 11 | -- | 11 | 11 | -- | 11 |
| OASH | -- | -- | -- | -- | -- | -- | 15 | 47 | 62 |
| PHSSEF FTE Total..... | 878 | 100 | 978 | 1,047 | 105 | 1,152 | 1,214 | 174 | 1,388 |

PHSSEF FTE Crosswalk to OMB MAX A-11 Entries

| | FY 2020 | FY 2021 | FY 2022 |
|---------------------|----------------|----------------|----------------|
| Base FTE | 978 | 1,152 | 1,388 |
| Supplemental FTE /1 | 6 | 90 | -- |
| Total FTE | 984 | 1,242 | 1,388 |

1/ Includes FTE funded by COVID-19 emergency supplemental appropriations.

DETAIL OF POSITIONS

| Public Health and Social Services Emergency Fund | FY 2020 Final | FY 2021 Enacted | FY 2022 President's Budget |
|---|--------------------------|----------------------------|---|
| Executive level I | - | - | - |
| Executive level II..... | - | - | - |
| Executive level III | 1 | 1 | 1 |
| Executive level IV..... | 1 | 1 | 1 |
| Executive level V..... | 1 | 1 | 1 |
| Subtotal Executive Level Positions ... | 3 | 3 | 3 |
| Total - Exec. Level Salaries | 530,200 | 533,500 | 542,523 |
| | - | - | - |
| 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 | 1,903,736 | 1,991,357 | 2,043,733 |
| | - | - | - |
| GS-15..... | 155 | 163 | 176 |
| GS-14..... | 267 | 302 | 333 |
| GS-13..... | 236 | 304 | 374 |
| GS-12..... | 145 | 174 | 212 |
| GS-11..... | 19 | 29 | 56 |
| GS-10..... | 8 | 17 | 30 |
| GS-9..... | 22 | 28 | 47 |
| GS-8..... | 9 | 11 | 11 |
| GS-7..... | 18 | 18 | 20 |
| GS-6..... | - | - | - |
| GS-5..... | - | - | - |
| GS-4..... | - | - | - |
| GS-3..... | - | - | - |
| GS-2..... | - | - | - |
| GS-1..... | - | - | - |
| Subtotal | 879 | 1,046 | 1,259 |
| Total - GS Salary | 107,295,915 | 117,154,170 | 149,213,599 |
| | | | |
| Average ES level | ES-1 | ES-1 | ES-1 |
| Average ES salary..... | 190,374 | 199,136 | 204,373 |
| Average GS grade..... | GS-13 | GS-13 | GS-13 |
| Average GS salary..... | 122,066 | 112,002 | 118,518 |
| Average Special Pay categories | | | |

PROGRAMS PROPOSED FOR ELIMINATION

No programs within the PHSSEF are proposed for elimination.

SIGNIFICANT ITEMS IN APPROPRIATION COMMITTEE REPORTS

SIGNIFICANT ITEM

Budget Submission.—The Committee directs that a professional judgement budget be submitted at the same time as the fiscal year 2022 President’s Budget with respect to expenditures necessary to maintain the minimum level of relevant supplies in the Strategic National Stockpile, including in case of a significant pandemic, in consultation with the working group under section 319F(a) of the Public Health Service Act and the Public Health Emergency Medical Countermeasures Enterprise established under section 2811-1 of such Act. (House Report 116-450)

RESPONSE

The Strategic National Stockpile’s (SNS’s) primary focus when it was formed in 1999 was building capacity to respond to chemical, biological, radiological, nuclear, and explosive (CBRNE) incidents. This mission has expanded to include responses to a wide range of events including natural disasters, pandemics such as H1N1 and COVID-19, and support for unaccompanied children.

SNS has historically prioritized investments in medical countermeasures (MCMs) necessary to respond to a CBRNE event. As a result, SNS had insufficient PPE to respond to the COVID-19 pandemic when it emerged in 2020. The FY 2022 President’s Budget request includes \$905 billion for SNS, a 28 percent increase above 2021 enacted, and prioritizes funding for COVID-19 and other CBRN threats, including future pandemics. SNS also anticipates relying on various COVID-19 supplemental appropriations to continue its response efforts in FY 2022. The Professional Judgement estimate would build on the FY 2022 President’s Budget by investing in MCMs that will protect the United States from the full range of CBRNE threats as well as pandemics and natural disasters.

In addition to products funded in the President’s Budget request, at the Professional Judgement estimate of \$1,844.3 million in FY 2022, SNS would fully fund all products transitioning from BARDA in FY 2022 and maintain current levels of preparedness across SNS’s portfolios. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget Report (MYB) has previously identified the primary PHEMCE challenge as being SNS’s ability to fund replenishment of products transitioning from BARDA procurement. Many of these products, including vaccines and therapeutics for smallpox and anthrax, lack a commercial market and the USG is the primary or sole customer. .

The Professional Judgement estimate does not include additional funding for the COVID-19 pandemic response, which will continue to be supported with COVID-19 supplemental resources.

Specific investments with the Professional Judgement estimate include:

Anthrax: The additional \$380.3 million within the Professional Judgement estimate supports procurement of three products previously supported by BARDA: a second-generation anthrax vaccine, as well as therapeutics used to treat patients exposed to inhalational anthrax.

Smallpox: The additional \$301.1 million within the Professional Judgement estimate supports procurement of smallpox vaccine as well as an antiviral previously supported by BARDA used to treat orthopox viruses such as smallpox and monkeypox.

Public Health and Social Services Emergency Fund

Radiological and Nuclear Threats: The additional \$134.3 million within the Professional Judgement estimate supports procurement of antineutropenic drugs previously supported by BARDA.

Pandemic Influenza: The additional \$83.2 million within the Professional Judgement estimate supports procurement of additional influenza antivirals to expand the portfolio of antiviral drugs to respond to pandemic influenza. Procurements at this level would build upon investments made in the President’s Budget request.

Ancillary: The additional \$40.4 million within the Professional Judgement estimate supports procurement of ancillary items needed for infusion pumps necessary to treat patients during public health emergencies.

| Strategic National Stockpile <i>(Dollars in millions)</i> | |
|---|--|
| Programmatic Activities | FY 2022 Professional Judgement Estimate |
| Ancillary | 113.1 |
| Anthrax | 557.9 |
| Botulinum | 14.3 |
| Burkholderia | 0.5 |
| Chemical | 107.5 |
| FMS | 0.2 |
| Influenza | 152.1 |
| Plague | 37.5 |
| Radiological and Nuclear (Rad/Nuc) Threats | 163.9 |
| Smallpox | 363.2 |
| Operating | 120.6 |
| Sustainment Total | 213.5 |
| <i>Warehousing (Sustainment non-add)</i> | <i>173.4</i> |
| Totals | 1,844.3 |

Public Health and Social Services Emergency Fund

| FY 2022 BARDA Transfer Assumptions <i>(Dollars in Millions)</i> | |
|---|--|
| Description | FY 2022 Professional Judgement Estimate |
| Anthrax Therapeutic | 93.3 |
| Anthrax Vaccine | 287.0 |
| Smallpox Antiviral | 112.5 |
| Chemical Anticonvulsant | 41.6 |
| Rad/Nuc Antineutropenic | 134.3 |
| Rad/Nuc Other Supportive | 4.0 |