



DEPARTMENT of HEALTH and HUMAN SERVICES

**Fiscal Year
2023**

Public Health and Social Services
Emergency Fund

*Justification of Estimates for
Appropriations Committee*

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We are pleased to present the Fiscal Year (FY) 2023 Congressional Justification for the Public Health and Social Services Emergency Fund (PHSSEF). The FY 2023 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 2023 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 (OGA) 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)

ASPR leads the nation's medical and public health preparedness for, response to, and recovery from natural disasters, pandemics, and other public health emergencies. ASPR collaborates with hospitals, health care coalitions, biotech firms, community members, state, local, tribal, and territorial governments, and other partners across the country to improve readiness and response capabilities. ASPR leads the development, acquisition, and stockpiling of medical countermeasures such as vaccines, therapeutics, personal protective equipment, medical devices, and other resources needed during public health emergencies. To help meet this medical countermeasure mission, in February ASPR relaunched the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to enhance collaboration between federal, state, and local governments as well as private industry, nonprofits, academia, and other partners. ASPR also deploys National Disaster Medical System (NDMS) response teams to states and territories during or following disasters to bolster the local response. And through the Medical Reserve Corps, ASPR supports the mobilization of volunteer units to assist in communities' public health needs such as vaccination clinics, blood donations, and more. During the COVID-19 response, ASPR expanded its impact in many ways, perhaps most notably by establishing a coordinated operations and response element within ASPR and investing significantly in industrial base expansion and increased domestic manufacturing of key materials and capability.

The Assistant Secretary for Preparedness and Response leads the ASPR organization and, at the direction of the HHS Secretary, serves as COVID-19 coordinator for HHS. In this capacity, ASPR coordinates among multiple HHS agencies and other federal partners on many aspects of the pandemic response. In addition to this coordination role, ASPR has led the Administration's efforts to make available vaccines, therapeutics, masks, and tests to the American people free of charge. ASPR has also deployed hundreds of NDMS team members to support hospitals during the Delta and Omicron surges.

ASPR, through the Biomedical Advanced Research and Development Authority (BARDA) supported the development of many of the vaccines, therapeutics, and tests that are available today to respond to COVID-19. BARDA directly supported seven vaccine candidates including Moderna and Johnson & Johnson's Janssen vaccine; 13 therapeutics, including development of the Regeneron monoclonal antibody therapeutic; 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. Twenty-seven BARDA-supported COVID-19 tests have received emergency use authorization from the U.S. Food and Drug Administration.

Through the HHS Coordination Operations and Response Element (H-CORE) and the prior Countermeasures Acceleration Group, ASPR has led the purchase and delivery of more than 690 million

doses of COVID-19 vaccines to 90,000 vaccination sites nationwide. This effort contributed to the 65% of Americans who are now fully vaccinated. In addition, since September 2021, ASPR has distributed more than 6 million courses of therapeutics to states and territories, and federally funded health clinics for free.

ASPR played a lead role in significantly increasing access to COVID-19 testing and expanding industrial capacity to manufacture those tests. There were zero over-the-counter tests in January 2021, but by December 2021 there was capacity to manufacture more than 300 million tests per month. ASPR, in partnership with the U.S. Postal Service, has delivered free COVID-19 tests to 68 million American households—that's 261 million tests—via COVIDTests.gov. This effort is part of the Biden Administration's commitment to buy and distribute one billion free at-home tests to Americans.

Over the course of the pandemic, ASPR's Strategic National Stockpile (SNS) has worked to backstop states and territories' medical supply needs, providing hundreds of millions of items to Americans in need including personal protective equipment (PPE), ventilators, pharmaceuticals, and more. Since January, the SNS has delivered more than 250 million American-made N95 masks to pharmacies and community health centers nationwide. The initiative is part of the Administration's commitment to make higher quality masks available for free to anyone who would like one. This effort represents the largest deployment by the Strategic National Stockpile to date and it's also the largest deployment of PPE in U.S. history.

ASPR's Hospital Preparedness Program has invested in health care preparedness at the hospital level for years and those investments helped coalitions of local health care systems provide surge medical capacity throughout the COVID-19 response and remains critical to enabling the federal, state, and local coordination necessary to respond to future public health emergencies. Health care coalitions worked within communities to implement health emergency plans, including establishing COVID-specific hospital wings, reducing elective surgeries, and transferring patients within health care systems or health care coalitions, to provide care for a surge of patients.

ASPR also provided on-the-ground support to states and territories through the National Disaster Medical System (NDMS). NDMS teams made up of intermittent federal employees contain physicians, nurses, advance healthcare providers, fatality management professionals, paramedics, veterinarians, and other support staff, such as logisticians and information technology specialists. In 2021, NDMS supported 214 COVID-related missions, deploying 1,904 personnel to 31 states and territories. These teams provided hospital augmentation for critical and emergent care facilities critically depleted of resources and subject matter experts to manage medical and mortuary issues.

In addition to NDMS, the civilian volunteer Medical Reserve Corps (MRC), a national network of over 300,000 volunteers, has also been supporting the COVID-19 response. In FY 2021 MRC volunteers contributed over 2.7 million hours of service to their communities. The total economic value of this contribution, which included the efforts of a variety of medical professionals, is estimated at over \$91 million. In 2021, the MRC received \$100 million in funding from the American Rescue Plan to expand and improve the corps and help respond to the pandemic.

In order to respond to the current pandemic and prepare for future ones, ASPR has taken significant steps to strengthen the industrial base and increase domestic manufacturing of key public health materials and supplies. ASPR has invested in U.S.-based manufacturing of PPE and the supplies and ancillary

equipment needed for vaccines, therapeutics, and diagnostic tests. The pandemic response has shown this is a critical capacity that will need to be sustained in the future.

In addition to COVID-19 response activities, ASPR continues to invest in and strengthen the nation's preparedness for future health emergencies.

Having medical countermeasures ready in a public health crisis requires long-range investment in the research and development as well as the procurement of highly specialized products. BARDA'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.

These efforts focus on combatting the medical consequences of 20 chemical, biological, radiological, and nuclear (CBRN) threats identified by the Department of Homeland Security (DHS). These advanced development programs have supported 30 products that have transitioned from BARDA's advanced research and development program to support under Project BioShield; 22 of these products have been procured for the SNS. In all, BARDA's efforts have led to 62 FDA licensures, approvals, or clearances of medical countermeasures since 2008.

Further, BARDA has become a national and global leader 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 92 different candidates and currently has 58 active programs for the development of 39 therapeutics, eight vaccines, and 11 diagnostics. Nine CARB-X portfolio candidates have entered clinical development and two companies previously supported by CARB-X are now funded by BARDA, highlighting the success of this program in accelerating early-stage product development.

Finally, 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 expand efforts to promote innovation in manufacturing capacity along with subsequent licensure of pre-pandemic vaccine.

ASPR proposes to continue and greatly expand this work through a proposed once-in-a-generation investment in pandemic preparedness. The critical request is a cross-agency effort to carry out priorities for national pandemic preparedness. ASPR will implement an integrated system that will develop and license, stockpile, and provide infrastructure for rapid large-scale manufacturing of the new diagnostics, therapeutics, vaccines, and non-pharmaceutical interventions such as masks, required to contain known diseases with pathogenic potential and rapidly adapted to address new diseases. These investments are needed now in order to prepare the Nation for the next public health emergency.

The discretionary FY 2023 President's Budget request for ASPR is \$3,595,392,000, which is \$821,273,000 above the FY 2022 Continuing Resolution (CR). The Budget also requests \$40 billion in mandatory pandemic preparedness funding for ASPR.

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. 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 2023 President's Budget for the HHS Cybersecurity program is \$161,326,000, which is \$103,506,000 above the FY 2022 Continuing Resolution. Of this increase, \$50,000,000 is provided for zero trust implementation and security logging requirements, pursuant to Executive Order 14028. \$500,000 of the increase will be used to establish a Supply Chain Risk Management (SCRM) program in response to the 145 recommendations from GAO-21-171: *Information and Communications Technology: Federal Agencies Need to Take Urgent Action to Manage Supply Chain Risks*. 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. Separately, the Budget provides \$21.9 million for the HHS Protect Program, to enable the U.S. government to harness the full power of public health data including the COVID-19 response, which will be implemented by CDC.

Office of National Security

The Office of National Security (ONS) provides strategic all-source information, intelligence, counterintelligence, insider threat, cyber threat intelligence, supply chain risk management (SCRM), security for classified information, and communications security support across the Department using funding from the Public Health and Social Services Emergency Fund. 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 and the Secretary's Senior Intelligence Official. The FY 2023 President's Budget for ONS is \$8,983,000, which is \$473,000 above the FY 2022 Continuing Resolution

Secretary's 1% Transfer Authority

The FY 2023 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.

Dawn O'Connell

Assistant Secretary for Preparedness and
Response

La Monte Yarborough

Acting HHS Chief Information
Security Officer

Andrea Palm

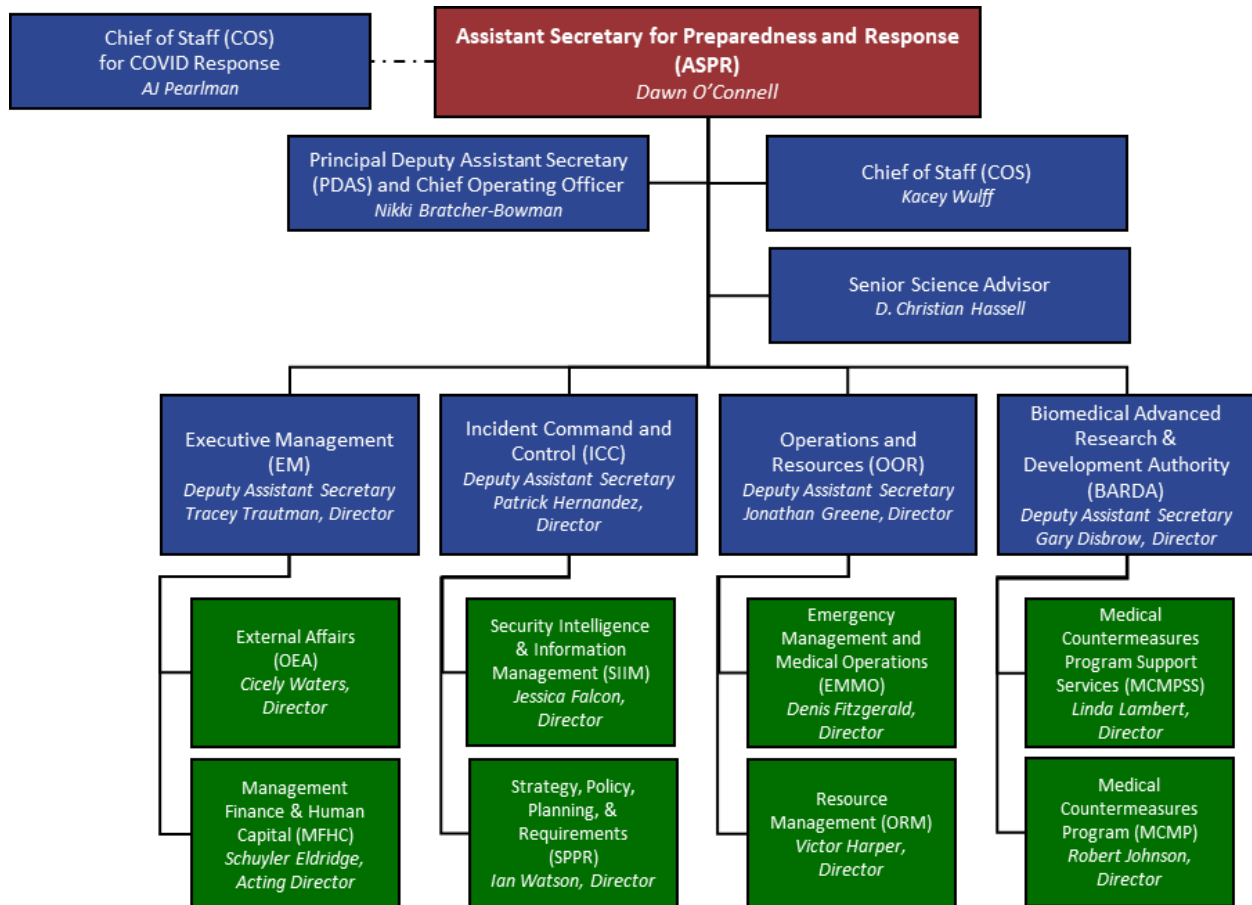
HHS Deputy Secretary

Lisa Aguirre

Acting 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 Assistant Secretary Dawn O'Connell.

The Principal Deputy Assistant Secretary (PDAS) and Chief Operating Officer, Nikki Bratcher-Bowman; Deputy Assistant Secretary and Chief of Staff (COS) Kacey Wulff; Deputy Assistant Secretary and Senior Science Advisor D. Christian Hassell; and Deputy Assistant Secretary and Chief of Staff (COS) for the COVID Response, AJ Pearlman provide executive support to the Assistant Secretary.

Deputy Assistant Secretary Tracey Trautman serves as the executive managing the two (2) offices within Executive Management (EM): The Office of External Affairs (OEA) led by director Cicely Waters and the Office of Management Finance and Human Capital (MFHC) led by acting director, Schuyler Eldridge.

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

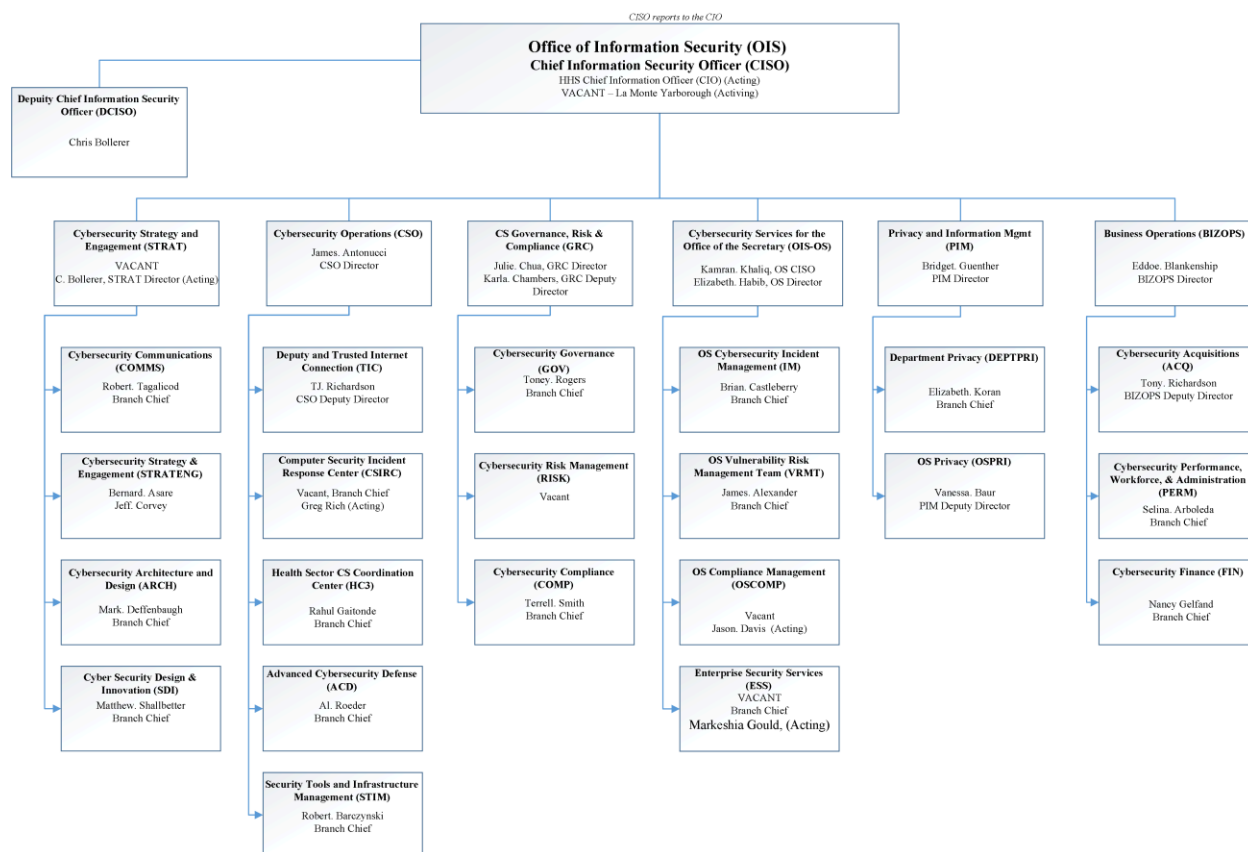
Deputy Assistant Secretary Jonathan Greene serves as the executive managing the two (2) offices within Operations and Resources (OOR): The Office of Emergency Management and Medical Operations

Public Health and Social Services Emergency Fund

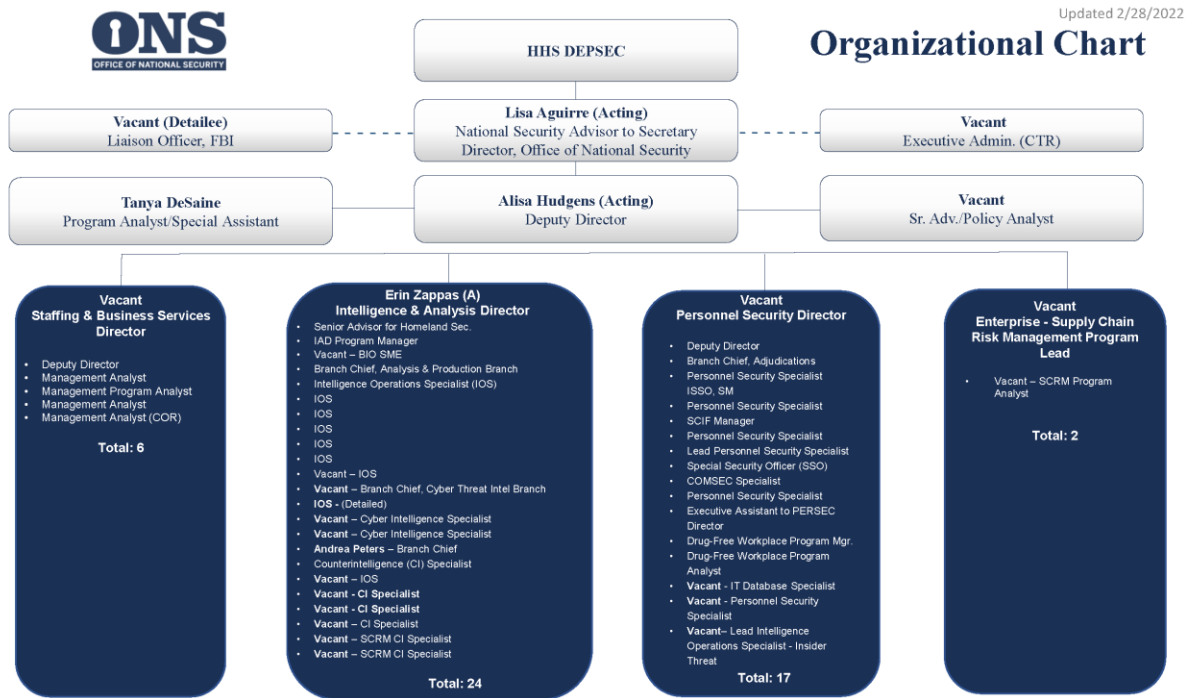
(EMMO) led by director Denis Fitzgerald and The Office of Resource Management (ORM) led by director Victor Harper.

Deputy Assistant Secretary Gary Disbrow serves as the executive managing the two offices within the Biomedical Advanced Research and Development Authority (BARDA): The Office of Medical Countermeasures Program Support Services (MCMPS) led by director Linda Lambert and the Office of Medical Countermeasures Program (MCMP) led by director Robert Johnson.

Cybersecurity



Office of National Security



INTRODUCTION AND MISSION

The Public Health and Social Services Emergency Fund supports the Department's cross-cutting efforts to improve the Nation's preparedness and response 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 (ONS) provides strategic all-source information, intelligence, counterintelligence, insider threat, cyber threat intelligence, supply chain risk management (SCRM), and special security (classified information) and communications security support across the Department.

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 discretionary FY 2023 President's Budget for the Public Health and Social Services Emergency Fund (PHSSEF) is \$3,814,610,000, which is an increase of +\$967,152,000 above the FY 2022 Continuing Resolution. Additionally, the FY 2023 President's Budget includes a request for \$40,019,000,000 in mandatory funding as part of a department-wide plan to prepare for future pandemics and other biological threats. The FY 2023 request for PHSSEF will provide the necessary resources to:

- Support a new, once-in-a-generation investment in a cross-agency effort to carry out priorities for national pandemic preparedness, resulting in rapid, large-scale development and manufacturing of new vaccines, treatments, and protective equipment
- Support and coordinate Departmental programs 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, reserve staffing, and rapid 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 the FY 2022 Continuing Resolution):

Strategic National Stockpile (SNS) (increase of +\$270 million, \$975 million total): The FY 2023 President's Budget request includes \$975 million for the SNS to procure products transitioning from Project BioShield (PBS) support. The FY 2023 President's Budget prioritizes funding for sustainment of current product lines and procurement of several products previously supported by BARDA that lack a significant commercial market. These items include procurement of sufficient quantities of a domestically manufactured, FDA approved, smallpox antiviral to treat an estimated 350,000 people during a smallpox incident, meeting the stockpiling requirement for this product. Additionally, SNS would be able to procure enough bandages to treat an estimated 14,000 people impacted by a radiological/nuclear incident, meeting the stockpiling requirement for this product. Finally, with remaining funding at this level, SNS would procure limited quantities of anthrax therapeutics.

BARDA Advanced Research and Development (increase of +\$231.680 million, \$828.380 million total): The FY 2023 President's Budget request for Advanced Research and Development is \$828,380,000, which is \$231,680,000 above the FY 2022 CR. The additional funds are being requested to support numerous program areas, including: 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, and 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.

HHS Coordination Operations and Response Element (new program, \$132.801 million total): The FY 2023 President's Budget request includes \$133 million for the HHS Coordination Operations and Response Element (H-CORE), which was established January 1, 2022, as the successor to the previous Countermeasures Acceleration Group and Operation Warp Speed. H-CORE is the operational engine behind COVID-19 vaccine and therapeutics procurement and distribution, and also plays an important role in making masks and tests available nationwide. The program is currently funded through COVID-19 supplemental appropriations.

Pandemic Influenza (increase of +\$95 million, \$382 million total): The FY 2023 President's Budget request includes \$347 million in no-year funding and \$35 million in annual funding. Based on lessons learned from the COVID-19 response, the requested \$95 million in additional funding will 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 addition to lessons learned from COVID-19, this strategy aligns with the Presidential Executive Order 13887 Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health and the HHS Pandemic Influenza Plan Update.

National Disaster Medical System (NDMS) (increase of +\$66.626 million, \$130.030 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 \$50 million to support the recruitment and hiring of intermittents, as well as meet demands for additional individual and team training to ensure mission readiness, including additional hands-on and online training for new NDMS intermittent employees. Additionally, the President's Budget includes an additional \$13 million to maintain NDMS caches and equipment. The budget continues to include \$6 million for 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 +\$6.540 million, \$21.417 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 enhance quantitative and economics analytics and modeling capabilities to evaluate its medical countermeasure programs. The modeling capabilities will enable the Department to 1) estimate and compare the public health consequences of incidents and attacks involving biological, chemical, radiological, and nuclear agents as

well as emerging infectious diseases of pandemic potential; and 2) quantify the range of personnel, medical countermeasures, and other resources needed to protect and treat the affected population. The increased funding 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. The additional funds will also build on lessons learned from the COVID pandemic to enhance biodefense.

Preparedness and Emergency Operations (increase of +\$3.646 million, \$28.300 million total): The request supports preparedness and response efforts to public health and medical emergencies and a robust Continuity of Operations (COOP) program. The President's Budget request will ensure ASPR can support its increasing PEO staff costs. Without these additional funds, ASPR will be unable to maintain its current staff level and support the current level of activities. 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.

Operations (increase of +\$3.438 million, \$34.376 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. The President's Budget includes an additional \$2.2 million to provide operational support for a new ASPR Working Capital Fund (WCF). The WCF will provide greater scalability for ASPR support services to meet evolving program requirements. The request also includes inflationary adjustments to ensure ASPR can provide continued program support.

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 to develop, prototype, and procure innovative health security products and technologies beyond medical countermeasures that equip responders to meet health needs that result from disasters. The FY 2023 request will sustain current program investments.

Cybersecurity (increase of +\$103.506 million, \$161.326 million total): The request supports the implementation of Executive Order 14028, "Improving the Nation's Cybersecurity" with \$50 million. The FY 2023 budget also includes \$500,000 for a Supply Chain Risk Management (SCRM) program in response to the 145 recommendations from GAO-21-171: *Information and Communications Technology: Federal Agencies Need to Take Urgent Action to Manage Supply Chain Risks*. The remaining increase supports activities proposed in last year's budget including \$25 million for heightening the security of the department's internet infrastructure, and \$27 million for enterprise-wide security technologies that provide encryption services, malware protection, and data loss prevention.

Office of the Assistant Secretary for Health (increase of +\$20 million, \$20 million total): The Budget requests \$20 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.

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.

OVERVIEW OF PERFORMANCE

The Office of the Assistant Secretary for Preparedness and Response (ASPR) uses performance management to provide accountability and transparency by reporting program accomplishments, analysis, and feedback about how well activities match ASPR programs' goals and objectives. This is done through the integration of performance activities with strategic planning, the use of research and evaluation data, evidence synthesis, and Enterprise Risk Management (ERM) efforts in ways that support decision-making. By using data, ASPR promotes value by focusing resources where there is the greatest potential for impact. To do this, performance and ERM results are fed back to ASPR programs and leadership in ways that support systematic improvement, the generation of new knowledge, and a culture of learning.

During February of 2022, ASPR relaunched the Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE. The PHEMCE was established in 2006 to advance the country's preparedness against chemical, biological, radiological, and nuclear threats, and emerging infectious disease preparedness. The PHEMCE is a multi-sector partnership of federal, state, local, tribal, academic, private industry, and non-governmental organizations that advise the U.S. Department of Health and Human Services on medical countermeasures that may be used to protect the American people, including vaccines, drugs, tests, and devices and also addresses key issues, such as priorities for the Strategic National Stockpile.

One way that ASPR aligns resources with strategic priorities is through a multiyear strategy to measure financial performance and ensure course corrections. The PHEMCE Multiyear Budget (MYB) report for Fiscal Year (FY) 2018-2022 is one of the tools used to promote such alignment. For HHS PHEMCE partners, including the National Institutes of Health and the Food and Drug Administration (FDA), the [PHEMCE MYB](#) brings together 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. The draft PHEMCE MYB for FY 2020-2024 has been submitted to departmental clearance and is being reviewed. The draft report covers FY 2020-2024, thereby skipping a year due to the COVID-19 pandemic response.

Performance and Enterprise Risk Management

ASPR ensures the accountability and effectiveness of its financial programs and operations through risk-based performance management, consistent with OMB Circulars A-123 and A-11. ASPR assesses, mitigates, and reports on its internal controls. This includes monitoring, analyzing, and generating both risk and performance data. Benefits of this integration include operational improvements, a risk-aware culture, and better understanding about the best use of resources. ASPR is increasingly incorporating analysis of risk appetite (appreciation of levels for risk), into its goals and objectives, including how best to manage unavoidable risks. ASPR creates performance measures that capture risk, then implements actions designed to manage, mitigate, and/or spend-down the risk. Performance and ERM collaborate in ways that reduce organizational silos. Expanded educational training events have been held since 2020 to expand understanding of key topics relevant to a culture of learning, including the use of evidence, the integration of ERM with performance management, and also project management.

Implementation of the Evidence Act and HHS Priorities

To support implementation of the Foundations for Evidence-Based Policymaking Act of 2018 (H.R.4174), ASPR established a Chief Data Officer (CDO), an Evaluation Officer, and a Data Governance (DG) Workgroup. The CDO role was established to provide strategy, governance, project management support, and orchestrate shared data services across ASPR. The Evaluation Officer role participates in overall HHS evaluation efforts, including development of a learning agenda and educational materials regarding evaluation and evidence-building that helps ASPR. The CDO, in collaboration with the DG Workgroup, facilitates better use of data to support decisions and evaluate projects and services. This includes formulating plans to identify critical data skills and determine how these skills facilitate accomplishing ASPR's mission.

ASPR is collaborating with several HHS partners on a proposed new HHS Agency Priority Goal (APG) to address emergency preparedness. This APG is designed to strengthen the systems for domestic and global health, human services, and public health to protect the nation's well-being before, during, and after disasters and public health emergencies.

To further integrate ASPR's contributions to the HHS Secretary's priorities and the HHS FY 2022-2026 Strategic Plan, ASPR contributes data to promote accountability and transparency for the following HHS Strategic Plan objectives:

- 2.1 Improve capabilities to predict, prevent, prepare for, respond to, and recover from emergencies, disasters, and threats across the nation and globe
- 2.2 Protect individuals, families, and communities from infectious disease and non-communicable disease through equitable access to effective, innovative, readily available diagnostics, treatments, therapeutics, medical devices, and vaccines, and,
- 2.4 Mitigate the impacts of environmental factors, including climate change, on health outcomes.

ASPR also contributes to the following additional objectives:

- 4.1 Improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion;
- 4.2 Invest in the research enterprise and the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs;
- 5.1 Promote effective enterprise governance to ensure programmatic goals are met equitably and transparently across all management practices;
- 5.2: Sustain strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust;
- 5.3 Uphold effective and innovative human capital resource management resulting in an engaged, diverse workforce with the skills and competencies to accomplish the HHS mission, and,
- 5.4 Ensure the security and climate resiliency of HHS facilities, technology, data, and information, while advancing environment-friendly practices.

COVID-19 Pandemic Response

Following the HHS Secretary's announcement of a nationwide [public health emergency](#) on January 31, 2020, ASPR spearheaded the development of an innovative COVID-19 Medical Countermeasures

(MCM) program in partnership with the Department of Defense; deployed personnel to support quarantine facilities, hospitals, and healthcare facilities across the nation; and provided critical equipment to meet surge demands and protect the American people from the virus. ASPR continues to support the development, procurement, and distribution of MCMs that fight the COVID-19 pandemic and learn lessons that inform the management of threats. The Budget institutionalizes these efforts in the new HHS Coordination Operations and Response Element within ASPR.

During 2020 and 2021, ASPR entered into 116 new partnerships to fight the SARS-CoV-2 virus, investing in development and/or procurement of [100 products](#). [Seven COVID-19 vaccine candidates](#) received research and development funding or advance purchase agreements. ASPR increased the availability and diversity of COVID-19 diagnostic tests, leveraging existing platform technologies. ASPR supported the development and distribution of safe and effective therapeutics to treat COVID-19 patients. For example, ASPR developed, purchased, and allocated [monoclonal antibody therapeutics](#), which help to keep COVID-19 patients with mild to moderate symptoms from later needing intensive care.

In support of the COVID response, ASPR has invested over \$90 billion in medical countermeasures including vaccines and therapeutics, personal protective equipment including N-95 respirators, diagnostics tests for the early detection of the virus, grants to state healthcare coalitions for surge capacity, contracts to industry to expand the supply chain for critical materials, and expanded data modeling and forecasting systems.

In coordination with the U.S. Department of State, the HHS Administration for Children and Families, and the HHS Centers for Disease Control and Prevention, ASPR worked to bring Americans home following the initial outbreak of the virus. ASPR continues working with our partners in communities across the country. During 2020 and 2021, ASPR deployed hundreds of federal disaster responders and 108 tons of medical equipment and supplies to support field operations at disaster sites. As of August 8, 2021, the U.S. had donated more than 107 million doses of COVID-19 vaccines worldwide, helping to protect people in 65 countries from the deadly pandemic and slow the spread of dangerous new variants. As of January 2022, ASPR had procured 500 million doses of Pfizer's vaccines for international vaccine efforts. These doses are being donated to low- and middle-income countries.

Impact Reporting: Examples of Data Driven Results

ASPR focuses on programs and initiatives designed to enhance public health and national health security. ASPR achieves its operational responsibilities for the advancement of research, the development and stockpiling of medical countermeasures, as well as the coordination of the Federal public health and medical response to emergencies and disasters.



9,460+ response personnel deployments

More than 9,460 COVID-19 international and national individual deployments

2.7 million volunteer hours from over 600

Medical Reserve Corps units in FY 2021

17,086+ tons of cargo shipped

More than 17,086 tons of cargo shipped by the Strategic National Stockpile in support of the COVID-19 response

Public Health and Social Services Emergency Fund

ALL PURPOSE TABLE

(Dollars in Millions)

Activity	FY 2021 Final	FY 2021 Supplemental Funding /1	FY 2022 CR	FY 2022 Supplemental Funding	FY 2023 President's Budget	FY 2023 President's Budget +/- FY 2022 CR
Assistant Secretary for Preparedness and Response (ASPR):						
Preparedness and Emergency Operations	24.654	--	24.654	--	28.300	+3.646
<i>National Special Security Events (NSSE) (non-add)</i>	5.000	--	5.000	--	5.000	--
National Disaster Medical System (NDMS)	63.404	--	63.404	--	130.030	+66.626
Hospital Preparedness	280.555	--	280.555	--	291.777	+11.222
Medical Reserve Corps	6.000	100.000	6.000	--	6.240	+0.240
Preparedness and Response Innovation	2.000	--	2.000	--	2.080	+0.080
Biomedical Advanced Research and Development Authority (BARDA)	596.700	24,895.000	596.700	--	828.380	+231.680
Project BioShield	770.000	--	770.000	--	770.000	-
Strategic National Stockpile (SNS)	705.000	3,250.000	705.000	--	975.000	+270.000
Policy and Planning	14.877	--	14.877	--	21.417	+6.540
Operations	30.938	--	30.938	--	34.376	+3.438
HHS Coordination and Response Element (H-CORE)	--	--	--	--	132.801	+132.801
ASPR Pandemic Influenza						
No-Year Pandemic Influenza	252.000	--	252.000	--	347.000	+95.000
Annual Pandemic Influenza	27.991	--	27.991	--	27.991	-
Subtotal, ASPR Pandemic Influenza	279.991	--	279.991	--	374.991	+95.000
ASPR Mandatory Funding						
Pandemic Preparedness	--	--	--	--	40,019.000	+40,019.000
Subtotal, ASPR Program Level	2,774.119	28,245.000	2,774.119	--	43,614.392	+40,840.273
<i>Subtotal, ASPR Budget Authority</i>	<i>2,774.119</i>	<i>28,245.000</i>	<i>2,774.119</i>	<i>--</i>	<i>3,595.392</i>	<i>+821.273</i>
<i>Subtotal, ASPR Mandatory Funding</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>40,019.000</i>	<i>+40,019.000</i>
Other Office of the Secretary:						
Office of Global Affairs (OGA) Annual Pandemic Influenza	7.009	--	7.009	--	7.009	--
Cybersecurity	57.820	--	57.820	--	161.326	+103.506
Other PHSSEF - Cybersecurity	--	--	--	--	21.900	--
Office of National Security (ONS)	8.510	--	8.510	--	8.983	+0.473
Office of the Assistant Secretary for Health (OASH)	--	--	--	--	20.000	+20.000
<i>USPHS Readiness & Training</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>2.000</i>	<i>+2.000</i>
<i>Public Health and Emergency Response Strike Team (PHERST)</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>4.400</i>	<i>+4.400</i>
<i>Commissioned Corps Ready Reserve</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>13.600</i>	<i>+13.600</i>
Subtotal, Other Office of the Secretary	73.339	--	73.339	--	219.218	+145.879
PHSSEF Total:						
HHS Pandemic Influenza Budget Authority	287.000	--	287.000	--	382.000	+95.000
<i>No-Year Pandemic Influenza (non-add)</i>	<i>252.000</i>	<i>--</i>	<i>252.000</i>	<i>--</i>	<i>347.000</i>	<i>+95.000</i>
<i>Annual Pandemic Influenza (non-add)</i>	<i>35.000</i>	<i>--</i>	<i>35.000</i>	<i>--</i>	<i>35.000</i>	<i>--</i>
Other Budget Authority	2,560.458	89,418.000	2,560.458	--	3,432.610	+872.152
Total, PHSSEF Program Level	2,847.458	117,663.000	2,847.458	--	43,833.610	+40,986.152
<i>Mandatory ASPR Pandemic Preparedness</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>--</i>	<i>40,019.000</i>	<i>--</i>
Total, PHSSEF, Discretionary Budget Authority	2,847.458	--	2,847.458	--	3,814.610	+967.152
FTE						
ASPR	916	64	1119	175	1365	+246
OGA	16	--	18	--	20	+2
Cybersecurity	110	--	143	--	143	--
ONS	37	--	38	--	38	--
OASH	--	31	0	175	118	+118
Total FTE, PHSSEF	1,079	95	1,318	350	1,684	+366

1/ 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 2023 Appropriations Language

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, \$1,687,610,000, of which \$828,380,000 shall remain available through September 30, 2024, 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, 2025. Provided further, that \$132,801,000 of the amounts made available to support coordination of the development, production, and distribution of vaccines, therapeutics, and other medical countermeasures shall remain available through September 30, 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, \$975,000,000, to remain available until expended.

For an additional amount for expenses necessary to prepare for or respond to an influenza pandemic, \$382,000,000; of which \$347,000,000 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 2023 General Provision

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>Provided further, that \$132,801,000 of the amounts made available to support coordination of the development, production, and distribution of vaccines, therapeutics, and other medical countermeasures shall remain available through September 30, 2024.</i></p>	<p>This language is inserted to specify and make available for two years funding for the Health and Human Services Coordination Operations and Response Element (H-CORE), which is the institutional component within the Office of the Assistant Secretary for Preparedness and Response that leads the COVID-19 response for medical countermeasures and related supplies.</p>
<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>

SUMMARY OF CHANGES

2022 CR						
Total budget authority.....						\$2,847.458
2023 President's Budget						
Total estimated budget authority.....						\$3,814.610
Net Change.....						+967.152
	FY 2022 CR		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	BA	FTE	PB BA	PB FTE	BA	FTE
Increases:						
Assistant Secretary for Preparedness and Response						
Preparedness and Emergency Operations.....	24.654	86	28.300	86	+3.646	--
National Disaster Medical System.....	63.404	148	130.030	162	+66.626	+14
Hospital Preparedness Program.....	280.555	62	291.777	62	+11.222	+13
Medical Reserve Corps.....	6.000	12	6.240	12	+0.240	--
Preparedness and Response Innovation.....	2.000	3	2.080	3	+0.080	--
Biomedical Advanced Research and Development Authority	596.700	267	828.380	364	+231.680	+97
Strategic National Stockpile.....	705.000	329	975.000	329	+270.000	+70
Policy and Planning.....	14.877	66	21.417	83	+6.540	+17
Operations.....	30.938	135	34.376	142	+3.438	+7
Coordination and Response Element.....	0.000	0	132.801	111	+132.801	+111
Pandemic Influenza.....	279.991	11	374.991	11	+95.000	--
Office of National Security	8.51	38	8.983	38	+0.473	--
Cybersecurity	57.82	110	161.326	143	+103.506	+33
Other PHSSEF Cybersecurity	--	0	21.9	0	+21.9	--
Office of the Assistant Secretary for Health	0	0	20.000	118	+20.000	+118
Office of Global Affairs Pandemic Influenza	7.009	18	7.009	20	--	+2
Total Increases.....	2077.458	1318	3044.61	1684	+967.152	+366
Decreases:						
Total Decreases.....	0	0	0	0	--	--
Net Change.....					+967.152	+366

BUDGET AUTHORITY BY ACTIVITY

Activity	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget
Bioterrorism and Emergency Preparedness	2,560.458	2,560.458	3,432.610
Pandemic Influenza	287.000	287.000	382.000
Total Budget Authority	2,847.458	2,847.458	3,814.610
FTE	1,079	1,318	1,684

AUTHORIZING LEGISLATION

Activity	FY 2022 Amount Authorized	FY 2022 Amount Appropriated	FY 2023 Amount Authorized	FY 2023 President's Budget
ASPR				
National Disaster Medical System	57.404	63.404	57.404	130.030
Hospital Preparedness Program	385.000	280.555	385.000	291.777
Medical Reserve Corps	11.000	6.000	11.000	6.240
BARDA	611.700	596.700	611.700	823.380
Project BioShield	710.000	710.000	710.000	770.000
Strategic National Stockpile	610.000	705.000	610.000	975.000
Pandemic Influenza	250.000	287.000	250.000	374.991

APPROPRIATIONS HISTORY

(Dollars in millions)

Details	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2013				
Appropriation	642.262			584.205
Transfer to CDC				(1.919)
Transfer to OMHA				(0.629)
Supplemental Appropriation	800.000	800.000	800.000	800.000
Transfer to ACF - SSBG				(500.000)
Transfer to ACF - Head Start				(100.000)
Transfer to OIG				(5.000)
Transfer to OGA				(0.250)
Sequester				(38.343)
Subtotal	1,442.262	800.000	800.000	738.064
FY 2014				
Appropriation	1,289.531		1,304.400	1,243.430
Subtotal	1,289.531	--	1,304.400	1,243.430
FY 2015				
Appropriation			1,389.813	1,233.069
Supplemental Appropriation				733.000
Subtotal	-		1,389.813	1,966.069
FY 2016				
Appropriation	1,909.981			1,532.958
Supplemental Appropriation (PL 114-223)				387.000
Transfer to CMS				(75.000)
Transfer to HRSA				(66.000)
Transfer to OIG				(0.500)
Transfer to GAO				(0.500)
Subtotal	1,909.981	-	-	1,777.958
FY 2017				
Appropriation	1,431.117	1,631.258	1,517.958	1,532.958
Transfer to ACF				(3.520)
Subtotal	1,431.117	1,631.258	1,517.958	1,529.438
FY 2018				
Appropriation	1,662.616	1,739.258	1,552.958	1,953.458
Supplemental Appropriation (PL 115-123)				162.000
Transfer to HRSA				(60.000)
Transfer to SAMHSA				(20.000)
Transfer to OIG				(2.000)
Subtotal				2,033.458
FY 2019				
Appropriation	2,303.877	2,046.458	2,813.128	2,021.458

Public Health and Social Services Emergency Fund

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)
Mandatory Funding (PL 117-02)				70,110.000
FY 2022				
Continuing Resolution (P.L. 117-86)				2,847.458
FY 2023				
Requested Appropriation				3,814.610
Requested Mandatory Funding				40,019.000

APPROPRIATIONS NOT AUTHORIZED BY LAW

(Dollars in Millions)

Program	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2022
ASPR				
Preparedness and Emergency Operations	N/A	N/A	N/A	24.654
Policy and Planning	N/A	N/A	N/A	14.877
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)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	2,774.119	2,774.119	3,595.392	+821.273
FTE	1,080	1,080	1,365	+285

The Fiscal Year (FY) 2023 President's Budget request for the Office of the Assistant Secretary for Preparedness and Response (ASPR) is \$3,595,392,000, which is \$821,273,000 above an annualized FY 2022 Continuing Resolution (CR) level. The funding request increase will ensure that ASPR has the people, programs, and resources it needs to continue responding to the COVID-19 pandemic, restore resources and capabilities that have been diminished, and prepare for future health emergencies.

Increases above FY 2022 CR:

Strategic National Stockpile (SNS): The President's Budget requests \$975,000,000 for SNS, which is +\$270,000,000 above the FY 2022 CR. Building on the COVID-19 response, the request would make meaningful investments across several portfolios necessary to ensure readiness for future public health emergencies. With the proposed increase, SNS would sustain current product lines, procure sufficient quantities of an FDA approved smallpox antiviral, and procure anthrax therapeutics. Additional funds will also be used to sustain on-going investments in SNS capacity and infrastructure, such as warehousing costs.

Pandemic Influenza: The President's Budget requests \$374,991,000 for BARDA Pandemic Influenza activities, which is +\$95,000,000 above the FY 2022 CR. The FY 2023 request includes an additional \$30 million to build recombinant pandemic influenza manufacturing capacity and an additional \$17 million to develop needleless or patch technology. Additional funds will be used to: (1) advance synthetic influenza vaccine platforms; (2) continue efforts to transfer technologies to public-private partnerships to improve influenza pandemic response; and (3) develop alternative influenza vaccine delivery systems. 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. A diversified and expanded seasonal influenza vaccine production base lowers the risks associated with the pandemic response. The successful initiatives that ASPR has undertaken resulted in a robust base for ongoing efforts to improve vaccine delivery, including ongoing advances in adjuvants and fill-finish capacity to achieve the HHS goal of timely vaccine availability in a pandemic emergency.

BARDA Advanced Research and Development (ARD): The FY 2023 request for ARD is \$828,380,000, which is +\$231,680,000 above the FY 2022 CR. The budget will expand BARDA innovation efforts through its Division of Research Innovation and Ventures 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: (1) vaccines and therapeutics for viral hemorrhagic diseases; (2) next generation smallpox therapeutics; (3) countermeasures against chemical threats; (4) development of next generation therapeutics against botulinum toxin; and (5) vaccines against anthrax.

HHS Coordination Operations and Response Element (H-CORE): The FY 2023 President's Budget proposes \$132,801,000 for the HHS Coordination Operations and Response Element (H-CORE), which was established January 1, 2022, as the successor to the previous Countermeasures Acceleration Group and Operation Warp Speed. H-CORE is the operational engine behind COVID-19 vaccine and therapeutics procurement and distribution, and also plays an important role in making masks and tests available nationwide. The program is currently funded through COVID-19 supplemental appropriations resources.

National Disaster Medical System (NDMS): The FY 2023 President's Budget requests \$130,030,000 for NDMS, which is +\$66,626,000 above the FY 2022 CR. 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 request includes an additional \$13 million to maintain NDMS caches and equipment and an additional \$50 million to expand the number of NDMS intermittent staff. The NDMS total also continues to include \$6,000,000 for the Pediatric Disaster Care program.

Hospital Preparedness Program (HPP): The budget requests \$291,770,000, which is +\$11,220,000 above the FY 2022 CR. 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.

Operations (ASPR Administration): The President's Budget requests \$34,376,000 for Operations, which is +\$3,438,000 above the FY 2022 CR. Of the additional funds, \$2.2 million is proposed to establish a new Working Capital Fund to provide greater structure for ASPR support services in ways that meet evolving program requirements.

Policy and Planning: The budget includes \$21,417,000, which is +\$6,540,000 above the FY 2022 CR. The additional funds will help ASPR establish quantitative and economic analytics and modeling capabilities to evaluate medical countermeasure activities.

Preparedness and Emergency Operations (PEO): The budget requests \$28,300,000 for PEO, which is +\$3,646,000 above the FY 2022 CR. The FY 2023 request supports preparedness and response efforts for public health and medical emergencies and a robust Continuity of Operations program. The budget proposes an increase PEO staff costs and other inflationary increases. 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. The request will continue support for the Information Management, Intelligence Operations, Personnel Security, and the HHS Secretary's Operations Center to ensure execution of 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.

Medical Reserve Corps (MRC): The budget requests \$6,240,000, which is +\$240,000 above the FY 2022 CR. 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 2022 CR. The FY 2023 request for PRI will continue funding several accelerators attached to academic or clinical research centers, with one award to an accelerator in the US and one accelerator in Israel.

Pandemic Preparedness

Budget Summary

(Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Mandatory Funding	--	--	40,019,000.000	+40,019,000.000

Allocation Method..... Direct Federal/Intramural, Contracts

Program Description and Accomplishments

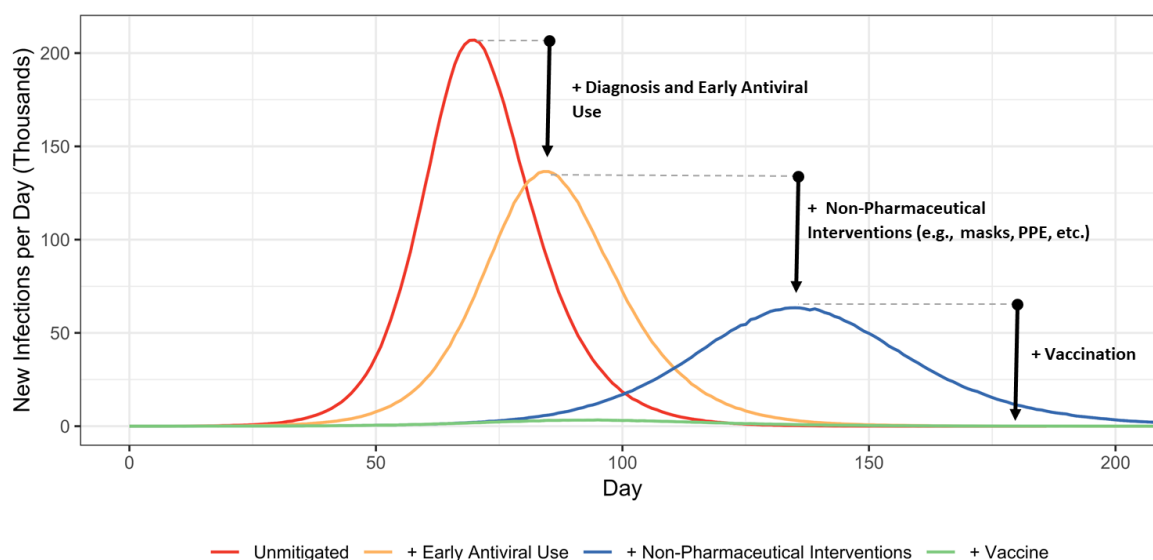
The FY 2023 Budget includes an effort totaling \$81.7 billion in mandatory funding, available over five years, across the Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Food and Drug Administration (FDA) to support the Administration's plan to transform U.S. capabilities to prepare for and respond rapidly and effectively to future pandemics and other high consequence biological threats. Within this total, the Budget requests \$41 billion in mandatory funding for ASPR to carry out the activities described herein to advance the Administration's vision for pandemic preparedness.

Through advanced development of medical countermeasures against viral families with the greatest pandemic potential and strategic investments that will innovate and expand critical manufacturing, supply chain and response capabilities, ASPR will implement an integrated system that will develop and license, stockpile, and provide infrastructure for rapid large-scale manufacturing of the new diagnostics, therapeutics, vaccines, and non-pharmaceutical interventions required to contain known diseases. The scale, speed, infrastructure and efficiencies realized through this effort will provide the necessary adaptable capabilities to mount rapid and comprehensive responses against emerging pathogens.

While SARS-CoV-2 has confirmed what were once only "near-worst-case" scenarios for a global pandemic within exercises and projections, HHS has a long history of leading responses to outbreaks, including smaller, localized outbreaks, such as Zika and Ebola, that have always had potential of reaching pandemic status and increasing the already significant health security concerns if not properly contained. HHS's initiatives and achievements in all phases of these responses have broadened the pool of strong contributors in this space, proven the strategies to develop medical countermeasures at a previously unthinkable pace while critically and necessarily retaining all safety and efficacy assurances, and significantly widened the realm of the possible.

Looking ahead to an elevated position of pandemic preparedness, HHS is proposing to take strong action now to again make transformational advances within all pillars of preparedness and response, tighten coordination across the Department and continue in its leading role in responding to public health emergencies and developing the systems, infrastructure, research and medical countermeasures that will be required within a whole of Government response to emerging public health emergencies and threats. As demonstrated by the figure below, only by having a layered end-to-end solution can the USG be better prepared for the next pandemic. A critical lesson learned from the COVID-19 response is that a gap in any one of these critical defenses results in increased disease, death, and an unsustainable burden on the health care system.

Medical Defenses that Flatten the Curve



The Department's efforts are highly aligned with *American Pandemic Preparedness: Transforming our Capabilities* published by the White House Office of Science and Technology Policy (OSTP) and the National Security Council (NSC) on September 2, 2021, and also build on knowledge and experience gained during the COVID 19 pandemic and through prior domestic and global pandemic preparedness efforts.

HHS believes the activities and investments indicated here and in similar documents prepared by CDC, FDA and NIH will enable the United States to advance priority efforts essential to the Secretary's ambitious vision for future pandemic preparedness, including the identification and swift resolution of potential biological threats. HHS looks forward to working with the White House, Congress, federal partners, academia, and other stakeholders domestically and abroad to achieve this shared vision.

Funding History	
Fiscal Year	Amount
FY 2019	--
FY 2020	--
FY 2021 Final	--
FY 2022 CR	--
FY 2023 President's Budget	\$40,019,000,000

Budget Request

The FY 2023 President's Budget requests \$40,019,000,000 in new mandatory funding for ASPR, available through FY 2027, to prepare for pandemics and other biological threats.

End-to-End Advanced Development of Vaccines and Therapeutics Against High Priority Viral Families (\$12.0 billion): ASPR will develop and license new vaccines and therapeutics against viral families with the highest pandemic potential.

Therapeutics. ASPR will implement a robust antiviral program in alignment with the *American Pandemic Preparedness Plan* which indicates inhibiting key viral functions with antivirals is an important tool for controlling a pandemic. Proposed drugs will have the ability to alleviate symptoms of disease, prevent severe disease and hospitalizations, and/or lower mortality. Preferred antivirals will target entire virus families, thus allowing development of products that can be used immediately against known/existing threats, as well as protecting against unknown threats.

Vaccines. ASPR will develop vaccines against “prototype” members of seven of the 26 viral families through full regulatory approval and commercial scale manufacturing, prioritizing those viral families with high pandemic or pathogenic potential. Vaccines utilizing established and new platform technologies to ensure ability to rapidly manufacture at large scale will be targeted. ASPR will support advanced development through FDA licensure to include Phase 2 and 3 clinical evaluation and the requisite manufacturing scale up and validation activities to ensure these vaccines can rapidly be utilized to support an outbreak response.

Capital Investments in Vaccine Production Capacity and for Warm Surge Capacity for Manufacturing Vaccines, Vials, and Syringes/Needles (\$15.0 billion): ASPR will address three critical deficiencies within the COVID-19 response by building a robust vaccine manufacturing capability through investing in: (a) up to eight bulk and ten final container fill/finish capabilities and capacity that are continuously manufacturing licensed product at commercial scale such that they can rapidly pivot and manufacture vaccine against a new threat; (b) domestic manufacturing of raw materials, consumables, and ancillary supplies such as vials and needles and syringes; and (c) development, licensure, and large scale manufacturing capability of established and novel vaccine platform technologies that can readily be modified to express new antigens--the latter in conjunction with the vaccine development effort. This effort will also include a broad-based effort to develop new manufacturing platforms (e.g., vectors, new mRNA processes, etc.) that significantly improve on current platforms.

Warm Surge Capacity for PPE and Diagnostic Tests (\$4.0 billion): The domestic medical industrial base is at a disadvantage in competition with low-cost providers that are further subsidized by their national governments. As was seen with COVID-19, this puts the U.S. at a disadvantage when other countries prevent export of these life-saving items. Through economic incentives of \$4 billion, including direct payments, capital investments, as well as incentives to increase productivity, ASPR will ensure continued capability of domestic PPE and diagnostic test kit manufacturing.

Refill and Modernize Depleted Pandemic Stockpiles (\$3.0 billion): ASPR will support ongoing COVID-19 response activities, including replacement of expiring PPE, support for the federal vaccination campaign, storage and distribution capacity for PPE procured during the COVID-19 response, and maintenance of ventilators.

Advanced Development of Diagnostics and Technologies for Advanced Biosurveillance and Early Warning, including Pathogen-Agnostic Clinical and Environmental Surveillance Technologies (\$1.5 billion): ASPR will develop threat agnostic pathogen Next Generation Sequencing (NGS)-based diagnostics for use in laboratory and remote settings, which is a cornerstone technology for rapid response in the National Biodefense Strategy. ASPR will also invest in new affordable home use testing technologies and rapid screening tools for use in settings like homes and transportation hubs and develop novel diagnostics for up to 4 pathogens or virus families with high pandemic potential.

Technology and Manufacturing for New Vaccine Administration Tools (\$1.5 billion): ASPR will support technologies to manufacture vaccine administration tools (e.g., microneedle patches or controlled release devices) that would support single-dose regimens or reduce reliance on traditional ancillary supplies like needles and syringes. Investments in this area will be critical to change the paradigms under which vaccines are currently manufactured and administered, and ultimately reduce the timeline to vaccine availability for the US and the world.

Capital Investments in Active Pharmaceutical Ingredient (API) Manufacturing and Innovative Manufacturing Processes (\$1.4 billion): ASPR will make capital investments in API manufacturing and other innovative processes. These platform technology investments will avail manufacturing capabilities for key starting materials, active pharmaceutical ingredients, biologics, and finished dose form drugs using continuous, distributed manufacturing methods, instead of batch manufacturing, to gain efficiencies in footprint, labor, and production costs. This will enable HHS to have a resilient, highly distributed manufacturing base on which to rely that will be able to withstand foreign pricing competition for these products.

Next-Generation PPE (\$1.0 billion): ASPR will invest in non-pharmaceutical interventions, specifically in the development of next-generation personal protective equipment. The request includes specific targets for improvement including advanced development of platform technologies that can imbue different textiles with microparticles or nanoparticles which, when used for nonwoven fabrics, the external layers of masks, gowns and other coveralls can render bacteria and viruses as non-infectious. In conjunction with development, investments will be made to expand manufacturing lines to produce these novel materials at scale in the commercial setting, and for demonstration and distribution into the healthcare sector, as name-brand recognition often drives acceptance of these technologies on the front lines of care.

Workforce Expansion Activities (\$180 million): ASPR will establish and implement cross-disciplinary educational and training programs to recruit and develop skilled professionals for the biomanufacturing industry. This will include support for partnership development and curriculum collaboration, as well as internships and scholarships that will include programs for HBCU, minority students, and former military to generate interest in biomanufacturing.

Manage the Mission within ASPR (\$439 million): ASPR will establish a centralized Mission Control to establish and maintain strong coordination of HHS agency efforts and transparent reporting and management of HHS's performance within all lines of effort. In addition to recruiting federal and contractor staff, Mission Control will retain transfer authority to conduct rapid countermeasure development and deployment operations and evaluation.

Preparedness and Emergency Operations

Budget Summary

(Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	24.654	25.640	28.300	+2.66
<i>National Special Security Events (non-add)</i>	<i>5.000</i>	<i>5.000</i>	<i>5.000</i>	-
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 has the lead 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 to coordinate the Federal public health 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 also supports HHS medical teams deployed in response to a public health emergency by provisioning medical supplies and services, including medical durable equipment, and coordinating emergency medical care in shelters, as needed. Through these functional designations, ASPR provides critical emergency management leadership and support for all major public health events 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 the following hurricanes: 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 2016 and 2017, ASPR was the lead federal agency for the Flint Water Contamination Crisis; coordinated assets for the major flooding in Louisiana and Texas; and established a Unified Coordination Group in Puerto Rico for Zika Virus response. In 2019, ASPR provided support to California for simultaneous wildfires, including the Kincadee fire, throughout the state. In 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 2021 and 2022 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 needs to respond to the pandemic. During 2021, ASPR supported the response to the January 6 Capital insurrection, the Unaccompanied Minor mission along the Southwest Border, Hurricane Ida, and the early stages of the repatriation of American citizens from Afghanistan and support for Afghan nationals offered entry into the United States as part of Operation Allies Welcome.

ASPR also supports several planned annual events including the President's State of the Union Address; the Peace Officer's Memorial and Independence Day celebrations in Washington, D.C.; the United Nations General Assembly in New York, New York; as well as other non-annual planned events, such as the Democratic and Republican National Conventions and Presidential Inaugurations.

Crisis, Contingency, Strategic Planning, and Mission Analysis

ASPR develops strategic and operational planning guidance, to implement national preparedness functions and to prepare the Department's response during incidents and events. These plans allow ASPR to coordinate 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 planning, senior-level decision makers are provided with support tools and recommended courses of action to advance HHS's mission. ASPR's plans provide a solid foundation that, when needed, ease 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 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 Plan as the Department's plan for supporting the NRF and the Federal Interagency Operations Plan. Functional annexes for this plan—such as operational coordination, health surveillance, medical surge, and patient movement—describe the essential missions and tasks that HHS may be requested to provide. 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 the different functions at the national level as the lead Agency in the Federal public health and medical response to various types of incidents. These annexes address HHS's capabilities, essential tasks, and resources in each phase of a response. They also specify HHS requirements for ESF 8 and other Federal partners who support HHS in carrying out its response mission.

In addition, ASPR leads interagency collaborations by coordinating the HHS input to the 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 outages; food and agriculture insecurity; 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). For these special events, ASPR coordinates medical and public health support for both the event and contingency response, managing the deployment of approximately 500 medical responders per year on average.

ASPR ensures that all plans are developed using historical, current, and contextual information. Plan development uses both quantitative and qualitative mission analysis and subject matter expertise to ensure that plans are based on the best-available data as well as tailored to leverage user experience and meet user needs.

In 2021, ASPR Planning:

- Began the initial revision of the All-Hazards Plan;
- Collaborated with interagency partners on revisions to the Response and Recovery Federal Interagency Operations Plan, Biological Incident Annex, and the National Security Emergency Plan, as well as the development of new guidance for COVID-19 Community Vaccination Clinics and Hospital Expansion;
- Conducted public health and medical support planning and training for several National events, including the 2021 Presidential Inauguration, Independence Day, the UN General Assembly, and the Peace Officers Memorial;
- Provided rapid response contingency planning for missions including the unaccompanied children missions at the Southwest Border (Operations Artemis and Apollo) and repatriation of US citizens from Afghanistan and COVID-19 vaccination of Afghani individuals; and,
- Developed mission analysis and crisis action planning for several natural disasters including Hurricane Ida and the Haitian earthquake.

In FY 2023, 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;
- Revise the HHS All-Hazards Plan Incident-specific annexes, including the Natural Disaster Annex and the Earthquake Annex;
- Update 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;
- Conduct a pilot mission analysis project to improve public health and medical planning for the underserved populations in the U.S. territories;
- Develop Medical Critical Infrastructure Disruption Annex; 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 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 the coast of Japan. It also continues to inform the ESF 8 response to COVID-19.

FY 2023 ASPR anticipated activities include:

- Using lessons learned, stakeholder engagement, and other materials to inform the missions and responsibilities associated with the IRF; and,
- Updating the IRF and incorporating it as a functional annex within the HHS All-Hazards Plan.

Leading Public Health and Medical Emergency Response Operations

Early detection is critical in mitigating events that have the potential to significantly impact public health. The HHS Secretary's Operation Center (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, Information Management Section, and Incident Management Team, and other activated NRCC ESFs and Sections within the NRCC, and FEMA headquarters. The SOC monitors information from the Federal government, states, 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 communication methods to inform decision-makers and enable rapid Federal ESF-8 response.

Under the COVID-19 Federal Public Health Emergency (PHE) declaration, SLTT can 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 serves 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. The

SOC coordinated and processed 5,233 COVID-19 Temporary Reassignment requests, resulting in the reassignment of the equivalent of over 60,000 federal employees to effectively respond to the pandemic.

The SOC has been activated at a Level 1 for over 700 consecutive days since the pandemic began and continues to coordinate the federal ESF-8 response to COVID-19 through the deployment of both personnel and equipment. In addition to the ongoing COVID-19 response, the SOC has coordinated and supported HHS response activities for 17 incidents, including five major tropical systems, two severe weather systems, mass migration, Haitian earthquake, repatriation of American Citizens and Afghan allies, and the Colonial Pipeline cyber-attack. In addition, the SOC also coordinated nine special events including the COVID-19 Vaccine Transfer Mission reporting, United Nations General Assembly, and Lying in State/Honor events. FY 2023 ASPR SOC anticipated activities include:

- Maintaining a comprehensive monitoring and detection program that includes all available data sources (including open source and classified) to support enhanced situational awareness, early notification, and decision-support to HHS Senior Leadership, in coordination with Security Intelligence and Information Management (SIIM);
- Implementing expanded notification systems to ensure the right people receive the right information at the right time;
- Completing the development of a training and exercise plan for each quarter in 2023 and creating a lifecycle of training and exercises for every three years;
- Strengthening the quality assurance, quality control, and quality improvement systems;
- Developing an instructor cadre for the execution of a SOC 101 training;
- Reviewing all SOC standard operating procedures for the correctness and rewrite current draft versions for implementation;
- Updating COOP roles and responsibilities for day-to-day maintenance and improvement, and ensure that the alternate SOC is always functional and ready;
- Implementing the Training and Readiness (T&R) manual to explain functions required of each position within the SOC, complete with conditions, standard, and performance steps;
- Conducting future operations planning to ensure that the SOC stays up to date with emerging technologies;
- Supporting the implementation of the Executive Order on American Supply Chains; and,
- Supporting the implementation of the Executive Order on Tackling the Climate Crisis at Home and Abroad.

Information Management and Situational Awareness

The ASPR information management program serves as the focal point for 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, Incident Analysis Briefs, and Community Profile Reports) 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 2021, more than 10,000 information, data, and analytic products were produced and distributed to support decision across the numerous ASPR responses. These products included senior leader briefs, regional deep dive portfolios for each of the 10 FEMA regions, and community profiles to identify COVID-19 trends. In addition, the program leveraged an ESRI enterprise license agreement to expand geospatial and visualization capabilities for information products, which enhanced the ability to identify impacted zones for resource planning and allocation decision. The program also established a regional presence with information managers within the regional offices to facilitate the flow of information. In early 2022, the information management program deployed a new Request for Information process to enhance ASPR's ability to track and respond to information requests before, during, and after a response.

In FY 2023, ASPR anticipates the following information management activities:

- Continue to produce information, data, and analytic products for ASPR response activities, to include pre-response. The number of products is anticipated to maintain at the FY 2021 level of products;
- Fully transition the ASPR Geospatial system (GEOHEALTH) to the cloud, which will enable the system to meet cybersecurity best practices while also meeting the ASPR geospatial and information sharing needs; and,
- Maintain an information management presence in the regions with regional information managers to facilitate information flow from the regions to ASPR headquarters and ASPR's partners.

Information Technology and Cybersecurity

ASPR's ability to execute its mission depends 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 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.

Since FY 2020, ASPR has seen a dramatic increase in its dependence on 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 provides 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 with NT50 partners and HHS' Office of National Security (ONS) to provide finished intelligence products to ASPR decision makers. Since 2018, 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. These activities include developing and delivering open-source weekly briefings to inform ASPR planning; and developing and providing pre-deployment force protection briefs for Incident Management Teams (IMT) and National Disaster Medical System (NDMS) personnel to inform mission planning. In addition, a supply chain risk management program has been established to assess the health of ASPR's supply chains and implement mitigation measures to maintain the health of its supply chains.

In FY 2023, ASPR anticipates the following intelligence operation activities:

- Continue development of pre-deployment force protection briefs for the IMT and NDMS personnel to inform mission planning;
- Continue assessment of ASPR's supply chain and observing and reporting on any early warnings of disruption to supply chains;
- Coordinate with the Critical Infrastructure Protection (CIP) program to provide threat awareness to HHS's private sector partners; and
- Maintain weekly open-source threat reporting to inform ASPR planning.

Continuity of Operations Before, During, and After Emergencies

In accordance with both Presidential and Federal directives and supported by Departmental policy, ASPR ensures the continuation of HHS's Primary Mission Essential Functions (PMEFs) supported by the Mission Essential Functions. Through management of the Department's Continuity of Operations (COOP), Continuity of Government (COG) and Continuity of the Presidency (COP) 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 the Department's continuity facility supported with continuity communications systems kept in a state of constant readiness. Additionally, ASPR manages the overarching policy and planning portfolio to scope and define the HHS Unified Continuity Program.

Further, ASPR is responsible for ensuring that all communication capabilities are available and functional in accordance with Office of Science and Technology Policy/Office of Management and Budget (OSTP/OMB) Directive 16-1. HHS has seen increased alternate, contingency, and emergency communications capabilities, including the management and implementation of Government Emergency Telecommunications Service and Wireless Priority Service, 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 alternate facility. These capabilities allow HHS to develop and maintain a strong, redundant communications capability to ensure its communications ability during emergencies (including relocation to an alternate site).

ASPR also leads the reviews and evaluations of the various plans, procedures, analyses, and other doctrine that comprise and structure the HHS Continuity programs. Most recently, updated in FY 2021 and under continuous review 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. HHS is on track in FY 2022 to host exercises with HHS 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 and this has continued in FY 2022.

For FY 2022 and continuing into FY 2023, 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 2022 and Oct 2022 and focused on return to the workplace and resuming normal operations. ASPR has planned internal continuity exercises with events tentatively scheduled to occur in November and December 2022 that will focus on cyber-security and disruptions to the power grid HHS and ASPR leadership. FY 2022 and 2023 will see continuity of operations included within National Level Exercise activities, tentatively scheduled for May or June 2022 and recurring on an annual basis.

Personnel Security Operations

The ASPR preparedness and response mission requires the proper security of ASPR assets—locations, systems, and personnel. To protect these assets, ASPR security personnel 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 2021 alone, ASPR processed more than 116 new applicant security packages and 500 security badge requests. In FY 2023, personnel security operations are expected to stay these current, higher than normal levels in order to meet the personnel security process activities necessary 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 for response and preparedness activities. The Center for Domestic Preparedness (CDP) in Anniston, Alabama provides 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. In addition, ASPR coordinates with FEMA's Center for Domestic Preparedness (CDP) to deliver training to NDMS teams with hands-on training as well as a National Hospital Preparedness Program (NHPP) coalition leadership course. ASPR works with CDP to identify any training 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.

Funding History	
Fiscal Year	Amount
FY 2019	\$24,654,000
FY 2020	\$24,654,000
FY 2021 Final	\$24,654,000
FY 2022 CR	\$24,654,000
FY 2023 President's Budget	\$28,300,000

Budget Request

The FY 2023 President's Budget request for PEO is \$28,300,000 which is +\$2,660,000 above FY 2022 CR. The increased funding ensures that ASPR can continue to maintain current PEO capabilities. The request will continue current Information Management, Intelligence Operations, Personnel Security, and SOC programs at their current staffing levels to ensure execution of these mission essential functions including monitoring and detection and alert and notification, as well as continued implementation of the

Public Health and Social Services Emergency Fund

ASPR Incident Response Framework and situational awareness activities for planning and decision support. Funds will be used to support information systems, data analysis and other tools necessary to support the preparedness and response mission.

This request also continues \$5,000,000 in three-year funding to prepare for, and respond to, National Special Security Events (NSSEs), public health emergencies, and other events that are not eligible for assistance under the Stafford Act. 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)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	63.404	63.404	130.030	+66.626
<i>Pediatric Disaster Care Program (non-add)</i>	6.000	6.000	6.000	-
FTE	124	148	162	+14

Authorizing Legislation:

Authorization Public Health Service Act

Allocation Method Direct Federal/intramural, contracts

Program Description and Accomplishments

When disaster strikes, the National Disaster Medical System (NDMS) activates to help communities respond, recover, and protect public health. NDMS capabilities are unique assets able to deliver surge medical and emergency management services and subject matter expertise when requested by a federal, state, local, tribal, or territorial (SLTT) agency.

The NDMS mission is to support communities with medical services during or after a disaster or public health emergency, and to support the U.S. Department of Defense (DOD) and Veterans Affairs (VA) in cases of a surge in military casualties that could overwhelm their medical systems. Since its establishment in 1984, NDMS has responded to over 300 domestic incidents, and two international 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. NDMS intermittent personnel typically hold positions in their own communities across the country and become temporary federal employees to provide healthcare assistance to communities impacted by natural and/or man-made incidents. NDMS responders 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 provided 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 7,052 personnel. This includes 69 NDMS response teams (6,290 personnel), logistics specialists (400 personnel), and Incident Management Team members (362 personnel) across three separate and distinct programs. As ASPR has not yet reached the goal of 7,052 personnel, approximately 3,000 personnel are deployable. NDMS teams are comprised of 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 can provide patient care, fatality management operations to include mortuary services, federal patient movement, and definitive care support. NDMS team employees are permanent, excepted-service, federal employees utilized on an episodic intermittent basis acting under official activation orders. Team employees receive protection under the Uniformed Services Employment and Reemployment Rights Act (USERRA), Federal Tort Claims Act (FTCA), and Workers' Compensation under the Federal Employees' Compensation Act (FECA), and are compensated, transported, and billeted based on civil service classifications and standards associated with a public health emergency or a designated and properly rated National Special Security Event (NSSE).

NDMS's recent initiatives and accomplishments include:

- Since the beginning of the COVID-19 response:
 - NDMS responded to over 5,389 individual deployments and with some personnel deploying multiple times. NDMS deployed 1,416 DMAT, 206 DMORT, 18 VIC, 86 TCCT, 20 NVRT, 122 IMT, and 83 LRAT personnel over the course of 2020 and 2021.
 - In support of early COVID-19 response efforts, NDMS was deployed for the repatriation of American citizens from China to the United States and then from two cruise ships, one of which was docked in Japan. This included supporting multiple locations throughout the country where Americans were being quarantined or required air transport care.
 - Air Medical Evacuation teams (AET) directly supported 39 flights, moving over 2,000 individuals, all of whom were either COVID-19 positive, persons under investigation (PUI), or individuals who were asymptomatic.
 - 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.
- ASPR deployed 944 tons of logistical equipment and communications assets and engaged in over 36,000 patient encounters across all 2021 NDMS deployments.
- Throughout FY 2021, NDMS teams provided public health and medical support for the following: the Senator Robert Dole funeral, the 2021 Presidential Inauguration, National Independence Day Celebration, the United Nations General Assembly, the Peace Officer's Memorial, ongoing operations in support of Puerto Rico and the United States Virgin Islands response and recovery efforts, Hurricane Ida, and support to missions on the Southwest Border.

NDMS Teams

NDMS is configured into the following teams to meet its mission requirements:

- ***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 can deploy within 24 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 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 skillsets.
- ***Disaster Mortuary Operational Response 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 work 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.
- ***Aeromedical Evacuation Team (AET):*** AETs provide care across a range of clinical acuity spanning ambulatory patients to the critically ill. Teams are staffed and equipped to ensure

sustained clinical stability of their respective patient populations and respond (when necessary) to medical complications and emergencies that may occur at any point throughout the patient transportation continuum.

NDMS Training

Given the unique mission sets of the NDMS teams highlighted above, specialized training in the unique skills and competencies is required for effective disaster medical response. NDMS provides individual and team training to all team members based on roles and team mission requirements. Currently, NDMS has a goal of training a minimum of 20 percent of its workforce per annum. Ideally, NDMS seeks 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 to ensure disaster medical skills and technical proficiency in the utilization of communications procedures and equipment. The unique nature of NDMS team employees as permanent excepted-service federal employees utilized on an episodic intermittent basis means that funding must be provided to pay for the salaries of these intermittent employees when they are activated for training.

In 2020 and 2021, 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-19 mission requirements including the novel treatment of monoclonal antibody therapeutics administration, vaccine administration, 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. Almost 2,000 NDMS employees completed the just-in-time COVID-19 prep training online, over 3,800 completed the revised blood-borne pathogen course, and approximately 1,000 NDMS employees combined completed vaccine and other new online COVID-19-related courses.

NDMS Supporting Functions

An NDMS activation is based on multiple factors including the request from a state, territorial, and local public health authorities, the time to get a team onsite, and which teams are on-call for the period of the event. Once NDMS teams are activated to deploy, they require support from multiple programs across ASPR. This support is provided by the following components:

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 warehouses maintain strategically positioned medical materiel 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.

To ensure a response is properly resourced and logistically supported, ASPR relies on Logistics Response Assistance Teams (LRAT), which include intermittent federal employees, augmented by 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), cellular, radio, and satellite communications support, transportation operations services, and materiel management during a 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).

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, local, tribal, and territorial (SLTT) emergency management and public health agencies, as well as other key federal partners to determine support and operational requirements during public health emergencies, critical incidents, and disasters. One of the fundamental responsibilities is to provide technical assistance, direct support, and interagency and intergovernmental coordination in the earliest phases of such evolving regional and national 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 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, response, and recovery, current structure, processes, and procedures are outlined in ASPR's Incident Response Framework (IRF). 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)-8¹ 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 augments logistical and policy support for strategic and operational planning of the ASPR missions in all phases of the emergency management cycle, particularly the Regions and Special Operations teams. The Mission Support program facilitates the identification of gaps, analysis of actual requirements, and derived requirements necessary to establish policies and business practices in support of staff and program integration and development.

Exercise, Evaluation and After Actions

The HHS/ASPR, Exercise, Evaluation and After Actions (E2A2) program provides a formal mechanism for a coordinated, collaborative program with a primary focus to promote and validate preparedness and readiness throughout the Department. A comprehensive, integrated exercise, evaluation and corrective actions program is one of ASPR's best means of assessing and improving the Department's ability to provide health and medical capabilities and resources, across this network, required in our emergency

¹ https://www.fema.gov/sites/default/files/2020-07/fema_ESF_8_Public-Health-Medical.pdf

plans and operational procedures. It is integral to determining the readiness of responders, resolving questions of command, control and coordination, and clarifying roles and responsibilities.

ASPR has a formal system to capture lessons learned and track associated corrective actions that strengthen the health and emergency response systems for future events. Following each response, ASPR meets with its HHS, federal, state, and local partners to conduct an After-Action Review and develop a subsequent report. ASPR also conducts staff-level engagements and meetings to identify root causes and opportunities to improve.

Community Mitigation and Recovery

The Office of Community Mitigation and Recovery provides services through the following 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 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) program 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 from overseas locations, 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 response teams have the ability to deploy internationally, if needed, by overseeing international 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. MEO routinely (monthly) meets with Public Health Agency of Canada to discuss emergency management and to collaborate cross boarder public health and medical issues. MEO continues to build relationships with other international partners and the Department of State, aligning closely with the ASPR preparedness and response priorities and mission, and Global Health Security Initiatives (GHSI).

Pediatric Disaster Care Initiative

The Pediatric Disaster Care Initiative continues to build on progress made since its inception in FY 2019 with the funding of two Pediatric Disaster Care Pediatric Centers of Excellence (COE) multi-state cooperative agreements that target the development and sharing of appropriate planning and response capabilities that will support the specific needs of children during public health emergencies and disasters, such as mass casualty incidents. Through the COEs, ASPR is addressing known gaps in the disaster care of children 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, COVID-19, and other emerging infectious disease, burn, and chemical/biological/radiological/nuclear (CBRN) incidents. The goal is to enhance the nation's capacity and capabilities to provide specialized care for injured and ill children in the United States.

The Pediatric COEs are building 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 developing improved 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 and national training exercises.

HHS emPOWER Program

The [HHS emPOWER Program](#) (emPOWER) is at the forefront of innovating and 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 4.4 million individuals who live independently and rely on life-maintaining electricity-dependent durable medical and assistive equipment and devices² and essential healthcare services.³ Using Medicare data, emPOWER provides NDMS, public health authorities (PHA), 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

² 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.

³ Essential health care services include outpatient facility dialysis, home oxygen tank services, home health care services, and home hospice care services.

and timely information on at-risk, Medicare populations to safeguard health, reduce health care system surge, and advance health equity in their emergency preparedness, response, recovery, and mitigation activities across 13 emergency support functions⁴ and 13 sectors⁵.

Demand for publicly accessible tools has sharply increased, with more than 11,000 individuals in FY 2021 alone using the HHS emPOWER Map to inform and support emergency preparedness, response, recovery, and mitigation activities for the pandemic and numerous disasters nationwide. The program adopts an agile innovation process to meet federal-to community user needs and demand by rapidly identifying and developing new tools and resources to ensure federal to community 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. Additionally, in FY 2021, 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 and community partners within seconds, wherever they are.

Funding History	
Fiscal Year	Amount
FY 2019	\$73,404,000
FY 2020	\$57,404,000
FY 2021 Final	\$63,404,000
FY 2022 CR	\$63,404,000
FY 2023 President's Budget	\$130,030,000

Budget Request

The FY 2023 President's Budget request for NDMS is \$130,030,000, which is +\$66,626,000 above FY 2022 CR. The request includes \$6,000,000 to continue the Pediatric Disaster Care program.

NDMS Intermittents: Building on the FY 2023 request, the budget proposes an additional +\$50,000,000 above the FY 2022 CR to support efforts to expand the number of NDMS intermittents. 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,

⁴ 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-15); Public Safety and Security (ESF-13); Cross-Sector Business and Infrastructure (ESF-14), and; External Affairs (ESF-15).

⁵ 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.

credential up to 2,600 new clinicians, conduct security background checks and ensure operational support for deployed teams.

Within this total increase, \$3.4 million would add 14 FTE to provide support to the program, such as administrative, training, operations, and patient movement. For example, staff would develop and track training requirements, validate credentials of new staff, ensure all pre-deployment requirements are met, manage deployments, and oversee and process travel authorizations and travel vouchers.

NDMS Caches: The President's Budget also proposes an additional +\$13,223,000 to maintain NDMS's caches and equipment. Funds would be used to award contracts for the improved maintenance and replenishment upgrades of NDMS kits and caches. Funds also will be used for cleaning, repair, reconditioning, and preventive maintenance of medical devices and the IT and communications equipment included in NDMS caches. This funding will ensure that all of current approximate 1,200 NDMS kits and caches can be maintained in deployable status for immediate response to any requirement. Funding for maintenance and replenishment of NDMS kits and caches is needed and reimbursable funds through Federal Emergency Management Agency (FEMA) mission assignments or other emergency response funds cannot appropriately be used to award the necessary contracts for management of NDMS assets before or after an associated deployment. The funding will support the maintenance of cache readiness for both deployments and training.

ASPR National Disaster Medical System - Outputs and Outcomes Table**Program: National Disaster Medical System**

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 Target
1.1 Maintain the percent of new NDMS intermittent staff that complete psychological first aid training (Output)	FY 2021: 16 % Target: 100 % (Target Not 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 (Intermediate Outcome)	FY 2021: 130,610 trained Target: 88,826 trained (Target Exceeded)	110,322 trained	118,494 trained	+8,172 trained
1.4 Maintain the percent of NDMS intermittent staff who complete basic, advanced, or specialized training (Intermediate Outcome)	FY 2021: 17 % ⁶ Target: 35 % (Target Not Met)	20 %	35 %	+15 percentage points

⁶The program has funding to send 17% of the workforce for specialized training during 2021.

Medical Reserve Corps

Budget Summary

(Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	6.000	6.000	6.240	+0.240
FTE	6	12	12	-

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 Medical Reserve Corps (MRC) is a national network of over 300,000 volunteers organized into approximately 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 most 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 ASPR does not have direct operational or tactical control over them.

MRC units are active in their communities, as evidenced by the over 18,000 activities reported during FY 2021. According to unit reporting, MRC volunteers contributed over 2.7 million hours of service. (As a point of reference, prior to the COVID-19 pandemic, in FY 2019 the MRC network contributed roughly 300,000 volunteer hours.) The total economic value of this contribution, which included the efforts of a variety of medical professionals, is estimated at over \$91 million. 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 over 300,000.

More than 600 MRC units in 48 states, the District of Columbia, Puerto Rico, American Samoa, and the Northern Mariana Islands have supported their communities in a wide array of responses to the COVID-19 pandemic, including: assisting with community screening and testing operations; COVID-19 vaccination administration; 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 (for example, assisting elderly and vulnerable community members with well check calls,

food distribution, errands, and medication pick-up); and logistics support (e.g., inventorying, packing, and distributing personal protective equipment). The network's contributions to COVID-19 vaccination efforts are especially noteworthy.

The following includes a sample of MRC COVID-19 related activities and accomplishments during FY 2021:

- Hampshire County MRC (MA) volunteers supported regional emergency vaccine dispensing efforts in Northampton & Amherst. Volunteers contributed over 19,000 hours.
- Orange County MRC (NY) volunteers assisted county employees with administering vaccine second doses. Over 2,200 doses were delivered to the community. Volunteers contributed over 500 hours.
- New York City MRC (NY) administered the COVID-19 vaccine to the community. Volunteers also documented the administration of the vaccine and managed the vaccine supply. Volunteers contributed over 49,000 hours.
- District of Columbia MRC (DC) volunteers performed medical sample extractions, medical screenings, patient registration, and other duties. Volunteers contributed over 45,000 hours.
- The Allegheny County Health Department MRC (PA) provided staffing for a county-level point of dispensing (POD) COVID-19 vaccination clinic. Volunteers assisted with registration support and mass vaccination. Volunteers contributed over 21,000 hours.
- Shelby County Health Department MRC (TN) utilized MRC volunteers, both medical and non-medical to assist with a city-wide COVID-19 vaccination POD. Volunteers contributed over 9,000 hours.
- Carroll, Stark and Tuscarawas MRC (OH) provided direct support to their county-wide vaccination campaign. Volunteers were utilized in all facets of the campaign. Volunteers contributed over 8,000 hours.
- The University of Texas at Austin MRC (TX) helped coordinate volunteers and supervise vaccine efforts in partnership with UT Austin. Volunteers contributed over 25,000 hours.
- The Alamo Area MRC (TX) provided support to San Antonio Metropolitan Health District. A POD operation was activated at the Alamo dome where COVID-19 vaccines were given to the community. Volunteers contributed over 21,000 hours.
- Tama County MRC (IA) assisted at a COVID-19 vaccination POD for Tama County residents and Iowa residents. Volunteers contributed over 500 hours.
- The Central Nebraska MRC (NE) volunteers assisted at a COVID-19 Testing Site. Volunteers contributed over 200 hours.
- Summit County Utah MRC (UT) staffed COVID-19 vaccination clinics. Volunteers contributed 12,000 hours.
- El Paso County MRC (CO) volunteers were requested to assist staff in homeless shelters in assessing which residents might be COVID-19 infected. Volunteers contributed over 700 hours.
- Sonoma County MRC (CA) assisted with the COVID-19 hotline, N-95 fit test training, contact tracing, vaccination, meal delivery, and an in-home vaccination project. Volunteers contributed over 10,000 hours.
- Public Health MRC of Seattle and King County (WA) volunteers supported a COVID-19 mass vaccination site in Kent, WA. Volunteer support enabled residents of Kent, WA and surrounding communities to access the vaccine, many of whom experienced barriers. Volunteers contributed over 4,000 hours.
- Pierce County MRC (WA) volunteers partnered with many community agencies and conducted COVID-19 vaccination clinics. Volunteers contributed over 3,000 hours.

Units have also responded to other public health emergencies caused by natural disasters, including tornadoes, extreme cold weather, and hurricanes. Other recent MRC activities and accomplishments include the following:

- Pomperaug Health District MRC (CT) medical volunteers assisted with the launch of a new blood pressure self-management program, designed to help older adults take control of hypertension and other chronic health conditions.
- Rhode Island MRC (RI), Franklin County and Columbus MRC (OH), and Northeast Missouri MRC (MO) provided flu vaccines to their communities.
- Philadelphia MRC (PA) assisted with the screening, triage, and interpretation for the displaced Afghan refugees at the Philadelphia international airport.
- NC Baptist Men MRC Central Region (NC) provided first aid during Hurricane Ida disaster relief response.
- Calcasieu MRC (LA) assisted with Hurricane Laura response and recovery.
- Marion County MRC (OR) distributed water to the community members that returned after a wildfire, as water system was damaged and not functioning.

At the national level, the MRC program continued its cooperative agreements with the National Association of County and City Health Officials (NACCHO) and the state of Utah. Under the NACCHO cooperative agreement, 137 MRC units received 2021 Operational Readiness Awards in early 2021 totaling over \$1.2 million, and 43 MRC units received awards totaling over \$360,000 under a second round of awards in late Spring 2021. The awards support efforts to build and strengthen MRC capabilities, raise stakeholder awareness of MRC capabilities, and initiate or sustain integration of the MRC into local, state, and/or regional emergency response plans. The MRC program also initiated a new five-year cooperative agreement for a learning management system available to all units. In addition, the MRC program launched a new MRC reporting website in July 2021 which better enables unit leaders to report their activities and provide profile information. The profile information in turn helps members of the public identify whom to contact to volunteer with a unit, while the activity information helps MRC leaders and the MRC Program learn about network-wide activities. By learning about the MRC network's activities, the MRC Program can highlight best practices, share ideas for activities with the network, and identify opportunities for collaboration between units and potential partner organizations.

Funding History	
Fiscal Year	Amount
FY 2019	\$6,000,000
FY 2020	\$6,000,000
FY 2021 Final	\$6,000,000
FY 2022 CR	\$6,000,000
FY 2023 President's Budget	\$6,240,000

Budget Request

The FY 2023 President's Budget request for the civilian volunteer MRC is \$6,240,000, which +\$240,000 above the FY 2022 CR. This funding builds on the American Rescue Plan (ARP) supplemental appropriations funding to support 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 cooperative agreements, including the award

that supports the system available to units to access and track training, and for the system used for maintaining unit profiles and activity reporting. The request maintains the proposed increase from the FY 2022 President's Budget to support cooperative agreements and enable additional sub-recipient 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 can 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)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	280.555	280.555	291.777	+11.222
<i>HPP Annual Cooperative Agreement (non-add) /1</i>	<i>231.500</i>	<i>231.500</i>	<i>240.000</i>	<i>+8.500</i>
<i>Regional Disaster Health Response System Cooperative Agreement (RDHRS) (non-add)</i>	<i>8.500</i>	<i>8.500</i>	<i>7.000</i>	<i>-1.500</i>
<i>National Special Pathogen System (NSPS) (non-add)</i>	<i>11.000</i>	<i>11.000</i>	<i>11.000</i>	<i>-</i>
<i>National Emerging Special Pathogens Training and Education Center (NETEC) (non-add)</i>	<i>5.000</i>	<i>5.000</i>	<i>5.000</i>	<i>-</i>
<i>Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs) (non-add)</i>	<i>6.000</i>	<i>6.000</i>	<i>6.000</i>	<i>-</i>
<i>Other costs (non-add) /2</i>	<i>29.555</i>	<i>29.555</i>	<i>33.777</i>	<i>+4.22</i>
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 Division of Community Mitigation & Recovery.				

Authorizing Legislation:

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

Program Description and Accomplishments

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

The Hospital Preparedness Program (HPP) and the other programs and activities funded under the HPP line item support the ASPR mission by strengthening health care sector readiness to providing coordinated, life-saving care in the face of emergencies and disasters. HPP is providing an unprecedented level of support to health care entities and workers on the front lines during the COVID-19 pandemic, while continuing to manage a broad portfolio of all-hazards health care preparedness programs and activities to mitigate impacts of manmade threats and natural events (e.g., wildfires and hurricanes) across the country.

As the COVID-19 pandemic continues to evolve, communities also continue to respond to concurrent public health emergencies and disasters. As the nation prepares for the all-hazards threats of tomorrow, it will be paramount to incorporate promising practices and lessons learned to build resilience into our nation's health care delivery system. Support for the portfolio of programs and activities within the HPP budget build and sustain health care readiness and resilience at every level – local, state, regional, and national. ASPR has already identified opportunities to evolve health care preparedness and response, including leveraging its individual programs and activities to drive toward an integrated, national system

for health care readiness through which all components work together systematically. Looking forward, ASPR will: continue to support health care on the front lines; sustain and expand programs that address critical gaps in the nation's readiness, including those integral to the COVID-19 response; and create and disseminate promising practices and protocols to drive coordinated health care readiness.

The programs and activities within the HPP budget – such as 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), Critical Infrastructure Protection (CIP), Community Mitigation and Recovery, and more – represent a collection of building blocks that form a comprehensive, national system for health care preparedness and response. The programs and activities funded through the HPP budget are crucial components for a comprehensive, national network for health care preparedness and response. ASPR works across its portfolio, with state, local, tribal, and territorial (SLTT) partners, within HHS, across the federal interagency, and with private sector stakeholders to create connection points between these initiatives.

To sustain a holistic health care readiness portfolio that meets the nation's needs now and into the future, ASPR's programs and activities require continued support and resources. ASPR will continue to innovate and evolve to address key priorities, such as:

- Increasing patient surge capacity;
- Improving access to specialty medical care, including chemical, biological, radiological, and nuclear (CBRN) events;
- Enhancing health care situational awareness;
- Expanding telehealth capabilities, especially for critical care;
- Improving patient transport and tracking;
- Integrating health equity considerations into readiness planning, which account for the needs of at-risk populations;^{7,8}
- Strengthening health system readiness through integration, collaboration, and coordination with entities across the health care continuum.

ASPR has identified opportunities to address these priorities and mitigate gaps, by promoting collaboration across the public and private sectors, sustaining and expanding regional readiness models, providing training and education resources for special pathogen care, and integrating special pathogen care frameworks into all-hazards readiness approaches.

⁷ Health equity, as defined by the [Health Resources & Services Administration \(HRSA\) – Office of Health Equity](#), is the absence of disparities or avoidable differences among socioeconomic and demographic groups or geographic areas in health status and health outcomes such as disease, disability, or mortality.

⁸ This document uses the term “at risk individuals” broadly, recognizing that this term encompasses a vast range of people and experiences, and fluidly, recognizing that each unique emergency or disaster may have different impacts on different individuals and groups. For example, at-risk individuals may include (but are not limited to) those “at higher risk for health disparities by virtue of their race or ethnicity, socio-economic status, geography, gender, age, disability status, or other risk factors including those associated with sex and gender” ([HRSA 2019-2022 Strategic Plan](#)); children, older adults, and pregnant women (as specified by the [Public Health Service Act](#)); individuals with access or functional needs, who live in institutionalized settings, who are from diverse cultures, who have limited English proficiency or are non-English speaking, who are transportation disadvantaged, who have chronic or complex medical conditions ([ASPR – At Risk Individuals](#)); and many others.

ASPR has laid the groundwork through the HPP portfolio of readiness programs and activities; however, a system-wide approach is needed to advance these programs and activities from individual initiatives to a fully developed, high-functioning national system for preparedness and response.

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

As the primary source for the nation's federal funding for health care delivery system preparedness and response, HPP promotes the improvement of patient outcomes during emergencies and enables rapid health care service resilience and recovery. Since 2002, investments administered through HPP improved individual health care entities' preparedness and built a foundation for coordinated health care delivery system readiness and response through health care coalitions (HCCs) and other partnerships that integrate with HCCs, such as the RDHRS demonstration project. During COVID-19, HPP leveraged its strong network to provide effective supplemental funding to health care entities on the front lines of the pandemic. These coalitions and partnerships coordinate activities across the local, state, regional, and national levels to ready health care delivery systems for disasters and emergencies – including developing mechanisms for effective patient movement, communicating situational awareness, and sharing resources. HPP enables individual facilities and coalitions to access a national response network, empowering health care delivery systems across the nation to save lives and protect Americans from health security threats.

ASPR developed the *2017-2022 Health Care Preparedness and Response Capabilities*⁹ (the Capabilities) to further inform and support health care delivery system preparedness. The Capabilities describe what the health care delivery system, including HCCs, hospitals, and emergency medical services (EMS), must do to effectively prepare for and respond to emergencies that affect the public's health. These capabilities include having: – 1) a strong foundation in health care and medical readiness, 2) an ability to coordinate health care and medical response efforts, 3) a plan for continuity of health care service delivery, and 4) a plan for medical surge – illustrate the range of preparedness and response activities that, if conducted, represent the ideal state of readiness in the U.S.

These capabilities are flexible enough to encourage all-hazards planning, including for natural disasters, terrorist events, infectious disease outbreaks, or industrial accidents, and to address all populations. From FY 2017 to FY 2020, HCCs collectively made significant improvements in FY 2020 in Health Care and Medical Response Coordination, which reached over 90 percent of full capacity.¹⁰

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

HPP performance measures enable ASPR to evaluate program performance and recipient progress toward achieving the objectives of the HPP cooperative agreement. To measure this, ASPR developed performance measures at the input, activity, output, and outcome levels. Key performance measures for outcome measurement are produced by an annual medical surge exercise, the Medical Response and Surge Exercise (MRSE). The MRSE is designed to examine and evaluate the ability of HCCs and other stakeholders to support medical surge, and specifically, how coalitions do the following: help patients

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 Ibid.

receive the care they need at the right place, at the right time, and with the right resources during medical surge; decrease deaths, injuries, and illnesses resulting from medical surge; and promote health care delivery system resilience in the aftermath of medical surge.

ASPR continues to apply rigorous analysis to better understand performance, trends, and new insights about national readiness. Starting in FY 2020, ASPR began to collect additional qualitative data to analyze themes across all recipients and take individual recipients' responses and unique situations into account when assessing performance and trends for readiness. These trends and highlights can be found on the [recipient fact sheets](#) webpage on ASPR.HHS.gov.

Health Care Coalitions (HCCs)

Since 2012, HPP's formula-based cooperative agreement program has required its recipients to invest in HCCs.¹¹ 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 #8 (ESF-8) activities in the context of incident command system responsibilities. 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 trained health care personnel. HCCs incentivize diverse and often competitive, health care organizations with differing priorities and objectives to work together. As of June 30, 2021, there are currently 43,789 HCC member organizations participating in 321 HCCs nationwide.¹² ASPR requires that each HCC funded by cooperative agreement recipients include, at minimum, the following core members: two acute care hospitals, public health agencies, EMS, and emergency management agencies.

The number of HCC members has more than tripled since HPP began focusing on regional health care coordination in July 2012. HCC membership diversity and the participation rates by member type, as of June 30, 2021, include 4,975 acute care hospitals participating in HCCs, which represents 91 percent of all U.S. acute care hospitals. Additionally, there are 4,385 EMS agencies participating in HCCs, which represents 43 percent of all U.S. EMS agencies.¹³

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 case surge. HCCs collected, analyzed, and managed information to support rapid patient distribution to appropriate facilities, patient tracking, family support, information coordination, and resource and transportation management. HCCs also disseminated specialty care knowledge to inform response and timely requests for additional resources.

¹¹ 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.

¹² The data used here were taken from EOY performance data from the HPP FY 2020/BP 2 (July 1, 2020 through June 30, 2021); FY 2021/BP 3 EOY data (July 1, 2021 through June 30, 2022) will be validated by mid-late October or early November 2022).

¹³ The data used here were taken from EOY performance data from the HPP FY 2020/BP2 (July 1, 2020 through June 30, 2021).

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. ASPR designed its other initiatives to complement and build upon the HCC model as well as address gaps in coordination and capacity. These other initiatives include regional systems for preparedness and response, such as the RDHRS, as well as national assets, such as the NSPS. Together, HCCs and these other 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.

Creating the National Special Pathogen System (NSPS)

Successful public-private partnerships have been formed to develop national systems 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, which similarly leveraged public-private partnerships to strengthen health care response capabilities during the Ebola response of 2014-2015. The NSPS builds on the Regional Ebola Treatment Network 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 recently demonstrated utility for COVID-19 response efforts, the intent of the NSPS is to create a nationwide network approach for all special pathogens.

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), 10 Regional Ebola and other Special Pathogen Treatment Centers (RESPTCs), 62 HPP recipients, and 53 hospital associations, which ASPR added as new recipients supported through COVID-19 supplemental funding. These components act as foundational building blocks for a tiered, national system for special pathogen identification, research, and treatment. In 2021, NETEC developed the National Special Pathogen System of Care Strategy¹⁴ to evolve and scale the NSPS's focus on coordination and standardization of patient care, promoting greater equity across the health care continuum and leveraging public-private partnerships to strengthen health care response capabilities for special pathogens in the future. By executing the National Special Pathogen System of Care Strategy, the NSPS will be better able to ready the nation's health care delivery system for special pathogen response, to coordinate health care's response across localities, states, and regions, and to establish a national infrastructure for special pathogen response more broadly.

National Emerging Special Pathogens Training and Education Center (NETEC)

The NETEC is a critical component of the NSPS. NETEC is a consortium of three U.S. academic medical centers that develop and share promising practices for special pathogen care – Emory University in Atlanta, Georgia; University of Nebraska Medical Center/Nebraska Medicine (UNMC) in Omaha,

¹⁴ For additional information on the National Special Pathogen System of Care Strategy, please refer to the website: <https://nsps.org/>

Nebraska; and the New York City Health and Hospitals Corporation (HHC) Bellevue Hospital Center in New York, New York. 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. NETEC¹⁵ has significantly influenced and improved the U.S.'s overall preparedness and response capabilities for current and future special pathogen events. The consortium has engaged and educated stakeholders, promoted grassroots relationship building, and fostered the ongoing exchange of promising practices among 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 the response to COVID-19, a new special pathogen. This network consists of research sites at each of the 10 RESPTCs, supported by centralized resources, including a common rapid response institutional review board, a data repository, a biorepository, research training protocols, and standardized policies. 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) and the Adaptive COVID-19 Treatment Trial (ACTT). NETEC's special pathogen research network also supported all 10 RESPTCs in isolating the first patients with COVID-19 and returning them safely to their families and supported patient enrollment in Remdesivir treatment trials for COVID-19.

During the response, NETEC pivoted to conducting virtual site visits with the 10 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, members of NETEC leadership provided a depth of expertise in their contributions as speakers and/or panelists.

Through the response to COVID-19, NETEC demonstrated its impact in improving national preparedness and response for special pathogens. NETEC's key accomplishments for FY 2021 include conducting 42 virtual and in-person readiness and response consultations, hosting 30 COVID-19 webinars, and establishing tools, such as a 24/7/365 phone line for emergency consultation with federal partners for health care facilities requiring assistance with patients suspected of being infected with, or confirmed to be infected with, special pathogens. In addition to offering webinars, NETEC also developed online courses and resources on important topics, such as dialysis and COVID-19, care of labor and delivery patients, and caregiver resilience. The most popular offering, viewed by over 500,000 people, was a YouTube video demonstrating how to safely use PPE. NETEC also provided virtual and on-site technical assistance to long-term care centers specifically, optimizing protocols to keep residents and staff safe.

¹⁵ 2020 NETEC Annual Report https://netec.org/wp-content/uploads/2020/12/NETEC-FY20-Annual-Report_12.2020.pdf.

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 Systems (RDHRS): a tiered system that builds upon and unifies existing health care and ASPR assets within states and across regions that supports a more coherent, comprehensive, and capable health care disaster response system able to respond to health security threats. The RDHRS helps improve disaster readiness capabilities and capacity, increase medical surge capacity, and extend provision of specialty care – including trauma, burn, and infectious disease, among others – during large-scale disasters or public health emergencies. Current sites include the Region 1 RDHRS, based at Massachusetts General Hospital; the Region 7 Regional Disaster Health Response Ecosystem (RDHRE), based at UNMC; the Region 8 Mountain Plains RDHRS, based at Denver Health and Hospital Authority; and the Region 4 Southern Regional Disaster Response System (SRDS), based at Emory University. The demonstration sites in Region 1 and Region 7 were initiated in FY 2018, the Region 8 site was initiated in FY 2020, and the Region 4 site was recently initiated in FY 2021.

RDHRS core capabilities include increasing coordination and collaboration across health care partners; providing clinical experience to support medical surge planning; optimizing clinical surge capacity and access to clinical specialists (e.g., pediatrics, trauma and burn care, and infectious disease); increasing situational awareness of health care delivery system capability and capacity; and training on regional response capabilities. Importantly, RDHRS sites are not standalone structures. They foster and leverage strong partnerships across all levels of government, and existing SLTT, regional, and national assets and structures. As a result, RDHRS work can serve to unify efforts across trauma centers and facilities, burn centers, HCCs, EMS systems and networks, and more. The mature sites have significantly improved clinical collaboration across the private health care sector in their states and initiated strategies to expand collaboration across their multi-state HHS regions.

Providing and Sharing Critical Information to a Nationwide Audience

Since FY 2015, the ASPR [TRACIE](#) website has been continually operational and available and includes [nearly 10,000 resources](#). The team works closely with several SMEs to provide technical assistance to state and local communities to both enhance their preparedness and response capabilities and ensure that stakeholders can readily access and download virtual resources as needs arise.¹⁶ Aligned with HPP's programmatic goals and priorities, ASPR TRACIE is committed to expeditiously connecting stakeholders with the right resources and experts.

Since ASPR TRACIE's launch, the platform has experienced an exponential increase in use and demand, from a few hundred visitors per month to current monthly web visitations surpassing 16,000 visits. Cumulative visitor volume reached over 1.3 million as of January 2022. ASPR TRACIE experiences spikes in both technical assistance requests and website visitation statistics during times of declared national emergencies, local disasters, and when offering widely promoted resources (e.g., webinars) and highly anticipated tools and templates – particularly those that can help stakeholders mitigate threats related to pending, active, or recent incidents. The team also provides surge assistance and resources to assist ASPR and local deployable personnel (e.g., NDMS, Medical Reserve Corps). In addition, ASPR TRACIE has:

¹⁶ ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) Homepage, <https://asprtracie.hhs.gov>.

- Consulted with more than 1,100 SMEs to develop and review new resources and augment responses to TA requests;
- Published nearly 450 [SME-validated resource materials](#);
- Created resource pages dedicated to topic areas of particular interest to our stakeholders (e.g., [CMS and Disasters](#), [CBRN](#), [Cybersecurity](#), [HCCs](#), [Infectious Disease](#), [Mass Violence](#), [Hurricanes](#), [Drug Shortages and Scarce Resources](#), [Emergency Medical Services](#), , [COVID-19 and COVID-19 Patient Surge and Scarce Resource Allocation](#));
- Developed and continuously maintained 59 SME-reviewed [topic-specific collections](#), including new collections on Disasters and Healthcare Disparity and Climate Change and Healthcare System Considerations;
- Developed and continuously maintained 20 COVID-19 specific [resource collections](#);
- Enabled user access to online plans, tools, templates, and trainings; and,
- Published 14 issues of [The Exchange](#) featuring lessons learned from the field.

HCCs are required to develop coalition-level annexes to their base medical surge/trauma mass casualty response plans to manage many casualties with specific needs (e.g., specialty care for burn, infectious disease, radiation/chemical injuries). In 2021, at ASPR's direct request to support its cooperative agreement recipients, TRACIE [developed HCC templates and tabletop exercises](#) toolkits for the Radiological Emergency Surge Annex and Chemical Emergency Surge Annex.

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

- Conducted [national webinars](#) and provided virtual [TA](#) to help better inform HPP recipients and their HCCs on several preparedness topics;
- Conducted a multi-phased effort to [capture lessons learned from HCCs response to COVID-19](#);
- Developed [radiological and chemical emergency surge annex templates and tabletop exercise \(TTX\) toolkits](#) for HCCs;
- Conducted online peer-to-peer engagement and support through the Information Exchange; and,
- Developed resource documents, tip sheets, and illustrative examples of promising practices (e.g., [After Action Report Resources and Examples](#); [Therapeutics and Supply Chain](#), [Healthcare Professional Stress and Resilience](#), [Patient Surge](#), [Role of Support Services During COVID-19](#), and [Pediatrics](#)).

ASPR TRACIE has focused on developing a robust collection of highly infectious disease resources and materials. In addition to maintaining its Novel Coronavirus Resource Page and 20 COVID-19 specific resource collections, in 2021, ASPR TRACIE [developed nearly 100 new resources](#). With the help of our stakeholders, we were able to address the multitude of challenges the year brought with it, from patient load balancing and crisis standards of care to civil unrest, workplace violence, and severe winter weather. 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, resilience, and recovery.

Managing Healthcare and Public Health (HPH) Sector Infrastructure Risks

ASPR's [Critical Infrastructure Protection \(CIP\) program](#) promotes the resilience of the nation's health infrastructure by leading a dynamic public-private partnership, drawing from all aspects of the HPH

Sector, to prepare for future threats, identify and manage risks, and coordinate effective response. CIP coordinates HPH Sector Risk Management Agency (SRMA) activities on behalf of HHS, as defined by the 2021 National Defense Authorization Act (NDAA). As SRMA, CIP is responsible for providing specialized expertise to critical infrastructure owners and operators and federal, state, local, tribal and territorial leaders (FSLTT). CIP draws from expertise across the Sector and HHS to organize the partnership to identify, analyze, and mitigate key risks and enhance Sector resilience. The NDAA codified six core SRMA responsibilities:¹⁷

1. Assessing sector risk;
2. Supporting sector risk management;
3. Coordinating across the HPH Sector;
4. Facilitating information sharing;
5. Contributing to emergency preparedness efforts; and,
6. Supporting incident management.

CIP leads cybersecurity efforts across its varied partners through the Joint Cybersecurity Working Group,¹⁸ a structure established through the Critical Infrastructure Partnership Advisory Council (CIPAC) in partnership with the U.S. Department of Homeland Security (DHS). The Working Group's mission is to align security approaches to manage threats and protect the critical infrastructure of the HPH Sector. Through the coordinated activities of its 12 Task Groups, the Working Group accomplishes this mission by mobilizing government and private sector partners to assess risks, identify and share mitigation measures, and enable information sharing among public and private sector stakeholders to support cybersecurity emergency response, recovery, and future mitigation. Through the Working Group, CIP coordinates with the private sector to optimize messaging on current and future threats and vulnerabilities to reach large, medium, and small industry partners and share priority mitigation measures.

CIP directly contributes to ASPR's health care readiness programs by using its unique role as SRMA (formerly referred to as the Sector-Specific Agency^[OBJ]) to manage risks and identify strategies¹⁹ by aligning public and private stakeholders to identify and mitigate supply chain risks and support supply chain visibility.

To carry out its complex statutory requirements and support national strategies, CIP engages public and private sector partners through the CIPAC framework. This collaborative structure, organized and maintained by CIP, facilitates public-private partnerships that enable better implementation science to strengthen health care readiness, response, and recovery. These partnerships enable data-driven implementation efforts which, in turn, bolster ASPR's mission-critical role in all-hazards preparedness, response, recovery, and mitigation.

¹⁷ FY 2021 National Defense Authorization Act, Section 2215 Sector Risk Management Agencies, Part A - [Text - H.R.6395 - 116th Congress \(2019-2020\): William M. \(Mac\) Thornberry National Defense Authorization Act for Fiscal Year 2021 | Congress.gov | Library of Congress.](#)

¹⁸ Healthcare Sector Coordinating Council Cybersecurity Working Group Charter - <https://healthsectorcouncil.org/hssc-cybersecurity-working-group-charter/>

¹⁹ National Strategy for a Resilient Public Health Supply Chain. Retrieved from: <https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf>

COVID-19 Supplemental Funding Impacts

Through infusions of COVID-19 supplemental funding, ASPR conducted a host of activities to support preparedness and response against the pandemic and resultant surges. These activities included expanding the NSPS, 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 an 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). ASPR used emergency COVID-19 supplemental funding to transform the Regional Ebola Treatment Network to support the urgent preparedness and response needs of hospitals, health systems, and health care providers on the frontlines of the COVID-19 outbreak. This support helped prepare health care providers to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens, or persons under investigation for such illnesses.

Two of the NSPS components, hospital associations and HPP recipients, which provided funding to state and jurisdiction Special Pathogen Treatment Center (SPTC) sub-recipients, specifically received COVID-19 emergency supplemental funding. Hospital associations were a new targeted recipient for awards and served as a mechanism to distribute funding more directly to hospitals and other related health care entities for special pathogen preparedness and response. Through the supplemental funding, hospital associations were able to make rapid funding distribution decisions at their discretion for health care entities rather than through the traditional route of public health departments, who were significantly burdened by their COVID-19 response activities. In FY 2020, hospital associations distributed funding to 3,740 sub-recipients across all 10 HHS regions. Sub-recipients included acute care hospitals, hospital systems, specialty care centers, home/residential care entities, health care delivery systems, support services, outpatient/ambulatory care, and other facilities.²⁰ Initial insights from hospital association data collection efforts include:

- The majority of funding spent by hospital associations and sub-recipients was used for the procurement and optimization of PPE and other supplies and equipment. Fifty-nine percent of sub-recipients who funded this activity reported instituting PPE optimization strategies. When sub-recipients did procure supplies and equipment, the most procured supplies and equipment were face masks and face shields followed by gowns;
- Hospital associations indicated that the most positive outcome of updating preparedness plans to include COVID-19 and pandemic preparedness was updated guidance and policies, but expressed facing challenges in implementing preparedness and response plans for COVID-19 due to staff equipment/supply shortages; and,
- Hospital associations found that leveraging partnerships and utilizing non-traditional suppliers and supplies to be the most successful supply and procurement tactics.

²⁰ Hospital Association COVID-19 Preparedness and Response, FY 2020 EOY data (period of performance was April 10, 2020 – April 9, 2021).

In addition, the cooperative agreement funding mechanism and distribution approach through the hospital associations proved effective to quickly distribute funding at the recipient's discretion to support the COVID-19 response. In the future, ASPR may explore using hospital associations as a funding mechanism to strengthen all-hazards readiness.

When launching support for health care on the frontlines of the COVID-19 pandemic response, ASPR included HPP cooperative agreement recipients and state and jurisdiction SPTCs as a key component of the NSPS. SPTCs are staffed, equipped, and assessed to have current capabilities, training, and resources to provide the complex treatment necessary to care for a special pathogen patient while minimizing risk to health care workers and are essential for the NSPS to be truly operational at the state and jurisdiction level. For NSPS to become a national system of care that drives readiness for special pathogens at every tier, it is important to sustain components at all levels. In the future and with additional funding, NSPS intends to sustain a heightened level of health care preparedness for future public health and medical emergencies so that the U.S. is not again faced with the dire consequences of an unprepared private health care sector during a special pathogen event. While the NSPS was created through COVID-19 supplemental funding, ASPR plans to maintain critical capabilities developed through this system to improve and sustain a national system and enhance resilience against highly pathogenic threats.

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 Health Care Outcomes) rapidly stood up the 'COVID-19 Clinical Rounds,' a peer-to-peer learning network for real-time information sharing for lessons learned, successes, and challenges in treating COVID-19 patients, which has engaged participants in all 50 states and more than 100 countries.²¹ 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, Department of Transportation's NHTSA Office of EMS, the NETEC, professional societies, and hospitals.

Recent Clinical Rounds session topics include pediatric vaccinations, preventing and mitigating attacks against clinicians, addressing workforce shortages, treatment of unvaccinated patients, ethics and personal challenges in providing care, and the Omicron variant. As of December 2021, 170 sessions have been conducted, engaging 53,265 total participants globally. Archived session recordings have been viewed 16,209 times.²² In November 2020, 70 percent of participants strongly agreed that information provided by COVID-19 Clinical Rounds helped them provide better care for their patients, and 89 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 also conducted a mini-series on Outpatient Therapeutics, which provides a deep dive on new and emerging COVID-19 outpatient

²¹ Hunt et al. "Virtual Peer-to-Peer Learning to Enhance and Accelerate the Health System Response to COVID-19: The HHS ASPR Project ECHO COVID-19 Clinical Rounds Initiative." [https://www.annemergmed.com/article/S0196-0644\(21\)00248-1/pdf](https://www.annemergmed.com/article/S0196-0644(21)00248-1/pdf).

²² Data on Clinical Rounds from March 24, 2020 – December 3, 2021. Due to data limitations, total participation over the 165 sessions were measured (these numbers do not reflect the number of unique participants).

therapeutics, including monoclonal antibodies. As of December 2021, the HHS/ASPR COVID-19 Outpatient Therapeutics sessions have been viewed 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 10-week, virtual peer-to-peer learning community. Altogether, 75,186 total participants have attended the COVID-19 Clinical Rounds, the COVID-19 Outpatient Therapeutics sessions, and the Telemedicine Hack.²³

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, ASPR 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, managing supplies and equipment related to infection control during blood donations. ASPR's support contributed to the American Red Cross operating 192,000 blood drives, distributing 4,600,000 units of red blood cells and approximately 953,000 platelets, conducting 2,200,000 COVID-19 antibody tests, and distributing 5,570,000 units of PPE. By collaborating with the American Red Cross to meet new challenges and costs incurred by the COVID-19 pandemic, ASPR's support helped maintain blood supply and strengthened partnerships between the American Red Cross and HCCs also supported through HPP funding. ASPR's goal for this cooperative agreement was for health care to be able to quickly draw upon a strong blood supply and provide lifesaving treatments for Americans.

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

The COVID-19 pandemic 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. Telemedicine offers the opportunity for specialties such as critical care to be available to support hospitals in need, and potentially other care sites or to be employed with more traditional deployed teams such as those within NDMS.

To address this gap in care for patients most at risk for dying from COVID-19, the Department of Defense Telemedicine & Advanced Technology Research Center (TATRC), in consultation with the Society of Critical Care Medicine and collaboration with ASPR, developed the National Emergency Tele-Critical Care Network (NETCCN). The NETCCN was established during the COVID-19 public health emergency and funded by COVID supplemental appropriations. With ASPR's influence, TATRC and

²³ Ibid.

ASPR evolved NETCCN to be for all-hazards events 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 also 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, support leadership population-health decision making, and ultimately improve patient outcomes.

In 2021, the NETCCN supported 26 hospitals from nine states and two territories, representing nearly 5,000 patient care days. COVID-19 served as a forcing function in accelerating the significant need for an established and maintained telemedicine network to support disaster response across the United States. With the NETCCN, ASPR began to address some of those needs, starting with providing standardized, flexible critical care to health care partners nationwide that lack such resources. These capabilities enhance 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 2019	\$264,555,000
FY 2020	\$275,555,000
FY 2021 Final	\$280,555,000
FY 2022 CR	\$280,555,000
FY 2023 President’s Budget	\$291,777,000

Budget Request

The FY 2023 President’s Budget request for the Hospital Preparedness Program line item is \$291,777,000, which is an increase of \$11,222,000 above the FY 2022 Continuing Resolution (CR). ASPR will use part of these funds to sustain the four RDHRS demonstration sites, the 10 RESPTCs, and the NETEC.

ASPR will use \$240,000,000, an increase of \$8,500,000, 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. ASPR will provide this funding to the HPP cooperative agreement to meet and sustain capabilities developed during the COVID-19 response, to support increased coordination activities, and to effectively maintain response and recovery efforts. ASPR will also support continued technical assistance and oversight to HPP, RDHRS, RESPTC, and NETEC recipients, sub-recipients, and health care stakeholders. ASPR’s role expanded rapidly during COVID-19, with the addition of new recipients, sub-recipients, and stakeholders. ASPR supported a broad spectrum of stakeholders throughout the COVID-19 response and various concurrent events, including the Texas winter storms, Hurricane Ida, cyberattacks, and annual tornado seasons. In FY 2023, ASPR will use funds to effectively maintain and

strategically serve the expanded recipient pool of health care partners who continue to respond to and recover from surges created by COVID-19 and other incidents.

ASPR will use \$33,777,000, an increase of \$4,222,000, for management and administration of readiness programs and activities including ASPR TRACIE, Community Mitigation and Recovery, and CIP.

ASPR TRACIE will use funds to provide more direct support to stakeholders and develop additional resources focused on improving the equitable preparedness, response, and recovery efforts of health care entities and HCCs. With the increasing security risks and complex disasters, the nation continues to face, ASPR TRACIE must be nimble to anticipate and respond to stakeholder needs, creating meaningful and implementable resources for stakeholders to use before a disaster strikes and to respond to the just-in-time needs of stakeholders during and following disasters and emergencies.²⁴ This includes: developing tools and templates to address requirements in the updated Healthcare Preparedness and Response Capabilities; expanding the development of a supply needs and usage tool for hospitals; developing resources to promote patient load balancing/Medical Operations Coordination Cells (MOCCs); resources to address workplace violence; technical assistance for providers and suppliers affected by updates to the CMS Emergency Preparedness Rule; and supporting initiatives focused on health care disparities, ethics, and climate change impacts.

The Community Mitigation and Recovery program will integrate ASPR's community resilience-focused suite of programs and Recovery operations to help achieve a regionally based and nationally-coordinated system for community health resilience to public health emergencies and, especially, to extreme weather events caused by the global climate emergency. The two core focus areas of this initiative will be addressing the problem of disparities in post-disaster outcomes and supporting community resilience for the behavioral health effects of emergencies.

Historically, disasters and other public health emergencies have produced inequitable harms for communities of color, women, and members of the Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) community. These disparities have generally become more pronounced over the recovery timeline. Community risk-focused interventions in preparedness, recovery, and mitigation phases can introduce an equity lens to ASPR's national health security mission, and address racial, gender, and sexual orientation disparities in post-disaster health outcomes. As the long-term effects of the pandemic and extreme weather events emerge, it is increasingly clear that behavioral health impacts are a growing area of concern, with cascading problems for public health and economic recovery. To strengthen ASPR's ability to mitigate the behavioral health harms of disasters and public health emergencies, a particular focus on integrating population-level behavioral health solutions into disaster recovery and community resilience work is the other core focus of ASPR Community Mitigation and Recovery.

Lastly, ASPR will use funds to enhance CIP activities and mitigate risks to the health care sector. Funds will fulfill CIP's SRMA roles and responsibilities and will prioritize properly informing the HPH Sector, ASPR, HHS, and other stakeholders on the risks facing the critical infrastructure of the nation's health care system. This includes coordination across ASPR and HHS around how to best prepare public health and health care owners, operators, and providers, as well as to meet the required activities/outcomes of government mandates for the HPH Sector.

²⁴ See select ASPR TRACIE Developed Resources for additional information: <https://asprtracie.hhs.gov/tracie-resources>.

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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 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 % Target: 40% (Target Exceeded)	55%	55%	Maintain
15a Increase the percent of HCCs that have tested the ability to coordinate among its members during an exercise or event (Intermediate Outcome)	FY 2020: 95.8 % Target: 100% (Target Not Met but Improved)	100%	100%	Maintain

Public Health and Social Services Emergency Fund

Grant Awards By State (in whole dollars)				
CFDA NUMBER/PROGRAM NAME: 93.899 Hospital Preparedness Program				
State, Locality, Territory	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Alabama	\$3,145,268	\$3,145,268	\$3,352,678	+ \$207,410
Alaska	\$1,111,466	\$1,111,466	\$1,241,134	+ \$129,668
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
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
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
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

Public Health and Social Services Emergency Fund

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
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
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
Pennsylvania	\$7,702,626	\$7,702,626	\$7,719,170	+ \$16,544
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
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
Indian Tribes	--	--	--	--
Migrant Program	--	--	--	--
American Samoa	\$279,211	\$279,211	\$283,641	+ \$4,430
Guam	\$356,511	\$356,511	\$367,041	+ \$10,530
Marshall Islands	\$268,164	\$268,164	\$270,830	+ \$2,666
Micronesia	\$283,060	\$283,060	\$289,612	+ \$6,552
Northern Mariana Islands	\$278,796	\$278,796	\$286,534	+ \$7,738
Palau	\$255,889	\$255,889	\$257,040	+ \$1,151
Puerto Rico	\$2,590,019	\$2,590,019	\$2,499,222	- \$90,797
Virgin Islands	\$305,421	\$305,421	\$309,887	+ \$4,466
Total Resources	\$231,500,000	\$231,500,000	\$240,000,000	+ \$8,500,000

Note: FY 2023 amounts are estimates

Public Health and Social Services Emergency Fund

Grant Awards Tables			
Hospital Preparedness Program	FY 2021 Final	FY 2022 Enacted	FY 2023 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	\$257,040 - \$22,465,160

Preparedness and Response Innovation

Budget Summary (Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	2.000	2.000	2.080	+0.080
FTE	3	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 in the office of Strategy, Policy, Planning and Requirements 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.

The PRI program highlights the importance of ASPR's mission to develop technologies beyond chemical, biological, radiological, and nuclear medical countermeasures (MCMs) and to adapt technologies and practical solutions to ensure the availability of the highest standards of care, when they are needed the most. The program activities emphasize the revolutionary advancements in health security products, technologies, tools, and solutions, specifically to invigorate operations, response, recovery, deployment, and dispensing activities.

FY 2021 PRI funds, as required by Congress, are supporting joint U.S. and Israeli cooperative research and development. Priorities include development of health technologies and establishing a bilateral cooperative program with the Israeli government including but not limited to the following: artificial intelligence, biofeedback, sensors, monitoring devices, and kidney care.

Funding History	
Fiscal Year	Amount
FY 2019	-
FY 2020	-
FY 2021 Final	\$2,000,000
FY 2022 CR	\$2,000,000
FY 2023 President's Budget	\$2,080,000

Budget Request

The FY 2023 President's Budget request for PRI is \$2,080,000 which is \$80,000 above the FY 2022 CR. The increase will support added inflationary costs incurred by the program. 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.

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, 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: Funds will be used 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.

Biomedical Advanced Research and Development Authority

Budget Summary (Dollars in Millions)

	FY 2021	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	596.700	596.700	828.380	+231.680
<i>Advanced Research and Development (non-add)</i>	<i>335.600</i>	<i>335.600</i>	<i>447.380</i>	<i>+111.780</i>
<i>DRIVE (non-add)</i>	<i>29.100</i>	<i>29.100</i>	<i>76.000</i>	<i>+46.900</i>
<i>Combatting Antimicrobial Resistance (non-add)</i>	<i>118.000</i>	<i>118.000</i>	<i>185.000</i>	<i>+67.000</i>
<i>Operations and Management (non- add)</i>	<i>114.000</i>	<i>114.000</i>	<i>120.000</i>	<i>+6.000</i>
FTE	222	267	364	+97

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 the Assistant Secretary for Preparedness and Response (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 uses the Advanced Research and Development (ARD) appropriation to support 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 Chemical, Biological, Radiological, and Nuclear (CBRN) threats and other emerging threats, while also advancing our day-to-day public health and medical capabilities. 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 that is built on longstanding collaborations with the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and Department of Defense (DoD). Together with the Department of Homeland Security (DHS), Department of Veterans Affairs (VA), Department of Agriculture (USDA), and the Director of National Intelligence (DNI), these agencies constitute the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a body that is led by the ASPR and sets research and

development priorities under a five-year strategy and implementation plan. The PHEMCE, which re-started in February, 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 commercially available products that can be repurposed for MCM uses as well as developing multipurpose MCMs with both commercial and MCM potential. For products with commercial markets, BARDA often uses rotated stocks (e.g., vendor managed inventory systems) of MCM products to enable more cost-efficient alternatives to stockpiling products in the SNS that must be constantly replaced as products expire.

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 companies to large pharmaceutical companies. Though the majority of BARDA's partnerships involve Federal Acquisition Regulation (FAR)-based research and development contracts, BARDA continues to leverage 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, partnerships like this have 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, Ebola, and COVID-19, among other threats.

In July 2016, BARDA established the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), a 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 December 2021, CARB-X has funded 92 different candidates and currently has 58 active programs for the development of 39 therapeutics, eight vaccines, and 11 diagnostics. Nine CARB-X portfolio candidates have entered clinical development and two companies previously supported by CARB-X are now funded by BARDA, highlighting the success of this program in accelerating early-stage product development to the clinic site. Recognizing the value and impact that preclinical support from CARB-X to innovator companies brings to the overall goal of reducing the incidence of drug-resistant bacteria, BARDA has committed to continuing to support a CARB Accelerator for another ten years.

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 to 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:

- ***Manufacturing Innovation:*** In June 2012, BARDA established novel public-private partnerships with industry and academia through the Centers for Innovation in Advanced Development and Manufacturing (CIADM) to 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 have supported the COVID-19 pandemic response. The pandemic response effort, however, revealed

many of the limitations of this model including the lack of trained experts to perform the necessary manufacturing work. As a result, in FY 2021, BARDA ended the CIADM partnership with Emergent, leaving one remaining CIADM partnership with Texas A&M University System (TAMUS). Looking forward, BARDA has released a request for information (RFI) to establish a new consortium of manufacturing partners under a different model that will be referred to as the Biopharmaceutical Manufacturing Partnership (BioMaP). Under this new model, BARDA will leverage its Other Transaction Authority to engage with multiple manufacturing partners and suppliers of raw materials to meet the ambitious goals highlighted in the American Pandemic Preparedness Plan and the National Biodefense Strategy. BARDA anticipates establishing the consortium of partners in FY 2022.

- ***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, in 2016 BARDA partnered with two additional contractors with experience in viral vectored 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. The relationships previously developed through the FFMN and the more expanded Contract Development Manufacturing Organization (CDMO) Network were critical in ensuring filling capacity for several vaccine and therapeutic product sponsors and for rapidly responding to the current COVID-19 pandemic. The CDMO Network expands the network to not only fill-finish services but also to other outsourced capabilities that may be needed by BARDA-partnered product developers. The connectivity with these many private service providers is critical for BARDA’s preparedness posture for that next public health emergency.
- ***Nonclinical Development Network:*** Established in 2011, the Nonclinical Development Network provides broad capabilities and capacity for testing MCMs to address CBRN threats, pandemic influenza, and emerging infectious diseases. Guided 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 the development of 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 projects to date. Licensed MCMs that have been brought to market with supportive data from BARDA-funded nonclinical studies include Anthrasil, BioThrax, Raxibacumab, Neupogen, Neulasta, Nplate, Anthim, Leukine, TPOXX, Jynneos, Ervebo, Inmaze, Ebanga, and Tembexa. 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 in support of the COVID-19 pandemic response.
- ***Clinical Studies Network (CSN):*** Formed in 2014 and revised in 2020, the CSN provides clinical services to support MCM development and evaluation and provides surge capacity for clinical trial capabilities during public health emergencies. Since its inception, the CSN has supported nine clinical research projects, including 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 threat-agnostic treatment for nerve agent toxicity (FY 2019-2020). Starting in FY 2020 and continuing today, 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 biosecurity and commercial indications as well as platform capabilities to reduce the time required to respond to an emerging event. The activities listed below are examples of BARDA's commitment to developing and repurposing multi-use MCMs.

- Development of antibiotics that address: 1) biothreats such as weaponized anthrax, plague, and tularemia, 2) secondary bacterial infections that arise following any public health emergency, and 3) high priority community- and healthcare-acquired drug-resistant bacterial infections.
- Development of platform discovery and manufacturing technologies that accelerate the capability to rapidly discover, develop, manufacture, and deliver safe and effective MCMs in response to newly emerging threats. This includes investments in new modular manufacturing technologies for on-demand, point-of-care manufacturing of critically needed MCMs at the time and place of need. Such capabilities reduce the dependency on, and risk of failure of, a single national MCM manufacturing line, compresses distribution logistics by ensuring MCMs are produced at or near the point of need, and reduces our reliance on costly-to-maintain and replenish MCM stockpiles.
- Development of new MCMs to prevent and/or treat the pathophysiological consequences of chemical, radiological, and nuclear 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) systemic injuries due to acute radiation exposure and trauma, and 4) a range of blast and burn injuries resulting from a nuclear detonation.
- Repurposing of existing treatments for injuries caused by chemical, radiological and nuclear threat agents including 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.
- Execution of a strategy for the development of threat agnostic technologies and MCMs capable of preventing and treating injuries and illnesses associated with biological (i.e., bacterial and viral) threats 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 threat agent-independent approaches such as host-direct immune modulators, have the benefit of being used effectively to counter a newly emerged and rapidly spreading threat agent when the identity of that agent is unknown.

- Investments in home use molecular testing platforms that have utility in care for routine health conditions as well as biothreat response.

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 20 CBRN threats as identified by DHS. These advanced development programs have supported 30 products that have transitioned to support under PBS, 22 of which have been procured for the SNS. BARDA's efforts have led to 62 FDA licensures, approvals, or clearances of MCMs since 2008, 28 of which focus on countering CBRN threats including those listed below. 14 of these were approved under the FDA's Animal Rule.

- 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. difficile* 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)
- INMAZEB to treat Ebola Virus Disease (2020)
- EBANGA to treat Ebola Virus Disease (2020)
- StrataGraft to treat deep-partial thickness burns (2021)
- NPLATE to treat thrombocytopenia from radiation exposure (2021)
- Lumify Ultrasound (2021)
- TEMBEXA to treat smallpox disease (2021)

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,
- ERVEBO (formerly V920/rVSV-ZEBOV), a vaccine that protects against disease caused by Ebola Zaire by Merck,
- Next Generation 'Phenotyping' (NGP) Platform for Positive Blood Culture and Sterile Body Fluid Samples by Selux Diagnostics,
- Cefepime-taniborbactam antibiotic cocktail for complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI), hospital-acquired bacteria pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), and melioidosis by Venatorx.

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), development and first procurement of an antibiotic (Nuzyra) for potential use under EUA, licensure of an anthrax vaccine for post-exposure prophylaxis (BioThrax), clearance of Applied Biosystems' anthrax detection kit, and licensure of a new facility to expand domestic vaccine manufacturing capacity. One of the next-generation anthrax vaccine candidates (AV7909) has transitioned to PBS and has now completed a Phase 3 clinical trial. The first procurement of the vaccine, for potential use under EUA, occurred in FY 2019 and a Biologics License Application will be submitted in 2022.

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 (NASEM). 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 licensed the JYNNEOS (MVA) smallpox vaccine to prevent smallpox disease, and JYNNEOS became the first vaccine approved for use against disease caused by monkeypox virus. In 2021 and 2022, BARDA is procuring 386,000 doses of frozen liquid vaccine doses to support end-user needs in parallel with manufacturing 35 drug substance lots and supporting development of a lyophilized formulation of JYNNEOS that may have a longer shelf-life and lower stockpiling costs.

With support from BARDA, FDA approved TPOXX, an oral antiviral drug developed by SIGA to treat smallpox disease, in July 2018. BARDA is continuing to support development and procurement of an intravenous formulation for patients who cannot swallow, which has already yielded a secondary benefit in 2021 during the treatment of the nation's first imported case of monkeypox in nearly 20 years. While TPOXX is approved for pediatric populations, BARDA is working with SIGA on a revised formulation that can be used to treat neonates and toddlers less than 13kg. In 2021, another BARDA-supported product, TEMBEXA, developed by Chimerix, Inc, was approved by the FDA. TEMBEXA is the second antiviral drug approved for the treatment of smallpox, which meets the National Academy of Medicine's recommendation to make available two licensed antiviral drugs against smallpox with different mechanisms of action. TEMBEXA is available in a tablet and suspension formulation. To further increase therapeutic options for healthcare workers, support the care of special populations, and mitigate the risk of engineered or naturally occurring resistance, BARDA awarded a contract to Biofactura in 2019 to support development of a monoclonal antibody cocktail against smallpox and this effort is currently ongoing.

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 both counter DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders) and treat healthcare- and community-acquired multi-drug resistant pathogens. To date, BARDA has supported the development of 125 antibacterial candidates: 92 under CARB-X, 32 within the Advanced Research and Development portfolio, and one using Project BioShield funding. Through these efforts BARDA has enabled three antibiotics to receive FDA marketing authorization.

In addition to CARB-X discussed above, the BSA Advanced Research and Development portfolio is actively supporting 17 clinical stage antibacterial candidates, including innovative technologies such as a microbiome-based therapy, a phage cocktail, and a phage-derived antibacterial candidate. Seven antibacterial candidates 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 pulmonary anthrax and community-acquired bacterial pneumonia. The first procurement of Nuzyra was made in June 2021.

Botulinum toxin: Botulinum neurotoxins (BoNT) pose a threat to public health both as potential weapons that can be disseminated by aerosol or through contamination of food and as naturally occurring contaminants in food or wounds. BAT is a licensed polyclonal equine antibody product produced in a vaccinated horse herd. However, there are concerns about BAT from the perspective of preparedness due to the sustainability and aging of the horse herd from which the antibodies are generated. BARDA is supporting a next gen pan-BoNT antitoxin development program that aims to produce an antibody cocktail product with efficacy against all seven BoNT serotypes. Initial data from the project are promising, though the project is in very early stages of 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 were 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. BARDA is continuing the procurement of ERVEBO while in parallel working with the product sponsor to seek expansion of the label to include special populations where possible.

Regeneron's INMAZEB Ebola therapeutic and Ridgeback's EBANGA Ebola therapeutic were licensed by the FDA in late 2020, and all work for both products is now being supported by BARDA. BARDA is procuring up to 50,000 treatment courses of INMAZEB to be delivered to the SNS. BARDA is also working with Ridgeback to develop a scale-up 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 there currently has no approved MCMs. BARDA is currently investing in two different vaccine candidates for Marburg virus and two candidates for Ebola Sudan. Enrollment was completed for a Phase 1b clinical trial for vaccines against Marburg and Ebola Sudan being developed by the Sabin Vaccine Institute, with a Phase 2 study start planned for 2022. BARDA will also initiate a Phase 1 clinical trial for a Marburg vaccine candidate using vesicular stomatitis virus vector in 2022. 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. The products have exhibited excellent efficacy in nonclinical models of Marburg virus and Sudan virus infection, respectively. The antibody product for Marburg is slated to file an Investigational New Drug (IND) application in 2022 and initiate a Phase 1 clinical trial soon after. The Sudan virus product is already enrolling a Phase 1 study and is advancing rapidly to pivotal studies that will support licensure through the Animal Rule.

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. Two candidate programs were transitioned from ARD to PBS in FY 2017, followed by another two candidates in FY 2018. During FY 2021, BARDA down selected to two biodosimetry candidates continuing under PBS, based upon product verification and validation data and extensive feedback from FDA. In FY 2022, continued

verification and validation studies along with extensive FDA consultation will continue with these PBS programs.

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) and host responses to bacterial toxins during the course of disease for *Bacillus anthracis*, *Burkholderia pseudomallei*, *Burkholderia mallei*, and *Yersinia pestis*. In FY2019, 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 FY2015 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 2014-2016 West Africa Ebola response and cleared the OraQuick Ebola test in FY 2019. OraQuick Ebola tests have been procured by BARDA, WHO, and the Foundation for Innovative Diagnostics (FIND) and are actively being used in DRC and Guinea to help contain recurring Ebola outbreaks. In FY 2021, BARDA continued development of biothreat diagnostics for anthrax, smallpox, glanders, melioidosis, tularemia, typhus, and plague tests. Additional FDA 510(k) submissions are expected in FY2022 & FY2023.

BARDA is also investing in diagnostics to inform appropriate use of antibiotics and help curb the emergence of antimicrobial resistant bacteria. BARDA has funded phenotypic and molecular technologies, including antibiotic susceptibility tests, viral vs. bacterial tests, and antimicrobial resistance tests. Additional investments in this space are envisioned in FY 2022.

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.

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. In FY 2021, Nplate, a commercial product to treat thrombocytopenia, was approved as a MCM to treat acute radiation injury. Products to treat thrombocytopenia are also being investigated for their potential role in addressing vascular injury. Vascular injury, inflammation, and coagulopathy, and our ability to quickly detect and treat these pathophysiologicals, will be a priority focus in FY 2022 and FY 2023. BARDA will collaborate closely with DoD, the National Aeronautics and Space Administration (NASA), and NIH to ensure appropriate pipeline development and targeted natural history. 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 that will be essential in mass casualty events.

Burn and Blast Threats: Since 2013, BARDA has been investing in the research and development of innovative technologies and approaches to mitigate severe burns and traumatic injuries resulting from a nuclear detonation. The focus of this program has been to identify and resolve anticipated bottlenecks due to limited treatment capabilities and inefficiencies in current treatment procedures. BARDA is developing next-generation treatments that not only address these bottlenecks but also can be integrated into routine burn and trauma care, thereby enabling BARDA to continually build robust and sustainable preparedness for burn and blast injuries with improved technologies and newer MCMs. This preparedness strategy will improve the quality of routine care, reduce costs, and promote a trained user base that is skilled in the new innovative technology products while also enhancing our nation's preparedness posture. BARDA's accomplishments include:

- Spectral MD DeepView burn-depth imaging and its machine learning algorithms program was granted Breakthrough Designation by the FDA.
- StrataGraft full-thickness off-the-shelf skin substitute and the NovoSorb temporizing wound coverage were granted Breakthrough Designation by the FDA. In FY2021, FDA granted approval to StrataGraft, which brings a new technology to the market for burn surgeons that can reduce or eliminate the need for autografting for deep-partial thickness burns injuries, thus reducing patient morbidity and aiding recovery.
- Avita's RECELL Spray-On Skin™ Cells received pre-market approval (PMA) for the treatment of acute thermal burn wounds in 2018 and continues to be integrated into routine care to become a standard of care as an autograft sparing technology.
- Philips Lumify ultrasound technology is in development as a point of care real-time diagnostic lung imaging device and for diagnostic assessment and management of lung damage including in COVID-19 patients. In 2021, the Philips Lumify received its first 510(k) clearance for one application important for COVID-19 within the first year of performance. In addition, this innovative product is being developed to aid in the assessment of abdominal and extremity trauma, both frequently seen in mass casualty incidents.

Chemical Threats: In 2015, BARDA's Chemical MCM Program 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, which will ensure the rapid availability and usability of MCMs at the time and place of need. One result of this strategy is the FDA approval of Seizalam (midazolam injection) for an indication of status epilepticus, inclusive of that resulting from nerve agent exposure. Another example is BARDA's support for Silverlon, a widely available burn and wound dressing that has become the first and only treatment ever approved for the skin injury resulting from exposure to sulfur mustard. Continuing this emphasis on repurposing, we are now developing Alteplase (an FDA-approved treatment for acute ischemic stroke) for the treatment of lung injury caused by sulfur mustard. In both of these cases, the mechanism of action of Alteplase is to dissolve fibrin: fibrin-based blood clots in stroke and fibrin casts that develop in the airways after exposure to sulfur mustard. 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 are leading 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 during preclinical development. While this is key for the Chemical MCM portfolio, there also may be vast implications for other MCM portfolios, as well as clinical research in general. 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 December 2021, the ReDIRECT program has awarded four 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, 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, 3) to Enalare for the development of ENA-001, an agnostic respiratory stimulant that represents an entirely new approach to the treatment of opioid overdoses, and 4) to Clarivate, which is using computational strategies like Artificial Intelligence to identify therapeutics for potential repurposing as MCMs for chemical threats. 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. Further, DRIVE is ideally positioned to help de-risk novel technologies and catalyze follow-on funding from private and other public funders. With a total investment of \$54 million from FY 2018–2021, DRIVE partners have been able to raise an additional \$712 million of follow-on investments from other sources and earn two FDA 510(k) clearances for novel technologies.

The ENACT (Early Notification to Act, Control, and Treat) Program was established as a founding program in FY 2018 to focus 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. Many partners are in the process of seeking market authorization by the FDA and EU authorities. Sound Life Science obtained 510(k) clearance for the industry's first sonar-based respiratory monitor for smart devices, using just a simple smart speaker. During COVID-19, particularly with high rates of asymptomatic transmission, the private and public investment in pre-symptomatic warning systems and devices has rapidly increased, marking successful catalytic early, high-risk investments by DRIVE starting in FY 2018. In FY 2022, two more focused programs were spun off from ENACT, one focused on developing routine lab tests for home environments to enable more enhanced telemedicine experience, and the other focused on developing purely digital MCMs that can be used in the initial days of an emergency while physical products are still in development. For example, DRIVE partnered with CVS Health in FY 2022 to pilot a project to use national COVID-19 testing sites to provide real-time detection of mildly symptomatic and asymptomatic breakthrough infections due to variants or waning immunity.

The Solving Sepsis Program, another founding DRIVE program, has been 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. Partner Immunexpress received an FDA 510(k) clearance for its DRIVE-supported validation studies for its Septicyte Rapid product for use to predict sepsis. 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. In partnership with Sepsis Alliance, DRIVE also developed an online “Disaster Medicine Sepsis Training” module, now available for free, with nearly 2000 enrollees so far. In FY 2021, the program was split into two more focused programs, one to develop host-based diagnostics such as infection severity detection tools to differentiate severe from mild illness across multiple care settings including the home, and the other focused on developing host-directed therapeutics that can modulate the immune system to avoid systemic dysregulation characteristic of severe infection that we call sepsis and that can be used for post-acute scenarios such as Long COVID following SARS-CoV-2 infection. In FY 2021, DRIVE made two pilot EZ-BAA awards for diagnostics and three for therapeutics.

The Beyond the Needle Program, started in FY 2021 as part of the COVID-19 response, has made eight 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, intranasal delivery, 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.

The Immunechip+ program, begun in FY 2021, is seeking to develop scalable, modular multi-organ, sensor-based microphysiological systems, or tissue chips, that can combine multiple organ types, including the immune system, to rapidly model disease and screen novel MCMs. Three initial investments were made in FY2021, with a goal of developing standardized approaches that can advance the technology to more commercial scales.

Additionally, DRIVE has begun utilizing the COMPETES Act prize authority to stimulate innovation. In FY 2021, DRIVE launched the Mask Innovation Challenge, in partnership with CDC’s National Institute for Occupational Safety and Health (NIOSH), which seeks to develop novel, evidence-based, and user-friendly public-use masks of the future. The \$500,000 challenge received over 1,400 submissions and selected 10 finalists for its initial phase. The second phase launched in early FY 2022, featuring world-class testing by NIOSH and the National Institute for Standards and Technology (NIST) towards the development of multi-hazard masks of the future. DRIVE also launched a challenge to develop electronic health record (EHR)-based algorithms to predict hospitalizations of pediatric COVID-19 patients, to better understand what factors might lead to severe disease, and to equip hospitals with the tools to be better prepared.

Driving Process Innovation: DRIVE continues to develop, pilot, scale, and establish new approaches to procurement, public-private partnerships, and other business and government processes. The customer-

friendly, rapid contracting mechanism, called the EZ Broad Agency Announcement (EZ-BAA), designed to make awards in under 30 days, was developed to support DRIVE, and was pivoted to support BARDA's COVID-19 diagnostics program, which has now led to 27 emergency use authorizations. The EZ-BAA has been used to help establish BARDA's chemical threats pipeline through a collaborative program called ReDIRECT and is now being scaled across BARDA. In FY 2022, DRIVE plans to establish a new EZ-BAA vehicle with a phase 2 component allowing for rapid follow-on funding to scale successful pilot and early-stage projects. 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 through a new BARDA-wide digital resources team. 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. The Accelerator Network successfully introduced BARDA to over 400 startup companies in FY 2021, leading to at least 5 new DRIVE awards. The Accelerator Network also completed six market research landscape reports and 5 stakeholder engagements/roundtable discussions for topics of future BARDA interest such as on-demand manufacturing and in silico drug discovery. The Accelerator Network will continue to provide these services into FY 2022 and FY 2023. The Blue Knight partnership with Johnson & Johnson's JLABS features a unique opportunity for 20 companies to reside in shared lab space across North America, including in a newly launched JLABS in DC at the new Children's National Hospital innovation campus on the former site of the Walter Reed Army Medical Center. JLABS now has 18 companies in its portfolio, with focus areas ranging from clinical trial engagement in underserved communities, microbiome therapies, pediatric vital monitors, next-generation syringes, to novel manufacturing platforms.

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, including equity-based and debt financing. In FY 2021, BARDA Ventures was formally launched with the selection and announcement of a partnership with the nonprofit Global Health Investment Corporation (GHIC), a global leader in health impact investing. The primary goals of BARDA Ventures are the following: (1) leverage private investment with public funding to amplify impact, (2) attract private capital towards development of platform-based, multi-use health security products, and (3) maximize taxpayer value by recycling returns from successful ventures in new investments. In FY 2021, BARDA invested an initial \$12 million into the partnership. Since then, the partnership has now become fully operational. In FY 2022, GHIC made its first equity investment, and plans on making 2–5 additional investments in FY 2022. In FY 2023, GHIC will plan on raising a formal global health security impact fund with matching funding from private sources.

COVID-19 Response: Since FY 2020, ASPR has worked across the interagency in 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 advanced purchase agreements and development and manufacturing of the following:

- Seven vaccine candidates, including Pfizer’s Comirnaty vaccine that is licensed for use for ages 16 and up and authorized for use for ages 5 to 15, Moderna’s SpikeVax that is licensed for use for ages 18 and up, and Janssen’s Ad26.CoV2.S that is authorized for ages 18 and up. BARDA and Operation Warp Speed supported advanced development, manufacturing, and procurement of the Moderna, Janssen, AstraZeneca, Novavax, and Sanofi/GSK vaccines. The U.S. Government de-risked the advanced development and manufacturing of the Pfizer vaccine with an advanced purchase agreement.
- 13 therapeutics, including development and procurement of the Regeneron’s monoclonal antibody cocktail REGEN-COV, purchase of the monoclonal antibodies developed by Eli Lilly and Company, GlaxoSmithKline, and AstraZeneca, and antivirals made by Pfizer and Merck; all of these products are authorized for emergency use by the FDA.
- 17 rapidly deployable and other technologies, including next generation technologies to administer vaccines.
- 42 diagnostic tests ranging from high-throughput tests for laboratories to rapid point-of-care and at-home tests, 29 of which have been granted EUA by the FDA, and these private sector partners have shipped more than 195 million tests as of February 2022 across the country.

BARDA also collaborated with the private sector to expand capacity for manufacturing active pharmaceutical ingredients as well as vaccines, therapeutics, and ancillary products, such as needles and syringes. Further, BARDA, in collaboration with the Department of Defense, funded expansion of domestic diagnostic test manufacturing capacity at six facilities in the U.S. These efforts are projected to increase testing capacity by 62 million test per month.

Funding History	
Fiscal Year	Amount
FY 2019	\$561,700,000
FY 2020	\$561,700,000
FY 2021 Final	\$596,700,000
FY 2022 CR	\$596,700,000
FY 2023 President’s Budget	\$828,380,000

Budget Request

The FY 2023 President’s Budget request for Advanced Research and Development is \$828,380,000 which is an increase of \$231,680,000 above the FY 2022 CR.

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 the following: vaccines and therapeutics for viral hemorrhagic diseases, including Marburg and Sudan viruses (two threats for which no MCMs exist); next generation smallpox and botulinum toxin therapeutics with increased efficacy and improved safety over currently approved and available drugs; next generation technologies 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 expansion of the portfolio of MCMs to treat injuries caused by nuclear detonation to include blast injuries. 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 successfully execute these critical missions.

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 Plan²⁵.

Specifically, such funding would support investments in new projects in the following programs:

1. New therapeutic and vaccine candidates against Ebola Sudan and Marburg viruses;
2. New antidotes for treatment of injuries induced by chemical agents (for example, sulfur mustard and chlorine gas exposure);
3. Diagnostic devices to confirm infection with biological agents, some of which will be suitable for use in point-of-care and near patient settings;
4. Innovations for advanced, portable extracorporeal membrane oxygenation (ECMO) devices;
5. Innovations in early stage MCM research and development focusing on sepsis, wearable diagnostics, and distributed manufacturing technologies;
6. New candidate products to address the pathologies caused by radiological or nuclear events, including blast injuries caused by nuclear detonation;
7. New diagnostic devices to help reduce the emergence of antimicrobial resistant bacteria by identifying the appropriate treatment sooner;
8. Multi-tissue human microphysiological models ("body-on-a-chip") that incorporate immune system models for screening of vaccines and therapeutics;
9. Novel patient triage technologies, including phone apps, for rapid patient assessment and information sharing within first responder and hospital networks;
10. Novel host-based therapeutic approaches that are agnostic to pathogen and address severe forms of disease and sepsis;
11. Novel host-based diagnostic approaches to address disease severity and identify health deterioration in a number of clinical settings (pre-hospital, hospital, post-discharge);
12. Novel antibacterial drugs, diagnostics, and vaccines;
13. Patient behavior modification approaches as an MCM;

²⁵ <https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx>

14. Diagnostic technologies suitable for use in limited healthcare resource settings, such as nursing homes, temporary treatment centers, tribal clinics, and even homes, by minimally trained personnel;
15. Antifungals intended for prophylactic and empiric therapy for invasive *Candida* and *Aspergillus* infections;
16. Two new technologies (one biomarker based and one non-invasive imaging) to advance treatment of Traumatic Brain Injury (TBI) that is seen both in routine trauma as well as mass-casualty scenarios; and
17. Threat-agnostic diagnostics for use in the early days of novel disease outbreak.

Combating Antibiotic-Resistant Bacteria (\$185 million): The FY 2023 request will support CARB-X and the advanced clinical stage development of broad-spectrum antimicrobials and novel antibiotic treatments for both complicated and uncomplicated infections. Funding will sustain and expand the scope of support provided by CARB-X to the preclinical development of antimicrobials, vaccines, and diagnostics. This will ensure the early-stage pipeline remains robust and delivers MCMs that are attractive for subsequent advanced development funding from BARDA as well as other funding organizations. New funding initiatives in FY 2023 will include transitioning two or more antibacterials from either CARB-X or NIAID into BARDA's advanced development portfolio and supporting the development of MCMs for invasive *Candida* and *Aspergillus* infections, which have been identified as priority threats by the CDC. Funding will also support continued progress across the broad-spectrum antimicrobial portfolio. It is also anticipated that one program that is currently supported will transition to PBS. All funded efforts are focused on the development of next generation therapeutics that address the growing incidence of antimicrobial resistance, secondary infections, and the potential threat of a bioterrorism event.

Chemical (\$75 million): FY 2023 funding will be used to explore cheminformatics strategies to discover candidates for repurposing as chemical MCMs. In addition, funding will be used to continue development of animal and organ-on-chip models to support their evaluation as well as 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, amendable to civilian concepts of operation. Further, BARDA will continue to support the development of drugs and non-pharmaceutical strategies aimed at treating the life-threatening effects of opioid-induced respiratory depression.

Acute Radiation Syndrome (\$75 million): FY 2023 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 2023, 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 FY2023. 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 a mixed sample; and 3) anthrax diagnostics candidates that are sufficiently mature to achieve FDA clearance.

Burns and Blast (\$50 million): In FY 2023, BARDA will continue to expand products that help address and mitigate the effects of blast trauma injuries. 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. Novel technological approaches (biomarker and imaging based) would address Traumatic Brain Injuries (TBI) and Fractures both seen in both routine care as well as mass-casualties.

Viral Hemorrhagic Fever (\$187.4 million): FY 2023 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. FY 2023 funds will support a Phase 2 clinical trial for a second Marburg virus vaccine and a Phase 1 clinical trial for a second Ebola Sudan vaccine. Funding will also be utilized to scale up manufacturing and generate additional clinical trial material for future studies.

FY 2023 funding will also support filovirus therapeutics. Advanced manufacturing and pivotal nonclinical studies will be supported for the lead Marburg virus therapeutic candidate. Additionally, funds will enable the development of additional Sudan and Marburg therapeutics to complement BARDA's current lead candidates. This is essential to mitigate the risk of resistance and increase the likelihood that products in the portfolio would have efficacy against new or emerging filoviruses. Finally, to address the challenges of severe infection and persistent infection, at least one small molecule antiviral with efficacy against filoviruses will be supported. Priority will be given to a product with broad filovirus activity and an oral route of administration. Funding for these efforts will primarily support continued development and accelerated manufacturing to ensure that sufficient quantities of therapeutics are available to mitigate the risk of global outbreaks reaching the US, even ahead of FDA approval. In addition, funding will support nonclinical studies and assay qualification/validation required for approval of therapeutics under the FDA's Animal Rule, which is the likely regulatory pathway for approval of Sudan and Marburg virus therapeutics and vaccines.

BARDA has long supported the development of threat agnostic medical countermeasures (MCMs) designed to treat the injuries resulting from chemical, radiological, and nuclear threat agents rather than targeting the threats themselves directly. Such an approach provides for the rapid use of MCMs in cases where the causative agent is unknown and time to treatment cannot be delayed. BARDA will apply this strategy toward the development of innovative MCMs against VHF and other biological threats when the agent itself has not been identified. Such MCMs will be designed to either 1) target and impede mechanisms of replication, propagation, and transmission common among a wide range of biological threat agents or 2) treat the medical consequences of biological threats. The availability of such threat agnostic MCMs will provide the capabilities to rapidly and effectively respond to newly emerging threats

and provide a bridge to reduce morbidity and mortality while definitive threat agent-directed MCMs (like vaccines) are developed and delivered.

Clinical Network and Nonclinical Studies Network (\$10 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 Networks will be re-awarded in FY 2022 enhancing the network's laboratory capabilities. 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. Product-agnostic models of viral hemorrhagic fever for Ebola Sudan and Marburg will be qualified as new candidate products come into BARDA's pipeline. Continued development of models and evaluation of chemical threat MCMs focused on chlorine, opioids, and vesicating agents will continue and support of BARDA's technology development programs including Beyond the Needle will be supported.

DRIVE and the Medical Countermeasures Innovation Partner (MCIP) - DRIVE (\$76 million): FY 2023 funding will both continue existing DRIVE programs and also expand the portfolio of programs. Existing programs include development of:

- Innovative approaches to detect and predict infection severity, e.g., severe COVID-19, MIS-C, and sepsis, to aid in triage of scarce resources;
- Novel host-based therapeutics that can be positioned to prevent and treat immune dysregulation characteristic of sepsis and severe infection;
- On-demand at-home detection of biochemical health markers, currently only available in CLIA-certified labs, including markers relevant to infectious diseases, rapid results of critical cardiac functions, complete blood counts, wellness testing such as lipids, hormones and metabolics;
- Digital medical countermeasures that could be immediately deployed at scale in the early phases of a public health emergency;
- Scalable multi-organ, sensor-based microphysiological systems, or tissue chips, to model disease, screen MCMs more efficiently;
- Alternative routes of vaccine and drug delivery, e.g., oral formulations and microneedle skin patches, to ease supply and distribution chains and lower barriers to access to life-saving MCMs; and
- Agnostic diagnostic tests using next-generation sequencing that can be available on the first day of an outbreak.

DRIVE will also continue to support the BARDA Accelerator Network, including the Blue Knight partnership with JLABs to provide ready access to a global network of innovators to feed BARDA's MCM pipeline and provide greater market intelligence to BARDA. BARDA Ventures is expected to make two to three direct investments in FY 2022, and approximately eight to nine additional investments

in FY 2023, with individual investments ranging from \$5-15 million per company. In FY 2023, it is also expected that many of the investments made across all DRIVE programs 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): These funds provide support to BARDA's programs for Advanced Research and Development, Project BioShield, Pandemic Influenza, and the COVID-19 Response. The BARDA organization has grown significantly over the years, and this growth was accelerated by the COVID-19 response. 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 also support staffing for federal personnel, contractors, awards for acquisition of services, central costs, travel, and training. In addition, funds will be used for related services and oversight provided by ASPR to support BARDA's mission. These services 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 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. These 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.

This spending is planned with careful review and high program integrity standards. In response to the HHS Inspector General's report, HHS's Office of the Assistant Secretary for Financial Resources (ASFR) completed an internal review of the use of advanced research and development funding from the Public Health and Social Services Emergency Fund (PHSSEF) for FY 2017 through FY 2019 to identify any potential Anti-deficiency Act violations. HHS also hired an outside accounting firm which reviewed ASPR's use of funds for administrative expenses. Based on these reviews, ASFR has determined that no Anti-Deficiency Act violation occurred when allocating the ASPR-wide shared services and that ASPR's use of BARDA ARD funding for administrative expenses was consistent with principles of appropriation law and the purpose of the PHSSEF appropriation for those years. The PHSSEF supports a variety of 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)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 Target
2.4.13a Increase the number of new licensed medical countermeasures across BARDA programs (Intermediate Outcome)	FY 2021: 6 medical countermeasures Target: 3 medical countermeasures (Target Exceeded)	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 2021: 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 2021: 13 manufacturers Target: 11 manufacturers (Target Exceeded)	11 manufacturers	11 manufacturers	Maintain

Project BioShield

Budget Summary

(Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	770.000	770.000	770.000	-
FTE	-	--	-	-

Authorizing Legislation:

AuthorizationPublic Health Service Act, Sec. 319F- 2(g) 42 U.S.C. 247d-6b(g)

Authorization StatusIndefinite

Allocation MethodDirect Federal/Intramural, Contracts

Program Description and Accomplishments

Disease outbreaks, both naturally occurring -- such as Ebola outbreaks in West Africa and the Democratic Republic of Congo, isolated cases of Marburg and monkeypox, and the ongoing COVID-19 pandemic-- and those caused by intentionally engineered or naturally occurring Chemical, Biological, Radiological, and Nuclear (CBRN) threats continue to jeopardize national and global health security. Over the last decade, the Office of the Assistant Secretary for Preparedness and Response's (ASPR) Biomedical Advanced Research and Development Authority (BARDA) has advanced medical countermeasure (MCM) research and development, enhanced partnerships with industry, and sustained investments in potential products made possible under Project BioShield (PBS). This has resulted in the support of 30 products that are critical to the nation's preparedness and response to these threats. Twenty-two of these MCMs have been delivered to the Strategic National Stockpile (SNS) or procured as vendor managed inventory, with additional products to be delivered in FY 2023 and FY 2024. As of December 2021, 28 MCMs to detect, prevent, or treat CBRN threats have achieved FDA approval, licensure, or clearance with additional approvals anticipated in FY 2022 and FY 2023.

The Project BioShield Act of 2004 (P.L. 108-276) provided specific authorities and funding through FY 2013 for late-stage development and procurement of CBRN MCMs. The law also provided the Food & Drug Administration (FDA) with the legal ability to quickly authorize the emergency use of unapproved, 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 PBS authorities in the Public Health Service Act. BARDA, created as a result of PAHPA, has made unprecedented progress in the development and acquisition of products necessary to protect health during CBRN incidents.

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 while continuing to support 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, post-

approval (e.g., Raxibacumab anthrax antitoxin and anthrax vaccine) depending on availability of funding. BARDA and the SNS work closely to align resources and timelines for transition of products.

Since FY 2005, BARDA has invested in 30 unique MCMs under PBS, 22 of which have been delivered to the SNS or procured as vendor managed inventory, including the following:

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

Based on the successful development of CBRN MCMs in BARDA's Advanced Research and Development (ARD) programs, BARDA is prepared to support the advanced development and/or procurement of up to six new CBRN MCMs under PBS by the end of FY 2023. Since 2014, BARDA has awarded 19 contracts under PBS for late-stage development and procurement of MCMs (30 contracts have been awarded since the inception of PBS in 2006). In FY 2023, BARDA will invest significant funds in late-stage activities of existing programs, to include initial procurements, to enable these products potential use during a declared emergency under EUA. Products from the following portfolios will in this area: smallpox antiviral, filiovirus therapeutic, diagnostics for burns and blasts, and treatments for exposure to chemical agents. BARDA will balance previous commitments while transitioning promising programs to PBS. BARDA anticipates the transition of three or more candidates to PBS in FY 2023. Remaining funds will continue the late-stage development and the potential procurement of programs previously funded under PBS.

The following promising candidates have the potential to transition to PBS in FY 2023:

- Additional antimicrobials to treat drug-resistant pathogens;
- Products to address thermal burn injuries, acute radiation injury, and chemical threats;
- A monoclonal antibody therapeutic for Marburg Virus; and,
- A novel autoinjector to deliver the nerve agent countermeasure 2-PAM.

Funding History	
Fiscal Year	Amount
FY 2019	\$735,000,000
FY 2020	\$735,000,000
FY 2021 Final	\$770,000,000
FY 2022 CR	\$770,000,000
FY 2023 President's Budget	\$770,000,000

Budget Request

The FY 2023 President's Budget for Project BioShield is \$770,000,000 which is flat with the FY 2022 CR. The FY 2023 request supports continued development and procurement of therapeutics for Sudan and Ebola viruses as well as a second smallpox antiviral drug, continued procurement of JYNNEOS for prevention of smallpox, 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. PBS 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 2023 request supports the eight investments listed below, which reflects the highest priority countermeasures for FY 2023.

1. **New antimicrobial drugs to address biothreat pathogens (\$150 million, approximately 10,000 treatment courses of each product):** In FY 2023, PBS funds will continue to be used to procure NUZYRA and up to two new antibiotic products. The inclusion of NUZYRA and two additional antibiotics will enhance the US Government'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 exposure (\$90 million, 350,000 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 published a second RFP to support New Drug Application (NDA)-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 2023 funding will be used to continue that procurement as well as further 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 (\$85 million, approximately 200,000 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 FY 2011 contract and a follow up PBS contract awarded in FY 2019 have now supported production and delivery of over two million treatment courses of oral TPOXX to the SNS. FY 2023 funds will support advanced development and procurement of alternate formulations of TPOXX (IV and pediatric) and procurement of two formulations (oral and suspension) of TEMBEXA, a second antiviral with a distinct mechanism of action that was approved by the FDA in FY 2021 for the treatment of smallpox. The procurement strategy aims to establish a stockpile of TEMBEXA (oral and suspension) and TPOXX (pediatric and intravenous) to complement the replenishment activities of SNS for oral TPOXX. Collectively, the shared BARDA and SNS TPOXX procurements ensure that the federal government retains 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 (TEMBEXA) to avoid a single point of failure in the supply chain and provide healthcare providers with multiple options for therapeutic intervention.
4. **Burn and Blast products (\$50 million, approximately 100 devices):** BARDA plans to procure allograft (cadaver) skin via vendor managed inventory (VMI). This builds on previous FY 2022 investment and would bolster integration of the VMI as part of the standard of burn care network to enhance preparedness for a mass casualty event involving large numbers of burn victims. FY 2023 funds will support the transition of at least one ARD product to PBS. These funds would support pivotal validation studies to seek 510(k) clearance for a novel imaging technology to aid emergency room and trauma surgeons to triage burn victims. Following these studies, about 100 devices would be integrated into multiple burn and trauma centers as part of the process. This would transform the future burn triage using next generation non-invasive burn imaging technologies. Furthermore, this would ensure that the products remain in routine clinical use and available to well-trained physicians in order to effectively respond to a mass casualty event.
5. **Smallpox vaccine, conversion to lyophilized formulation (\$110 million, five million doses):** In FY 2017, BARDA procured several lots of Bavarian Nordic's IMVAMUNE smallpox vaccine, now referred to as JYNNEOS, in bulk form. In FY 2023, BARDA expects to continue development of 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 with the Biologics License Application targeted for FY 2023. Funds will support the final development stages of the lyophilized formulation in parallel with a procurement strategy focused on drug substances that can be filled as freeze-dried drug products upon licensure.

6. **Therapies for acute ionizing radiation exposure (\$90 million, 26,250 treatment courses):**
Exposure to acute ionizing radiation can induce thrombocytopenia as part of 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. Funding will be used to procure additional treatment courses and initiate vendor managed inventory.
7. **Biodosimetry/Biodiagnostics (\$45 million):** Funds will support late-stage activities for devices to detect ionizing radiation absorption as well as late-stage development of biothreat diagnostics (Anthrax and Ebola).
8. **Filovirus therapeutics (\$150 million):** Through utilization of Ebola 2019 Supplemental Funding, BARDA secured deliveries of Regeneron's INMAZEB to the SNS through 2027 and anticipates that subsequent procurements of INMAZEB will be completed by the SNS. FY 2023 funding will be utilized to continue the development and procurement of initial stockpiles of BARDA's leading Sudan virus candidate and the continued scale-up and procurement of Ridgeback's Ebanga. Ebanga became the second therapeutic approved by the FDA for the treatment of Ebola Virus Disease in December 2020. Following the models of Anthrax, Smallpox, and other BARDA-supported therapeutics, continued investment in Ridgeback's Ebanga will enable the US Government to avoid a single point of failure in the supply chain for Ebola therapeutics and provide healthcare professionals with a second option for therapeutic intervention, thus improving care and reducing the likelihood of resistance.

ASPR Key Outputs and Outcomes Table
Project BioShield

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/- FY 2022 Target
2.4.14c Increase the number of medical countermeasures supported under Project BioShield (PBS) (Outcome)	FY 2021: 28 medical countermeasures Target: 28 medical countermeasures (Baseline)	30 medical countermeasures	35 medical countermeasures	+5 medical countermeasures
2.4.14d Increase the number of medical countermeasures delivered to the SNS or procured as Vendor Management Inventory (VMI) (Intermediate Outcome)	FY 2021: 18 medical countermeasures Target: 18 medical countermeasures (Baseline)	28 medical countermeasures	32 medical countermeasures	+4 medical countermeasures

Strategic National Stockpile

Budget Summary (Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	705.000	705.000	975.000	+270.000
FTE	259	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)²⁶ during a public health emergency. It is the largest federally owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations (FMS),²⁷ 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.

Recognizing the challenges SNS faced at the beginning of the COVID-19 response, SNS initiated modernization efforts in the spring of 2020 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

²⁶<http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm>

²⁷<https://www.phe.gov/Preparedness/support/medicalassistance/Pages/default.aspx#sns>

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 the SNS' ability to implement response capabilities for large-scale public health emergencies.

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 SNS's inventory of MCMs. In FY 2021, SNS sustained a 99.3 percent inventory accuracy rate for SNS product, matching the FY 2019 inventory accuracy rate for SNS product despite being unable to conduct physical inventories in FY 2020, due to COVID-19 related travel restrictions. SNS also ensured that no product was lost due to failure to comply with [FDA cGMP](#) practices.

In response to the COVID-19 pandemic and the supplemental funding SNS has received to expand its pandemic preparedness portfolio, the value of SNS's inventory has grown by more than 50 percent to \$13.5 billion during the COVID-19 response while the volume of SNS's inventory has grown by more than 400 percent. In FY 2021 SNS increased storage capacity at existing facilities by 146,000 pallet positions and brought a new storage facility online. Through these actions, SNS added more storage capacity in FY 2021 than it maintained prior to the COVID-19 pandemic. In addition to these warehouses, as of December 1, 2021, SNS maintains around 400k vendor managed inventory (VMI) pallet positions worth of PPE, ventilators, and pharmaceuticals procured to respond to the COVID-19 pandemic.

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 inventory 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 State, Local, Tribal, and Territorial (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 the U.S. Public Health Service. 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 to provide training and remote support. 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. This robust online training curriculum consisted of virtual Just-In-Time training, webinars, and informational videos reached a training audience of over 12,000 participants in FY 2021.

Following the transition from CDC to ASPR on October 1, 2018, SNS began working to integrate its logistics functions with ASPR's overall logistics functions. These efforts build on past efficiency measures, including the development of a unified pharmacy cache for use by either FMS or Disaster Medical Assistance Team (DMAT) deployment. In May 2019, SNS assumed inventory management responsibility for National Disaster Medical System (NDMS) medical materiel.

The SNS is capable of rapidly delivering materiel 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. Early in the response, NDMS materiel, including personal protective equipment (PPE), was integrated into the SNS. It 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. During the early stages of the response, SNS primarily supported the repatriation mission deploying NDMS caches, Federal Medical Stations, and resupplying PPE in support of 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 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.

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.

In the summer and fall of 2021 the United States saw a surge of COVID-19 cases and hospitalizations related to the Delta variant. Using medical material procured during the pandemic, SNS responded to this uptick in cases by deploying 2,919 ventilators and 1,279 High Flow Nasal Cannulas (HFNC) to 18 states and supported federal teams in 17 states.

The SNS is contributing its longstanding emergency response and medical logistics expertise to support full implementation of the National Strategy for the COVID-19 Response and execution of a comprehensive, safe, effective, and equitable vaccination campaign to counter COVID-19, protect Americans, save lives, and advance health security.

In concert with other federal agencies, private sector partners, and state, local, tribal, and territorial public health authorities, the SNS is supporting the national COVID-19 vaccination effort and COVID-19 vaccine distribution process by:

- Procuring and distributing personal protective equipment (PPE) and other critical medical supplies needed for the COVID-19 vaccination campaign, including therapeutic and clinical trials;
- Supporting point-of-care testing with needed PPE and supplies needed during vaccinations;
- Producing and distributing vaccine ancillary and mixing kits to support up to 1.32 billion doses of COVID-19 vaccine and booster doses;
- Supporting COVID-19 vaccine shipping requirements; and,
- Procuring and deploying autoinjectors of epinephrine to support community-based vaccine campaigns.

Acquiring Critical Medical Equipment and Supplies to Support COVID-19 Vaccination Strategy

Since the onset of the pandemic, the SNS has worked collaboratively with a multi-agency federal team and industry partners to strategically source and acquire medical equipment and ancillary supplies critical to the national COVID-19 vaccination strategy. The SNS provided support and program management to the Department of Defense's (DoD) Joint Program Executive Office for Chemical, Biological,

Radiological and Nuclear Defense and HHS' Biomedical Advanced Research and Development Authority (BARDA) for federal contracts awarded for needle and syringe procurement, and effective June 2021, the SNS assumed responsibility for the management and execution of needle and syringe contracts previously managed by BARDA.

Producing and Distributing COVID-19 Vaccine Ancillary Supply and Mixing Kits

To ensure vaccination sites across the nation are prepared and equipped to administer COVID-19 vaccines, the SNS uses federal contracts to produce, store and rapidly distribute vaccine ancillary supply and mixing kits containing needles, syringes, and other materiel necessary to support up to 1.32 billion total COVID-19 vaccine and booster doses. All COVID-19 vaccine ancillary kits needed to administer the pandemic vaccinations are automatically ordered and distributed by the contractor in amounts to match vaccine orders.

The ancillary kitting operation has required specific product components and configurations for each of the multiple COVID-19 vaccine candidates.

To date, SNS and the contractor have built 13 different ancillary kits and one diluent mixing kit to support administration of the three separate COVID-19 vaccines approved and authorized for emergency use by the U.S. Food and Drug Administration (FDA): [Pfizer- BioNTech COVID-19 vaccine](#), Moderna COVID-19 vaccine, and the [Janssen COVID-19 vaccine by Johnson and Johnson](#).

As of December 29, 2021, approximately 7.2 million vaccine ancillary and mixing kits have been produced, enough for 1.1 billion COVID-19 vaccinations, and approximately 2 million ancillary and mixing kits have been delivered nationwide to support the administration COVID-19 vaccine and booster doses.

Significant milestones to date:

- **December 2020:** SNS and the contractor successfully rolled out its first ancillary supply kits to support the safe administration of the first two FDA-authorized vaccines to prevent COVID-19 in the United States: the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine.
- **February 2021:** SNS and the contractor rolled out ancillary supply kits to support safe administration of the third FDA-authorized vaccine – the one-dose Janssen COVID-19 vaccine by Johnson & Johnson.
- **April 2021:** The federal COVID-19 vaccine campaign marked and surpassed a milestone with the nationwide delivery of more than 300 million doses of COVID-19 vaccine and more than 1.6 million ancillary kits to support the administration of the three separate COVID-19 vaccines authorized by FDA for emergency use.
- **May 2021:** SNS and the contractor produced and distributed ancillary kits uniquely configured to support safe administration of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12 through 15 years of age, per the FDA's expanded EUA.
- **June 2021:** The federal COVID-19 vaccine campaign marked a significant milestone with the nationwide delivery of COVID-19 vaccine and ancillary kits to support 660 million doses of COVID-19 vaccine.

- **September 2021:** SNS and McKesson marked one year since assembling the very first COVID-19 vaccine ancillary kit to support COVID-19 vaccine administration.
- **October 2021:** SNS and McKesson assembled more than 6.5 million COVID-19 vaccine ancillary supply kits, enough to support the administration of 1 billion COVID-19 vaccine and booster 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 for healthcare workers, and ventilators to ensure that the SNS can meet 90 days of need for pandemic response.

SNS continued the replenishment and rebuilding of the Stockpile to ensure that national MCM needs are met; while expanding the capability of the Stockpile for current and future public health emergencies. To date, SNS has obligated more than \$11.9 billion from supplemental funding to respond to the COVID-19 pandemic and to increase SNS's inventory of ventilators, PPE, and pharmaceuticals necessary to respond to the COVID-19 pandemic. In addition to efforts to expand SNS's holdings, supplemental funds have been used to support the federal vaccination campaign, expand domestic manufacturing capacity, transport medical material, and modernize the SNS.

SNS has made significant progress towards meeting COVID-19 stockpiling 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 December 16, 2021.

Item	Deployable Quantity	Goal	Status
N95 Respirators	747 million	300 million	Met
Masks (Surgical/Procedural)	274 million	400 million	In Progress – Increased Holdings
Eye/Face Shields	19.6 million	18 million	Met
Gowns/Coveralls	59.6 million	265 million	In Progress
Gloves	4,055 million	4,500 million	In Progress - Increased Holdings
Ventilators	158,000	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.

SNS Support for Small-Scale Events

In addition to ongoing work to respond to the COVID-19 pandemic, SNS has demonstrated its ability to simultaneously respond to multiple events by responding to a number of small-scale events in FY 2020 and FY 2021 including hurricanes, National Special Security Events, the unaccompanied children mission, and monkeypox.

In 2020, amid the COVID-19 pandemic response, the SNS responded to two Major hurricanes; Hurricane Laura and Hurricane Delta, as part of the overall HHS response and recovery operations to support people displaced by the storms and affected by ongoing public health concerns. As a critical player in disaster response, the stockpile deployed the following to support federal responders:

- 24 mobile lifesaving kits (MLKs) and MLK augmentation kits,
- Nine personal protective equipment (PPE) push packages,
- Six shelter kits,
- Six power kits, and,
- Five ASPR RX caches.

SNS also deployed transportation and material handling equipment, four FIT testing kits, COVID-19 BinaxNow testing kits, and additional pharmaceuticals to Incident Management Teams (IMT) and the National Disaster Medical System (NDMS) teams deployed to the affected regions. In total, SNS deployed 94 line items in support of the hurricane season response. SNS provided remote technical assistance to federal partners tasked with setting up the 250-bed FMS and medical services resupply support for non-acute care patients in communities with displaced persons vulnerable to the ongoing COVID pandemic.

In 2021, SNS responded to Hurricane Ida, providing 107 NDMS Caches, kits, bags, PPE push packs, etc. deployed in support of 91 Federal responders supporting the hurricane response.

In March and April of 2021, SNS provided more than 300,000 pieces of PPE and 60 NDMS caches to 14 sites in support of the unaccompanied minor mission.

SNS also responds to small events requiring the deployment of MCMs not readily available on the commercial market. In July 2021, SNS deployed tecovirimat to treat an internationally traveling patient with a case of monkeypox. Prior to this deployment, 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)*²⁸. 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 Support for Trainings and Exercises

SNS works closely with state and local jurisdictions to improve their ability to respond to public health emergencies requiring medical countermeasures. In FY 2021 SNS built on work begun in FY 2020 to expand web-based and virtual training opportunities, allowing more than 12,000 stakeholders to participate in training opportunities in FY 2021. Growth in the uptake of SNS training materials was in large part due to an FMS training videos²⁹, posted to YouTube which were viewed more than 10,000 times in FY 2021. In total, SNS provide training for 12,305 SLTT partners in 2021 through:

- 10,515 stakeholders viewed FMS training videos, available on YouTube
- 731 stakeholders participated in virtual training on topics including SNS Overview; Mass Dispensing; FMS training; and other topics
- 652 stakeholders participated in webinars on topics including SNS Stakeholders Partners; Introduction to the Strategic National Stockpile; Crisis and Risk Communications; and other topics
- 417 stakeholders participated in a mix of in person and virtual PHEMCE Courses

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 hosted 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. Collectively these webinars provided training to 453 registered participants. An audio recording of the instructional webinar is now posted to the AARC SNS webpage for respiratory therapist to access for just-in-time training or clinical resources.

²⁸ https://www.cdc.gov/mmwr/volumes/68/wr/mm6842a2.htm?s_cid=mm6842a2_w

²⁹ <https://www.phe.gov/about/sns/COVID/Pages/sns-trng-videos.aspx>

In addition to the live webinars, SNS partnered with the AARC to develop 15 SNS-held ventilator demonstration videos. Each video offers a demonstration on how to set-up and start mechanically ventilating a patient. The videos are housed on the AARC SNS webpage³⁰ as well as the ASPR webpage³¹.

In FY 2019, SNS provided exercise support for eight tabletop exercises and nine full-scale exercises and drills. Tabletop exercises are a forum used to discuss and validate the timelines for distributing and transferring assets from the SNS to state and local jurisdictions. Additionally, a major goal of tabletop exercises is to sign/update Memorandums of Agreement between ASPR/SNS and the state or local jurisdiction to delineate shared expectations for expected response timelines.

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

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

SNS work with High-Risk Urban Areas

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

³⁰ <https://www.aarc.org/resources/clinical-resources/strategic-national-stockpile-ventilator-training-program/>

³¹ <https://www.phe.gov/about/sns/COVID/ventilators/Pages/training.aspx>

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 for the initial shipment 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.

SNS Coordination with Industry Partners

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 Coordination within HHS

SNS has continued to collaborate with CDC to strengthen the nation's ability to respond to public health threats. In 2021, SNS collaborated with CDC NIOSH to enter 3-way MOUs with over 40 entities (including healthcare systems, doctors' offices, dentist's offices, and emergency medical services/ambulance services) to pilot test elastomeric half face mask respirators (EHMRs) during their regular work. SNS supplied EHMRs to entities participating in the pilot test. SNS also collaborated in 2021 with CDC to supply Ervebo (Ebola vaccine) to healthcare workers upon request, in accordance with ACIP guidelines. In 2021, SNS SMEs are also serving on CDC's new tularemia clinical guidance steering committee. SNS has collaborated with CDC Regulatory Affairs on various labeling exceptions and quality agreements for new pharmaceuticals. 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 served on the CDC steering committee updating plague clinical guidance and the Advisory Committee on Immunization Practices (ACIP) working group for Ebola vaccine. SNS has continued to collaborate with SMEs at CDC and FDA throughout the COVID-19 response in FY 2020 and 2021.

Funding History	
Fiscal Year	Amount
FY 2019	\$610,000,000
FY 2020	\$705,000,000
FY 2021 Final	\$705,000,000
FY 2022 CR	\$705,000,000
FY 2023 President's Budget	\$975,000,000

Budget Request

The FY 2023 President's Budget request for SNS is \$975,000,000, which is +\$270,000,000 above the FY 2022 CR. The FY 2023 President's Budget prioritizes funding for sustainment of current product lines and procurement of several products previously supported by BARDA that lack a significant commercial market. These items include procurement of sufficient quantities of a domestically manufactured, FDA approved, smallpox antiviral to treat an estimated 350,000 people during a smallpox incident, meeting the stockpiling requirement for this product. SNS has deployed this drug several times already to treat orthopox exposure. These deployments include successful treatment of a laboratory worker in 2018, and a monkeypox patient with a recent history of international travel in 2021.

Additionally, SNS would be able to procure enough bandages to treat an estimated 14,000 people impacted by a radiological/nuclear incident, meeting the stockpiling requirement for this product. Finally,

with remaining funding at this level, SNS would procure limited quantities of anthrax therapeutics. These investments support continued capacity for a life-saving drugs that lacks a significant commercial market.

Product procurement in FY 2023 will be guided by the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which was relaunched in February 2022, 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 2023 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 2023 by:

- Managing, storing, maintaining, and replacing MCM assets, valued at over \$13.5 billion;
- Supporting PHEMCE with subject matter expertise and data to inform strategic MCM requirements and procurement decisions;
- Establishing and strengthening public-private partnerships to integrate private resources into public health response plans for a fully functioning supply chain for delivery of critical MCMs; and;
- Providing timely, accurate, and relevant information to clinicians to respond to emerging threats and public health emergencies.

Key Outputs and Outcomes Table
Strategic National Stockpile

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 Target
13.4.6 Percentage of inventory accuracies that are attained by using quality inventory management systems. (Outcome)	FY 2021: 90.04 % ¹ Target: 97 % (Target Not Met)	90 %	90%	Maintain
13.4.7 Maintain the safety and efficacy of medical supplies SNS inventory (Outcome)	FY 2021: 100 % Target: 100 % (Target Met)	100 %	100 %	Maintain
13.4.8 Maintain the response rate of recall capability (Intermediate Outcome)	FY 2021: 99.9 % Target: 95 % (Target Exceeded)	95 %	95 %	Maintain
13.4.9 Increase the number of participants trained by SNS (Intermediate Outcome)	FY 2021: 12,305 ² Target: 1,250 trained (Target Exceeded)	1,500 trained	2,000 trained	+500 trained

¹ FY 2021 data includes NDMS data for the first time following the addition of NDMS caches to SNS's inventory in FY 2020 and FY 2021. SNS's inventory accuracy rate for all non-NDMS materiel was 99.3% in FY 2021, consistent with previous results. The inventory accuracy rate for NDMS material recently added to SNS was 77.5% primarily due to administrative discrepancies in the data provided to SNS.

² Due to the COVID-19 response, SNS videos posted to YouTube received more than 10,000 views in FY 2021. SNS believes these views are an outlier which should not be included in future targets.

SNS Projected Allocations¹

	FY 2022 CR		FY 2023 President’s Budget	
	Requested	Percentage of Total Appropriation	Requested	Percentage of Total Appropriation
Total	\$705.0M	100%	\$975.0M	100%
Product				
Product Total	\$572.2M	81.2%	\$850.8M	87.3%
Procurement Total	\$296.9M		\$647M	
Procurement – New ²	\$4.0M		\$152.0M	
Procurement – New (above replenishment) ³	\$91.2M		\$363.2M	
Procurement – Replenishment	\$201.7M		\$131.8M	
Sustainment Total ⁴	\$275.3M		\$203.8M	
Warehousing Costs	\$230.3M		\$162.5M	
Operations				
SNS Operational Costs ⁵	\$132.8M	18.8%	\$124.2M	12.7%

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 \$13.5 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)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	+/- FY 2022 Budget
Budget Authority	14.877	14.877	21.417	+6.540
FTE	66	66	83	+17

Authorizing Legislation:

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

Program Description

ASPR policy and planning activities bridge strategy, policy, planning, and requirements with other ASPR components to adapt and quickly shift between steady state and response operations. Policy and planning activities ensure that ASPR's operational preparedness and response capabilities: align with HHS and ASPR's priorities; are consistent with broader policy and planning considerations; are adequately resourced based on strategic priorities; and are effectively evaluated through data-driven analysis. This work includes coordinating relationships with internal and external stakeholders; promoting ASPR's mission and priorities; and creating synergistic opportunities to build, strengthen, and inform ASPR's programmatic policies and operational activities.

ASPR provides recommendations that enable the HHS Secretary to provide the best available public health and medical coordination 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.

ASPR policy and planning activities provide real-time support to HHS and Public Health and Medical Emergency Support Function 8 (ESF-8) partners during responses 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 personnel 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 public health and medical 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).

ASPR Planning and Policy FY 2021 accomplishments include:

- Developing the *National Health Security Threat Landscape: Reassessing Health Security Threats in a Pandemic Environment* document, which discusses specific risks identified during the COVID-19 pandemic and informs NHSS implementation and education of key stakeholders;
- Developing the *National Health Security Environmental Scan and Threat Assessment* identifying and analyzing key trends, emerging issues, and threats in the HHS health security mission;
- Engaging 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;
- Publishing a series of articles, in coordination with NACCHO, to provide education and guidance to local public health stakeholders on key priorities in the NHSS, NBS, and the evolving health security threat landscape;
- 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;
- Developing ASPR policy document to define ASPR's role in facilitating and coordinating the Export Cargo Review Working Group; and,
- Developing ASPR policy document on the Testing and Diagnostics Working Group allocation of COVID-19 tests and testing services to federal agencies.

National Biodefense Strategy (NBS)

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 United States Government (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 that ensure that the nation is prepared for biological incidents, including the COVID-19 pandemic. FY 2021 accomplishments include:

- Developing an annual request for information and improved a data collection and analysis tool; and,
- Completing the Biodefense Assessment.

Biosafety, Biosecurity, and Global Health Security Policy Development

The policies governing biosafety and biosecurity must be effectively coordinated across the USG, including 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 identified and 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. ASPR policy and planning activities lead several efforts that provide research oversight and also develop and contribute to the implementation of policies meant to ensure biosafety and biosecurity across HHS and the USG. FY 2021 accomplishments include:

- Co-leading, with NASA, the drafting of the backward contamination objectives of the National Strategy for Planetary Protection, and also drafted the implementation frameworks for these objectives;
- Leading the interagency effort draft updates for the 2010 HHS Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA;
- Leading the development of a unified HHS laboratory incident reporting survey, to fill Federal Experts Security Advisor Panel recommendation 1.7;
- Chaired the HHS Biosafety and Biosecurity Coordinating Council;
- Convening the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences (IWG) six times during FY21 and developed A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences;
- Providing training in bio-risk management at the Stimson Center's Security & Strategic Trade Management Academy (SSTMA) to participants from Asia, Africa, Latin America, and Europe.

ASPR currently supports several activities to achieve global health security which include:

- Serving as USG Senior Official for the Global Health Security Initiative (GHSI), including providing some technical expertise leading the Radiological/Nuclear Working Group;
- Functioning 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;
- Serving as HHS Liaison to the State Department 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; and,
- Providing guidance and inputs during consultation activities with the World Health Organization to revise the International Health Regulations State Party Annual Reporting Tool and the Joint External Evaluation.

National Influenza Modernization Strategy (NIVMS)

As required by White House 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 prepare for and respond more quickly and effectively to future influenza pandemics and, simultaneously, strengthen our response to seasonal influenza. ASPR continues to lead the interagency coordination for development of the NIVMS. 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 the progress made in support of the White House/NSC.

National Advisory Committees

ASPR leads the statutorily required National Biodefense Science Board (NBSB), National Advisory Committee on Children and Disasters (NACCD), National Advisory Committee on Seniors and Disasters (NACSD), and National Advisory Committee on Individuals with Disabilities and Disaster (NACIDD). 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 disabilities, and seniors in disasters and public health emergencies. The NACCD, NACSD, and NACIDD are uniquely positioned to examine the disproportionate impact of COVID19 on those specific populations. ASPR is also responsible for annually updating Congress on cross-agency coordination of these advisory committees.

During FY 2021, ASPR organized three public meetings of the NBSB, which resulted in 36 new recommendations in support of the National Health Security Strategy and lessons learned from COVID-19 for infectious disease preparedness. ASPR also engaged in a voting and ex-officio member selection process for the NACCD, NACSD, and NACIDD. The first public meeting of the NACCD occurred in February 2022 and the NACSD and NACIDD will hold their first meetings on March 30, 2022.

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 Department-wide coordination efforts 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's policy and planning activities include agency implementation of the Foundations for Evidence-Based Policymaking Act of 2018 ("Evidence Act"), which was signed into law on January 14, 2019, and emphasizes collaboration and coordination to advance data and evidence-building functions in the Federal Government by statutorily mandating Federal evidence-building activities, open government data, and confidential information protection and statistical efficiency. Evidence-building within ASPR includes foundational fact finding, contributions to performance and risk measurement, policy analysis, and program evaluation.

During FY 2021, ASPR established strategic direction, provided policy support and evaluation, developed response plans, and addressed resource capability gaps in response to the unprecedented needs that arose during the COVID-19 pandemic. ASPR defined HHS's policy and action plan for assuring a viable and resilient medical countermeasure (MCM) supply chain and industrial base and established the Innovation Program Office to strengthen, sustain, and secure the public health supply chain.

ASPR's FY 2021 accomplishments associated with the COVID-19 pandemic response include:

- Leading COVID-19 HHS response planning activities, including development of the modified pandemic crisis action plan for COVID-19 with interagency partners, engagement with hospitals to accelerate collection and administration of convalescent plasma, and collaboration on guidance for COVID-19 Community Vaccination Centers and COVID-19 Hospital Expansion;
- Collecting data to evaluate new Hospital Preparedness Program (HPP) performance measures focused on mitigation of patient surge on acute care facilities, training and educating staff, purchase of personal protective equipment, and introduction of innovative telemedicine technology; and,
- Issuing 66 priority ratings as of March 2022 under the Defense Production Act for COVID-19 vaccines, therapeutics, and diagnostics.

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.

Requirements Setting

ASPR maintains 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 the needs of all components of ASPR in a

fiscally responsible approach to address public health and medical 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 is:

- Drafting and submitting for clearance the NHSS Evaluation of Progress for the 2019 to 2022 quadrennial period;
- Drafting and submitting for clearance the NHSS and NHSS Implementation Plan for the 2023 to 2026 quadrennial period;
- Providing advanced 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;
- Participating in the NSC-led effort to develop a revised biodefense strategy and implementation plan, and executing elements of the plan assigned to ASPR;
- Providing 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;
- Evaluating key ASPR programs and initiatives, such as NHPP and COVID-19 related activities, to identify gaps, improve program performance, and meet Evidence Act and other USG, Departmental, and Agency goals;
- Delivering 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;
- Promulgating a final Health Resources and Priorities Allocation System regulation and business processes for Defense Production Act authorities of the Secretary;
- Leading, with NASA, the implementation of the backward contamination objectives of the National Strategy for Planetary Protection;
- Implementing the Laboratory Biological Incident Reporting Survey for all HHS biological laboratory staff;
- Continuing the work of the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences (IWG) led by HHS/ASPR and USDA/APHIS to engage with experts to promote responsible conduct of science and the norms against biological weapons; and,
- Issuing a Federal Register Notice of the Request for Information for Screening Framework Guidance for Providers and Users of Synthetic Oligonucleotides, which elicits stakeholder input on proposed revisions to the 2010 Screening Framework Guidance for Providers of Synthetic Double Stranded DNA and leading the interagency process of finalizing the updated guidance.

Funding History	
Fiscal Year	Amount
FY 2019	\$14,877,000
FY 2020	\$14,877,000
FY 2021 Final	\$14,877,000
FY 2022 CR	\$14,877,000
FY 2023 President's Budget	\$21,417,000

Budget Request

The FY 2023 President's Budget request for Policy and Planning is \$21,417,000, which is +\$6,540,000 above the FY 2022 CR. Within the increase, an additional +\$1.5 million will establish quantitative and economics analytics and modeling capabilities to evaluate medical countermeasure programs. The modeling capabilities will enable the Department to (1) estimate and compare the public health consequences of incidents and attacks involving biological, chemical, radiological, and nuclear agents as well as emerging infectious diseases of pandemic potential; and (2) quantify the range of personnel, medical countermeasures, and other resources needed to protect and treat the affected population. Economics analytics and modeling capabilities will provide decision support to guide the Department's investments into the most cost-effective and fiscally responsible solutions early, and to ensure we are well-prepared to meet the USG public health and emergency medical mission when pandemic and intentional threats emerge. Without this systematic prioritization and program oversight, ASPR will not be able to effectively harmonize across its many mission sets and ensure resources target the highest priority investments.

The FY 2023 President's Budget includes an additional \$5 million for COVID-19 After Action Reviews as well as support for COVID-19 administrative capacity.

The funds will also allow ASPR to continue providing policy leadership to address United States Government (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.

Key Outputs and Outcomes Table Policy and Planning

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 Target
2.4.13 Increase the number of National Health Security Strategy policy tools that support national and health security capabilities (Output)	FY 2021: 76 policy tools Target: 42 policy tools ³² (Target Exceeded)	80 policy tools	Prior Result + 4	N/A
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 2021: 13 actions Target: 7 actions (Target Exceeded)	14 actions	Prior Result + 1	N/A
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 2021: 68.0 stakeholder engagement contacts Target: 34.0 stakeholder engagement contacts ³ (Target Exceeded)	71.0 stakeholder engagement contacts ⁴	Prior Result + 3.0	N/A
2.4.18 Increase the number of identified ASPR activities designed to implement the National Biodefense Strategy across the entire Biodefense enterprise (Output)	FY 2021: 8 activities Target: 8 activities (Target Met)	9 activities	10 activities	+1 activities

³²Two above the baseline developed in support of national health security capabilities

Operations

Budget Summary (Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	30.938	30.938	34.376	+3.438
FTE	135	135	142	+7

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 for Preparedness and Response (ASPR) is committed to the highest level of 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 providing decisive leadership that bolsters the nation's health security. Operations provides enterprise-wide oversight and support in management of the organization and programs for public health preparedness and response. Operations also supports acquisitions and grants policy, strategic leadership and interagency coordination, and human capital management, including 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 of the Department of Health and Human Services (HHS) 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 HHS responsibilities for responding to, recovering from, and mitigating the lasting impacts of public health and medical emergencies of all kinds.

Operations supports management services and business activities that enable ASPR to carry out its mission, including human capital management, financial management, workforce development, and oversight of communications with the public and the media. Operations also ensures coordination for technology management and information security, facilities, external 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. Using special hiring authorities, ASPR expanded its workforce 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. ASPR has transitioned from its previous website (phe.gov) to a more modernized site (aspr.hhs.gov) with a new look and feel that provides clear messages and is optimized for mobile devices. This website is the primary platform ASPR uses for sharing information. Using the new site, private industry, state and local government agencies, and community organizations can 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 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. In support of the COVID-19 response, ASPR formulated five separate emergency supplemental budgets resulting in over \$90 billion invested in medical countermeasures including vaccines and therapeutics, personal protective equipment including N-95 respirators, diagnostics tests for detection of the virus, grants to state healthcare coalitions for surge capacity, contracts to industry to expand the supply chain for critical materials, and expanded data modeling and forecasting systems. The draft Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multiyear Budget (MYB) report for FYs 2020-2024 is currently under review within the Department. The draft report covers FY 2020-2024, thereby skipping a year due to the COVID response.

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 Emergency Support Function (ESF) 8 efforts under the National Response Framework, 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*"). These efforts include tracking, analyzing, and reporting 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 an environment of learning that includes a comprehensive view of risks in ways that drive strategic decisions, performance management, 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 2019	\$30,938,000
FY 2020	\$30,938,000
FY 2021 Final	\$30,938,000
FY 2022 CR	\$30,938,000
FY 2023 President's Budget	\$34,376,000

Budget Request

The FY 2023 President's Budget request for Operations is \$34,376,000, which is \$3,438,000 above FY 2022 CR. The increased funding will support a new Working Capital Fund (WCF) as well as support inflationary cost increases. The request will allow 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 ASPR's Enterprise Risk Management and strategic human capital management initiatives.

Working Capital Fund (WCF) Implementation and Management: An additional \$2.2 million will be used to build and support the capacity to implement and manage an ASPR WCF for support services. A team will be responsible for the primary activities in support of fund management including execution, communications, financial and performance reporting, policy, and documentation management, change management activities and support for governance and oversight. Funds will be used for up to seven staff and systems support including information technology platforms. ASPR also will seek a Delegation of Authority from the Secretary of HHS to operate under the existing statute Title 42 U.S Code 231 pertaining to the HHS, Office of the Secretary, Service and Supply Fund. Specifically, ASPR would use this authority to:

- 1) Specify the receipts or collections that the agency would credit to the fund;
- 2) Define the fund's authorized uses; the purpose for which funds may be expended (i.e., scope of services); and
- 3) Use receipts for those purposes without fiscal year limitation.

In FY 2022, ASPR is conducting a comprehensive analysis and developing a framework for implementing a WCF. Anticipated milestones include defining service activities and establishing cost drivers, capturing unit costs and rates for operations and payroll, developing projected levels of effort (LoE), and producing transparent program assessments that support future cost management. Within the phase of defining service activities, ASPR will determine which support functions will be funded through the WCF. During FY 2022, ASPR is working to implement and evaluate key WCF activities, including service catalogs, a chargeback methodology, accounting/budget execution processes to handle WCF operations, governance strategies, and change management facilitation and training. By FY 2023, the full array of WCF services will be available to all ASPR programs. Within the initial phase the primary focus will be to address services costs for the functions listed below.

Information Technology

Information Technology (IT) services provide ASPR with information, communication, knowledge infrastructure and quality customer service delivery to enhance and sustain systems and IT operations throughout ASPR's programs and regional operations. IT support also ensures robust cybersecurity controls are applied to ASPR systems to protect privacy, ensure confidentiality, integrity, and availability of ASPR information in accordance with Federal, Department and Agency regulations and during the rigorous challenges of emergency response. The IT function manages technology strategies to support the full life cycle of IT systems and infrastructure and leverages knowledge and resources to ensure security and protection against system failures. Funds also would support informatics and technology-based innovation needs.

Human Resources

Human Resources (HR) services support for ASPR's workforce happens through management of recruitment and staffing services, HR policy development and accountability, and the provision of labor support services. HR support coordinates ASPR's recruitment actions with service centers, interactions with labor unions and address labor practices through the employee and labor relations programs, as well as the ability to address the Commissioned Corps' unique needs. HR also utilizes a variety of hiring authorities to meet ASPR's needs for a multi-disciplinary workforce. This includes direct hiring authority to recruit members of the National Disaster Medical System. In FY 2021 ASPR supported a workforce of nearly 1,000 full time civilian and Commissioned Corps employees and over 4,000 intermittent public health and medical emergency responders.

Financial Management with Acquisition Policy and Oversight

Financial and Acquisition Policy services enable ASPR to perform budgetary, financial, acquisition, and grants functions. This includes formulating, monitoring, and evaluating budgets and financial plans to support program activities. ASPR's annual budget has increased 36 percent over the past five years to a total of close to \$2.8 billion. ASPR also manages reimbursements from FEMA to support the costs of deploying HHS responders and other assets during public health emergencies. This requires a continuous and extensive billing process to ensure that ASPR recovers its costs.

In support of ASPR's contracting activities, acquisition policy and oversight manage activities to foster procurement, awarding of contracts, grants, cooperative agreements, and Other Transaction Authority agreements. Oversight is provided for ASPR's current total contract valuation of over \$70 billion dollars.

Finally, the use of WCF reserves will be evaluated and improved over time. Additional services that will be evaluated for coverage by an operating WCF include personnel security, facilities and property management, external affairs and communications, and other administrative functions. A potential use of WCF reserves could facilitate IT infrastructure for the SOC and COOP sites remaining current and resilient. Lastly, reserves may be used to surge administrative services into the early stages of an emergency response that are not authorized for reimbursement under the Stafford Act or otherwise provided in support of agreements with other federal agencies.

HHS Coordination Operations and Response Element

Budget Summary (Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	-	-	132.801	+132.801
FTE	-	-	111	+111

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 HHS Coordination Operations and Response Element (H-CORE) institutionalizes the interagency coordination surrounding the development, production, and distribution of COVID-19 vaccines and therapeutics within the HHS/ASPR. These activities were previously carried out in partnership with the Department of Defense (DoD) as part of the Countermeasures Acceleration Group (CAG), formerly known as Operation Warp Speed (OWS). These efforts included the delivery of over 600 million doses of vaccines and 3.9 million courses of therapeutics to protect the American people from COVID-19. On December 31, 2021, the Memorandum of Understanding between HHS and DOD expired, and all efforts were successfully transitioned on January 1, 2022 to the newly established H-CORE within HHS and ASPR.

An important lesson learned during the COVID-19 pandemic response has been the need for a permanent, nimble, organizing entity to ensure the synchronization of the medical countermeasure efforts across the federal interagency. H-CORE was created to implement the HHS Secretary's COVID-19 vaccine and therapeutic production and distribution priorities and offer HHS the internal capability to coordinate the logistics of other materiel such as test kits and masks. In the future, H-CORE's capabilities can be refocused on non-pandemic priorities as needed.

HHS established H-CORE with the authorities and skills to lead, coordinate, and synchronize federal pandemic preparations and response in order to enhance and accelerate the ability of the United States Government to protect the health and safety of the US population before and during an infectious disease outbreak. HHS leadership set guiding principles and strategy and conducted planning for the development, production, distribution and administration of vaccine and therapeutics. H-CORE provides analysis to support prioritization of requirements and investments for accelerating manufacturing of vaccines, establishing and supporting clinical trial sites, procuring administration supplies (ancillary kits), defining cold chain requirements, planning for cold chain storage, and leading and synchronizing jurisdictional planning for vaccine distribution. Additional responsibilities include senior level tracking and synchronization of various working groups throughout the planning and procurement process,

establishing and operating the Vaccines and Therapeutics Operations Center, and planning at the national level for state distribution coordination. H-CORE serves as senior lead for various working groups, to include federal entities and industry partners to support the full spectrum of pandemic response operations.

Funding History	
Fiscal Year	Amount
FY 2019	-
FY 2020	-
FY 2021 Final	-
FY 2022 CR	-
FY 2023 President's Budget	\$132,801,000

Budget Request

The FY 2023 President's Budget request for the HHS Coordination Operations and Response Element is \$132,801,000, which is +\$132,801,000 above the FY 2022 CR. The program is currently supported through COVID-19 supplemental appropriations. The request establishes annual funding to ensure the continued operation of this critical program. An important lesson learned from the COVID-19 pandemic response is the need for a permanent, nimble, organizing entity to ensure the synchronization of the Government's medical countermeasure efforts. In the future, H-CORE's capabilities can be refocused on non-COVID-19 priorities as needed.

Funds will be used for acquisition support to procure COVID-19 vaccines, therapeutics, and other related medical countermeasures; support ASPR staff and related operational costs; and ensure the continuation of data analytics, modeling, and forecasting to respond to COVID-19 and prepare for future outbreaks and pandemics. ASPR may also use these funds to support other response efforts as the COVID-19 pandemic continues to evolve and other threats arise. Without these resources, HHS/ASPR will not be able to continue the coordinated development, production, and distribution of lifesaving COVID-19 medical countermeasures.

ASSISTANT SECRETARY FOR ADMINISTRATION

Cybersecurity

Budget Summary (Dollars in Millions)

	FY 2021 Final	FY 2022 CR/2	FY 2023 President's Budget	FY 2023 President's Budget +/- FY 2022
Budget Authority	\$57.820	\$57.820	\$161.326	\$103.506
FTE	110	143	143	--

1/ This column includes both supplemental funding and mandatory funds appropriated in the American Rescue Plan Act of 2021, P.L. 117-2 post-transfer and post-reallocation and the supplemental appropriation in the Consolidated Appropriations Act, 2021 (P.L. 116-260).

2/ Reflects the annualized amounts provided in the continuing resolution ending 3/11/2022.

3/ This column includes both supplemental funding and mandatory funds appropriated for FY 2022 in the Infrastructure and Jobs Act and in the Build Back Better Act.

Authorizing Legislation:

Allocation MethodDirect Federal

Program Overview and Cybersecurity Challenges

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 HHS Cybersecurity program 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.

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 the number of mandates increased to over 100 including the following President's Executive Orders: EO 14017 - *America's Supply Chains*, EO 14028 - *Improving the Nation's Cybersecurity*, and EO 14034 - *Protecting Americans' Sensitive Data from Foreign Adversaries*.

HHS continues to increase its protections against cyberthreats, 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 threats.

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 unprecedented volume of sector threat activity over the last several years, and in most recent months due to the global health pandemic, poses significant challenges to the HHS Cybersecurity program mission. High-profile global cybersecurity events and specific technology incidents such as those impacting SolarWinds, Microsoft, and

Pulse Connect Secure – show in part, cybersecurity vulnerabilities and have the potential to greatly impact the critically necessary HHS mission.

Cybersecurity, privacy, and end-of-life legacy systems remain the top three IT challenges facing HHS. 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. 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
- New threat vectors introduced by a more distributed workforce using unapproved tools and technologies while working remotely

The program executes a focus on an enhanced-heightened security framework to protect HHS from increased cyberthreats to ensure network operability. In response to the current and future landscape, HHS must continue efforts to hunt for the tactics, techniques, procedures, and indicators of compromise through advancement of cybersecurity threat intelligence. 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.

HHS continues to be a primary target for some of the most advanced cybercriminals in the world; thereby, as a matter of national security, the HHS Cybersecurity program requires the requested levels in support of the challenges that accompany rapidly changing technologies and the influences of hostile actors.

HHS Cybersecurity Program Description and Accomplishments

HHS Cybersecurity program implements a comprehensive, enterprise-wide program to protect the critical information with which the Department is entrusted.

The HHS Cybersecurity program has successfully defended against waves of cyber-attacks. During the pandemic HHS experienced a large-scale distributed denial-of-service (DDOS) attack and similar threats in the weeks that followed. The HHS cybersecurity operations team successfully defended nearly 2 billion events during an 18-hour period. The Cybersecurity program thwarted these attacks without a disruption in service while 95% of HHS' workforce teleworked. The program 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 the Operating Divisions (OpDivs) and Staff Divisions (StaffDivs), the Cybersecurity program streamlined collaboration during cyber events. Despite the impact to the workforce, and in response to the heightened threat environment, the program continued to bolster its cybersecurity posture. In FY 2021, the Cybersecurity program:

- Managed 7,683 cybersecurity incidents, an increase of 1,161 incidents over FY20
- Conducted 11,723 vulnerability scans, an increase of 2,061 over FY 2020 (scanning an estimated 4,140,032 targets), preventing 1,439,042 vulnerabilities from being exploited, an increase of

182,621 over FY 2020. This accounts for 12,332 hours of scan time, an increase of 2,619 hours over FY20

- Investigated 44,643 incidents of spam, 1,111 of which were malicious and, if gone unchecked, could have compromised HHS data. This is a slight reduction and attributed to the increasing effectiveness of 178 ethical phishing campaigns executed in FY21 maintaining a targeted 90% phishing resilience goal
- Hosted weekly HPH sector threat intelligence briefings and supported the OIG in 154 victim notifications, and increase of 31 notifications over FY21
- Reviewed 101,351 HPH sector websites and reported 12,463 malicious websites for takedown.
- Hosted 14 HPH sector webinars for over 1200 attendees on topics such as “Enterprise Risk Management, Internet of Medical Things, Monitoring and Responding to Cyber Threat”
- Released over 40 cybersecurity awareness products to the HPH sector including topics such as *Ransomware, Phishing, Social Engineering, and Health Industry Cybersecurity Practices (HICP)*
- Shared over 33,816 IOCs and 67 analyst products, an increase of 9,664 IOCs and 31 products demonstrating the high level of engagement and collaboration across HHS and with external HPH sector partners

The metric’s consistency and escalations from previous years demonstrates a constant threat to the department. The increases in threat methodology demonstrates HHS must continue to operate a robust, fully funded program necessary to meet current and future cybersecurity needs. 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’ 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. To accomplish this, the program 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
- Establishing and maintaining effective network protections

Improving the Department’s protection of assets, endpoints, and data include not only procuring technology, but also building and maturing programs and a highly skilled cybersecurity workforce. Together the program can ensure technologies, programs, and people achieves HHS objectives, protects information, and facilitates compliance with federal mandates and guidelines. The HHS comprehensive, enterprise-wide Cybersecurity program can be grouped as a tactical delivery of cybersecurity operations and a more strategic information security modernization program management. These capabilities and services include:

- 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 dedicated 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:

- Computer Security Incident Response Center (CSIRC)
- Advanced Cyber Defense (ACD)
- Security Tools and Information Management (STIM)
- Health Sector Cybersecurity Coordination Center (HC3)
- 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 and 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 and taking appropriate action and instituting network blocks as appropriate. CSIRC maintains HHS' mission critical operations, blocks malicious sites, filters spoofing emails and spam, and trains users through ethical phishing. These activities enable real-time visibility of threat elimination and protect the personal and 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' 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, Trusted Internet, and Security 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 Department and Trusted Internet Connection (TIC) access points. In FY 2021 provided over 37 petabytes of bi-directional HHS internet traffic.

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 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 provides core capabilities for the Department's continuous monitoring plan by acting as a single point of aggregation for internet traffic security data collection.

STIM 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. This initiative supports greater security in the government's internet connections and facilitates the necessary infrastructure to implement Department of Homeland Security (DHS) cybersecurity initiatives for the entire Department.

STIM will continue to execute and mature 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 advance innovations and security tools at Department internet connections. STIM will 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 has directly engaged with 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.

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** ensures HHS information and IT assets are appropriately secure and compliant with federal regulations and security industry best practices. Additionally, serves as the focal point to communicate mandatory cybersecurity requirements to the Department, and responsible for cybersecurity policy and training and awareness agency wide.
- b. Information Security Risk Management** evaluates Department-wide vulnerabilities and threats to HHS in support of effective risk-based decision-making. This includes the HHS High Value Assets (HVA) Program which integrates HVA management into enterprise planning and enterprise risk management efforts. This enables OpDivs and StaffDivs to better identify and understand the specific security needs of their most critical assets; and 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 HHS 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, cybersecurity audits, 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 information security policy and conducts risk management, compliance, and security operations for the Office of the Secretary (OS) and OS Staff Divisions.
- e. Privacy Services** provides privacy governance and advisory support, reduces exposure to privacy risks, mitigates privacy risks, develops privacy policy. These services ensure compliance with Federal mandates through privacy policy, training, and FISMA privacy requirements. Services include reviewing and approval all Privacy Impact Assessments (PIAs), coordinating breach response, FISMA reporting, while also reviewing website privacy, High Value Assets, and system privacy requirements.
- f. Aligning Healthcare Industry Security Approaches:** The Cybersecurity Act of 2015, Section 405(d) is addressed through the 405(d) Program and Task Group as a collaborative effort between industry and the federal government. This activity aims to raise cybersecurity awareness, provide vetted cybersecurity practices, and move organizations towards consistency in mitigating the current most pertinent cybersecurity threats to the sector. The 405(d) Program aims to develop consensus-based guidelines,

practices, and methodologies to strengthen the healthcare and public health (HPH) sector's cybersecurity posture against cyber threats.

Funding History		
Fiscal Year	Amount	COVID-19 Supplemental Funding
FY 2019¹	\$57,820,000	\$0
FY 2020	\$57,820,000	\$154,575,000
FY 2021 Final	\$57,820,000	\$0
FY 2022 CR	\$57,820,000	\$0
FY 2023 President's Budget	\$161,326,000	\$0

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

Budget Request

The FY 2023 President's Budget request for the HHS Cybersecurity program is \$161,326,000, which is a \$103,506,000 increase to the FY 2022CR.

HHS continues to be a primary target for some of the most advanced cybercriminals in the world; thereby, as a matter of national security, HHS requires the increased requested levels in support of the challenges that accompany rapidly changing technologies and the influences of hostile actors. HHS intends to enable better prevention, detection, assessment, and remediation of cybersecurity threats.

The request continues support and sustainment of the Department's cybersecurity and privacy posture by implementing and maturing 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. The requested level will allow HHS to manage existing solutions, address cybersecurity mandates through targeted initiatives, and compliment current network protection tools.

Increases enable deployment of cybersecurity initiatives aligned to the expanding threat environment, legislative mandates, and Presidential directives. The requested level allows for continued maturation of the departmental cybersecurity initiatives connected to Executive Order 14028.

Summary of Cybersecurity FY 2021-2023

Funding by Activity*(Dollars in Millions)*

	FY 2021 Final	FY 2022 CR/2	FY 2023 President's Budget	FY 2023 President's Budget +/- FY 2022
Cybersecurity Operations and Engagement	\$11.560	\$11.560	\$11.560	--
Cybersecurity Risk, Governance, FISMA Compliance, and Privacy Management	\$24.760	\$24.760	\$25.079	\$319
Cybersecurity Tools and Enterprise Solution	\$21.500	\$21.500	\$74.187	\$52.687
Zero Trust Architecture	--	--	\$50.500	\$50.500
Total	\$57.820	\$57.820	\$161.326	\$103.506

1/ This column includes both supplemental funding and mandatory funds appropriated in the American Rescue Plan Act of 2021, P.L. 117-2 post-transfer and post-reallocation and the supplemental appropriation in the Consolidated Appropriations Act, 2021 (P.L. 116-260)

2/ Reflects the annualized amounts provided in the continuing resolution ending 3/11/2022

3/ This column includes both supplemental funding and mandatory funds appropriated for FY 2022 in the Infrastructure and Jobs Act and in the Build Back Better Act.

Cybersecurity Operations and Engagement Activities (\$11,560,000): The request is flat to the FY 2022 CR. Funding to this activity aligns to continued Cybersecurity operational services and capabilities across the Department. *Cybersecurity Operations and Engagement Activities* include the program delivery of CSO 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. CSO capabilities proactively minimize attacks across the Department, in some cases, before the attacks escalate. CSO addresses several threat vectors simultaneously by having a central view into all Department networks.

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. HHS must invest in expanding cybersecurity technologies and an evolving remote workforce to stay ahead of challenges. Smartphones, mobile, VPN, and cloud computing significantly changed the way the HHS stores, accesses, and secures data while meeting the protection and accessibility demanded by the public's interest.

Cybersecurity Risk, Governance, FISMA Compliance, and Privacy Management Activities (\$25,079,000): The request is \$319,000 above the FY 2022 CR. Funding to this activity aligns with continued on-going execution of enterprise privacy, cybersecurity governance, risk, and compliance capabilities, and for the program's federal workforce. These capabilities determine compliance with Department policy and standards, including quarterly evaluation of security weakness Plans of Action and Milestones (POA&M), Privacy Impact Assessments (PIA), and system of records notice (SORN) compliance. Support will continue for the activities of the HHS PII Breach Response Team that enables the Department to evaluate OpDiv and StaffDiv breach response assessments to determine the appropriate

response to reported breaches of PII. Funds enable continued 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, risk management initiatives, and strategic and thought leadership. Funding continues the program's security compliance and annual FISMA program review efforts to effectively measure the Department and OpDiv/StaffDiv levels of compliance with FISMA requirements. Funding 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' information assets.

Cybersecurity Tools and Enterprise Solution Activities: (\$74,181,000): The request is \$52,687,000 above the FY 2022 CR. The request aligns with continued operations of a heightened security framework and additional cybersecurity initiatives responding to the President's cybersecurity Executive Order. Funding supports maturing and increasing Department-wide licenses, infrastructure, software, and next generation security technologies (Including solutions addressing, cloud logging, encryption, enterprise malware, content filtering, data loss prevention, vulnerability-scanning, automated reporting, logging, analysis, and security weakness tracking).

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
- Advancing enterprise-wise tool solutions to enable HHS' 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 through advancements in Zero-Trust architecture
- Increasing situational awareness and response to actions that could exploit or jeopardize HHS information systems
- Facilitating HHS' compliance against federal mandates and guidelines; and
- Refining HHS' network protection through deception solutions, intrusion detection, and threat response to better manage and prevent future attacks

Zero Trust and Supply Chain Risk Management Activities: (\$50,500,000): The request is \$50,500,000 above the FY 2022 CR. This request directly addresses systems and services to implement Executive Order 14028, specifically focusing on zero trust implementation and security logging requirements. This activity includes specific resources to establish a Supply Chain Risk Management (SCRM) program in response to the 145 recommendations from GAO-21-171: *Information and Communications Technology: Federal Agencies Need to Take Urgent Action to Manage Supply Chain Risks*.

HHS intends to enable better prevention, detection, assessment, and remediation of cybersecurity threats by coordinating and supporting the deployment of Zero Trust architectures across the Department, including on-premise and cloud platforms. The request enables the program to apply a granular analysis of the context, device, and user identity to strictly enforce least-privilege authorizations for each access request. Implementation requires significant investment to prioritize use cases, redesign networks, and implement modern policy control points. It also requires resources to develop an active and ongoing assessment of each program's core capabilities required to implement Zero Trust. HHS will also implement smart automation to better protect data based on risk levels and principles of least privilege access.

Specific initiatives from this request include:

- Development of a Zero Trust architecture, which will be integrated into a selection of tools for next generation secure cloud implementation
- Modernizing the enterprise network to enable Zero Trust principles and capabilities: improving Zero Trust and supply chain cybersecurity competencies
- Expanding identity and access management tools and services to enable Zero Trust policy-based access
- Reprioritizing dedicated FTEs, developing funding streams, or increasing base funding to implement supply chain risk management, endpoint detection and response, insider threat, and counterintelligence

HHS Cybersecurity - Outputs and Outcomes Table

Program/Measure	Most Recent Result	FY 2022 Target	FY2023 Target	FY2023 Target +/- FY2022
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 2021 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 2021 Actual: 75.0%	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 2021 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 2021 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 2021 Actual: 95.0%	90.0%	90.0%	Maintain

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Other PHSSEF Cybersecurity – HHS Protect

Budget Summary

(Dollars in Millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	--	--	21.9	+21.9

Authorizing Legislation:

Allocation Method Direct Federal

Program Description and Accomplishments

The COVID-19 pandemic has created unprecedented challenges for the HHS and for the delivery of health care and human services to beneficiaries. HHS leads the Federal public health and medical response during public health emergencies and recognizes, harnessing data to improve health and well-being of individuals. HHS and the healthcare and public health sector rely heavily on information systems to fulfill their missions, including delivering healthcare-related services and responding to national health emergencies, such as COVID-19.

At the onset of the pandemic, it became clear that HHS needed a central way to make data collected by various operating divisions, including CDC, CMS, HRSA, and others, visible to first responders at federal, state, and local levels and we needed to collect this data as fast as possible. To fulfill this need, HHS built HHS Protect, a secure data integration, analytics, and situational awareness platform for the whole-of Government response to the COVID-19 pandemic.

The HHS Protect serves as the common operating picture and central hub to collect, integrate, and share COVID-19 data in near-real time across federal agencies as well as with state, local, territorial, and tribal stakeholders on the frontlines of the pandemic. Bringing together over 3,000 unique users and 250 data sources from 50 states, US territories, and tribal areas, HHS Protect has enabled multilateral data sharing among critical response entities, while protecting data through granular, government-defined access controls and protection capabilities. The data system management and governance are critical pieces to ensure continued support for the COVID-19 response, as well as the long-term stability and strategic investment in these capabilities.

At the onset of the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) transferred HHS Protect to the Office of the Chief Information Officer (OCIO) in HHS. At the point of transfer, HHS Protect was a pilot system which OCIO expanded and reconfigured for the COVID-19 response before releasing it on April 10, 2020. Building on the system that CDC established, 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 timeseries based immutability, and leading-edge data analytics capabilities to create a public health surveillance capability to create visibility into the COVID-19 pandemic.

In less than 80 days, HHS collected more than 4 billion data elements from numerous public health sector entities, including private sector, hospitals, and state governments. Over 6,000 hospitals report data to HHS daily to provide insights into American healthcare system capacity and inform government response systems. HHS Protect data empowers decision makers with data based on a common operating picture depicting the public health environment in the United States at the federal, state, and local level.

Funding History	
Fiscal Year	Amount
FY 2019	--
FY 2020	--
FY 2021	--
FY 2022 CR	--
FY 2023 President's Budget	\$21,900,000

Budget Request

The FY 2023 President's Budget level for HHS Protect is \$21,900,000. This funding will complement ongoing supplemental investments for the system. The FY 2023 budget assumes that the HHS Protect system will continue to be implemented by CDC. HHS Protect will enable the U.S. government to harness the full power of healthcare data for public health, including for the COVID-19 response.

HHS Protect must remain secure, ensure privacy, protect transparency, and enable data sharing with integrity to combat COVID-19 and support future pandemic response efforts. In partnership with CDC, HHS Protect provides insight to decision-makers on COVID-19 with over 4 billion data elements. Collaboration with federal, state, local governments, and hospitals across the country to collect data has been instrumental in the country's response to this crisis. This data provides a nationwide view of key response areas such as COVID-19 cases, laboratory testing, hospital capacity, hospitalization, COVID-19 deaths, supply of personal protective equipment (PPE), use of therapeutics, vaccinations, and personnel, as well as insight into critical capacity and supply issues.

The whole-of-America response to the COVID-19 pandemic demands holistic data sharing in near-real time. Collaboration across many lanes, has resulted in greater visibility across the health system, empowering health professionals to make better decisions about patient access and care. HHS Protect has helped inform the federal government's decisions on where and how resources can be mobilized to help on the front lines of the pandemic response.

Sustainable funding for HHS Protect will enable this key data sharing and analysis used for decision-making during the ongoing COVID-19 pandemic and sustain HHS Protect's flexible capabilities for potential future application to other public health needs.

IMMEDIATE OFFICE OF THE SECRETARY

Office of National Security

Budget Summary (dollars in millions)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	8.510	8.510	8.983	+0.473
FTE	37	38	38	0

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 Staffing and Business Services Division (SBSD) and the Personnel Security (PerSec) Division. 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 others across the Department. In addition, ONS represents HHS on a number of external committees and councils responsible for interagency coordination on security threats, intelligence, counterintelligence, insider threat and cyber threat intelligence issues, including the sharing and safeguarding of national security information.

Funding History	
Fiscal Year	Amount
FY 2019	7,470,000
FY 2020	8,510,000
FY 2021 Final	8,510,000
FY 2022 CR	8,510,000
FY 2023 President's Budget	8,983,000

Budget Request

The FY 2023 request for ONS is \$8,983,000 which is a \$473,000 increase over the FY 2022 Continuing Resolution (CR).

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

Ebola Epidemic; 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 continues to 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)

	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Program Level	287.000	287.000	382.000	+95.000
<i>Budget Authority (non-add)</i>	287.000	287.000	382.000	+95.000
<i>ASPR No-year funding (non-add)</i>	252.000	252.000	347.000	+95.000
<i>ASPR Annual Funding (non-add)</i>	27.991	27.991	27.991	-
<i>OGA Annual Funding (non-add)</i>	7.009	7.009	7.009	-
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

The global and domestic impact of the COVID-19 pandemic has been devastating. However, infectious disease models indicate that other highly contagious and virulent airborne pathogens, 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 influenza viruses with pandemic potential, including H7N9, H5N1, and H5N6 influenza viruses, as well as other emerging infectious diseases that could cause pandemics. Furthermore, while there is no currently circulating strain of influenza A(H2Nx) virus in humans, A(H2Nx) strains continue to circulate in wild birds, with occasional spillover into domestic poultry, and in swine. Finally, the recent identification of the "G4" influenza A/H1N1 as a circulating virus with potential to cause a global pandemic clearly demonstrates that the threat continues to exist and evolve, underscoring the need for continued development of better, faster medical countermeasures (MCMs).

The astonishing speed of the SARS-CoV-2 spread from Wuhan to the United States and the ensuing disruption of societal functions demonstrate 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 a pandemic, the United States Government (USG) must continue to improve medical countermeasures, 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. These lessons learned further guide and shape Biomedical Advanced Research and Development Authority's (BARDA's) Pandemic Influenza portfolio in the Office of the Assistant Secretary for Preparedness and Response (ASPR).

Strengthening Pandemic Influenza Preparedness

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 US 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 efficacious and effective;
- Expanded the surge capacity of domestic vaccine manufacturing, while increasing its flexibility to help manufacture pandemic influenza vaccines as quickly as possible;
- Established Vendor Managed Inventory of adjuvant in a public-private partnership. This includes rotation of inventory to support pandemic preparedness;
- Completed technology transfer of adjuvant production to a domestic US facility; and fill-finish activities to support surge production;
- 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 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 three clinical trials focused on reducing transmission to uninfected individuals;
- Opened a new program for the treatment or prevention of acute lung injury and acute respiratory distress syndrome focused on hospitalized patients with respiratory disease;
- Worked with FDA and academia to establish clinical endpoints for hospitalized influenza disease which lead to the endpoints, time to recovery on the ordinal scale, used for COVID-19 therapeutic development for hospitalized patients;

- 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;
- Improved technical knowledge and capacity for manufacturing in developing countries in order to increase global pandemic influenza vaccine capacity; and
- 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.

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. FDA has since extended the indication for Flucelvax to include persons two 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. 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, Audenz, indicated for use in persons 6 months of age and older.

Recombinant Vaccines: The PI program supported the first recombinant-based vaccine for seasonal influenza licensed in the US. This recombinant vaccine technology 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 circulating virus strain, maximizing the likelihood of its effectiveness. In 2015, the Flublok indication was extended to people ages 18 years and above. The Quadrivalent Influenza Virus Vaccine was approved by FDA in the winter of 2016. The PI program completed 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 enables selection of the optimal vaccine formulation for pandemic response, as the adjuvanted vaccine induces a strong immune response, and a substantial proportion of subjects showed high cross-reactivity to antigenically distinct heterologous A(H7N9) viruses from the first epidemic wave of 2013. These results provide critical information to develop a pandemic response strategy and paves the way for both dose selection as well as future trials to examine other dosing regimens and suitability of other adjuvants. These efforts laid critical groundwork, enabling the rapid development of the COVID-19 mRNA vaccines.

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 (GSK) 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, Audenz, 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.

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 can shorten 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.

Expanded Domestic Influenza Vaccine Manufacturing Surge Capacity: 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 finalizing its validation of 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 EO 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.

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 intravenous infusion. 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 therapeutics for critically ill persons with influenza. The advanced development projects include influenza drugs with novel mechanisms of action to reduce 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 2021, BARDA continued support for one ongoing efficacy trial of a therapeutic candidate to reduce the transmission of influenza to uninfected individuals. FY 2022 and 2023 funds will continue to support ongoing and new programs to develop novel influenza antiviral drugs and other therapeutics for the treatment of severe complications of influenza infections.

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 cleared by FDA, 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 Diasess (now Lucira Health) in 2018, 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 COVID-19 response. 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 have home-use potential, if authorized by FDA, improving the nation's preparedness for co-circulating influenza and SARS-CoV-2. In FY 2022 and beyond, 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. In FY 2018, investments were made for development of a reusable elastomeric respiratory protection device as alternative to disposable N95s.

Applied Research Associates completed development of their prototype device, which is expected to achieve NIOSH approval and enter the market in FY 2022.

Enhancing global pandemic preparedness: OGA fills a unique role within HHS by providing strategic coordination and policy coherence for the Department and the 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 actionable steps and initiatives that support core principles (e.g., equity, accountability, transparency) and achieve progress on priorities for HHS, as well as 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 World Bank Group, the World 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 and pandemic threats. Building on lessons learned from influenza preparedness and response efforts over the past twenty years and from the experience with other health security threats, OGA provides essential policy development support and coordinated diplomatic outreach to bolster global health security and equity, inform domestic preparedness and response efforts, and strengthen and expand partnerships that are crucial to face the challenges of influenza pandemic threats, and other emerging infectious disease threats of global concern.

As an interlocutor between international public health and domestic public health and to strengthen U.S. influenza pandemic preparedness efforts, 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 with the White House National Security Council (NSC), the Departments of State (DOS), Agriculture, and Defense, and other Federal departments and agencies; as well as with non-governmental and private sector partners, and international 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 security 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 or other pandemic threat.

Significant accomplishments include:

- Strengthening diplomatic and political support:
 - o 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.

- o Promoted adaptation of influenza pandemic preparedness resources and tools for the global COVID-19 response.
- o Supported the NSC, by developing and implementing the interagency diplomatic engagement strategy on Influenza/H7N9 sample sharing to identify opportunities and 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 (e.g., Ministry of Finance and Commerce) involved in the export of virus samples from the China-CDC to support the Pandemic Influenza Preparedness-Framework (PIP-FW).
- o 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*.
- o 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 regions. 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 core capacity development aligned with the obligations under the WHO International Health Regulations [IHR]).
- o 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 United States
- o Established and updated national pandemic influenza plans in Africa and other vulnerable regions to support the prioritization of influenza at the national level.
- o Supported the implementation of influenza vaccination programs in at-risk populations in low-and-middle-income countries through the Partnership for Influenza Vaccination Introduction.
- o 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.
- o Led the global discussion to promote rapid, systematic, and timely international influenza virus sharing, including seasonal influenza viruses.
- o 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, as well as COVID-19 response activities.
- o Led U.S. engagement in the Global Health Security Agenda (GHSa), including engagement in the Steering Group, Action Package Working Groups (e.g., Sustainable Financing for Preparedness, Legal Preparedness), and contributed to additional working groups and task forces (e.g., Advocacy & Communications).
- o Contributed to several USG-wide and global consultations for setting directions and elements for future pandemic preparedness and response, including ahead of the G20 Global Health Summit in Rome, G20 Health and Finance meetings on sustainable financing for pandemic preparedness and response, for WHO consultations on

- assessment tools, and to achieve global health security priorities in national strategies and Executive Orders.
- o Sponsored the National Academies of Science, Engineering and Medicine (NASEM) initiative, “Pandemic and Seasonal Influenza Vaccine Preparedness and Response: Harnessing Lessons from the Efforts to Mitigate the COVID-19 Pandemic”, to study how technological and scientific advances from the COVID-19 response could inform influenza vaccine preparedness. As a part of this initiative, NASEM conducted four fast-tracked consensus studies focusing on R&D and vaccine manufacturing; distribution and supply chains; non-pharmaceutical interventions and other countermeasures; and global coordination, partnerships, and sustainable financing. These studies will have recommendations at the end of CY 2021.
 - o Supported the Pan American Health Organization (PAHO) influenza team to ensure that the lessons learned and capacities built during the regional response to COVID-19 are captured and put to use to strengthen regional genomic surveillance capacities to prepare for and respond to future epidemics and pandemics of influenza and other respiratory diseases.
 - o Led the trilateral and multi-sectoral North American Plan for Animal and Pandemic Influenza (NAPAPI) Health Security Working Group as the Co-Chair and Secretariat to promote greater cross-border health security in the region, leveraging the partnership for the COVID-19 response and fostering close technical collaboration and information exchange among the United States, Canada, and Mexico to address key issues like tracking the spread of SARS-CoV-2 variants.
 - Provided global health security policy leadership, analysis, and technical support to:
 - o 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.
 - o 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.
 - o 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.
 - o Facilitate the request from the China-FDA for technical assistance to evaluate submissions from Chinese manufacturers for LAIV and quadrivalent inactivated vaccines.
 - o 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.
 - o Convene a high-level stakeholder meetings and action plans for development and updating of National Pandemic Influenza Preparedness Plans (NPIPP).
 - o 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.

- o 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.
- o Lead efforts to strengthen the sustainable financing and legal preparedness elements of the Joint External Evaluation and State Party Self-Assessment Annual Report country health security capacity assessment tools.
- o Develop multilateral tools for tracking country commitments and progress on addressing health security capacity gaps.
- o Work closely with financing partners to drive G20 establishment of a new finance-health task force to improve cross-sectoral coordination, governance, and financing for pandemic preparedness and response.
- o 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.
- o As Secretariat of the GHSI Pandemic Respiratory Virus Working Group (PIWG+), lead coordination of a series of deep-dive discussions on progress and challenges during the rollout of COVID-19 vaccinations and the impact of newly emerging SARS-CoV-2 variants.

Funding History	
Fiscal Year	Amount
FY 2019	\$260,000,000
FY 2020	\$260,000,000
FY 2021 Final	\$287,000.000
FY 2022 CR	\$287,000.000
FY 2023 President's Budget	\$382,000,000

Budget Request

The FY 2023 President's Budget request for pandemic influenza is \$382,000,000, which is +\$95,000,000 above the FY 2022 CR. The request includes \$347 million in no-year funding and \$35 million in annual funding. Based on lessons learned from the COVID-19 response the requested \$95 million in additional funding will be utilized 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 addition to lessons learned from COVID-19, this strategy aligns with the Presidential Executive Order to modernize influenza vaccines and the HHS Influenza Plan Update.

In addition to funding activities that maintain and strengthen 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 product.

Funding will support 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 the requested 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 2023 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 2023 funding request will support critically important programs to develop and maintain domestic capacity to prevent, diagnose, and treat pandemic influenza and emerging infectious diseases that will ultimately save lives and enhance national security.

Annual Funding Request for FY 2023 (\$35,000,000)

Vaccine Stockpiling, Storage and Stability Testing (\$14,991,000): The request includes funds to continue support of the risk-based stewardship of the National Pre-Pandemic Influenza Vaccine Stockpile, 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.

Facilities and Infrastructure Development (\$13,000,000): Funds will sustain a key pillar of domestic influenza vaccine manufacturing capacity: cell-based vaccine manufacturing infrastructure. This effort includes annual manufacturing of pre-pandemic influenza vaccine which maintains a guaranteed domestic manufacturing capacity of a licensed, cell-based influenza vaccine candidate for response to a pandemic. This annual manufacturing ensures the readiness of this ‘built for purpose’ domestic manufacturing facility in Holly Springs, North Carolina.

OGA International Influenza Activities (\$7,009,000): The FY 2023 President’s budget for the Office of Global Affairs of \$7,009,000 is flat with the FY 2022 CR. With this Pandemic Influenza budget

authority, the Office of Global Affairs will continue to provide leadership, technical expertise, oversight, policy and program coordination, and global health diplomacy in global health security, prioritizing preparedness for seasonal influenza epidemics, influenza pandemic, and other emerging infectious disease (EID) threats.

Influenza viruses and other 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. The world is unprepared for an influenza pandemic and experts maintain that influenza remains the pathogen of highest probability for causing a severe pandemic in the future. Influenza preparedness efforts and key USG and global influenza experts have greatly assisted in the domestic and international response to the COVID-19 pandemic, and these 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. HHS will support global, multilateral, bilateral, and inter- and intra-government initiatives to ensure the United States, other countries, and international organizations advance sustainable financing for and use the most effective approaches to better prepare for and respond to global health security threats.

In accord with the *National Security Strategy*, the *National Biodefense Strategy*, the *Global Health Security Strategy*, the *Global Health Security Agenda 2024*, 2016 Executive Order (EO) 13747 on *Advancing the Global Health Security Agenda To Achieve a World Safe and Secure From Infectious Disease Threats*, 2019 EO 13887 on *Modernizing Influenza Vaccines in the United States*, and the *HHS Strategic Plan*, OGA will bring its technical, policy, and diplomatic expertise to promote policies that include:

- Enhancing local, national, regional, and global influenza preparedness and response efforts for seasonal influenza and pathogens of epidemic or pandemic potential, including by supporting the implementation of the WHO *Global Influenza Strategy 2019-2030*;
- Aligning national influenza preparedness efforts with the goals and strategic objectives of the WHO *Global Influenza Strategy 2019-2030*, including by, developing or updating national pandemic influenza preparedness plans, creating an enabling environment for the development of better global tools, and considering implementing annual influenza vaccination campaigns for one or more target populations;
- Strengthening other nations' commitments to fulfill their obligations under the Pandemic Influenza Preparedness-Framework;
- Enhancing influenza surveillance through WHO and partner nations, including by taking steps to eliminate or mitigate delays and disruptions to rapid, systematic, and timely international influenza virus sharing, including seasonal viruses to advance HHS programs and countermeasure development;
- Promoting linkages between influenza capabilities and national influenza preparedness and response plans, together with broader IHR and immunization implementation efforts, including through linkages with national action plans for health security;
- Strengthening of EID networks to improve risk-communication and promote vaccine confidence/trust to enhance seasonal influenza vaccination;
- Working with 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;

- Coordinating all relevant GHSA and GHSI-related activities, including those policies focused on pandemic influenza and biological threats and leading multilateral working groups on sustainable financing for preparedness and legal preparedness;
- Advancing global efforts to establish governance and financing for pandemic preparedness and response;
- Coordinating all relevant 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 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 2023 (\$347,000,000)

Facilities and Infrastructure Readiness and Sustainment (\$87,000,000): Funds will sustain a key pillar of domestic influenza vaccine manufacturing capacity: cell-based vaccine manufacturing infrastructure. This effort includes annual manufacturing of pre-pandemic influenza vaccine which maintains a guaranteed domestic manufacturing capacity of a licensed, cell-based influenza vaccine candidate for response to a pandemic. This annual manufacturing ensures the readiness of this ‘built for purpose’ domestic manufacturing facility in Holly Springs, North Carolina. Furthermore, 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 reach the targeted goal of 660 million bulk antigen vaccine doses (FY 2023). Without the sustainment of this capability, the year-round manufacturing capacity so critical to a pandemic influenza response will be lost. The FY 2023 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 pandemic vaccine production as needed.

Influenza Therapeutics Advanced Development (\$50,000,000): 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 2023, BARDA will initiate a Phase II type trial to assess efficacy of at least one influenza therapeutic.

Improved Influenza Vaccine Advanced Development (\$185,000,000): 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 requested funds will address 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. An 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); and
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 capacity to mitigate public health emergencies due to other emerging infectious diseases.

Influenza Diagnostics Advanced Development (\$25,000,000): Funding will be used to continue ongoing activities supporting rapid and specific diagnostic platforms for use in near-patient and point of-need settings. The goal of these activities will be to move toward fast, real-time, and in-home notification of positive influenza infection. With COVID-19 funding, great strides were made to bring diagnostic tests closer to the user, including in-home testing. The requested funds will primarily be utilized to expand those platforms to include influenza testing, develop additional platforms with the capability, and begin further expanding platform manufacturing capacity to eventually further support better detection of different influenza strains that allow for more targeted treatments.

Key Outputs and Outcomes Table
ASPR Pandemic Influenza

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2022 Target	FY 2023 Target	FY 2023 Target +/-FY 2022 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 2021: 600 million antigen doses Target: 600 million antigen doses (Target Met)	600 million antigen doses	660 million antigen doses	+60 million antigen doses
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 2021: 2 programs Target: 2 programs (Target Met)	2 programs	3 programs	+1 programs

ASSISTANT SECRETARY FOR HEALTH

Commissioned Corps Readiness Training

Budget Summary

(Dollars in Millions)

Commissioned Corps Readiness and Training	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	--	--	2.000	+2.000
FTE	--	--	2	+2

Authorization Legislation.....PHS Act, Title I, Section 204 & 204a
 FY 2023 Authorization Permanent
 Allocation Method..... Direct Federal

Program Description and Accomplishments

The Office of the Assistant Secretary for Health (OASH) helps lead the development of public health policy recommendations across the Department of Health and Human Services (HHS) and oversees several of the Department's core public health offices – including the Office of the Surgeon General (OSG) and the U.S. Public Health Service (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 are engaged in public health and healthcare areas including disease control and prevention, biomedical research, food, drugs, and medical device regulation, mental health and substance abuse, sanitation, and health care delivery. 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 HHS Operating and Staff Divisions and non-HHS agencies including the 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 public health emergencies. Examples of such deployments include but are not limited to national and global crises involving natural disasters, infectious disease threats, urgent public health needs, and bio security threats. Furthermore, the Commissioned Corps continues to provide public health and medical support at large scale national events including the State of the Union, Boston Marathon, and large Independence Day celebrations in Washington, DC. USPHS officers must maintain readiness to deploy and respond to public health crises, disease outbreaks, and humanitarian missions. In recent years, requests for deployment of USPHS officers have expanded considerably. From January, 2013 to December, 2021, Corps officers deployed 11,695 times contributing to 264,754 deployment days, excluding deployments from ongoing missions as of 2020 and 2021. Deployments have included critical support from 2014 to 2015 West Africa Ebola outbreak, 2017 Hurricanes Harvey, Irma, and Maria where USPHS provided public health support to displaced families, as well as from 2021 support of the southwestern border providing medical screenings and primary care for migrant children and families. As of February 10, 2022, the Corps deployed over two-thirds of its officers in support of COVID-19, the highest historic deployment of officers.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act included funding for immediate readiness and training for USPHS officers. The funding is being utilized to ensure that the readiness and public health training reaches 25% of USPHS officers. CARES Act funding allowed for a direct increase of staff resources, building from the existing Corps teams of three officers to teams of 10 civilian and officer training subject matter experts. Additional funding has also allowed CCHQ to develop a new USPHS training standard which will be the model for Corps education development including clinical, emergency management, and leadership skills. This will directly support OASH's ongoing efforts to modernize the Commissioned Corps. CCHQ has also used CARES Act funding to develop new career development courses that target mid-grade officers to develop the leadership and officership skills necessary for progression in the USPHS. Finally, additional training staff are working with partner organizations to develop a comprehensive catalogue of current training to enhance USPHS education for leadership, officership, and clinical deployment skills.

CARES Act funding is currently in use to support the improvement of clinical deployment skills through the Innovative Readiness Training (IRT) partnership with the Department of Defense. Teams of over 40 USPHS officers trained in clinical and public health roles and positions are embedded with DOD enlisted ranks and officers in rural settings in Alaska, Mississippi, and Arkansas. This experience will serve as a critical component of engineering, occupational health, clinical care, and clinical support specialty skills training, which will enhance the skills that officers bring to current and future deployments. Increased use of the IRT training partnership will continue for future fiscal years, depending on availability of funds, further supporting the annual training needs of the USPHS Ready Reserve and PHERST.

One of the activities supported by the CARES funding is the creation of a training program comprised of three training support contracts, utilizing expert academic, governmental, and NGO partners who specialize in medical and public health related education development to promote the enhancement of training opportunities for USPHS officers, critical care skills for emergency response missions, and advanced leaderships skills training for officers. This program initiated by the CARES Act funding will transition to PHSSEF funding over FY 2022 and FY 2023.

Funding History	
Fiscal Year	Amount
FY 2019	--
FY 2020	--
FY 2021 Final	--
FY 2022 CR	--
FY 2023 President's Budget	\$2,000,000

Budget Request

The FY 2023 President's Budget request for Commissioned Corps Readiness and Training is \$2,000,000, which is \$2,000,000 above the FY 2022 Annualized Continuing Resolution. The funding will support two training FTEs, support and sustain three training contracts, and training related travel for approximately 10% of the Corps. The funding will support training enhancement and development of officers to better meet the Corps' regional, national, and global public health emergency responses.

U.S Public Health Service Ready Reserve

Budget Summary

(Dollars in Millions)

U.S Public Health Service Ready Reserve	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	--	--	13.600	+13.600
FTE³³	--	--	92	+92

Authorization Legislation..... CARES Act, Title III, Section 3214

FY 2023 Authorization Permanent

Allocation Method Direct Federal

Program Description and Accomplishments

The Assistant Secretary for Health (ASH) oversees the Department's key public health offices and programs, 10 regional health offices across the nation, 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, 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 approximately 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, including Health and Human Services (HHS) Operating and Staff Divisions (e.g., Indian Health Service, National Institutes of Health, Centers for Disease Control, and others), as well as non-HHS agencies (e.g., Federal Bureau of Prisons (BOP), Department of Defense and Department of Homeland Security, and others).

All USPHS Ready Reserve officers are part-time officers, and they are paid when on Active Duty (such as training or deployment). These officers are required to train ("drill") for a minimum of 2 weekends/month (on average) and 14 days/year for annual training. Based on critical specialized skill sets, the Ready Reserve officers can also be placed on Active Duty (temporary/part-time) to support personnel shortages in HHS or non-HHS agencies with critical need to fill positions. The Ready Reserve is trained, ready and equipped with surge capacity to respond to any public health emergency. Recruitment is focused on high-demand, already-trained clinical professionals. When not activated, the Ready Reserve officers work in their respective civilian jobs in the private and public sector.

The Commissioned Corps officers respond to public health emergencies, disease outbreaks, and humanitarian missions. In recent years, requests for deployment of Corps Officers have expanded considerably. From January 2013 to December 2021 Corps officers deployed 11,695 times contributing to 264,754 deployment days, excluding deployment data from ongoing missions as of 2020 and 2021. Deployments have included critical support from 2014 to 2015 West Africa Ebola outbreak, 2017

³³ One (1) part-time Ready Reserve officer is 0.25 FTE.

Hurricanes Harvey, Irma, and Maria where USPHS provided public health support to displaced families, as well as from 2021 support of the southwestern border providing medical screenings and primary care for migrant children and families. As of February 10, 2022, the Corps deployed over two-thirds of its officers in support of COVID-19, the highest historic deployment of officers. PHS Ready Reserve officers will focus on those much-needed clinical skills and specialties required for disaster response.

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 missions to underserved and vulnerable populations. 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.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act has provided the necessary legislative changes to implement the Ready Reserve Corps by providing appropriate statutory authority for consistent pay and benefits and issuance of retired pay for the Ready Reserve. The CARES Act also provided the initial funding to build the infrastructure for the Ready Reserve program and begin recruitment and training of the initial cohort. In accordance with the statute, the USPHS Reserve shall:

- a) be available and ready for calls to Active Duty during national emergencies and public health crises, similar to the armed service reserve personnel;
- b) be available for backfilling critical positions left vacant during deployment of active Commissioned Corps members or for deployments to respond to public health emergencies, both foreign and domestic;
- c) be available for service assignments 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.

To date, recruitment, training, communication plans, IT infrastructure and corresponding standard operating procedures have been developed and implemented to operationalize the Ready Reserve. This includes hiring of key personnel in Commissioned Corps Headquarters. As of March 2022, the Ready Reserve has onboarded 32 officers, of which 20 are readily available for deployment.

Funding History	
Fiscal Year	Amount
FY 2019	--
FY 2020	--
FY 2021 Final	--
FY 2022 CR	--
FY 2023 President's Budget	\$13,600,000

Public Health and Emergency Response Strike Team

Budget Summary

(Dollars in Millions)

Public Health and Emergency Response Strike Team	FY 2021 Final	FY 2022 CR	FY 2023 President's Budget	FY 2023 +/- FY 2022
Budget Authority	--	--	4.400	+4.400
FTE	--	--	24	+24

Authorization Legislation.....PHS Act, Title I, Section 204 & 204a

FY 2023 Authorization Permanent

Allocation Method..... Direct Federal

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, 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 officers.

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 respond immediately to any emergent situations, including, but not limited to, outbreaks, natural and man-made disasters, and domestic events such as repatriation, border control, and inauguration. PHERST complements 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 officers' primary function is as first responders. Managed and hired by CCHQ, PHERST officers are full-time Active Duty officers who are "first on the ground teams". This means they do not require agency supervisory approval and can be immediately deployed. The PHERST will be on standby and ready to deploy within 8 hours of a national emergency declarations. When not deployed, the PHERST officers are assigned full-time to various federal agencies such as the Indian Health Service, Bureau of Prisons, and Immigrations and Customs Enforcement to fill short-term staffing gaps as well as staffing shortages in hard to fill locations such as rural, remote, or underserved communities.

In recent years, demand for Commissioned Corps officer responses have expanded significantly. From CY 2013 to 2021 including CCHQ and agency deployments, Corps officers deployed 11,695 times contributing to 264,754 deployment days. Ongoing missions are not included for 2020 to 2021 in this data. Deployments included critical support from 2014 to 2015 West Africa Ebola outbreak, 2017 Hurricanes Harvey, Irma, and Maria where USPHS provided public health support to displaced families, as well as from 2021 support of the southwestern border providing medical screenings and primary care for migrant children and families. As of February 10, 2022, the Corps deployed over two-thirds of its officers in support of COVID-19, the highest historic deployment of officers.

In FY 2020, CARES Act supplemental funding supported the establishment of the PHERST and the initial infrastructure build, including management and manpower requirements to adequately recruit and train the initial PHERST cohort. CCHQ has used this funding to develop plans for recruitment, training, and communications, infrastructure and management development, and standard operating procedures for

PHERST operations. As of September 30, 2021, a total of 20 PHERST officers have been selected and 16 were onboarded.

The addition of 20 PHERST officers provides the Corps with the resources needed for mission critical deployment requests, and meet public health challenges with agility, without taking away key officers from the operating or staff division that they serve. Rapid response time and ability to deploy for extended durations reduces stress on the system and allows officers to get ahead of the disaster. This ensures continuity of operations and minimizing the information loss that occurs when rotating personnel during a deployment. The PHERST addresses the strain on agencies whose assigned Public Health Service officers would have otherwise been deployed repeatedly or for prolonged periods of time. When officers are assigned to repeated or prolonged Corps deployments, their absence from their assigned agency has the potential to compromise that agency's mission. This, in turn, could discourage agencies from supporting PHS deployments or employing officers.

Funding History	
Fiscal Year	Amount
FY 2019	--
FY 2020	--
FY 2021 Final	--
FY 2022 CR	--
FY 2023 President's Budget	\$4,400,000

Budget Request

The FY 2023 President's Budget request for PHERST is \$4,400,000, which is \$4,400,000 above the FY 2022 Annualized Continuing Resolution. At this funding level, PHERST will sustain 20 PHERST officers and 4 management FTEs. The funding ensures the Corps has resources to meet its missions for regional, national, and global public health emergency responses. This funding will allow the Corps to rapidly respond to urgent, emergency public health events with highly trained professional staff.

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 2020, 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 2021	FY 2022	FY 2023	FY 2023
<u>Personnel compensation:</u>				
Full-time permanent (11.1)	121.798	126.217	186.161	+60.191
Other than full-time permanent (11.3)	9.322	9.231	13.285	+4.054
Other personnel compensation (11.5)	9.622	9.760	0.556	-9.201
Military personnel (11.7)	14.150	14.150	53.445	+39.295
Special personnel services payments (11.8)	1.250	1.250	--	-1.250
Subtotal, Personnel Compensation	156.142	160.608	253.447	+93.088
Civilian benefits (12.1)	42.772	43.733	56.403	+12.693
Military benefits (12.2)	1.600	1.600	5.687	+4.087
Benefits to former personnel (13.0)	--	--	0.019	+0.019
Total Pay Costs	200.514	205.941	315.556	+109.887
Travel and transportation of persons (21.0)	4.195	4.545	11.817	+7.272
Transportation of things (22.0)	7.153	7.153	10.089	+2.936
Rental payments to GSA (23.1)	5.407	5.446	7.773	+2.337
Rental payments to Others (23.2)	11.400	11.400	15.892	+4.492
Communication, utilities, and misc. charges (23.3)	1.986	1.990	4.293	+2.307
Printing and reproduction (24.0)	0.018	0.018	0.008	-0.010
<u>Other Contractual Services:</u>	--	--	--	
Advisory and assistance services (25.1)	1,151.849	1,146.967	1,436.282	+289.498
Other services (25.2)	105.185	103.910	198.368	+94.464
Purchase of goods and services from government	234.587	235.132	272.200	+37.064
Operation and maintenance of facilities (25.4)	0.594	0.858	6.413	+5.555
Research and Development Contracts (25.5)	31.000	31.000	65.108	+34.108
Medical care (25.6)	0.043	0.043	0.043	+0.000
Operation and maintenance of equipment (25.7)	30.946	30.946	33.232	+2.286
Subsistence and support of persons (25.8)	--	--	--	--
Subtotal, Other Contractual Services	1,554.204	1,548.857	2,011.645	+462.975
Supplies and materials (26.0)	781.527	781.527	1,000.482	+218.955
Equipment (31.0)	0.205	0.205	7.034	+6.829
Land and Structures (32.0)	0.100	0.100	--	-0.100
Investments and Loans (33.0)	--	--	--	--
Grants, subsidies, and contributions (41.0)	280.750	280.750	430.000	+149.250
Insurance claims and indemnities (42.0)	--	0.000	0.020	+0.020
Interest and dividends (43.0)	--	--	--	--
Refunds (44.0)	--	--	--	--
Total Non-Pay Costs	2,646.944	2,641.991	3,499.054	+857.264
Total, Budget Authority by Object Class	2,847.458	2,847.932	3,814.610	+967.152

SALARIES AND EXPENSES

Description	FY 2021 Final	FY 2022 Enacted	FY 2023 President's Budget	FY 2023 +/- FY 2022
<u>Personnel compensation:</u>				
Full-time permanent (11.1)	120.176	125.955	147.186	+21.231
Other than full-time permanent (11.3)	9.289	9.200	0.253	-8.947
Other personnel compensation (11.5)	9.643	9.787	0.587	-9.200
Military personnel (11.7)	14.150	14.150	17.347	+3.197
Special personnel services payments (11.8)	1.250	1.250	--	-1.250
Subtotal personnel compensation	+154.508	+160.343	+165.373	+5.030
Civilian benefits (12.1)	42.216	43.705	42.686	-1.019
Military benefits (12.2)	1.600	1.600	5.890	+4.290
Benefits to former personnel (13.0)	--	--	0.019	+0.019
Total Pay Costs	+198.323	+205.648	+213.968	+8.320
Travel and transportation of persons (21.0)	4.278	4.545	11.817	+7.272
Transportation of things (22.0)	7.150	7.153	10.089	+2.936
Rental payments to GSA (23.1)	5.344	5.431	7.196	+1.765
Rental payments to Others (23.2)	11.400	11.400	15.892	+4.492
Communication, utilities, and misc. charges	2.059	1.982	4.293	+2.311
Printing and reproduction (24.0)	0.010	0.018	0.008	-0.010
<u>Other Contractual Services:</u>				
Advisory and assistance services (25.1)	1,150.872	1,146.784	1,536.183	+389.400
Other services (25.2)	105.471	103.904	181.474	+77.570
Purchase of goods and services from	234.917	235.173	372.200	+137.027
Operation and maintenance of facilities	0.878	0.851	6.414	+5.563
Research and Development Contracts (25.5)	33.085	31.000	75.000	+44.000
Medical care (25.6)	--	0.043	0.043	+0.000
Operation and maintenance of equipment	30.970	30.946	33.232	+2.286
Subsistence and support of persons (25.8)	--	--	--	--
Subtotal, Other Contractual Services	+1,556.192	+1,548.701	+2,204.546	+655.845
Supplies and materials (26.0)	0.417	0.380	0.485	+0.105
Equipment (31.0)	0.285	0.202	7.002	+6.800
Land and Structures (32.0)	0.100	0.100	--	-0.100
Grants, subsidies, and contributions (41.0)	280.750	280.750	430.000	+149.250
Total Non-Pay Costs	+1,867.985	+1,860.661	+2,691.327	+830.666
Total Salary and Expense	+2,066.308	+2,066.308	+2,905.295	+838.987
Direct FTE	1,079	1,318	1,684	+366

DETAIL OF FULL-TIME EQUIVALENT EMPLOYMENT

	2021 Actual Civilian	2021 Actual Military	2021 Actual Total	2022 Est. Civilian	2022 Est. Military	2022 Est. Total	2023 Est. Civilian	2023 Est. Military	2023 Est. Total
<u>ASPR</u>									
Preparedness and Emergency Operations	74	12	86	71	15	86	71	15	86
National Disaster Medical System	86	38	124	100	48	148	109	53	162
Hospital Preparedness	38	11	49	50	12	62	50	12	62
Medical Reserve Corps	6	--	6	12	--	12	12	--	12
Preparedness and Response Innovation	3	--	3	3	--	3	3	--	3
BARDA	216	6	222	260	7	267	354	10	364
Pandemic Influenza	11	--	11	11	--	11	11	--	11
Strategic National Stockpile	240	19	259	304	25	329	304	25	329
Coordination and Response Element	--	--	--	--	--	--	111	--	111
Operations	123	12	135	123	12	135	129	13	142
Policy and Planning	61	5	66	61	5	66	77	6	83
<u>Cybersecurity</u>	110	--	110	143	--	143	143	--	143
<u>Office of National Security</u>	35	2	37	36	2	38	36	2	38
<u>OGA Pandemic Influenza</u>	16	--	16	18	--	18	20	--	20
<u>OASH</u>	--	--	--	--	--	--	35	83	118
PHSSEF FTE Total	1,019	105	1,124	1,192	126	1,318	1,466	218	1,684

DETAIL OF POSITIONS

Public Health and Social Services Emergency Fund	FY 2021 Final	FY 2022 Enacted	FY 2023 President's Budget
Executive level I	-	-	-
Executive level II	-	-	-
Executive level III	-	-	-
Executive level IV	1	1	1
Executive level V	1	1	1
Subtotal Executive Level Positions	2	2	2
Total - Exec. Level Salaries	334,200	343,223	359,011
ES-6	1	1	1
ES-5	-	-	-
ES-4	-	-	-
ES-3	-	-	-
ES-2	-	-	-
ES-1	9	9	9
Subtotal ES positions	10	10	10
Total - ES Salary	2,056,600	2,112,910	2,210,104
GS-15	147	157	199
GS-14	276	291	365
GS-13	295	354	458
GS-12	177	216	288
GS-11	47	81	103
GS-10	17	30	37
GS-9	28	44	61
GS-8	11	11	13
GS-7	19	19	23
GS-6	-	-	-
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	1,017	1,203	1,547
Total - GS Salary	114,722,907	133,128,477	154,156,445
Average ES level	ES-2	ES-2	ES-2
Average ES salary	205,660	211,291	221,010
Average GS grade	13	13	12
Average GS salary	112,805	110,664	99,649
Average Special Pay categories			

PROGRAMS PROPOSED FOR ELIMINATION

No programs within the PHSSEF are proposed for elimination.

PROPOSED LAW

FISCAL YEAR 2023 DHHS LEGISLATIVE PROPOSAL Office of the Assistant Secretary for Preparedness and Response

Extension of National Disaster Medical System Direct Hire Authority

The Office of the Assistant Secretary for Preparedness and Response seeks to extend the National Disaster Medical System (NDMS) direct hire authority beyond its current sunset date of September 30, 2023. NDMS has used its direct hire authority to expand NDMS intermittent workforce during the COVID-19 pandemic. Ultimately, the hiring authority reduced the hiring time from a year to an average of six months. Extension of this authority will aid NDMS in expanding a workforce that has been an integral part of the COVID-19 response, deploying multiple times to assist in all 50 states and in the territories to help save lives. NDMS continues to have a goal of 6,000 response personnel to ensure all mission rosters can be adequately staffed and can support multiple operations concurrently. ASPR recommends modifying the sunset date beyond the current expiration of September 30, 2023.

Disasters can impact anyone. However, underserved communities are disproportionately impacted by disasters and emergencies. This proposal supports staffing programs and addressing mission requirements to increase HHS's capacity to address unmet needs during disasters.

SIGNIFICANT ITEMS IN APPROPRIATION COMMITTEE REPORTS

SIGNIFICANT ITEM

BARDA and BioShield Professional Judgement Budget.—The Committee directs ASPR to submit a report to the Committee in conjunction with the fiscal year 2023 Congressional Budget Justification detailing a professional judgement on the necessary budget and infrastructure requirements to fully operationalize these programs in fiscal year 2023. This report shall also include an assessment of current agency capabilities, as well as current and planned activities related to pandemic preparedness.

RESPONSE

The Biomedical Advanced Research and Development Authority (BARDA) was created as part of the Office of the Assistant Secretary for Preparedness and Response (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).

Emerging infectious diseases (EIDs), especially those with pandemic potential, threaten the citizens, economy, and national security of the United States on an ongoing basis. Every year, Americans die despite the billions of dollars that have been spent on research and development, surveillance, medical care, and other efforts aimed at identifying, preventing, and containing EID outbreaks. While significant funding is spent annually on early research and development, sustained advanced development and manufacturing funding is necessary to take these products, platforms, and capabilities from early development to licensure. The result of this ‘valley of death’ is the current situation where vaccine, therapeutic, and diagnostic candidates that could save lives are identified, but do not move towards licensure where they could be made widely available. Further, the large-scale manufacturing capability so essential for a rapid response to a new infectious disease is not maintained. Nowhere was this more apparent than in COVID-19 MCM response. Despite great success in early development, the need to complete advanced development and validate large scale manufacturing delayed availability of vaccines, therapeutics, and diagnostics for several months. Availability of authorized and approved vaccines, therapeutics, and diagnostics could have occurred much earlier had this infrastructure been available. With the proposed 2023 Budget investments for advanced development and manufacturing, ASPR can transform the nation’s preparedness and response posture against existing and future EIDs, moving from a reactive to a proactive posture. BARDA’s EID program will utilize the same approach that is successfully addressing a similar situation with pandemic influenza and chemical, biological, radiological, and nuclear medical countermeasures: taking life-saving products from early development to licensure, manufacturing them, and making them available to save lives as soon as a new emerging pathogen is detected

The professional judgement budget for BARDA assumes funding levels to address all DHS-identified threats with Material Threat Determinations. This professional judgement also includes funding to address advanced development and manufacturing of MCMs to detect, prevent and treat emerging infectious diseases. The estimate does not include funding to support COVID-19-related activities in FY 2023.

Public Health and Social Services Emergency Fund

The overall FY 2023 professional judgement estimate for BARDA is approximately \$3 billion. The FY 2023 President's Budget includes \$828 million for BARDA and \$770 million for Project BioShield. In addition, the FY 2023 President's Budget proposes \$81.7 billion across HHS public health agencies, including \$40 billion in ASPR to support pandemic preparedness. The professional judgement estimate for BARDA Advanced Development and Research (ARD) program is \$1.3 billion for FY 2023. The FY 2023 estimate for Project BioShield (PBS) is \$0.9 billion. The professional judgement estimate for BARDA Emerging Infectious Diseases is \$775 million.

FY 2023 BARDA ARD Estimate

<i>Portfolio</i>	<i>Funding</i>
Rad/Nuc	\$278
Broad Spectrum Antimicrobials	\$190
BARDA Program Management	\$120
Filoviruses	\$226.5
Chemical	\$125
BARDA DRIVE and MCIP	\$274.5
Cross-Cutting Science	\$12.5
Smallpox	\$25
Botulinum	\$25
Anthrax	\$7.3
CIADM OR New BioMap Program	-
Total ARD FY 2023 Estimate	\$1,284

FY 2023 BARDA PBS Estimate

<i>Portfolio</i>	<i>Funding</i>
Broad Spectrum Antimicrobials	\$189
Filoviruses	\$120
Smallpox	\$161
Rad/Nuc	\$200
Chemical	\$150
Biodosimetry/Biodiagnostics	\$50
Thermal Burns	\$50
Total PBS FY 2023 Estimate	\$920

<i>Emerging Infectious Diseases</i>	<i>Funding</i>
Vaccine	\$400
Therapeutic	\$250
Diagnostic	\$25
Manufacturing and Readiness Capability	\$100
Total EID FY 2023 Estimate	\$775

SIGNIFICANT ITEM

Cold Chain Technologies. —The Committee recognizes the limitations that are presented by cold chain requirements for vaccine distribution and storage. The Committee directs the Secretary to explore opportunities for new technologies such as dry power approaches or thin-film freeze drying that allow for

vaccines to be physiochemically stable for an extended period without causing degradation or reduction in immunogenicity. The Committee requests an update on such efforts in the fiscal year 2023 Congressional Budget Justification.

RESPONSE

ASPR/BARDA continues to seek new technologies that will improve the cold-chain logistics across the vaccine portfolio. Recent examples include the incorporation of a lyophilized form of the smallpox vaccine, JYNNEOS, and development of a more stable formulation for a lead Marburg vaccine. BARDA will continue to assess new technologies that could be applied to vaccines in its portfolio. In addition, BARDA continues to make investments in technologies such as microneedle skin patches for vaccine delivery and thin-film storage which are designed to improve shelf stability and reduce the need for cold-chain requirements, especially during a pandemic. Lastly, BARDA has some early investments in on-demand vaccine production that would obviate the need for long-term storage entirely. In FY 2023, ASPR would work towards further validating and integrating these technologies into commercial scale vaccine pilot production, storage, and distribution across a variety of threat areas.

SIGNIFICANT ITEM

Pathogen-Reduced Red Blood Cell Technology. —The Committee recognizes BARDA's investments for clinical trial development of nucleic acid targeted pathogen reduction technology to improve red blood cell transfusion safety. Such investments will ensure protection for blood products in the nation's blood supply. The Committee requests an update of these activities in the fiscal year 2023 Congressional Budget Justification.

RESPONSE

ASPR/BARDA is advancing innovations in next-generation blood products to address life-threatening bleeding associated with radiation and traumatic injuries following nuclear detonation. These blood technologies may have extended stability at room temperature and a smaller, streamlined packaging footprint. Next-generation blood products also have the potential to transform routine emergency medicine when deployed with first responders into prehospital settings and to address critical hospital care gaps during a blood shortage crisis. This is particularly meaningful recently as the Red Cross declared the worst blood shortage in over a decade, describing situations in which doctors were forced to make difficult decisions regarding who receives blood transfusions and who must wait until more product becomes available. BARDA is currently pursuing the following next generation blood product concepts:

1. A platelet-derived freeze-dried hemostatic agent, to address life-threatening blood loss in the prehospital setting, in other resource-limited environments, or for conditions where conventional platelets are refractory. This product is currently in Phase 2 clinical trials.
2. A system to inactivate blood-borne pathogens such as bacteria, viruses, and parasites in red blood cells donated for transfusion. This technology uses a small molecule to form covalent crosslinks within nucleic acids of leukocytes and contaminating pathogens, preventing their replication. It will reduce pathogens in donated blood, making more blood products available when there are scarce resources, such as after a nuclear incident. This product is currently in Phase 3 clinical trials.
3. A spray dry plasma product to addresses the traumatic blood loss associated with a mass casualty event and provide an opportunity to forward deploy a dried plasma product that is easily

rehydrated and administered within minutes with potential for use in a prehospital setting. A Phase 1 trial is about to commence for this product.

SIGNIFICANT ITEM

Saline. —The Committee encourages the review of the stockpile quantity of normal IV saline and related medical supplies, and to include an update in the fiscal year 2023 Congressional Budget Justification.

RESPONSE

Public health consequence assessments, subject matter expert evaluations, and estimates of current national response capabilities inform requirements for medical countermeasure needs and quantities to be maintained in the Strategic National Stockpile (SNS). During the COVID-19 response, additional quantities of normal saline in 1L bags as well as 100ml piggyback bags were added to the SNS. These products have been in periodic shortage situations for numerous reasons including surges in demand during seasonal and pandemic outbreaks, and reliance on a limited number of manufacturers. When Hurricane Maria devastated Puerto Rico it also shut down a facility that produced approximately half of the United States' saline supply. The products also have a relatively short shelf life, are not eligible for shelf-life extension, and require large amounts of storage space. As these products were procured with COVID supplemental funding, indefinite maintenance of these quantities may become difficult when prioritized against all other needs. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is the entity traditionally tasked with conducting an interagency threat-based review of the contents of the SNS. The Office of the Assistant Secretary for Preparedness and Response (ASPR) relaunched the group in February 2022, in order to contribute to future reviews.

Additionally, there is ongoing work at ASPR to develop on-demand saline production technology. ASPR is developing a highly automated, cGMP capable, scalable, and distributed manufacturing technology to provide local mobile manufacturing of bags of IV fluid therapy at the point of need. This will address the need to shore up the US pharmaceutical industrial base through scalable and distributed manufacturing and production of normal saline IV fluid therapies with the potential to expand into other fluids and/or medications for infusion therapy or dialysis, at point-of-need in healthcare, pharmacy, and outpatient medical center settings and forward combat casualty care locations. This is a micro-manufacturing system, fully enclosed and automated, that fits in a space the size of two residential refrigerators.