



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

Fiscal Year

2024

Administration for Strategic
Preparedness and Response

*Justification of Estimates for
Appropriations Committee*

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MESSAGE FROM THE ASSISTANT SECRETARY



I am pleased to present the Fiscal Year (FY) 2024 Congressional Justification for the Administration for Strategic Preparedness and Response (ASPR). Since the FY 2023 President’s Budget, ASPR has become an Operating Division, implemented a reorganization that improves alignment and transparency between ASPR’s mission and work, and released a five-year strategic plan to guide our agency through the complex threat landscape that lies ahead. The FY 2024 President’s Budget Request directly supports ASPR’s mission to help the country prepare for, respond to, and recover from public health emergencies and disasters.

Today, ASPR is working on more high-consequence, no-fail missions than ever before. We are living in an increasingly interconnected world where diseases and other threats can travel quickly, unnoticed for days. In addition, infectious disease outbreaks are becoming more frequent and natural disasters more deadly as a result of the increasing changes to our climate. ASPR’s growing mission, while a reflection of the world in which we live, is also a testament to the strength and dedication of our team—our greatest asset. To keep up with the evolving threat landscape, ASPR must remain nimble and ever vigilant while learning from each response it leads.

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. 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 (MRC), ASPR supports the mobilization of volunteer units to assist in communities’ public health needs such as vaccination clinics, blood donations, and more.

Having medical countermeasures ready in a public health crisis requires long-range investment in the research and development of highly specialized products. ASPR, through the Biomedical Advanced Research and Development Authority (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). 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 address chemical, biological, radiological, and nuclear threats (CBRN) threats, emerging infectious diseases, pandemic influenza, and the growing public health threat of antimicrobial resistance. To date, BARDA’s efforts have led to 69 FDA licensures, approvals, and clearances of MCMs. Through investments in innovation, future products developed by BARDA have the potential to revolutionize emergency response and basic health care for all Americans.

As we learned during the COVID-19 response, it is not enough to research and develop these products, we must ensure they are manufactured and stockpiled so they are ready to deploy when needed. To strengthen this MCM continuum, ASPR, as part of our reorganization, established the Industrial Base Management and Supply Chain Office. This office will ensure that critical supplies are manufactured in the United States. Also, as part of our reorganization, the Strategic National Stockpile (SNS), whose work

has grown significantly in scale and scope, has become its own Office reporting directly to me. This increased visibility and accountability within the organization will help ensure that we are developing, manufacturing, and stockpiling the right countermeasures in the right quantities.

Preparing for the next threat is more than having the right countermeasures, however. We must also be able to act quickly and nimbly. Last year, HHS successfully transitioned the operations and logistics capability that the Department of Defense brought to Operation Warp Speed into ASPR's HHS Coordination Operations and Response Element (H-CORE). H-CORE now serves as a logistics and operations "Swiss army knife" for key ASPR missions.

Last year, ASPR successfully executed one of the largest deployments of personnel and equipment in support of a hurricane in the last five years. ASPR deployed ten National Disaster Medical System (NDMS) teams, with hundreds of additional incident management, logistical, and regional staff, supporting seven free-standing emergency room sites around the State of Florida in the aftermath of Hurricane Ian. Throughout 2022, ASPR's NDMS teams supported over 4,000 patients in need across the U.S. While impact on a community is difficult to calculate, the value and good will that NDMS brings to ASPR is incalculable.

In addition to NDMS, the civilian volunteer MRC, a national network of over 300,000 volunteers, has also been supporting the COVID-19 response. In FY 2022 MRC volunteers contributed over 528,000 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 \$2.1 million.

Finally, ASPR will continue supporting our nation's health systems and clinical care workers as they prepare for and respond to emergencies. ASPR's Health Care Readiness and Recovery portfolio will continue to invest in programs and activities that strengthen health care entities on the local and regional levels to provide innovative, coordinated, and lifesaving care in the face of emergencies and disasters.

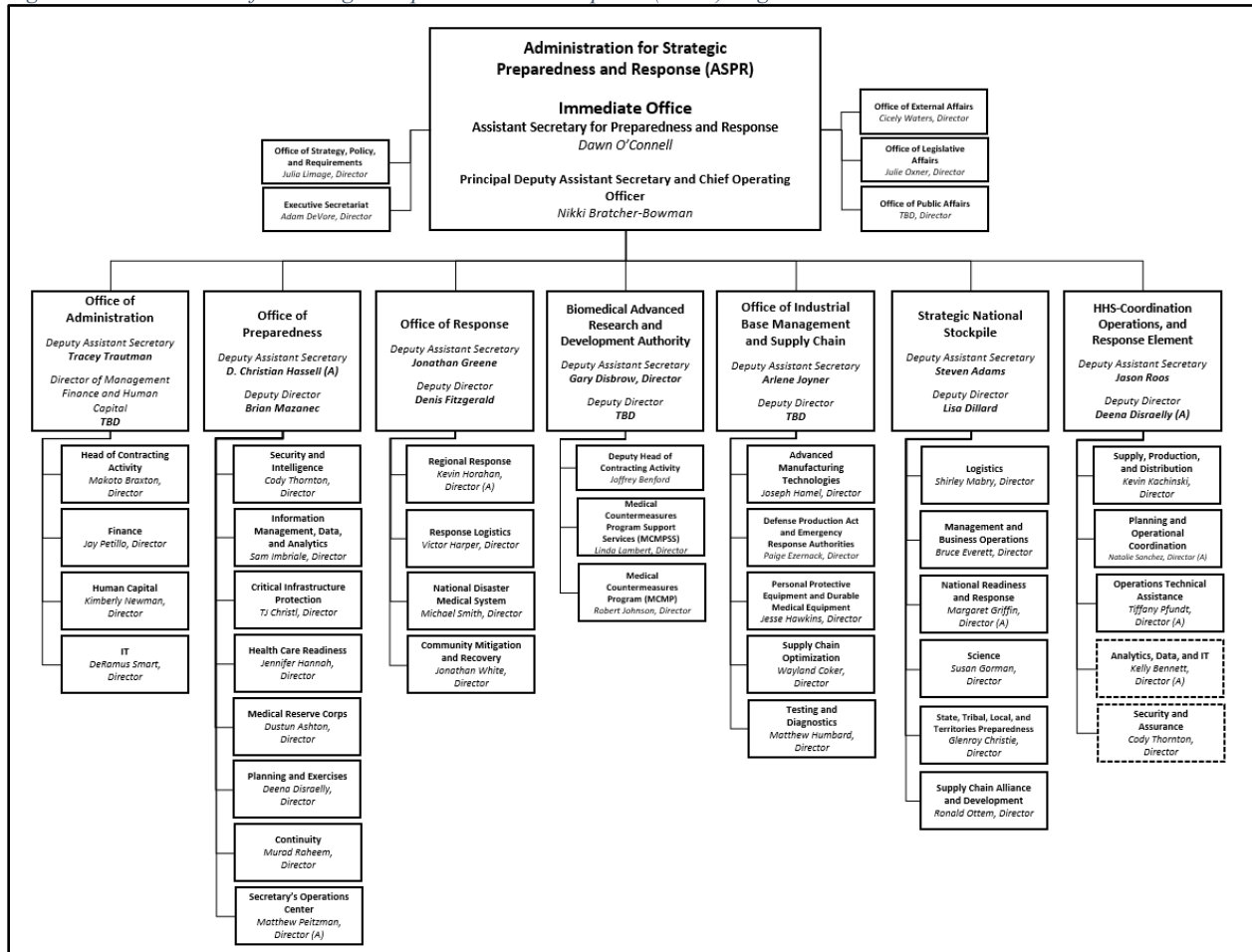
Given the significant work for which ASPR is responsible, I am pleased to present the discretionary FY 2024 President's Budget request for ASPR is \$4,271,913,000 which is \$642,236,000 above the FY 2023 Enacted. The President's Budget also proposes \$20 billion in mandatory funding across HHS to prepare for pandemics and other biological threats, of which \$10.5 billion would support ASPR activities.

Dawn O'Connell
Assistant Secretary for Preparedness and
Response

EXECUTIVE SUMMARY

Administration for Strategic Preparedness and Response Organization Chart

Figure 1: Administration for Strategic Preparedness and Response (ASPR) Organizational Chart



ASPR Organizational Chart – Text Description of a Complex Image

The Administration for Strategic Preparedness and Response (ASPR) is led by Assistant Secretary for Preparedness and Response Dawn O'Connell and Principal Deputy Assistant Secretary and Chief Operating Officer, Nikki Bratcher-Bowman.

There are five (5) program offices within the Immediate Office:

1. **Office of Strategy, Policy, and Requirements** | Julia Limage, Director
2. **Executive Secretariat** | Adam DeVore, Director
3. **Office of External Affairs** | Cicely Waters, Director
4. **Office of Legislative Affairs** | Julie Oxner, Director
5. **Office of Public Affairs** | TBD, Director

ASPR has seven (7) Deputy Assistant Secretary (DAS) Level Offices.

1. **Office of Administration:** Deputy Assistant Secretary Tracey Trautman serves as the executive managing the four (4) offices within the Office of Administration. The Office of the Director also includes a Director of Management Finance and Human Capital, this position is currently vacant.
 - a. **Head of Contracting Activity** | Makoto Braxton, Director
 - b. **Finance** | Jay Petillo, Director
 - c. **Human Capital** | Kimberly Newman
 - d. **IT** | DeRamus Smart
2. **Office of Preparedness:** Deputy Assistant Secretary D. Christian Hassell, the Acting Director of the Office of Preparedness, and the Deputy Director Brian Mazanec serve as the executives managing the eight (8) offices within the Office of Preparedness.
 - a. **Security and Intelligence** | Cody Thornton, Director
 - b. **Information Management, Data, and Analytics** | Sam Imbriale, Director
 - c. **Critical Infrastructure Protection** | TJ Christl, Director
 - d. **Health Care Readiness** | Jennifer Hannah, Director
 - e. **Medical Reserve Corps** | Dustun Ashton, Director
 - f. **Planning and Exercises** | Deena Disraelly, Director
 - g. **Continuity** | Murad Raheem, Director
 - h. **Secretary's Operations Center** | Matthew Peitzman, Acting Director
3. **Office of Response:** Deputy Assistant Secretary Jonathan Greene and Deputy Director Denis Fitzgerald serve as the executives managing the four (4) offices within the Office of Response.
 - a. **Regional Response** | Kevin Horahan, Acting Director
 - b. **Response Logistics** | Victor Harper, Director
 - c. **National Disaster Medical System** | Michael Smith, Director
 - d. **Community Mitigation and Recovery** | Jonathan White, Director
4. **Biomedical Advanced Research and Development Authority:** Deputy Assistant Secretary Gary Disbrow serves as the BARDA Director and executive managing the two (2) offices within the BARDA. The Deputy Director position is vacant.
 - a. **Deputy Head Contracting Activity** | Joffrey Benford
 - b. **Medical Countermeasures Program Support Services** | Linda Lambert, Director
 - c. **Medical Countermeasures Program** | Robert Johnson, Director
5. **Office of Industrial Base Management and Supply Chain:** Deputy Assistant Secretary Arlene Joyner serves as the executive managing the five (5) offices within the Office of Industrial base Management and Supply Chain. The Deputy Director position is vacant.
 - a. **Advanced Manufacturing Technologies** | Joseph Hamel, Director
 - b. **Defense Production Act and Emergency Response Authorities** | Paige Ezernack, Director
 - c. **Personal Protective Equipment and Durable Medical Equipment** | Jesse Hawkins, Director
 - d. **Supply Chain Optimization** | Wayland Coker, Director
 - e. **Testing and Diagnostics** | Matthew Humbard, Director

6. **Strategic National Stockpile:** Deputy Assistant Secretary Steven Adams and Deputy Director Lisa Dillard serve as the executives managing the six (6) offices within the Strategic National Stockpile.
 - a. **Logistics** | Shirley Mabry, Director
 - b. **Management and Business Operations** | Bruce Everett, Director
 - c. **National Readiness and Response** | Margaret Griffin, Acting Director
 - d. **Science** | Susan Gorman, Director
 - e. **State, Tribal, Local, and Territories Preparedness** | Glenroy Christie, Director
 - f. **Supply Chain Alliance and Development** | Ronald Ottem, Director

7. **HHS-Coordination Operations and Response Element:** Deputy Assistant Secretary Jason Roos and Acting Deputy Director Deena Disraelly, serve as the executives managing the five (5) offices within the HHS-Coordination Operations and Response Element.
 - a. **Supply, Production, and Distribution** | Kevin Kachinski
 - b. **Planning and Operational Coordination** | Natalie Sanchez, Acting Director
 - c. **Operations Technical Assistance** | Tiffany Pfundt, Acting Director
 - d. **Analytics, Data, and IT** | Kelly Bennett, Acting Director. This office provides support to H-CORE but reports to the Office of Information Management, Data, and Analytics within the Office of Preparedness.
 - e. **Security and Assurance** | Cody Thornton, Director. This office provides support to H-CORE but reports to the Office of Security and Intelligence within the Office of Preparedness.

Introduction and Mission

Today, the Administration for Strategic Preparedness and Response (ASPR) is working on more high-consequence, no-fail missions than ever before. We are living in an increasingly interconnected world where diseases and other threats can travel quickly, unnoticed for days. In addition, infectious disease outbreaks are becoming more frequent and natural disasters more deadly as a result of the increasing changes to our climate. ASPR's growing mission, while a reflection of the world in which we live, is also a testament to the strength and dedication of our team—our greatest asset. To keep up with the evolving threat landscape, ASPR must remain nimble and ever vigilant while learning from each response it leads. This budget lays out the resources necessary for ASPR to help the country prepare for, respond to, and recover from whatever comes next—no matter what that might be.

Since the publishing of the last President's budget, and in recognition of the increasing magnitude and scope of what we do, HHS Secretary Xavier Becerra recently elevated ASPR from an HHS Staff Division to an Operating Division (OpDiv) and renamed us the Administration for Strategic Preparedness and Response. Becoming an OpDiv gives ASPR additional administrative tools to enhance our ability to respond to current and future public health emergencies. We will use those new tools to grow our capabilities and strengthen our foundation to ensure we continue to meet every challenge effectively and efficiently. ASPR has also released a five-year Strategic Plan that envisions a nation more prepared to prevent, respond to, recover from, and reduce the adverse health effects of public health emergencies and disasters.

Overview of Budget Request

The FY 2024 President's Budget discretionary request for the Administration for Strategic Preparedness and Response (ASPR) is \$4,271,913,000, which is an increase of +\$642,236,000 above FY 2023 Enacted. The budget also proposes \$20 billion in mandatory funding across HHS to prepare for pandemics and other biological threats, of which \$10.54 billion would support ASPR activities. Please see the Public Health and Social Services Emergency Fund Congressional Justification for details on the mandatory request.

Discretionary Programmatic Increases (relative to the FY 2023 Enacted level):

Pandemic Preparedness and Biodefense (increase of \$400 million, \$400 million total): The FY 2024 President's Budget proposes \$400 million in new resources to bolster pandemic preparedness and biodefense against new and emerging threats. This funding will support scope activities that are strongly aligned with the tenets of the National Biodefense Strategy and similar objectives within several other Administration priorities. More explicitly, this funding will be utilized for investments that significantly accelerate the availability of medical countermeasures upon identification of an emerging pathogen which, dependent upon the threat space and medical countermeasure pipeline, may include investments to accelerate advanced development of investigational vaccines, therapeutics and diagnostics; support emergency manufacturing of critical medical countermeasures and ancillary supplies; and, to the extent feasible, invest in the expansion and sustainment of the domestic medical supply chain.

The funding will advance ASPR's permanent industrial base management capabilities, inclusive of global supply chain situational awareness, market capabilities, rapid acquisition execution, and coordination of Defense Production Act (DPA) and Emergency Support Function (ESF)-8 authorities. These activities are currently funded with supplemental appropriations and cannot be sustained without additional ASPR base resources.

BARDA Advanced Research and Development (increase of +\$65.132 million, \$1,015.132 million total): The FY 2024 President's Budget request for Advanced Research and Development (ARD) includes additional funding to expand BARDA's threat agnostic advanced development portfolio. This approach focuses on developing tools that can work against more than one pathogen, or platforms that can be used to rapidly pivot to produce vaccines, therapeutics, diagnostics, and other tools against different diseases. Such approaches support rapid advancement of products against the highest priority threats, namely those with a Material Threat Determination, while also providing new tools to address other threats. Additional FY 2024 funding will also support critical ongoing work assessing impacts of COVID-19 viral variants on medical countermeasures (MCMs).

Pandemic Influenza (increase of +\$47 million, \$374.991 million total): The Budget proposes an additional \$47 million in no-year funding for additional investments on BARDA's mRNA vaccine platform technology in support of the 2021 American Pandemic Preparedness Plan (APPP) goals, and to cover increasing sustainment costs for manufacturing capacity for pandemic response readiness.

Operations (increase of +\$35.491 million, \$69.867 million total): ASPR uses Operations funding to support its unique role in public health emergencies, as well as its responsibilities for preparedness,

response, and recovery. The President's Budget request includes an additional \$35.5 million, which will enhance ASPR's financial management, acquisition, and information technology support. These activities provide support across ASPR's programs and will also ensure an optimal infrastructure as ASPR takes on its additional responsibilities in the future.

National Disaster Medical System (increase of +\$33.126 million, \$130.030 million total): The additional \$33 million will be used to support hiring and training of NDMS Responders; sustainment of mission essential infrastructure; and critical response planning, coordination, and technical assistance to build public health and medical resiliency. The request will allow NDMS to resolve critical shortfalls in federal public health and medical capabilities and infrastructure based on COVID-19 lessons learned and build resilience in the NDMS system to support the next disaster or critical incident.

Strategic National Stockpile (SNS) (increase of +\$30 million, \$995 million total): The request prioritizes funding for sustainment of current product lines and procurement of several products previously supported by BARDA that lack a significant commercial market. Specifically, the SNS increase will ensure that the United States Government (USG) is better prepared to respond to a potential radiological or nuclear event occurring on American soil. SNS also plans to procure anti-neutropenic drugs necessary to treat acute radiation syndrome which are scheduled to transition from BARDA to SNS procurement in FY 2024.

Project BioShield (increase of +\$10 million, \$830 million total): The additional \$10 million will support smallpox vaccine procurement to partially restore vaccines used for the mpox response. The budget supports continued development and procurement of therapeutics for Sudan and Ebola viruses as well as a second smallpox antiviral drug. This level also continues procurement of JYNNEOS vaccine for prevention of smallpox including additional manufacturing requirements due to diversion of product to support the USG mpox response.

BARDA will continue advanced development and procurement of novel drugs to treat drug resistant bacterial infections, procurement of MCMs to treat injuries resulting from exposure to chemical threats including nerve agents, 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.

HHS Coordination Operations and Response Element (an increase of +\$7.801 million, \$82.801 million total): The FY 2024 request includes an additional +\$7.8 million to support H-CORE's operations and logistics architecture, pilot novel and innovative operations and logistics capabilities, and incorporate new data sources and technologies that provide information regarding health, health safety, and health security.

Health Care Readiness and Recovery (HCRR, formerly Hospital Preparedness Program) (increase of +\$7.000 million, \$312.055 million total): The requested increase of +\$7 million will support HCRR's other programs including Technical Resources Assistance Center and Information Exchange (TRACIE), Recovery, and Critical Infrastructure Protection (CIP) as well as additional internal ASPR support for the HHP cooperative agreements and other Health Care Readiness activities.

Within the President's Budget total, ASPR will use \$28.5 million, the same as the FY 2023 Enacted, for the National Special Pathogen System (NSPS). This will provide \$21 million to the Regional Emerging Special Pathogen Treatment Centers (RESPTC) network to sustain a regional network for special pathogen care and \$7.5 million to the National Emerging Special Pathogens Training and Education Center (NETEC) to act as the coordinating body for the NSPS.

Within the total, \$240 million 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.

Policy and Planning (increase of +\$6.540 million, \$21.417 million total): The FY 2024 President's Budget request \$21,417,000 for Policy and Planning, an additional +\$6,540,000 above FY 2023 Enacted to establish quantitative and economics analytics and modeling capabilities to evaluate medical countermeasure programs.

Preparedness and Emergency Operations (increase of +\$0.146 million, \$31.300 million total): The President's Budget will support critical preparedness investments that support ASPR and HHS-wide activities. The budget will provide an increase of \$3,000,000 for ASPR Ready to fund the operations and maintenance to the interoperable system for tracking ASPR's information, resources, and personnel before, during and after a response. The budget will also provide an increase of \$3.65 million to ensure that ASPR can continue to maintain current preparedness capabilities including Information Management, Intelligence Operations, Personnel Security, and Secretary's Operations Center (SOC) programs to ensure execution of these 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. Funds will be used to support information systems, data analysis and other tools necessary to support the preparedness and response mission.

The FY 2024 President's Budget does not include funding for National Emergency Tele-Critical Care Network (NETCCN), a decrease of -\$6.5 million below the FY 2023 Enacted.

Mandatory Programmatic Increases (relative to the FY 2023 Enacted level):

Pandemic Preparedness (increase of \$10.54 billion, \$10.54 billion total): The FY 2024 budget includes a \$20 billion mandatory investment across HHS to prepare for pandemics and other biological threats. This proposal provides funding within PHSSEF, allocated to NIH, CDC, FDA, and ASPR. The \$10.54 billion allocated to ASPR will be used to conduct advanced research and development of vaccines, therapeutics, and diagnostics for high priority pathogens; scale up domestic manufacturing capacity for medical countermeasures; bolster personal protective equipment (PPE) and critical medicines supply chain; develop technologies for biosurveillance and early warning; and support training for the public health workforce. A more detailed description can be found in the Public Health and Social Services Emergency Fund (PHSSEF) Congressional Justification.

Overview of Performance

The Administration for Strategic Preparedness and Response's (ASPR) mission is to assist the country in preparing for, responding to, and recovering from public health emergencies and disasters.

ASPR accomplishes our mission in several ways, including: developing, stockpiling, and distributing response tools against multiple threats; sending clinical response teams to places in times of crisis; and ensuring our healthcare and public health partners have the knowledge and tools they need to navigate today's challenges and confront whatever challenges lay ahead.

ASPR envisions a nation more prepared to prevent, respond to, recover from, and reduce the adverse health effects of public health emergencies and disasters. Performance in each of these areas and in all of ASPR's work is strengthened through the use of rigorous and ongoing performance metrics and program evaluation data to monitor program effectiveness and compare performance to established targets.

Strategic Planning

ASPR has recently released a five-year Strategic Plan which will ultimately help ASPR evaluate and track our performance. The 2022 – 2026 ASPR Strategic Plan sets the direction of the organization, prioritizes agency actions, and facilitates coordination and collaboration with partners. The development and implementation of this Strategic Plan reflects ASPR's continuing commitment to strengthen our ability to prepare, respond and recover quickly from multiple health threats. This Strategic Plan will allow us to build upon past successes while focusing on the current needs of the nation, inspiring innovation, and pursuing excellence. Importantly, this Strategic Plan also offers ASPR something against which we can clearly measure performance. ASPR is in the process of drafting the Strategic Plan Road Map where ASPR will outline how we will meet the goals and objectives put forward in the Strategic Plan and look forward to sharing this with Congress upon completion.

Preparing for, Responding to, and Recovering from Public Health Emergencies and Disasters

Throughout 2022:

- ASPR conducted allocation planning and execution for 14 COVID-19 vaccine rollouts and campaigns in coordination with CDC, totaling more than 300 million vaccine doses distributed, and end-to-end management, partner education, and distribution of 8 therapeutics, including more than 13.9 million treatment courses distributed nationwide.
- ASPR collaborated across the USG to distribute more than 670 million at-home COVID-19 test kits and 270 million N95 respirators – all free to those who wanted them.
- ASPR distributed over 890,00 vials of JYNNEOS, over 80,000 bottles of oral TPOXX, and over 11,000 vials of IV TPOXX across all 57 jurisdictions in support of the mpox response.
- ASPR supported Operation Fly Formula, which has successfully landed twenty-six flights transporting more than 97.9 million 8-ounce bottle equivalents to the U.S.
- ASPR successfully executed one of the largest deployments of personnel and equipment in support of a hurricane in the last five years. ASPR deployed 10 National Disaster Medical System (NDMS) teams, with hundreds of additional incident management, logistical, and regional staff, supporting seven free-standing emergency room sites around the State of Florida in the aftermath of Hurricane Ian.

Tracking Performance Metrics

Implementation of the Evidence Act

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 to orchestrate shared data services across ASPR. The Evaluation Officer participates in Departmental evaluation efforts and develops learning agendas and educational materials regarding evaluation and evidence-building for ASPR. The CDO facilitates the use of data to foster data stewardship and support decision-making and to manage and evaluate the performance of data projects and services. These activities include formulating plans to implement data maturity tools for ASPR leadership to determine the adoption of Data Management best practices for ASPR.

Performance and Enterprise Risk Management (ERM)

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, as well as The [Government Performance and Results Act \(GPRA\) of 1993 \(P.L. 103-62\) - PDF](#) and the [GPRA Modernization Act of 2010 \(P.L. 111-352\) - PDF](#). ASPR assesses, mitigates, and reports on its internal controls. This includes monitoring, analyzing, and generating both risk and performance data. Benefits of such integration include operational improvements, a risk-aware culture, and better understanding about the best use of resources. ASPR incorporates analysis of risk appetite (appreciation for levels of risk), into its goals and objectives. To do this, ASPR creates performance measures that capture risk, then implements actions designed to manage, mitigate, and/or spend-down the risk. Measurement of risks that are directly associated with performance measurement are currently in development. Enterprise-wide educational training events have been held regularly to expand understanding of key topics relevant to a culture of learning. These topics include the use of evidence, the integration of ERM with performance management, and the use of data as part of project management.

Agency Priority Goals and HHS Priorities

ASPR collaborates with several HHS partners on an 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. In support of this APG, ASPR is providing funding to states, territories, and eligible major metropolitan areas for health care delivery system preparedness and response and to provide health care organizations and their partners access to a national response network. Also, ASPR's Industrial Base Management and Supply Chain (IBM/SC) program is building a diverse, agile public health supply chain that will sustain long-term United States manufacturing capabilities. This is cemented by the ASPR reorganization that establishes this office as part of the ASPR organizational structure with direct reporting to the ASPR. The goals for the IBM/SC program include:

- Transforming the United States Government's (USG) ability to manage the public health supply chain through coordination of stockpiles, visibility, and engagement and ensure fair, equitable, and effective allocation of scarce resources;

Administration for Strategic Preparedness and Response

- Defining a procurement strategy with enabling authorities in place to assess supplier risk levels and diversify the supplier base to provide strategic sourcing if needed during periods of crisis; and,
- Investing in innovative technologies that will facilitate the USG's ability to meet demands for future public health emergencies.

To further integrate ASPR's contributions to the HHS Secretary's priorities, the HHS FY 2022-2026 Strategic Plan, and the HHS Annual Performance Plan and Report, 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. In addition, ASPR joins the rest of HHS in pursuit of Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All.

All Purpose Table

(Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted ²	FY 2024 President's Budget	FY 2024 +/- FY 2023
Preparedness and Emergency Operations.....	24.654	31.154	31.300	+0.146
National Special Security Events (NSSE) (non-add).....	5.000	5.000	5.000	--
National Emergency Tele-Critical Care Network (NETCCN) (non-add)....	-	6.500	-	-6.500
Health Care Readiness and Recovery /4.....	295.555	305.055	312.055	+7.000
National Special Pathogen System (non-add).....	27.500	28.500	28.500	--
NETEC (non-add).....	6.500	7.500	7.500	--
RESPTCs (non-add).....	21.000	21.000	21.000	--
HPP Cooperative Agreements (non-add).....	231.500	240.000	240.000	--
RDHRS (non-add).....	7.000	7.000	7.000	--
Other Costs (non-add).....	29.555	29.555	36.555	+7.000
Medical Reserve Corps.....	6.240	6.240	6.240	--
National Disaster Medical System (NDMS).....	75.404	96.904	130.030	+33.126
Mission Zero (non-add).....	2.000	4.000	-	-4.000
Public Health Preparedness Equipment (non-add).....	10.000	20.000	-	-20.000
Pediatric Disaster Care (non-add).....	6.000	7.000	7.000	--
Biomedical Advanced Research and Development Authority (BARDA).....	745.005	950.000	1,015.132	+65.132
Program Operations and Management (non-add).....	120.000	170.000	170.000	--
Project BioShield.....	780.000	820.000	830.000	+10.000
Pandemic Influenza	292.991	327.991	374.991	+47.000
No-Year Pandemic Influenza (non-add).....	265.000	300.000	347.000	+47.000
Annual Pandemic Influenza (non-add).....	27.991	27.991	27.991	--
Strategic National Stockpile.....	845.000	965.000	995.000	+30.000
HHS Coordination Operations and Response Element.....	--	75.000	82.801	+7.801
Operations	30.938	34.376	69.867	+35.491
Policy and Planning.....	14.877	14.877	21.417	+6.540
Preparedness and Response Innovation.....	2.080	3.080	3.080	--
Pandemic Preparedness and Biodefense (NEW).....	--	--	400.000	+400.000
Total, ASPR Discretionary Budget Authority.....	3,112.744	3,629.677	4,271.913	+642.236
Total, ASPR Program Level.....	3,112.74	3,629.68	4,271.91	+642.236
<i>Pandemic Preparedness (Mandatory) (non-add) /3.....</i>	-	-	10,540.000	+10,540.000

¹ ASPR previously received appropriations via the Public Health and Social Services Emergency Fund. The FY 2024 President's Budget requests ASPR be funded directly in a new appropriations account. FY 2022 and FY 2023 columns show ASPR funding previously received through the Public Health and Social Services Emergency Fund.

² Excludes emergency and supplemental funding of \$24 million in the Disaster Relief Supplemental Appropriations Act (P.L. 117-328 Division N).

³ The FY 2024 budget also provides \$20 billion in mandatory funding across HHS to prepare for pandemics and other biological threats, which is reflected in the Public Health and Social Services Emergency Fund Congressional Justification. Of this total, ASPR will receive \$10.54 billion.

⁴ Formerly known as the Hospital Preparedness Program.

APPROPRIATIONS LANGUAGE

FY 2024 Appropriations Language

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

For carrying out, except as otherwise provided, titles III, XII, and XVII, and parts A and B of title XXVIII of the PHS Act, with respect to public health emergency preparedness and response, biodefense, medical countermeasures, and preparing for or responding to an influenza pandemic, \$4,271,913,000, of which:

(1) \$1,015,132,000 shall remain available through September 30, 2025, 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;

(2) \$830,000,000 shall remain available until expended for expenses necessary for procuring security countermeasures (as defined in section 319F-2(c)1)(B) of the PHS Act);

(3) \$995,000,000 shall remain available until expended for expenses necessary to carry out section 319F-2(a) of the PHS Act:

(4) \$374,991,000 shall be for expenses necessary to prepare for or respond to an influenza pandemic, of which \$347,000,000 shall remain available until expended for activities including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools;

(5) \$82,801,000 shall remain available through September 30, 2025, to support coordination of the development, production, and distribution of vaccines, therapeutics, and other medical countermeasures; and

(6) \$400,000,000 shall remain available through September 30, 2025, for an additional amount for necessary expenses of advanced research and development, manufacturing, production and purchase of medical countermeasures, including the development, translation, and demonstration at scale of innovations in manufacturing platform, and to carry out titles I, III, and VII of the Defense Production Act of 1950 to meet critical public health needs of the United States: Provided, That such amounts may be used for the purchase, production (including the construction, repair, and retrofitting of government-owned or private facilities as necessary), or distribution of medical supplies and equipment (including durable medical equipment):

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 of the amounts available for emergency operations, \$5,000,000 shall remain available through September 30, 2026.

Appropriations Language Analysis

Language Provision	Explanation
<i>For carrying out, except as otherwise provided, titles III, XII, and XVII, and parts A and B of title XXVIII of the PHS Act, with respect to public health emergency preparedness and response, biodefense, medical countermeasures, and preparing for or responding to an influenza pandemic, \$4,271,913,000, of which:</i>	This language is inserted to specify new appropriations account for the Administration for Strategic Preparedness and Response (ASPR). This language is modeled on ASPR’s portions of the Public Health and Social Services Emergency Fund (PHSSEF) appropriation.
<i>(1) \$1,015,132,000 shall remain available through September 30, 2025, 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;</i>	This language provides funding for BARDA Advanced Research and Development (ARD).
<i>(2) \$830,000,000 shall remain available until expended for expenses necessary for procuring security countermeasures (as defined in section 319F-2©(1)(B) of the PHS Act);</i>	This language provides funding for Project BioShield (PBS).
<i>(3) \$995,000,000 shall remain available until expended for expenses necessary to carry out section 319F-2(a) of the PHS Act:</i>	This language provides funding for the Strategic National Stockpile (SNS).
<i>(4) \$374,991,000 shall be for expenses necessary to prepare for or respond to an influenza pandemic, of which \$347,000,000 shall remain available until expended for activities including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools;</i>	This language provides funding for Pandemic Influenza.
<i>(5) \$82,801,000 shall remain available through September 30, 2025, to support coordination of the development, production, and distribution of vaccines, therapeutics, and other medical countermeasures; and</i>	This language provides funding for the Health and Human Services Coordination Operations and Response Element (H-CORE).

Language Provision	Explanation
<p><i>(6) \$400,000,000 shall remain available through September 30, 2025, for an additional amount for necessary expenses of advanced research and development, manufacturing, production and purchase of medical countermeasures, including the development, translation, and demonstration at scale of innovations in manufacturing platform, and to carry out titles I, III, and VII of the Defense Production Act of 1950 to meet critical public health needs of the United States: Provided, That such amounts may be used for the purchase, production (including the construction, repair, and retrofitting of government-owned or private facilities as necessary), or distribution of medical supplies and equipment (including durable medical equipment):</i></p>	<p>This language provides funding for a new program, Pandemic Preparedness and Biodefense. The funding has two-year availability.</p>
<p><i>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 of the amounts available for emergency operations, \$5,000,000 shall remain available through September 30, 2026.</i></p>	<p>This language provides funding for ASPR National Special Security Events (NSSE). This funding has three-year availability.</p>

AMOUNTS AVAILABLE FOR OBLIGATION

(Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS, Ag, or Interior).....	-	-	4,271.913
Subtotal, adjusted appropriation.....	-	-	4,271.913
Total, Discretionary Appropriation.....	-	-	4,271.913
Total obligations.....	-	-	4,271.913

Note: For columns FY 2022 and FY 2023, this exhibit does not include ASPR funds which were appropriated to the PHSSEF but made available to ASPR. The FY 2024 column includes ASPR's budget request.

SUMMARY OF CHANGES

(Dollars in Millions)

2023 Enacted							
Total budget authority.....							3,629.677
2024 President's Budget							
Total estimated budget authority.....							4,246.913
Net Change.....							+642.236
	FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023		
	BA	FTE	BA	FTE	BA	FTE	
Increases:							
Built-in:							
Annualization of 2022 commissioned corps pay increase	5.000	-	10.000	-	+5.000	-	
Annualization of 2022 civilian pay increase.....	35.000	-	80.000	-	+45.000	-	
Subtotal, Built-in Increases.....	40.000	-	90.000	-	+50.000	-	
Expanded programs							
Preparedness and Emergency Operations.....	31.154	86	31.300	86	+0.146	-	
National Disaster Medical System.....	96.904	148	130.030	162	+33.126	+14	
Health Care Readiness and Recovery.....	305.055	49	312.055	49	+7.000	-	
Biomedical Advanced Research and Development Authority	950.000	300	1,015.132	364	+65.132	+64	
Project BioShield.....	820.000	-	830.000	-	+10.000	-	
Pandemic Influenza	327.991	-	374.991	-	+47.000	-	
Strategic National Stockpile.....	965.000	329	995.000	329	+30.000	-	
HHS Coordination Operations and Response Element	75.000	111	82.801	111	+7.801	-	
Operations	34.376	142	69.867	288	+35.491	+146	
Policy and Planning.....	14.877	66	21.417	83	+6.540	+17	
New Programs.....							
Pandemic Preparedness and Biodefense.....	-	-	400.0000	53	+400.000	+53	
Subtotal, Program Increases.....	3,620.357	1,231	4,262.593	1,525	+642.236	+241	
Total Increases.....	3,620.357	1,231	4,262.593	1,525	+642.236	+241	
Decreases:	-	-	-	-	-	-	
Net Change.....						+642.236	+241

BUDGET AUTHORITY BY ACTIVITY

Activity	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Bioterrorism and Emergency Preparedness	2,819.753	3,301.686	3,896.922
Pandemic Influenza	292.991	327.991	374.991
Total Budget Authority¹	3,112.744	3,629.677	4,271.913
FTE	972	1,246	1,540

¹ ASPR previously received appropriations via the Public Health and Social Services Emergency Fund. The FY 2024 President's Budget requests ASPR be funded directly in a new appropriations account. FY 2022 and FY 2023 columns show ASPR funding previously received through the Public Health and Social Services Emergency Fund.

AUTHORIZING LEGISLATION

Activity	FY 2023 Amount Authorized	FY 2023 Amount Appropriated	FY 2024 Amount Authorized	FY 2024 President's Budget
National Disaster Medical System	57.404	96.904	N/A	130.030
Hospital Preparedness Program	385.000	305.055	N/A	312.055
Medical Reserve Corps	11.200	6.240	N/A	6.240
BARDA	611.700	950.000	N/A	1,015.132
Project BioShield	710.000	820.000	710.000	830.000
Strategic National Stockpile	610.000	965.000	N/A	995.000
Pandemic Influenza ¹	250.000	327.991	N/A	374.991

¹ The Pandemic Influenza authorization reflects the combined allocation for both ASPR and the HHS Office of Global Affairs (as appropriated together within the PHSSEF appropriation.) In FY 2024, the budget proposes a separate appropriations account for ASPR.

APPROPRIATIONS HISTORY

(Dollars in millions)

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2024				
Annual	4,271.913	-	-	-
Subtotal	4,271.913	-	-	-

Note: For years prior to FY 2023, this exhibit does not include ASPR funds which were appropriated to the PHSSEF but made available to ASPR. The FY 2024 column includes ASPR's budget request.

APPROPRIATIONS NOT AUTHORIZED BY LAW

(Dollars in Millions)

Program	Last Year of Authorization	Authorization Level	Appropriations in Last Year of Authorization	Appropriations in FY 2023
Operations	N/A	N/A	N/A	34.376
Preparedness and Emergency Operations	N/A	N/A	N/A	31.300
Policy and Planning	N/A	N/A	N/A	14.877
H-CORE	N/A	N/A	N/A	75.000
Pandemic Preparedness and Biodefense	N/A	N/A	N/A	-

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

Summary of Request

Budget Summary
(Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	3,112.744	3,629.677	4,271.913	+642.236
Program Level	3,112.744	3,629.677	4,271.913	+642.236
<i>Mandatory Pandemic Preparedness (non-add)</i>	-	-	10,540.000	+10,540.000
FTE	1,215	1,246	1,540	+294

The Fiscal Year (FY) 2024 President’s Budget request for the Administration for Strategic Preparedness and Response (ASPR) is \$4,217,913,000, which is \$642,236,000 above FY 2023 Enacted. The budget also proposes \$20 billion in mandatory funding across HHS to prepare for pandemics and other biological threats, of which \$10.54 billion would support ASPR activities. Please see the Public Health and Social Services Emergency Fund Congressional Justification for details on the mandatory request.

Discretionary Increases above FY 2023 Enacted:

Pandemic Preparedness and Biodefense: The FY 2024 President’s Budget proposes \$400,000,000, in new resources to bolster pandemic preparedness and biodefense against new and emerging threats. This funding will support scope that is strongly aligned with the tenets of the National Biodefense Strategy and similar objectives within several other Administration priorities. More explicitly, this funding will be utilized for investments that significantly accelerate the availability of medical countermeasures upon identification of an emerging pathogen which, dependent upon the threat space and medical countermeasure pipeline, may include investments to accelerate advanced development of investigational vaccines, therapeutics and diagnostics; support emergency manufacturing of critical medical countermeasures and ancillary supplies; and, to the extent feasible, invest in the expansion and sustainment of the domestic medical supply chain.

The funding will advance ASPR’s permanent industrial base management capabilities, inclusive of global supply chain situational awareness, market capabilities, rapid acquisition execution, and coordination of Defense Production Act (DPA) and Emergency Support Function (ESF)-8 authorities. These activities are currently funded with supplemental appropriations and cannot be sustained without additional ASPR base resources.

BARDA Advanced Research and Development (ARD): The FY 2024 President’s Budget request for ARD is \$1,015,132,000, which is +\$65,132,000 above FY 2023 Enacted. With the additional funding,

BARDA will be able to expand its threat agnostic advanced development portfolio. This approach focuses on developing tools that can work against more than one pathogen, or platforms that can be used to rapidly pivot to produce vaccines, therapeutics, diagnostics, and other tools against different diseases. Such approaches support rapid advancement of products against the highest priority threats, namely those with a Material Threat Determination, while also providing new tools to address other threats. Additional FY 2024 funding will also support critical ongoing work assessing impacts of COVID-19 viral variants on medical countermeasures (MCMs).

Pandemic Influenza: The FY 2024 President's Budget request for Pandemic Influenza is \$374,991,000, which is +\$47,000,000 above FY 2023 Enacted. The request includes \$347 million in no-year funding and \$27.991 million in annual funding. The additional \$47 million in no-year funding will support additional investments on BARDA's mRNA vaccine platform technology to support American Pandemic Preparedness Plan (APPP) goals and cover increasing sustainment costs for manufacturing capacity for pandemic response readiness.

Operations: The President's Budget requests \$69,867,000 for Operations, which is +\$35,491,000 above FY 2023 Enacted. Additional funding will enhance ASPR's financial management, acquisition, and information technology support. These activities provide support across ASPR's programs and will also ensure an optimal infrastructure as ASPR takes on its additional responsibilities in the future.

National Disaster Medical System: The FY 2024 President's Budget requests \$130,0300,000 for the National Disaster Medical System (NDMS), an increase of +\$33,126,000 above FY 2023 Enacted. The additional \$33 million will be used to support hiring and training of NDMS Responders; sustainment of mission essential infrastructure; and critical response planning, coordination, and technical assistance to build public health and medical resiliency.

Strategic National Stockpile (SNS): The FY 2024 President's Budget requests \$995,000,000 for SNS, which is +\$30,000,000 above FY 2023 Enacted. The request prioritizes funding for sustainment of current product lines and procurement of several products previously supported by BARDA that lack a significant commercial market. Specifically, the SNS increase will ensure that the United States Government (USG) is better prepared to respond to a potential radiological or nuclear event occurring on American soil. SNS also plans to procure anti-neutropenic drugs necessary to treat acute radiation syndrome which are scheduled to transition from BARDA to SNS procurement in 2024.

Project BioShield: The FY 2024 President's Budget requests \$830,000,000 for Project BioShield (PBS), which is +\$10,000,000 above the FY 2023 Enacted. The additional \$10 million will support smallpox vaccine procurement to partially restore vaccines used for the mpox response. The budget supports continued development and procurement of therapeutics for Sudan and Ebola viruses as well as a second smallpox antiviral drug. This level also continues procurement of JYNNEOS vaccine for prevention of smallpox including additional manufacturing requirements due to diversion of product to support the USG mpox response.

BARDA will continue advanced development and procurement of novel drugs to treat drug resistant bacterial infections, procurement of MCMs to treat injuries resulting from exposure to chemical threats

including nerve agents, 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.

HHS Coordination Operations and Response Element (H-CORE): The FY 2024 President's Budget requests \$82,801,000 for SNS, which is +\$7,801,000 above FY 2023 Enacted. The additional funds will support H-CORE's operations and logistics architecture, pilot novel and innovative operations and logistics capabilities, and incorporate new data sources and technologies that provide information regarding health, health safety, and health security.

Health Care Readiness and Recovery (HCRR) (formerly Hospital Preparedness Program): The FY 2024 President's Budget requests \$312,055,000 for HCRR, which is +\$7,000,000 above FY 2023 Enacted. The requested increase of +\$7 million will support HCRR's other programs including Technical Resources Assistance Center and Information Exchange (TRACIE), Recovery, and Critical Infrastructure Protection (CIP) as well as additional internal ASPR support for the HHP cooperative agreements and other Health Care Readiness activities.

Within the President's Budget total ASPR will use \$28.5 million, the same as the FY 2023 Enacted, for the National Special Pathogen System (NSPS). This will provide \$21 million to the Regional Emerging Special Pathogen Treatment Centers (RESPTC) network to sustain a regional network for special pathogen care and \$7.5 million to the National Emerging Special Pathogens Training and Education Center (NETEC) to act as the coordinating body for the NSPS.

Within the total, \$240 million 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.

Policy and Planning: The FY 2024 President's Budget request \$21,417,000 for Policy and Planning, an additional +\$6,540,000 above FY 2023 Enacted to establish quantitative and economics analytics and modeling capabilities to evaluate medical countermeasure programs.

Preparedness and Emergency Operations (PEO): The FY 2024 President's Budget requests \$31,300,000 for PEO, which is +\$146,000 above FY 2023 Enacted. The President's Budget will support critical preparedness investments that support ASPR and HHS-wide activities. The budget will provide an increase of \$3,000,000 for ASPR Ready to fund the operations and maintenance to the interoperable system for tracking ASPR's information, resources, and personnel before, during and after a response. The budget will also provide an increase of \$3.65 million to ensure that ASPR can continue to maintain current preparedness capabilities including Information Management, Intelligence Operations, Personnel Security, and Secretary's Operations Center (SOC) programs to ensure execution of these 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. Funds will be used to support information systems, data analysis and other tools necessary to support the preparedness and response mission.

The FY 2024 President's Budget does not include funding for National Emergency Tele-Critical Care Network (NETCCN), a decrease of -\$6.5 million below the FY 2023 Enacted.

Mandatory Increases above FY 2023 President's Budget:

Pandemic Preparedness: The FY 2024 budget includes a \$20 billion mandatory investment across HHS to prepare for pandemics and other biological threats. This proposal provides funding within PHSSEF, allocated to NIH, CDC, FDA, and ASPR. The \$10.54 billion allocated to ASPR will be used to conduct advanced research and development of vaccines, therapeutics, and diagnostics for high priority pathogens; scale up domestic manufacturing capacity for medical countermeasures; bolster personal protective equipment (PPE) and critical medicines supply chain; develop technologies for biosurveillance and early warning; and support training for the public health workforce. A more detailed description can be found in the Public Health and Social Services Emergency Fund (PHSSEF) Congressional Justification.

Pandemic Preparedness and Biodefense Budget Summary

(Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	-	-	400.000	+400.000
FTE	-	-	53	+53

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

To prepare for and quickly respond to emergent pathogens with outbreak or pandemic potential, the Administration for Strategic Preparedness and Response (ASPR) needs flexible resources that can be utilized to rapidly close critical gaps identified during the acute phase of response and accelerate progress, as need arises, within long-term programs.

This funding will support scope that is strongly aligned with the tenets of the National Biodefense Strategy and similar objectives within several other Administration priorities (e.g., American Pandemic Preparedness Plan, Global 100 Days Mission, etc.). More explicitly, this funding will be utilized for investments that significantly accelerate the availability of medical countermeasures upon identification of an emerging pathogen which, dependent upon the threat space and medical countermeasure pipeline, may include investments to accelerate advanced development (i.e., preclinical/clinical safety and efficacy studies, manufacturing process improvement and scale-up, regulatory submissions, etc.) of investigational vaccines, therapeutics and diagnostics; support emergency manufacturing of critical medical countermeasures and ancillary supplies; and, to the extent feasible, invest in the expansion and sustainment of the domestic medical supply chain.

This funding can also be leveraged to complement efforts to support advanced development of novel medical countermeasures against viral families with high pandemic potential, expand and/or retain warm base manufacturing to address demand surges, and advance threat agnostic and pathogen independent platform approaches to greatly expand preparedness for a wide range of potential threats.

ASPR is responsible for developing and manufacturing the countermeasures required to respond to a diverse and complex threat landscape. This flexible funding will go a long way towards ensuring the country will have what it needs when it needs it no matter the threat. As examples of use, had discretionary funding been available during recent responses, ASPR would have been better positioned to rapidly expand distribution capacity for medical countermeasures from the Strategic National Stockpile (e.g., TPOXX, TEMBEXA, JYNNEOS for mpox; Tamiflu for influenza). Also from recent responses,

ASPR would have also been able to accelerate fill/finish of the JYNNEOS vaccine for the mpox outbreak, and speed manufacturing of investigational countermeasures for the Ebola Sudan Virus outbreak.

In addition, the threat of a highly virulent flu strain is an ever-present concern. As of March 2023, HHS is tracking an avian influenza strain circulating in birds and mammals in the Americas and Europe. This funding could be used to fill/finish ASPR’s H5N1 candidate that currently exists in bulk drug substance and accelerate clinical trials, or support early efforts to bring the current egg-based vaccines to a more nimble response platform such as mRNA. Within current base funding, these efforts are out of reach. Additional, nimble funding is called for to respond to emerging pathogens of pandemic potential and biothreats.

The funding will also support ASPR’s industrial base management capabilities, including global supply chain situational awareness, rapid acquisition execution, and continued coordination of activities related to medical industrial base expansion and sustainment through its Industrial Base Management and Supply Chain Office.

Funding History	
Fiscal Year	Amount
FY 2020	-
FY 2021	-
FY 2022 Final	-
FY 2023 Enacted	-
FY 2024 President’s Budget	\$400,000,000

Budget Request

The FY 2024 President’s Budget request for pandemic preparedness and biodefense is \$400,000,000 which is +\$400,000,000 above the FY 2023 Enacted. This request is for a new flexible, rapid response and long-term preparedness fund to bolster pandemic preparedness and biodefense, including to develop next-generation medical countermeasures that protect against multiple strains or multiple viruses within a viral family (i.e., universal flu vaccine) and to support warm base manufacturing for surge production of vaccines, therapeutics, diagnostics, and PPE. The budget proposes two-year availability for these funds.

Preparedness and Emergency Operations

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	24.654	31.154	31.300	+0.146
<i>National Special Security Events (non-add)</i>	<i>5.000</i>	<i>5.000</i>	<i>5.000</i>	<i>-</i>
<i>National Emergency Tele-Critical Care Network (NETCCN) (non-add)</i>	<i>-</i>	<i>6.500</i>	<i>-</i>	<i>-6.500</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

In order to support the Administration for Strategic Preparedness and Response’s (ASPR’s) mission to help the country prepare for, respond to, and recover from public health emergencies and other disasters, the Preparedness and Emergency Operations (PEO) program leads many coordination and response functions. 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. Managing these responsibilities rests with ASPR’s PEO program. PEO supports the delivery of Federal mass care, emergency assistance, housing, and human services when response and recovery needs exceed a state or local jurisdiction’s capabilities. PEO also supports HHS medical teams deployed in response to a public health emergency by providing medical supplies and services, including medical durable equipment, and coordinating emergency medical care in shelters, as needed.

Funding History	
Fiscal Year	Amount
FY 2020	\$24,654,000
FY 2021	\$24,654,000
FY 2022 Final	\$24,654,000
FY 2023 Enacted	\$31,154,000
FY 2024 President’s Budget	\$31,300,000

Budget Request

The FY 2024 President’s Budget request for PEO is \$31,300,000, which is +\$146,000 above FY 2023 Enacted. This includes an increase of \$3.0 million for ASPR Ready which will fund the operations and

maintenance of the interoperable data management system used for tracking ASPR's information, resources, and personnel before, during and after a response. The budget will ensure that ASPR can continue to maintain PEO capabilities at current levels. An additional \$3.65 million will be allocated to continue current Information Management, Intelligence Operations, Personnel Security, and Secretary's Operations Center (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 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.

The request will maintain the ASPR activities for strategic and operational planning, the SOC monitoring and alerting, HHS continuity, which includes continuity of the Presidency, Government and Operations, information management, situational awareness, information technology and cybersecurity, intelligence analysis and requirements, personnel security, and exercises.

The request 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 2022 UN General Assembly (UNGA).

The FY 2024 President's Budget does not include funding for National Emergency Tele-Critical Care Network (NETCCN), a decrease of -\$6.5 million below the FY 2023 Enacted. This program is discussed in more detail in the Health Care Readiness and Recovery (HCRR) section. The NETCCN is operated out of the HRCC program but was appropriated via the PEO budget line in the FY 2023 Omnibus.

Program Accomplishments

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. ASPR supported recovery activities after hurricanes Harvey, Irma, and Maria in 2017; Florence, Michael, and Typhoon Yutu in 2018; Dorian and Typhoon Wutip in 2019, Ida and Henri in 2021 and Fiona and Ian in 2022. 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.

ASPR has continued its COVID-19 response activities from 2021 to present which has included 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 in response to the pandemic. ASPR supported the response to the January 6th Capital insurrection, the Unaccompanied Minor mission along the Southwest Border, 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. In 2022, ASPR also supported Operation Fly Formula to address the shortage of infant formula across the United States and the mpox outbreak, including distribution of vaccines.

ASPR supports all planned annual NSSEs 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, and other non-annual planned events such as the Democratic and Republican National Conventions, Presidential Inaugurations, State funerals for dignitaries, and when someone is Lying in State/Honor.

Contingency and Crisis Action Planning, Deliberate Planning, and Mission Analysis

ASPR develops operational planning guidance designed to implement national preparedness and recovery functions and to prepare the Department's response during incidents and events. The plans allow ASPR to coordinate Federal public health and medical response capabilities, to deliver health care during and after incidents, to maximize emergency response systems, and to minimize the effects of manmade or natural disasters. In both deliberate and crisis action planning, senior-level decision makers are provided with support tools and recommended courses of action to execute HHS's mission. ASPR's plans provide a solid foundation that, when needed, ease the transition to State and regional-level responses during public health emergencies.

ASPR writes and coordinates the Department's All-Hazards Plan (AHP) and scenario-specific operational plans in coordination with Federal partners to support Federal ESF-8 response missions. It is ASPR's responsibility to update HHS's All-Hazard Plan as the Department's plan for supporting the NRF and the Response and Recovery Federal Interagency Operational Plan. Functional annexes for the AHP, 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. The annexes address HHS's capabilities, essential tasks, and resources in each phase of a response.

ASPR leads interagency collaborations by coordinating the HHS input to the Response and Recovery Federal Interagency Operational Plan and co-leading, with the Federal Emergency Management Agency (FEMA), the development of several Incident Annexes focusing on biological events (BIA); power outages; food and agriculture insecurity; nuclear radiation (NRIA); and federal evacuation incidents. ASPR collaborates with FEMA and other interagency partners to maintain and 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.

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 these plans, 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 also supports crisis response to 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 high-risk special events such as NSSEs.

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 2022, ASPR Planning accomplished the following:

- Continued revision of the All-Hazards Base Plan;
- Collaborated with interagency partners on revisions to the Response and Recovery Federal Interagency Operations Plan, Biological Incident Annex, Nuclear-Radiological Incident Annex, and the National Security Emergency Plan, and development of the DOD/Interagency plan for the Integrated CONUS Medical Operations Plan (ICMOP). The Planning Division also developed new guidance for COVID-19 Community Vaccination Clinics and Hospital Expansion, and the ASPR Cyber Response Plan for the Hospital / Public Health sector;
- Conducted public health and medical support planning and training for multiple NSSEs, including Independence Day, the UN General Assembly, and the Peace Officers Memorial;
- Provided rapid response contingency planning for missions; and,
- Developed mission analysis and crisis action planning for several natural disasters.

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. The IRF forms the basis from which ASPR personnel (permanent, intermittent, augmentees, and contract staff) and agency representatives, both internal and external to HHS, 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.

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) remains at the forefront of real-time incident detection and response coordination to public health emergencies. The SOC Watch provides uninterrupted surveillance of emerging threats and critical incidents, nationally and internationally, 24 hours a day, seven days a week, 365 days a year. During the period between July 26, 2021 and July 26, 2022, the SOC Watch Distributed approximately 2,581 notifications, alerts, and reports regarding emergent situations that required a Federal ESF-8 response, HHS coordination, and/or situational awareness. This unique capability ensures that HHS is fully prepared to activate its lead role for ESF-8 and its support role for ESF-6 with accurate and timely situational awareness. The SOC Division coordinates the HHS Incident Support Team, ensuring communication, deconfliction, and synchronization of all response efforts. The SOC Division is often at the cutting edge of real time information sharing from the Federal government,

states, localities, territories, and tribes (SLTT), private sector, non-profit, and international partners 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.

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. Public Health Service (USPHS) Act program-funded work to roles supporting the public health emergency response. The SOC coordinated and processed 5,899 COVID-19 Temporary Reassignment requests, resulting in the reassignment of the equivalent of over 91,000 federal employees to effectively respond to the pandemic.

The SOC was activated for over 900 consecutive days since the start of the COVID-19 pandemic 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 19 incidents, including the emergence of mpox, H5N1, and polio in the United States in addition to six major tropical systems, two severe weather systems, mass migration, a major earthquake in Haiti, the repatriation of American Citizens and Afghan allies, and multiple Wildfires. The SOC has coordinated 15 special events including the COVID-19 Vaccine Transfer Mission reporting, United Nations General Assembly, and Lying in State/Honor events.

Information Management and Situational Awareness

The ASPR information management program serves as the focal point for data management and information collection, analysis, and reporting for ASPR and ESF8 during all responses to public health emergencies and national special security events; and plays a key role in the implementation of the ASPR's responsibilities for public health situational awareness. This program leads the production of various information products (e.g., Senior Leadership Briefs, Incident Analysis Briefs, Modeling Scenarios and Community Profile Reports) that support the needs of decision makers at various levels within HHS and other federal agencies. Information management activities include the integration of quantitative and qualitative information that supports regional and headquarters 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. Since FY 2021, more than 30,000 information, data, and analytic products were produced and distributed to support decisions across responses. The products used during responses include senior leader briefs, regional deep dive portfolios for each of the 10 HHS regions, and community profiles to identify public health trends for specific incidents including hurricanes, COVID-19, mpox and pediatric respiratory illness surge. 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 analyst within the regional offices to facilitate the flow of information. As part of ASPR Ready, in early 2022, the information management program deployed a new Request for Information Module to significantly enhance ASPR's ability to track and respond to information requests before, during, and in 2023 a Request for Resources module was launched to modernize and improve how ASPR resources are requested, processed and tracked. In April 2023, the Personnel Accountability Module will be launched,

which allows for real time tracking and reporting of deployed personnel. Shortly following the Personnel Accountability Module, will be the launch of the Asset Accountability Module.

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 the National Disaster Medical System (NDMS), to the development of systems like GeoHEALTH, and the Strategic National Stockpile 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 given the sensitive nature, including business proprietary commercially sensitive data that is collected and shared in these systems. The connection of these systems to the internet introduces significant vulnerability and susceptibility to cyber threats that compromise 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 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. In FY 2022, ASPR expanded its IT security practices by implementing multi-factor authentication on newly deployed systems and will continue to enhance cybersecurity in FY 2023.

Intelligence

ASPR established an intelligence function in 2018 to enhance alerting and situational awareness. The intelligence mission provides ASPR leadership and personnel with accurate, timely, and tailored intelligence information to reduce uncertainty, increase situational awareness, and enhance the planning and execution of ASPR's preparedness and response mission. ASPR's intelligence function provides the necessary infrastructure to maintain ASPR's threat awareness as directed in the 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA). Intelligence personnel operate within the appropriate parameters of HHS as a non-Title 50 (NT50) agency and focus primarily on coordinating within HHS and with federal, state, local, tribal, territorial, and private sector organizations to provide comprehensive intelligence support to the ASPR. Since 2019, ASPR Intelligence Division (ASPRID) 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 or deployments. These activities include developing and delivering open-source weekly briefings to inform ASPR planning; developing and delivering open-source and classified briefings and products to inform ASPR planning; and developing and delivering pre-deployment force protection briefs for Incident Management Teams (IMT) and NDMS personnel to inform mission

planning and execution. In addition, in 2020, ASPRID established a supply chain risk management program to assess the health of ASPR's supply chains and implement mitigation measures as needed.

Continuity Programs

In accordance with Presidential and Federal directives and supported by Departmental policy, ASPR ensures the Department's Primary Mission Essential Functions continue, regardless of threat or condition, and with the understanding that adequate warning may not be available.

ASPR serves the Department's twelve Operating Divisions and sixteen Offices through management of the Continuity of Operations (COOP), Continuity of Government (COG) and Continuity of the Presidency (COP) programs. This leadership provides HHS with a unified and proactive program integrated into daily operations.

Further, ASPR handles the day-to-day operations and implementation of the Office of the Secretary and ASPR Continuity Programs, including maintenance of the Department's alternate operating facility. Finally, ASPR manages the overarching policy and planning portfolio to scope and define the HHS Unified Continuity Program. 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 successfully completed FY 2023 exercises (Eagle Horizon) with HHS senior leadership, including the Secretary, Deputy Secretary, and leaders of all divisions to meet FEMA and White House annual continuity exercise and interagency evaluation requirements.

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 continues to improve alternate, contingency, and emergency communications capabilities. In addition, HHS continues to innovate in the areas of priority communications service, diverse path secure and non-secure communications both internally with our partners. This started by, restarting the Health Care and Public Health National Radio System (HNARS). HNARS provides a resilient HHS-owned and managed system connecting various parts of the Health Care and Public Health Sector. These capabilities allow HHS to continue its mission of responding to Health Care and Public Health threats and responses anywhere emergency conditions occur.

For FY 2024 the focus will be on Federal Mission Resilience. Special attention will be directed to Cyber and power resilience, including the use of renewable energy wherever possible and supporting the Federal fleet electrification initiative. ASPR will lead HHS participation in interagency activities focused on resuming post-pandemic operations and facing the evolving threat landscape, and supporting Department-wide policy compliance for continuity of operations.

Personnel Security Operations

ASPR's 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, all public trust clearance functions, and all personnel on-boarding security functions for ASPR, including personnel assigned to the NDMS. Currently, ASPR tracks and manages over 600 national security clearances and 400 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 150 plus granted special accesses. In FY 2022, ASPR

processed more than 200 request packages for initial investigations, more than 150 request packages for reinvestigations, and more than 600 security badge requests. In FY 2023 and FY 2024, personnel security operations are expected to stay at 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 monthly to identify overall mission training needs. In addition, ASPR coordinates with FEMA's CDP to deliver training to NDMS teams with hands-on training as well as a 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.

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 experiences to 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.

Starting in FY 2023, ASPR will lead ESF-8 planning and participation in National Level Exercise 2024 (NLE24). In FY 2024, ASPR will lead HHS and ESF-8 partners in the planning, preparation, and participation in National Level Exercise 2024 (NLE24). The national level exercises are congressionally mandated events coordinated by the NSC and FEMA designed as a whole of government response test to a specified emergency(s). Additionally, ASPR will continue to plan and conduct its established cycle of exercises with plans to conduct four Nimble Challenge Exercises designed to test/validate HHS/ASPR capabilities. ASPR will also continue its Secretary's Quarterly Exercise Series with four tabletop exercises conducted at the Assistant Secretary Level designed to validate preparedness to organize and take action to respond to emerging threats. Internally, ASPR will conduct resilient supply chain exercises, bioterrorism specific exercises, and/or a large-scale infectious disease exercise as the operational tempo permits.

National Disaster Medical System

Budget Summary
(Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	75.404	96.904	130.030	+33.126
<i>Pediatric Disaster Care Program (non-add)</i>	<i>6.000</i>	<i>7.000</i>	<i>7.000</i>	<i>-</i>
<i>Mission Zero (non-add)</i>	<i>2.000</i>	<i>4.000</i>	<i>-</i>	<i>-4.000</i>
<i>Public Health Preparedness Equipment (non-add)</i>	<i>10.000</i>	<i>20.000</i>	<i>-</i>	<i>-20.000</i>
FTE	148	148	162	+14

Authorizing Legislation:

AuthorizationPublic Health Service Act
Allocation Method Direct Federal/intramural, contracts

Program Description

When disaster strikes, the Administration for Strategic Preparedness and Response (ASPR) activates a suite of integrated federal medical response capabilities to respond. This allows ASPR to fulfill its responsibilities under the National Response Framework as the Lead for Emergency Support Function #8 (ESF-8), Public Health and Medical. These 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. As the nation’s premier medical surge capability, the National Disaster Medical System (NDMS) is at the heart of this federal medical response effort.

The NDMS mission is to support communities by providing 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. 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.

For each incident, ASPR deploys trained NDMS medical teams, incident management personnel, logistics specialists, and other public health assets to provide medical services and/or augment healthcare facilities in impacted communities. These interdependent response capabilities ensure the success of the core NDMS medical mission. Together these federal response capabilities save lives and protect Americans by helping communities respond to and recover from public health emergencies.

Funding History	
Fiscal Year	Amount
FY 2020	\$57,404,000
FY 2021	\$63,404,000
FY 2022 Final	\$75,404,000
FY 2023 Enacted	\$96,904,000
FY 2024 President’s Budget	\$130,030,000

Budget Request

The FY 2024 President’s Budget requests for NDMS is \$130,030,000, which is +\$33,126,000 above FY 2023 Enacted. The request will allow NDMS to resolve critical shortfalls in federal public health, medical capabilities and infrastructure based on COVID-19 lessons learned and build resilience in the NDMS system to support the next disaster or critical incident. Additional funding is necessary to address increasing costs and mission requirements to support SLTT partners in the wake of the COVID-19 pandemic. Current funding is not sufficient to cover mission essential infrastructure and operating capabilities, often creating a dependence on supplemental appropriations to meet core NDMS programmatic activities.

The additional \$33 million will be used to support:

- Hiring and training of NDMS Responders;
- Sustainment of mission essential infrastructure; and,
- Critical SLTT planning, coordination, and technical assistance to build public health and medical resiliency.

The request also includes \$7,000,000 to continue the Pediatric Disaster Care program.

Funding at the requested FY 2024 level will allow NDMS to provide a capable, trained, and competent force of medical disaster responders to meet the Nation’s continually increasing emergency needs. The FY 2024 allows the program to:

- Hire sufficient personnel to replace those lost during the last three years of prolonged COVID-19 response and fill vacancies to make NDMS teams ready for deployment. The request also enables directed recruiting efforts to target experienced clinical personnel.
- Provide essential orientation and onboarding training, including in-person skills and equipment familiarization for all newly hired employees making them suitable for deployments. There are approximately 600 projected personnel that have never received operational training on disaster medicine.
- Implement a three-year training cycle for all its disaster medical responders whereby each responder would attend the minimum requirement of one in-person disaster medicine field skills refresher training every three years.
- Repeat the highly successful 2022 Training Summit, at a minimum, every three years. The Summit was the pinnacle training event for the system with lectures on current pressing issues balanced with hands on skills training and interactive simulation training. Each Training Summit would provide valuable training and professional continuing education credits to over 1,500 personnel.

Hiring and Training of NDMS Responders: 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 can 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.

Mission Essential Infrastructure: To ensure NDMS can rapidly deploy to an emergency, NDMS relies on critical mission essential infrastructure that must be sustained and quickly mobilized. This infrastructure consists of programs such as emPOWER and other NDMS programs tasked with prepositioning life-saving medical assets, emergency vehicles, and tactical communications assets at forward staged locations throughout the Nation to support the rapid deployment of NDMS both inside and outside the continental United States. Maintaining these capabilities at forward staged locations ensures NDMS assets are prepositioned appropriately in disaster prone locations based on ASPR's risk profile.

SLTT Planning, Coordination, and Technical Assistance: A critical, invaluable resource that is required by SLTT to improve resilience is ASPR's ability to provide (on-site) regional expertise to assist the SLTT community with public health and medical planning; coordination and understanding of federal response resources; and initial (on-site) staff in their emergency operations center before, during, and after on disaster response and emergency when required.

The FY 2024 request does not continue the funding for Mission Zero, a decrease of -\$4 million, and Public Health Preparedness Equipment, a decrease of -\$20 million. Funding will be re-directed to core NDMS activities described above.

Program Accomplishments

Since the beginning of the COVID-19 response, NDMS accomplishments are listed below.

- NDMS responded to over 15,352 individual deployments, with some personnel deploying multiple times. NDMS deployed 5,500 Disaster Medical Assistance Teams (DMAT), 206 Disaster Mortuary Operational Response Teams (DMORT), 28 Victim Identification Center Teams (VIC), 86 Trauma Critical Care Teams (TCCT), 20 National Veterinary Response Teams (NVRT), 122 Incident Management Teams (IMT), and 83 Logistics Response Assistance Teams (LRAT) personnel over the course of 2020 and 2021.
- COVID-19 missions continued into 2022 with 18 additional deployments, over 110 personnel, to several states, territories, and Pacific islands including American Samoa, Palau, Republic of Marshall Islands, and the Federated States of Micronesia.
- In 2022, NDMS' most significant responses were for two major hurricanes, Hurricane Fiona in Puerto Rico and Hurricane Ian in Florida and the southeastern US. In September and October, NDMS deployed teams to support response operations in Puerto Rico after the devastating effects of Fiona. Before the response to Fiona had concluded, Hurricane Ian struck and necessitated the largest deployment of NDMS assets in several years. Over 650 NDMS responders from 60 different teams responded to provide medical services after the deadly category 4 hurricane devastated parts of Florida. In all, NDMS providers treated 3,802 Floridians.

- In 2022, NDMS provided both direct medical support and contingency medical capabilities to nine Special Events and National Security Special Events (NSSE) including the State of the Union Address, United Nations General Assembly, African Leaders Summit, and three dignitaries Lying in State. In all, 253 NDMS responders from 38 different teams deployed to support the Nation's special events in 2022.

NDMS Medical Response Teams

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

- ***Disaster Medical Assistance Teams (DMATs)***: 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). During a response, these teams are responsible for providing stabilizing emergency medical care to the affected communities. These teams include physicians, advanced practice clinicians, nurses, paramedics, and non-clinical support staff.
- ***Trauma Critical Care Teams (TCCTs)***: 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 staffed with board-certified and practicing surgical and trauma professionals.
- ***Disaster Mortuary Operational Response Teams (DMORTs)***: The DMORTs provide services for the management of fatalities resulting from natural and man-made disasters. 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) with respect to major transportation incidents that have mass fatalities.
- ***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.
- ***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.

Response Logistics Teams

The Response Logistics Team ensures that responders and medical capability are synchronized for rapid deployment where they are needed to provide an effective response. The team encompasses FTE staff, intermittent logistics responders, fleet assets, tactical communications, and medical caches prepositioned at forward staged locations throughout the United States that must be maintained at a high state of

readiness to rapidly deploy and support NDMS and Public Health Service responders during emergency responses, disasters, and national security events. This function is a highly complex, coordinated effort to rapidly deploy staff and materiel to setup tactical hospitals, communications, and command and control infrastructure in a highly austere environment. Except for the Department of Defense (DoD) and the Federal Emergency Management Agency (FEMA), very few federal organizations have this organic response capability and conduct similar operations.

Regional Coordination Teams

The success of NDMS is directly related to its ability to facilitate coordinated preparedness activities in each HHS region and to engage with affected 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 NDMS' 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.

Personnel responsible for performing these critical functions include:

- ***Regional Emergency Coordinators (RECs):*** 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 Personnel (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 MCM operations.

Incident Management Team

ASPR's preparedness, response, 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 Incident Management Team (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 manage NDMS deployed field resources and capabilities to ensure successful completion of assigned missions.

At the 2024 President's Budget level, IMTs would be able to retain many additional personnel that are needed to manage deployments for large scale public health and medical events, such as COVID or multijurisdictional responses.

Special Operations Team

Special Operations provides essential 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 and NDMS personnel to ensure best practices in ESF-8 response.

International Operations Team

The International Operations team leads ASPR's outreach for preparedness and response engagement with international partners, and coordinates with USG partners on international operations ASPR supports (e.g., NDMS support for emergency repatriation planning). The team is ASPR's subject matter expert for international operations, response, and deployments. The team continues to build relationships with other international partners (i.e., Mexico, Taiwan, Australia, Republic of Korea, World Health Organization/PAHO, United Kingdom) and with the Department of State, aligning closely with the ASPR preparedness and response priorities and mission.

Community Mitigation and Recovery Teams

ASPR Community Mitigation and Recovery provides significant services for impacted communities in the wake of a disaster or other critical incident:

- ***At-Risk Individuals (ARI) Team:*** The ARI team 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. 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.
- ***Behavioral Health Team:*** The Behavioral Health team 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 to help address the psychological consequences of disasters and public health emergencies. 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.

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 4.3 million individuals who live independently and rely on life-maintaining electricity-dependent durable medical and assistive equipment and devices¹ and essential healthcare services.² Using Medicare data, emPOWER provides NDMS, public health authorities (PHA), and their partners with accurate 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 functions³ and 13 sectors⁴.

Demand for publicly accessible emPOWER data and tools has sharply increased. In FY 2022, over 16,700 individuals used the HHS emPOWER Map and consumed data using the HHS emPOWER REST Service over 121,000 times to inform and support emergency preparedness, response, recovery, and mitigation activities for the pandemic and numerous disasters nationwide. Additionally, in FY 2022, over 10,300 individuals accessed and downloaded over 3,700 informational resources from the publicly accessible HHS emPOWER Program Platform website that provides technical assistance, informational resources, and best practices. Partners also continued to use the [award winning](#), voice-activated artificial intelligence (AI) tool, [emPOWER AI](#) that 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. The emPOWER Program's readily meaningful, consumable and actionable data and tools continued to help federal-to-community responders to better address the needs of community-based at-risk individuals, ensure continuity of care, and reduce healthcare system surge through a broad array of disasters.

Lessons Learned: Exercise, Evaluation and After Actions Program

The HHS/ASPR Exercise, Evaluation and After Actions (E2A2) program provides a formal mechanism for a coordinated, collaborative program with a primary focus on promoting and validating 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, as required in our

¹ 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.

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

³ 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-(ESF-12); Public Safety and Security (ESF-13); Cross-Sector Business and Infrastructure (ESF-14), and; External Affairs (ESF-15).

⁴ 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.

emergency 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 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 for improvement.

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 three Pediatric Disaster Care Pediatric Centers of Excellence (COE) multi-state cooperative agreements, and adding a new COE in FY 2022, that target the development and sharing of appropriate planning and response capabilities to 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 of the COEs is the management of pediatric care related to trauma, infectious diseases including pandemic influenza, COVID-19, burn, and chemical/biological/radiological/nuclear incidents.

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. The COEs routinely seek to link to other ASPR-funded initiatives, like the Regional Disaster Health Response System sites funded through Health Care Readiness and Recovery (HCRR), the National Special Pathogen System, also funded by NHPP, and the National Emergency Telemedicine Network (NETN) with the end state of building a national medical response ecosystem for disasters.

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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
1.1 Maintain the percent of new NDMS intermittent staff that complete psychological first aid training (Output)	FY 2022: 95% Target: 100 % (Target Not Met but Improved)	100%	100%	Maintain
1.3 Maintain the number of staff trained in-person (Intermediate Outcome)	FY 2022: 152,461 trained Target: 110,322 trained (Target Exceeded)	102,150 trained	102,150 trained	Maintain
1.4 Maintain the percent of NDMS intermittent staff who complete basic, advanced, or specialized training (Intermediate Outcome)	FY 2021: 17% Target: 35% (Target Not Met)	Discontinued	Discontinued	N/A
1.5 Maintain the number of staff trained in-person ¹ (Output)	FY 2023: Result Expected Dec 31, 2023 Target: 20 % (Pending)	20%	20%	Maintain

¹ This measure replaces 1.4 based on adjustments in training.

Medical Reserve Corps

Budget Summary *(Dollars in Millions)*

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	6.240	6.240	6.240	-
FTE	12	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

In order to further the Administration for Strategic Preparedness and Response’s (ASPR’s) mission for preparedness, ASPR supports the Medical Reserve Corps (MRC) which is a national network of over 300,000 volunteers organized into approximately 750 community-based units committed to improving local emergency response capabilities, reducing vulnerabilities, and building community preparedness and resilience. 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 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.

Funding History	
Fiscal Year	Amount
FY 2020	\$6,000,000
FY 2021	\$6,000,000
FY 2022 Final	\$6,240,000
FY 2023 Enacted	\$6,240,000
FY 2024 President’s Budget	\$6,240,000

Budget Request

The FY 2024 President’s Budget request for the civilian volunteer MRC is \$6,240,000, which is level with the FY 2023 Enacted. This funding builds on the 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, as well as the system used for maintaining unit profiles and activity reporting.

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 the National Association of County and City Health Officials (NACCHO) with support from the MRC program, and many units have found the tools helpful in improving or broadening their unit’s capabilities.

Program Accomplishments

MRC units are active in their communities, as evidenced by the over 14,000 activities reported during FY 2022. According to unit reporting, 125,000 MRC volunteers have contributed 528,000 hours of service with an economic value of \$2.1 million. The total economic value of this contribution, which included the efforts of a variety of medical professionals, is estimated at over \$93.1 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; and logistics support. The network’s contributions to COVID-19 vaccination efforts are especially noteworthy.

Units have also responded to other public health emergencies caused by natural disasters, including tornadoes, extreme cold weather, and hurricanes, as well as other community healthcare needs.

At the national level, the MRC program continued its cooperative agreements with NACCHO. Under the NACCHO cooperative agreement, 145 MRC units received Operational Readiness Awards totaling over \$11.5 million. 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.

There was an additional 111 MRC units awarded at \$3.4 million in the Respond, Innovate, Sustain, and Equip (RISE) Awards. The MRC COVID-19 RISE awards are intended to provide resources to the MRC network to support COVID-19 response efforts. The MRC program also initiated a new five-year cooperative agreement for a learning management system available to all units with a focus on improving core competencies that were identified during the pandemic response. 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 can be used to 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.

American Rescue Plan (ARP) Funding

The American Rescue Plan was written to aid and provide resources to assist the country's recovery from economic and health effects of COVID-19. During the COVID-19 response, MRCs made significant contributions to support the work of local health departments. While many MRCs were responding, it became clear that more unit capacity was needed to vet volunteers, train corps members, conduct data surveillance, and build the workforce. Through the first round of the previously described RISE awards, MRC was able to award \$14,910,000 to 186 units increasing their capacity to address the ongoing COVID-19 response efforts, and ensuring those units are resourced for future mission requirements. Some examples the RISE awards supported are as follows:

1. Updating the volunteer management IT system;
2. Purchasing Cardio-Pulmonary Resuscitation mannequins and American Heart Association training aids and videos;
3. Hiring staff to support local MRC units;
4. Conducting pilot community behavioral support training sessions;
5. Creating online training sessions to address adult mental health resiliency from COVID-19 for 50 participants;
6. Recruiting and onboarding 300 new volunteers to support ongoing COVID-19 response activities for nine area counties; and,
7. Purchasing equipment to conduct in-person training, exercises, and deployments.

ASPR Medical Reserve Corps is currently launching grants of up to \$50 million in ARP funding to states, territories, tribes, public/private partnerships, and other public entities to expand the work of the network. MRC will accept applications for the State, Territory and Tribal Nations, Representative Organizations for Next Generation (MRC-STTRONG) Awards. The funding notice ASPR is issuing for the MRC-

STTRONG awards will ultimately help the network continue to grow as it has over the past two decades. MRC volunteers are a force multiplier for local emergency responses. In fact, state partners estimate the value of MRC volunteer efforts for COVID-19 at more than \$131 million between March 2020 and March 2022. These new grant awards can help meet community health, health emergency preparedness, and health equity needs. With this MRC-STTRONG funding, Jurisdictions can foster MRC unit growth and engagement in their communities.

Health Care Readiness and Recovery

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	295.555	305.055	312.055	+7.000
<i>Hospital Preparedness Program (HPP) Annual Cooperative Agreement (non-add) /1</i>	231.500	240.000	240.000	-
<i>Regional Disaster Health Response System Cooperative Agreement (RDHRS) (non- add)</i>	7.000	7.000	7.000	-
<i>National Special Pathogen System (NSPS) (non-add)</i>	27.500	28.500	28.500	-
<i>National Emerging Special Pathogens Training and Education Center (NETEC) (non-add)</i>	6.500	7.500	7.500	-
<i>Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs) (non-add)</i>	21.000	21.000	21.000	-
<i>Other costs (non-add) /2</i>	29.555	29.555	36.555	+7.000
FTE	49	49	49	-
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 United States 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 Community Mitigation and Recovery.				

Authorizing Legislation:

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

Program Description

To further the Administration for Strategic Preparedness and Response’s (ASPR’s) mission for preparedness, ASPR supports the Health Care Readiness and Recovery (HCRR) (formerly the Hospital Preparedness Program (HPP))⁵ budget line, which strengthens health care sector readiness to provide

⁵ The budget line was renamed from the Hospital Preparedness Program (HPP) budget line to the Health Care Readiness and Recovery budget line to mitigate confusion with the HPP cooperative agreement, which is only one cooperative agreement within the broader portfolio of health care readiness programs and activities funded by the budget line.

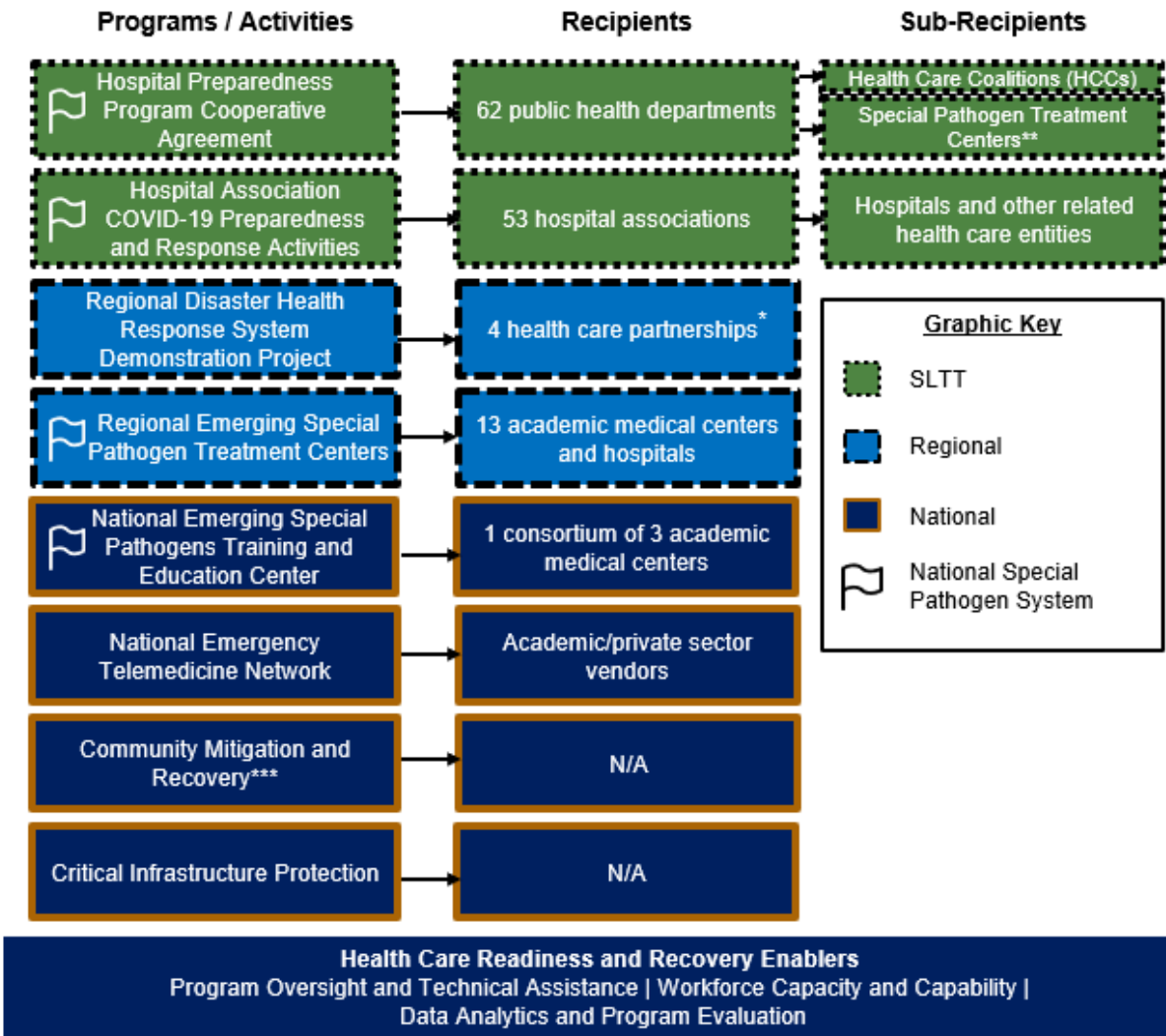
innovative, coordinated, and lifesaving care in the face of emergencies and disasters. Recent events, such as the COVID-19 pandemic, revealed critical gaps in the nation's health care preparedness and response infrastructure, demonstrating the need to support care delivery to improve patient outcomes. The HCRR portfolio focuses on building emergency preparedness capabilities throughout the health care delivery system.

Lessons we have learned from recent surge events – events where health care entities face sudden, high demands on inpatient bed, workforce, or other resource capacity due to an influx of patients during an emergency – highlight the need to strengthen patient care delivery, load-balancing, and coordination across health care entities. Successful implementation of these strategies is dependent on collaboration between partners at the State, Local, Territorial, and Tribal (SLTT), regional, and national levels.

The HCRR portfolio engages partners from all 50 states, United States (U.S.) territories, and freely associated states, providing leadership to improve the capacity of the health care delivery system to plan for and respond to disasters. During a disaster, health care delivery occurs at the local level. Yet, delivery may require sub-state, interstate, and regional coordination, as well as resource support among federal, SLTT governments, and industry. This support is critical, particularly to address gaps in access to clinical sub-specialty care for individuals exposed to chemical, biological, radiological, or nuclear agents, emerging infectious diseases, and trauma and burn injuries. ASPR invests in programs and activities across these different operational levels to drive effective coordination and health care response to all-hazards threats.

Investment in the HCRR program is necessary to mitigate the many challenges that impact our nation's ability to prepare for, respond to, and recover from public health emergencies. Beyond addressing the challenges that exist today, the HCRR portfolio is uniquely positioned to identify opportunities to evolve health care preparedness and response to improve the nation's capability to respond to the novel threats of tomorrow. The programs and activities within the HCRR portfolio (**Figure 1**) represent a collection of building blocks that strengthen health care emergency preparedness and response at all levels to form a comprehensive, national system.

Figure 2: HCRR FY 2024 Portfolio of Programs and Activities



* Partnerships include at least one hospital; one local health care facility; one political subdivision; one state; and one emergency medical service or emergency management organization.

** While HPP recipients and health care coalitions (HCCs) receive funding through the annual cooperative agreement, SPTCs only received COVID-19 emergency supplemental funding as part of the NSPS.

*** Community Mitigation and Recovery includes ASPR TRACIE.

Funding History	
Fiscal Year	Amount
FY 2020	\$275,555,000
FY 2021	\$280,555,000
FY 2022 Final	\$295,555,000
FY 2023 Enacted	\$305,055,000
FY 2024 President's Budget	\$312,055,000

Budget Request

The FY 2024 President's Budget request for Health Care Readiness and Recovery is \$312,055,000, which is an increase of \$7,000,000 above FY 2023 Enacted.

The budget proposes \$240,000,000, equal to FY 2023 enacted, to fund the Hospital Preparedness Program (HPP) cooperative agreement recipients. This funding will be distributed across 62 recipients at levels determined by HPP's statutorily required funding formula. This funding will be used to meet and sustain capabilities developed during the COVID-19 response and other concurrent responses, to support increased coordination activities, and to effectively maintain response and recovery efforts.

The President's Budget also proposes \$7,000,000, equal to FY 2023 enacted, to sustain four existing Regional Disaster Health Response System (RDHRS) sites.

For the National Special Pathogen System (NSPS), the budget includes \$28,500,000, equal to FY 2023 Enacted. Within this total, \$21,000,000 is for the Regional Emerging Special Pathogen Treatment Center (RESPTC) network to continue to act as regional hubs for special pathogen readiness, providing resources for patient care and clinical operations. In addition, \$7,500,000 is provided for National Emerging Special Pathogens Training and Education Center (NETEC) to continue implementation of the NSPS of Care Strategy, which seeks to create a formal, tiered care delivery network that provides high-quality, equitable care for patients suspected of, or infected with, a special pathogen.

The FY 2024 Budget includes \$36,555,000, an increase of \$7,000,000, to support its other program costs. Of this amount, \$4,222,000 will support management and administration of readiness programs and activities, including ASPR TRACIE, Community Mitigation and Recovery, and Critical Infrastructure Protection (CIP). The additional \$2,778,000 will support information technology needs and other infrastructure costs that support the program portfolio.

ASPR TRACIE will use funds to provide more direct support to external partners and develop additional resources focused on improving the equitable preparedness, response, and recovery efforts of health care entities and HCCs. This includes: developing tools and templates to address requirements in the updated Healthcare Preparedness and Response Capabilities; enhancing the Disaster Available Supplies Hospitals (DASH) Tool; developing resources to promote patient load balancing/Medical Operations Coordination Cells (MOCCs); developing additional resources to address workplace violence; providing technical assistance for providers and suppliers affected by updates to the CMS Emergency Preparedness Rule; and supporting initiatives focused on health care disparities, workforce sustainability, ethics, and climate change impacts.

The Community Mitigation and Recovery program will use funds to integrate ASPR's community resilience-building efforts, missions focused on post-disaster behavioral health, and recovery operations to help achieve a regionally based and nationally coordinated system for community health resilience to public health emergencies. 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 mitigation interventions in response and recovery phases can introduce an equity lens to ASPR's national health security mission. A core focus of ASPR Community Mitigation and Recovery will also be to integrate population-level behavioral health solutions into disaster response and recovery missions.

To meet directives from Congress laid out in the Sector Risk Management Agency (SRMA) responsibilities, ASPR will enhance CIP-led SRMA activities, such as assessing and coordinating response to risks and threats against the country's Healthcare and Public Health (HPH) Sector. As risks to and attacks against the HPH Sector have become increasingly sophisticated, CIP will prepare the Sector to confront challenges of today and whatever lies ahead, including disease outbreaks, supply chain disruptions, and cyberattacks.

The ASPR Health Care Readiness Portfolio will support continued technical assistance and oversight to HPP, RDHRS, NSPS recipients, sub-recipients, and other health care partners who continue to respond to and recover from surges created by COVID-19 and other incidents. ASPR supported a broad spectrum of partners throughout the COVID-19 response and various concurrent events, including the West Kentucky tornado, cyberattacks, and annual hurricane and wildfire seasons.

The FY 2024 request does not include funding for the NETCCN program. This program is funded through the Preparedness and Emergency Operations (PEO) budget line. The funding will be reallocated to higher priority projects within the PEO budget. The PEO section provides additional details on these changes.

Program Accomplishments

Hospital Preparedness Program (HPP) Cooperative Agreement

As the primary source of federal funding for health care delivery system preparedness and response, HPP provides leadership and funding through cooperative agreements to states, territories, and eligible major metropolitan areas. The HPP enables health care organizations and their partners to access a national response network, empowering health care delivery systems across the nation to save lives and protect Americans from health security threats.

HPP complements the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) Program, which also provides cooperative agreements to public health departments; however, HPP focuses on the health care delivery system – with critical point of care health care delivery and coordination during a health care emergency – while also facilitating partnerships between health care and public health. Since 2012, HPP's formula-based cooperative agreement has required recipients to invest in health care coalitions (HCCs), providing a foundation for health care readiness.

An HCC is a network of individual public and private organizations in a defined state or sub-state geographic area that partner to prepare health care systems to respond to emergencies and disasters. These coalitions 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. HCCs coordinate activities among their members, who in turn actively contribute to strategic planning, operational planning and response, information sharing, and resource coordination and management. As

of June 30, 2022, there are 47,028 HCC member organizations participating in 318 HCCs nationwide.⁶ ASPR requires that each HCC funded by cooperative agreement recipients include, at minimum, the following core members: two acute care hospitals, public health agencies, emergency medical services (EMS), and emergency management agencies.

As a result, HCCs collaborate to prepare each member to respond to emergencies and planned events, which include providing medical equipment and supplies, real-time information, communication systems, and educating and training health care personnel. Through HPP, 98 percent of public health agencies, 91 percent of acute care hospitals, 84 percent of emergency management agencies, and 47 percent of EMS organizations form a part of an HCC.⁷

Investments administered through HPP improve health care entities' preparedness for emerging, all-hazards threats by strengthening collective response planning and health care capabilities across jurisdictions. In December 2021, the West Kentucky Healthcare Coalition, established by the HPP cooperative agreement, helped save lives when an Enhanced Fujita 4 (EF4) scale tornado devastated the Western region of Kentucky. The HCC's activities and role in coordinating the response among several partners provided the necessary situational awareness for emergency response teams to access, triage, treat, and relocate hundreds of affected patients within a 171-mile radius across the 24 counties of Western Kentucky.⁸

During the COVID-19 response, which required coordination across multiple health care partners, HCCs' mechanisms for communication and planning across member types became integral to health care 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. More broadly, HCCs collaborated with other parts of the HCRR program – including the Regional Disaster Health Response System (RDHRS), NSPS, and others – to scale and enhance coordination across multiple networks for health care response.

Regional Disaster Health Response System (RDHRS)

To address gaps in regional health care delivery during disasters, ASPR developed the RDHRS: a tiered system that builds upon and unifies existing health care and ASPR assets within states and across regions to support a more coherent, comprehensive, and capable health care disaster response system. RDHRS demonstration sites support regional level-loading and resource allocation efforts that are proven to increase quality of patient care during health care emergencies.⁹

Currently, HCRR funds four RDHRS demonstration sites:

- Region 1 RDHRS, based at Massachusetts General Hospital (established in FY 2018)

⁶ HPP Cooperative Agreement budget period three (BP3) end-of-year (EOY) performance data (Period of Performance: July 1, 2021 – June 30, 2022).

⁷ Ibid.

⁸ ASPR, "[West Kentucky Healthcare Coalition Coordinates Emergency Response to a Devastating Tornado](https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/KY-HCC-Tornado-Response-Dec2021.aspx)," December 2021, <https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/KY-HCC-Tornado-Response-Dec2021.aspx>.

⁹ Lee, A. H., Dunn, P. F., Cooper, S., Seger, R., Raja, A. S., Safavi, K. C., & Yun, B. J. 2021. [COVID-19 Level-Loading: Transferring Emergency Department Patients to a Partner Academic Medical Center Within a Healthcare System](https://doi.org/10.1097/01.JMQ.0000743384.54212.e7). American journal of medical quality: the official journal of the American College of Medical Quality, 36(5), 368–370. <https://doi.org/10.1097/01.JMQ.0000743384.54212.e7>.

- Region 4 Southern Regional Disaster Response System (SRDRS), based at Emory University (established in FY 2021)
- Region 7 Regional Disaster Health Response Ecosystem (RDHRE), based at the University of Nebraska Medical Center (UNMC) (established in FY 2018)
- Region 8 Mountain Plains RDHRS, based at Denver Health and Hospital Authority (established in FY 2020)

RDHRS establishes and develops multi-state partnerships to meet regional health care delivery needs during an emergency response. As an example, the Region 7 RDHRE hosted multiple Region 7 pediatric acute care calls during a surge of pediatric patients starting in October-November 2022, leveraging experts to impart promising practices on adult critical care in support of pediatric patients, share information on hospital capacity, and identify challenges and potential solutions. The RDHRE convened the calls with partners across Region 7, including pediatric hospitals, public health, hospital associations, and federal staff.

The RDHRS demonstration sites use their multi-state partnerships to support other health care partners with effective interventions. During the ongoing pediatric surge, the Region 1 RDHRS rapidly engaged experts across the region to lead a six-part weekly regional education series on caring for pediatric patients. Approximately 1,800 individuals registered for the webinars, with the webinar recordings garnering an additional 950 views. The accompanying pediatric surge resource compilation had demonstrable utility for other health care partners, reaching over 2,800 views in three weeks.

RDHRS sites are also creating tools and teams to build upon, unify, and support the broader existing regional infrastructure. For instance, a Region 1 RDHRS survey showed that over 81 percent of the 189 surveyed hospitals and free-standing emergency departments across the region reported that they were “somewhat likely” or “very likely” to use a regional disaster telehealth system to access specialists if they were affected by a no-notice disaster.¹⁰ The Region 1 RDHRS worked with partners to enhance disaster telehealth capabilities in the region by setting up the platform, recruiting teleconsultants, and surveying partners for potential implementation barriers.

RDHRS demonstration sites enhance regional health care preparedness and response efforts, maturing models for multistate collaboration that ultimately saves lives. This demonstration project will continue to build on lessons learned from wildfires, hurricanes, COVID-19, and other multi-state responses to scale to a national network of regional response structures capable of surging to meet all-hazards response needs.

National Special Pathogen System (NSPS): HPP and Special Pathogen Treatment Centers (SPTCs)

The NSPS provided funding to 62 HPP recipients and their SPTCs to bolster state and local readiness against special pathogens. 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. As the “spokes” of the NSPS hub-and-spoke system, the 55 SPTCs play a vital role in delivering and managing special pathogen care at the community level, coordinating with RESPTCs and other components of the system to operate as one cohesive network.

¹⁰ Region 1 Regional Disaster Health Response System. (2022). [2021 Annual Report](https://www.rdhrs.org/wp-content/uploads/2022/02/R1-RDHRS-Year-Three-Annual-Report-2021-Final.pdf). <https://www.rdhrs.org/wp-content/uploads/2022/02/R1-RDHRS-Year-Three-Annual-Report-2021-Final.pdf>.

One example of the SPTCs' role at the community level is illustrated by their use of COVID-19 supplemental funding to meet the needs created by COVID-19 patient surge. Thirty-two percent of SPTCs reported using staff that had participated in just-in-time trainings to provide surge capacity and accept a COVID-19 patient when other facilities exceeded patient capacity.¹¹

NSPS: Hospital Associations

One of the major components of the NSPS is the network of 53 hospital associations, established as new ASPR funding recipients through COVID-19 supplemental funding. Like the SPTCs, hospital associations were positioned to provide a critical level of support for activities at the local level during the COVID-19 response, awarding funds to health care entities as sub-recipients. These health care entities used funding to prepare for and respond to the pandemic, supporting the delivery of specialized care to a large number of patients. In Fiscal Year (FY) 2021, 69 percent of the hospital association sub-recipients provided trainings on transmission-based precautions. For triage, 75 percent delivered trainings on assessment, transport, and treatment of COVID-19 suspected or confirmed patients.¹² Hospital associations also provided needed supplies and equipment for local health care organizations. Hospital associations impacted local and community level COVID-19 response activities by providing a mechanism for rapid funding and situational awareness across the health care delivery system, facilitating collaboration across health care entities, HCCs, and ASPR to maintain awareness of response needs during the pandemic response.

NSPS: National Emerging Special Pathogens Training and Education Center (NETEC)

NETEC is a consortium comprised of Emory University, the University of Nebraska Medical Center/Nebraska Medicine, and the New York Health and Hospitals Corporation, Bellevue Hospital Center. As the national hub for the NSPS, NETEC maintains a focus on building special pathogen preparedness and response capacity across health systems in the U.S. with the goals of driving promising practices, closing knowledge gaps, and developing innovative resources. For example, in FY 2021, NETEC made a significant impact through their virtual education offerings which equipped health care workers with tools to facilitate safe and effective care during a time when resources were overwhelmed by the COVID-19 response. NETEC continues to provide and highlight course offerings and educational materials to support preparedness and response for evolving special pathogen threats, including mpox and the recent Ebola outbreak in Uganda.¹³

NETEC provides critical support to other programs in the HCRR portfolio, particularly RESPTCs. The RESPTCs work closely with NETEC to improve regional capabilities. NETEC annually assesses the readiness of RESPTCs; all RESPTCs that reported receiving services from NETEC used these resources to improve operational and clinical outcomes.¹⁴ NETEC also developed an integrated national clinical research network for special pathogens, the Special Pathogens Research Network (SPRN), which consists

¹¹ HPP Cooperative Agreement COVID-19 Supplemental Funding year end performance data (Period of Performance: March 29, 2020 – June 30, 2021).

¹² Hospital Association COVID-19 Preparedness and Response Activities Cooperative Agreement Year 2 performance data (Period of Performance: April 10, 2021 – April 9, 2022).

¹³ NETEC, "[Education and Training](https://netec.org/education-training/)," <https://netec.org/education-training/>.

¹⁴ RESPTC COVID-19 Preparedness and Response Activities Administrative Supplement year end performance data (Period of Performance: March 28, 2020 – June 14, 2021). These data insights are based on responses from eight of the RESPTCs.

of research sites at each of the original 10 RESPTCs,¹⁵ supported by centralized resources, including a common rapid response institutional review board, data repository, biorepository, research training protocols, and standardized polices.

At the local level, HCCs and their members regularly enhance their capabilities by attending NETEC trainings and utilizing NETEC resources. Additionally, recognizing the importance of medical transport, including EMS and critical care transport, NETEC developed the Special Pathogens Operational Readiness Self-Assessment (SP-ORSA) for EMS.

Finally, NETEC is a primary driver in implementing the NSPS of Care Strategy. This strategy, developed by NETEC in partnership with over 70 entities across health care, seeks to expand the NSPS into a sustained, standardized special pathogen system of care that enables health care personnel and administrators to provide agile and high-quality care across the care delivery continuum. As NETEC implements the NSPS of Care Strategy, it will unify and strengthen patient-centered care across the care delivery continuum and incident lifecycle.

National Emergency Telemedicine Network (NETN)

The National Emergency Telemedicine Network (NETN) is an evidence-based ecosystem that connects local providers in any patient care setting to specialized virtual providers as needed during federal responses to disasters and other public health emergencies. This disaster telemedicine network is unique in its ability to quickly deploy and seamlessly scale according to the degree and location of need. NETN uses a virtual clinician network including hard-to-find specialists, such as intensivists, pulmonologists, and burn specialists, enabling it to instantly deploy specialized care from “anywhere to anywhere” at any time of day. The NETN also facilitates electronic information exchange, patient monitoring, and operational decision support, in addition to peer consultation, relief coverage, and tiered staffing.

The first key initiative within the NETN was the National Emergency Tele-Critical Care Network (NETCCN), a joint ASPR and Department of Defense (DoD) research and development project designed to support critically ill COVID-19 patients. NETN will utilize a lightweight Health Insurance Portability and Accountability Act (HIPAA)-compliant app. The back end will connect to a federal node to normalize the data for sharing with response partners, as well as customizable data analysis, visualization dashboards, and reporting for situational awareness.

Throughout NETCCN’s exploratory work, ASPR tested the ability to integrate telemedicine into state-level COVID-19 response strategies. NETCCN teams worked with state Critical Care Coordination Centers, hospital associations, and departments of health to deploy remote providers to individual facilities in Guam (2020), Puerto Rico (2020), and state systems in Vermont (2022) and Michigan (2022). ASPR’s SLTT partners continue to express an interest in leveraging a federal telemedicine program for public health and medical emergencies; NETN is positioned to address this gap.

Telemedicine demonstrated its utility and efficacy during the COVID-19 pandemic. During the Delta and Omicron waves, ASPR funds supported the deployment of critical care nurses, intensivists, and

¹⁵ The SPRN operates at each of the original 10 RESPTC sites. ASPR created three new RESPTC sites in FY 2024 and these sites are not yet fully operational and are currently not part of the SPRN. Additional information about SPRN and its regional partners can be found on NETEC’s “[About the Special Pathogens Research Network](https://netec.org/for-researchers/about-the-special-pathogens-research-network/)” site: <https://netec.org/for-researchers/about-the-special-pathogens-research-network/>.

respiratory therapists to 61 hospitals across the nation. ASPR's actions also increased rural access to high quality critical care. ASPR collaborated with states on efforts to utilize the telehealth platform for a Test to Treat model that enabled rapid access to COVID-19 therapeutics. ASPR is evaluating strategies to develop NETN into a nimble and efficient all-hazards disaster telemedicine capability to enable virtual deployment of ASPR clinical resources in support of ESF-8 responses nationwide.

NSPS: Regional Emerging Special Pathogen Centers (RESPTCs)

Established in response to the 2014–2015 Ebola outbreak, the RESPTCs were designed to be able to receive a confirmed special pathogen patient within a few hours from their region, across the U.S., or medically evacuated from outside of the U.S., as necessary. The 13 current RESPTC facilities serve as a critical component of the NSPS.

ASPR expanded the RESPTC network by three centers to increase the total number of sites from 10 to 13 in FY 2022. ASPR selected three new RESPTC sites through a competitive award process, providing \$3 million to each: Washington Hospital Center in Washington, District of Columbia (D.C.), University of North Carolina at Chapel Hill in Chapel Hill, North Carolina, and Corewell Health (formerly Spectrum Health System) in Grand Rapids, Michigan. In addition, ASPR awarded \$1.2 million to the 10 existing RESPTCs.¹⁶

RESPTCs contribute to regional preparedness across six key functions which include: developing and maintaining standards and guidance for the NSPS; accelerating capability and capacity for research to develop insights about special pathogens and data access; supporting a ready, safe, and resilient health care workforce; providing effective patient medical transport and care delivery; leading communication, coordination, and partnership within their regions and across the NSPS; and continuously monitoring performance to maintain high-quality and seamless operations, evaluate readiness, and drive informed decision-making within their region and across the NSPS.

The COVID-19 pandemic highlighted underlying inequities in health and health care delivery, with racial and ethnic minority groups at higher risk of becoming infected and dying from the disease.^{17, 18} RESPTCs are working to address these disparities by strengthening emergency preparedness planning with a particular focus on the needs of at-risk populations. During the response, 70 percent of RESPTCs developed plans for at-risk populations and 86 percent of them implemented those plans.¹⁹

ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE)

The ASPR [TRACIE](#) website provides technical assistance to health care partners nationally and has been operational and available since FY 2015, 24/7, 365 days a year. The team works with subject matter experts (SMEs) to provide technical assistance to SLTT communities to both enhance their preparedness and response capabilities, and to ensure that partners can readily access and download virtual resources.

¹⁶ ASPR, "[ASPR Awards \\$21 million to Health Facilities to Enhance Nation's Preparedness for Special Pathogens](https://aspr.hhs.gov/newsroom/Pages/RESPTC-Prep-Award-24Oct2022.aspx)," Oct. 24, 2022, <https://aspr.hhs.gov/newsroom/Pages/RESPTC-Prep-Award-24Oct2022.aspx>.

¹⁷ Stokes EK, Zambrano LD, Anderson KN, et al. [Coronavirus Disease 2019 Case Surveillance — U.S., January 22–May 30, 2020](https://doi.org/10.15585/mmwr.mm6924e2). MMWR Morb Mortal Wkly Rep 2020;69:759–765. <http://dx.doi.org/10.15585/mmwr.mm6924e2>.

¹⁸ Killerby ME, Link-Gelles R, Haight SC, et al. (2020). [Characteristics Associated with Hospitalization Among Patients with COVID-19](https://doi.org/10.15585/mmwr.mm6925e1) — Metropolitan Atlanta, Georgia, March–April 2020. MMWR Morb Mortal Wkly Rep. <http://dx.doi.org/10.15585/mmwr.mm6925e1>.

¹⁹ RESPTC FY 2020 Administrative Supplement year end performance data (Period of Performance: March 28, 2020 – June 14, 2021).

Since ASPR TRACIE's launch in September 2015, the platform has experienced an exponential increase in use and demand, with cumulative visitor volume reaching over 1.5 million as of November 2022. The monthly number of technical assistance requests has also increased, with an average of 126 technical assistance requests per month. ASPR TRACIE experiences spikes in both technical assistance requests and website visitation statistics during times of declared national emergencies and local disasters, and after release of tools and templates. The team also provides surge assistance and resources during and after incidents, to support ASPR staff and local deployed/deployable personnel.

ASPR TRACIE has established innovative processes for sharing existing and developing new resources, and since 2015, the team has added [nearly 10,000 resources](#) to the ASPR TRACIE database. They have also:

- Published and maintained over 450 [SME-validated resource materials](#).
- 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 [resource collections](#) on COVID-19 specific to health care system preparedness, response, and recovery.
- Published 16 issues of the newsletter *The Exchange* featuring lessons learned from practitioners in the field in topic areas such as [disaster behavioral health](#), [impact of civil unrest and workplace violence](#), [disaster ethics](#), [providing health care during no-notice incidents](#), and [decedent management during disasters](#).
- Provided direct support of HPP cooperative agreement requirements, such as developing [HCC-level annex plan and tabletop exercise \(TTX\) templates](#) (specialty care for pediatrics, burn, infectious disease, radiation/chemical injuries) and conducting a multi-phased effort to capture [lessons learned from HCCs response to COVID-19](#).
- Continued to nimbly anticipate and respond to partners' needs, create meaningful and implementable resources for partners to use in an equitable manner before a disaster strikes (e.g., [Disaster Available Supplies in Hospitals \[DASH\] Tool](#)), and address the just-in-time needs of our partners before, during, and following emergencies (e.g., [pediatric surge](#), [mpox](#)).

ASPR Division of Community Mitigation and Recovery (DCMR)

The DCMR coordinates federal efforts to support sustainable restoration of the health care system and to address disaster-caused health and social services recovery challenges to improve health and well-being outcomes for Americans affected by disasters. The policy and doctrinal guidance under the National Disaster Recovery Framework (NDRF), through the Health and Social Services (HSS) Recovery Support Function (RSF), guides the development of recovery capabilities.

When the HSS RSF is activated, ASPR is responsible for leading a coalition of 17 federal agencies to conduct joint assessments of disaster-related recovery barriers and priorities, and to develop actionable interventions to improve the recovery of the health care, behavioral health, social services, and educational systems, with careful attention to ensuring that interventions are supportive of the needs of children, youth, and families; integrate access and functional needs; support climate resilience and sustainability; and support equity in post-disaster outcomes, particularly across racial/ethnic, gender, and LGBTQ+ communities.

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

DCMR supports health care systems and SLTT jurisdictions to close critical gaps exposed by disasters, both in active recovery missions and in ongoing community mitigation efforts designed to replicate promising practices. In 2022, DCMR conducted long-term disaster recovery missions in Puerto Rico and in the states of Louisiana, California, New Mexico, Kentucky, Missouri, and Florida. The team delivered community mitigation support to SLTT jurisdictions nationwide, both for natural disasters and the COVID-19 pandemic.

- In Puerto Rico, DCMR completed its multi-year mission for Hurricane Maria recovery, which involved building an island-wide “hub and spoke” system of hospitals trained, equipped, and prepared to sustain hospital services through future disasters. The successful continuous operation of the hospital system of the island through Hurricane Fiona in fall 2022 demonstrated the effectiveness of the “hub and spoke” hospital capacitation effort.
- In Connecticut, DCMR coordinated a state priority project for comprehensive services to the homeless designed to prevent a wider COVID-19 outbreak among those experiencing homelessness.
- In HHS Region 5, DCMR led an interagency federal and state task force that developed tools and resources that supported equity in recovery.
- In multiple states affected by wildfires, including California and New Mexico, DCMR helped jurisdictions with assessment of environmental health risks caused by the fire, and linkage to federal resources to mitigate those health risks.
- In multiple states affected by hurricanes and flooding events, including Louisiana, Kentucky, Missouri, and Florida, DCMR supported jurisdictions with interventions that supported recovery in the areas of environmental, public health, health care, and education.
- In individual regions nationwide, DCMR partnered with FEMA and state jurisdictions to build the capacity of states and HCCs to direct recovery from disaster events, including development of new tools.
- In HHS Region 9, DCMR supported the development of a regional strategic plan for recovery from the COVID-19 pandemic.

During FY 2023, to support recovery from disasters, DCMR developed and provided 36 webinars reaching over 2,500 participants nationwide; operationalized the Deployment Call Back Program – reaching over 3,600 first responders; and trained 115 behavioral health leaders to provide Psychological First Aid or Skills for Psychological Recovery trainings in their communities. Based on FY 2023’s missions, DCMR identified the need to further expand ASPR’s capabilities for disaster behavioral health in preparedness, response, and recovery.

Division of Critical Infrastructure Protection (CIP)

The nation’s critical infrastructure provides the essential services that underpin American society and serve as the backbone of the country’s economy, security, and health. The 2021 National Defense

Authorization Act²⁰ (NDAA) charges each Sector Risk Management Agency (SRMA) to proactively manage all physical and cyber risks to their designated critical infrastructure sector. ASPR's CIP serves as the HHS SRMA designee for the Health Care and Public Health (HPH) Sector.²¹

Assessing Sector Risk, Supporting Sector Risk Management

Central to CIP's role for the SRMA is leading the private and public partnership to uphold the Sector's National Critical Functions,²² manage risk, and coordinate effective responses. The HPH Sector Partnership²³ (the Partnership) unites 277 private sector organizations with representatives from 31 federal agencies (a 15 percent increase over FY 2021). At the heart of ASPR's Sector risk assessment capability is the CIP-developed Risk Identification and Site Criticality (RISC) Toolkit 2.0, which has an anticipated Quarter three (Q3) FY 2023 launch. Recognizing ASPR's role in advancing cybersecurity for the Sector, the Office of the National Cyber Director and the National Security Council partnered with CIP to pilot an assessment of SRMA cyber capabilities, to better understand HHS's resource needs to support HPH Sector risk management. CIP also led the first-of-its-kind landscape assessment of cyber risks to the Sector and HHS's existing legislative authorities. This effort was led in coordination with the HHS Offices of the Deputy Secretary, General Counsel and seven Operating and Staff Divisions. The assessment identified 14 critical cyber risks and 22 unique vulnerabilities, and laid the foundation for ongoing HHS collaboration with the White House to modernize HHS's cybersecurity authorities and capabilities.

Coordinating Across the HPH Sector, Facilitating Information Sharing

The Partnership oversees several working groups of its members addressing the largest threats to the Sector. In FY 2022, CIP delivered 203 steady state and response bulletins to 5,262 partners (a 16 percent increase since FY 2021) sharing critical preparedness and cyber threat information related to the Log4j²⁴ vulnerability, Russian cyber threats, and resources to better protect the Sector. In response to exploitations of cyber vulnerabilities in the health care supply chain, the Partnership revitalized the HHS HPH SRMA Cyber Working Group (HS-CWG) and launched the Joint Supply Chain Resilience Working Group (Joint SCRWG).

Leading Emergency Preparedness & Response Activities, Supporting Incident Management

CIP provides critical support to ESF-8 and ESF-14,²⁵ enabling effective and coordinated management of all-hazard incidents. To bolster preparedness and better support incident management, CIP developed 15 state and three regional Preparedness Profiles, to enable senior HHS leadership to rapidly assess critical needs and support response decisions, conserving resources and saving lives. In FY 2022, CIP completed the HPH Sector Cyber Incident Response: Tracking, Assessment, and Communication Plan (the Plan)

²⁰ FY21 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](#)

²¹ [The Pandemic and All-Hazards Preparedness and Advancing Innovation Act.](#)

<https://www.phe.gov/Preparedness/legal/pahpa/Pages/pahpaia.aspx>

²² Cybersecurity & Infrastructure Security Agency, "[National Critical Functions | CISA](#)," <https://www.cisa.gov/national-critical-functions>.

²³ ASPR, "[HPH Sector Partnership](#)," <https://www.phe.gov/Preparedness/planning/cip/HPH/Pages/HPH-Sector-Partnership.aspx>.

²⁴ International Association of CIP Professionals, "[CISA Issue Apache Log4j Vulnerability Guidance](#)," <https://cip-association.org/cisa-issue-apache-log4j-vulnerability-guidance/>.

²⁵ ASPR, "[Emergency Support Functions](#)," <https://www.phe.gov/Preparedness/support/esf8/Pages/default.aspx#eme>.

which, upon implementation, will establish an HHS-wide coordinated process for managing cyber incidents across the Sector. CIP successfully stress-tested the Plan during Cyberstorm 2022, a whole-of-government cyber exercise which engaged key private sector partners to validate the Plan. CIP also developed HPH-Specific DHS-CISA Tabletop Exercises and CISA Tabletop Exercise Packages (CTEP), which are a comprehensive set of resources to assist private sector partners in conducting their own tabletop exercises.²⁶

²⁶ Cybersecurity & Infrastructure Security Agency, “[CISA Tabletop Exercises Packages | CISA](https://www.cisa.gov/cisa-tabletop-exercise-packages),” <https://www.cisa.gov/cisa-tabletop-exercise-packages>.

**Key Outputs and Outcomes Table
ASPR: Health Care Readiness and Recovery**

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 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)	Discontinued	Discontinued	N/A
14b Increase the percent of HCCs that completed the Medical Response and Surge Exercise of equal to or greater than twenty percent of the coalition's calculated bed capacity (Intermediate Outcome)	FY 2023: Result Expected Dec 31, 2024 ¹ Target: 90% (Pending)	90%	90%	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 2021: 96.1% Target: 100% (Target Not Met but Improved)	90%	90%	Maintain

¹Preliminary 2023 data is expected in early 2024 with a full year of 2023 data to be reported in late December 2024

Administration for Strategic Preparedness and Response

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE				
FY 2024 MANDATORY STATE/FORMULA GRANTS				
CFDA NUMBER/PROGRAM NAME: <u>93.889 Hospital Preparedness Program</u>				-
STATE/ TERRITORY	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Alabama	\$3,145,268	\$3,352,678	\$3,352,678	-
Alaska	\$1,111,466	\$1,241,134	\$1,241,134	-
Arizona	\$4,716,474	\$4,729,894	\$4,729,894	-
Arkansas	\$2,099,822	\$2,298,630	\$2,298,630	-
California	\$23,171,118	\$22,465,160	\$22,465,160	-
Chicago	\$2,818,423	\$3,252,117	\$3,252,117	-
Colorado	\$3,281,648	\$3,584,461	\$3,584,461	-
Connecticut	\$2,261,523	\$2,358,240	\$2,358,240	-
Delaware	\$1,086,723	\$1,183,687	\$1,183,687	-
District of Columbia	\$1,187,386	\$1,417,404	\$1,417,404	-
Florida	\$11,800,098	\$11,319,855	\$11,319,855	-
Georgia	\$7,950,996	\$7,033,277	\$7,033,277	-
Hawaii	\$1,276,715	\$1,365,086	\$1,365,086	-
Idaho	\$1,318,146	\$1,467,523	\$1,467,523	-
Illinois	\$8,353,473	\$9,241,271	\$9,241,271	-
Indiana	\$3,956,143	\$4,095,023	\$4,095,023	-
Iowa	\$2,049,436	\$2,152,263	\$2,152,263	-
Kansas	\$2,009,918	\$2,060,821	\$2,060,821	-
Kentucky	\$2,803,092	\$2,954,813	\$2,954,813	-
Los Angeles County	\$9,142,488	\$8,777,493	\$8,777,493	-
Louisiana	\$2,934,248	\$3,100,990	\$3,100,990	-
Maine	\$1,122,201	\$1,249,871	\$1,249,871	-
Maryland	\$5,297,615	\$6,363,498	\$6,363,498	-
Massachusetts	\$4,090,461	\$4,136,693	\$4,136,693	-
Michigan	\$5,799,153	\$5,797,065	\$5,797,065	-
Minnesota	\$3,399,515	\$3,513,195	\$3,513,195	-
Mississippi	\$2,062,902	\$2,179,572	\$2,179,572	-
Missouri	\$3,626,688	\$3,814,018	\$3,814,018	-
Montana	\$1,099,880	\$1,214,234	\$1,214,234	-
Nebraska	\$1,401,496	\$1,490,149	\$1,490,149	-
Nevada	\$2,531,286	\$2,930,418	\$ 2,930,418	-
New Hampshire	\$1,106,453	\$1,198,839	\$1,198,839	-
New Jersey	\$5,370,096	\$5,403,047	\$5,403,047	-
New Mexico	\$1,581,141	\$1,744,689	\$1,744,689	-

Administration for Strategic Preparedness and Response

STATE/ TERRITORY	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
New York	\$9,895,682	\$11,453,105	\$11,453,105	-
New York City	\$7,486,901	\$7,499,429	\$7,499,429	-
North Carolina	\$6,083,849	\$6,153,069	\$6,153,069	-
North Dakota	\$1,071,922	\$1,149,321	\$1,149,321	-
Ohio	\$7,059,431	\$7,082,951	\$7,082,951	-
Oklahoma	\$2,549,685	\$2,679,957	\$2,679,957	-
Oregon	\$2,614,621	\$2,823,529	\$2,823,529	-
Pennsylvania	\$7,702,626	\$7,719,170	\$7,719,170	-
Rhode Island	\$1,071,962	\$1,149,415	\$1,149,415	-
South Carolina	\$3,147,824	\$3,378,383	\$3,378,383	-
South Dakota	\$1,083,466	\$1,176,125	\$1,176,125	-
Tennessee	\$4,013,830	\$4,056,260	\$4,056,260	-
Texas	\$15,577,836	\$15,541,402	\$15,541,402	-
Utah	\$2,373,046	\$2,373,014	\$2,373,014	-
Vermont	\$1,067,602	\$1,139,291	\$1,139,291	-
Virginia	\$6,857,550	\$8,642,449	\$8,642,449	-
Washington	\$4,367,027	\$4,743,095	\$4,743,095	-
West Virginia	\$1,400,530	\$1,470,623	\$1,470,623	-
Wisconsin	\$3,417,594	\$3,558,652	\$3,558,652	-
Wyoming	\$1,076,454	\$1,159,845	\$1,159,845	-
Subtotal	\$226,882,929	\$235,436,193	\$235,436,193	-
Indian Tribes	-	-	-	-
Migrant Program	-	-	-	-
American Samoa	\$279,211	\$283,641	\$283,641	-
Guam	\$ 356,511	\$367,041	\$367,041	-
Marshall Islands	\$268,164	\$270,830	\$270,830	-
Micronesia	\$283,060	\$289,612	\$289,612	-
Northern Mariana Islands	\$278,796	\$286,534	\$286,534	-
Palau	\$255,889	\$257,040	\$257,040	-
Puerto Rico	\$2,590,019	\$2,499,222	\$2,499,222	-
Virgin Islands	\$305,421	\$309,887	\$309,887	-
Subtotal	\$4,617,071	\$4,563,807	\$4,563,807	-
Total States/ Territories	\$231,500,000	\$240,000,000	\$240,000,000	-
TOTAL RESOURCES	\$231,500,000	\$240,000,000	\$240,000,000	-

Note: FY 2023 amounts are estimates

Administration for Strategic Preparedness and Response

Grant Awards Tables			
	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Number of Awards	62	62	62
Average Award	\$3,733,871	\$3,870,968	\$3,870,968
Range of Awards	\$255,889 - \$23,171,118	\$257,040 - \$22,465,160	\$257,040 - \$22,465,160

Biomedical Advanced Research and Development Authority

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	745.005	950.000	1,015.132	+65.132
<i>Operations and Management (non-add)</i>	<i>120.000</i>	<i>170.000</i>	<i>170.000</i>	-
FTE	276	300	364	+64

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

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). 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. BARDA focuses on evaluating, developing, and potentially acquiring commercially available products that can be repurposed for MCM uses as well as developing multipurpose products 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.

Funding History	
Fiscal Year	Amount
FY 2020	\$561,700,000
FY 2021	\$596,700,000
FY 2022 Final	\$745,005,000
FY 2023 Enacted	\$950,000,000
FY 2024 President's Budget	\$1,015,132,000

Budget Request

The FY 2024 President's Budget request for Advanced Research and Development is \$1,015,132,000 which is +\$65,132,000 above FY 2023 Enacted. With the additional funding, BARDA will be able to expand its threat agnostic advanced development portfolio. This approach focuses on developing tools that can work against more than one pathogen, or platforms that can be used to rapidly pivot to produce vaccines, therapeutics, diagnostics, and other tools against different diseases. This supports products against the highest priority threats, namely those with a Material Threat Determination, while also providing new tools to address other threats. Additional FY 2024 funding is also required to support critical ongoing work assessing impact of MCMs on COVID-19 viral variants.

The Budget request supports the advanced development of the highest priority MCMs against all 20 material threats identified by DHS and prioritized in the [PHEMCE Strategy and Implementation Plan](#)²⁷. 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 injuries 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;

²⁷ <https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx>

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;
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. New technologies to advance detection and treatment of Traumatic Brain Injury (TBI) that is seen both in routine trauma as well as mass-casualty scenarios; and,
16. Threat-agnostic diagnostics for use in the early days of novel disease outbreak.

Combating Antibiotic-Resistant Bacteria (\$155 million): The FY 2024 request will support CARB-X and the advanced clinical stage development of novel broad-spectrum antimicrobials to prevent and treat drug-resistant bacterial infections in both adult and pediatric populations. 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 investment from BARDA and other funding organizations. New funding initiatives in FY 2024 will include transitioning two or more antibacterial from either CARB-X or NIAID into BARDA's advanced development portfolio while also supporting continued progress across the broad-spectrum antimicrobial portfolio. It is also anticipated that one program that is currently supported by ARD funding will transition to PBS. All funded efforts are focused on the development of next generation therapeutic candidates that address the growing incidence of antimicrobial resistance, secondary infections, and the potential threat of a bioterrorism event.

Chemical (\$80 million): FY 2024 funding will be used to continue support for all the existing candidates, including those identified through BARDA's ReDIRECT program (whose goal is to develop and seek licensure of FDA approved drugs for new chemical threat indications), that show promise in treating conditions resulting from exposure to priority chemical threat agents and to continue development of animal and organ-on-chip models to support evaluation of candidate MCMs. In addition, funding will be used to expand use of informatics strategies to discover drug candidates for repurposing as chemical MCMs. 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, amenable to civilian concepts of operation. Further, funds 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 (\$92 million): FY 2024 funds will be used to maintain support for existing, well performing partners who are developing treatments for acute radiation injury and trauma. In addition, funding will be used to broaden the portfolio to include treatments for vascular injury as well as to address inflammation, coagulopathies, and ischemia 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 2024, funds will continue building a diagnostic portfolio that includes advanced research and development of the following: 1) Diagnostic devices to confirm infection with biological agents, some of which will be suitable for use in point-of-care and near patient settings; 2) New diagnostic devices to help reduce the emergence of antimicrobial resistant bacteria by identifying the appropriate treatment faster, such as through identification of viral vs bacterial infections and antimicrobial susceptibility testing; 3) Diagnostic technologies suitable for use in limited healthcare resource settings such as remote locations where diseases are endemic, nursing homes, temporary treatment centers, tribal clinics, and even homes, by minimally trained personnel; 4) Biodosimetry devices that detect ionizing radiation absorption; and 5) Threat-agnostic diagnostics for use in the early days of a novel disease outbreak.

Burn and Blast (\$55 million): In FY 2024, funds will continue to expand the portfolio of products that address and mitigate the effects of blast trauma injuries, including point-of-care injury detection and treatment technologies. This work complements and extends previous investments to transform the continuum of care for burns due to thermal energy to include blast injuries that are also caused by nuclear detonation. Further, BARDA plans to develop imaging technologies to assess burn depth and severity as well as invest in additional ultrasound-based technologies to broaden the impact on delivery of care using multiple platforms. Novel technological approaches (biomarker and imaging based) will address traumatic brain injury (TBI) and fractures seen in both routine care as well as mass-casualty incidents.

Viral Hemorrhagic Fever (\$162 million): FY 2024 funding will focus on development of vaccines and therapeutics for Sudan ebolavirus and Marburg viruses. Funds will be used to continue to develop vaccine candidates for both viruses into Phase 2 clinical development. FY 2024 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 2024 funding will also support existing and new filovirus therapeutic candidates. Advanced manufacturing and pivotal nonclinical studies will progress for the lead Marburg virus therapeutic candidate. Additionally, funds will enable the development of an additional Marburg therapeutic 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 will have efficacy against new or emerging filoviruses. At least one small molecule antiviral with efficacy against filoviruses will be supported, with a focus on broad anti-filovirus activity, penetration of sites where the virus can be dormant, and an oral route of administration.

Smallpox Therapeutics (\$20 million): Funds will continue to support a monoclonal antibody cocktail for the treatment of smallpox disease in FY 2024. The product, which is anticipated to be a safe alternative treatment for special populations, would also provide risk mitigation for the purposeful or natural development of resistance to the approved antivirals for smallpox.

Broad Spectrum MCMs (\$60 million): 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 emerging biological threats, including by developing pathogen-directed therapeutics that are effective against broad classes of pathogens, host-directed approaches that treat the medical consequences of infection, vaccines against current threats built on platforms that can be rapidly redirected to new strains as they emerge, and technologies that can be applied across a variety of MCMs. The availability of such threat agnostic MCMs, platforms and technologies, provides new or additional tools to prevent and treat current known threats as well as the capability to rapidly and effectively respond to newly emerging threats.

Centralized Capabilities: Clinical Network, Nonclinical Studies Network, and Manufacturing (\$70.132 million): The Clinical Studies Network (CSN) will continue to develop 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, including the provision for long-term storage services for investigational product retains and clinical and nonclinical specimens to support future assay development and a statistical and data coordinating center for harmonization of data across BARDA projects and the archival of trial master file documents.

The next generation of Nonclinical Studies Networks was awarded in FY 2022 to enhance 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 through the accelerated Program or under the Animal Rule. Further nonclinical studies are critical to evaluate the efficacy of MCM candidates that are in development to treat acute radiation syndrome (ARS) sub-syndromes, including gastrointestinal, skin, and pulmonary injury. Product-agnostic models for Ebola Sudan and Marburg Virus infection will be qualified as new MCM candidates are brought into BARDA's pipeline. FY 2024 funding will also support continued development of models to evaluate MCM candidates for treatment of injuries caused by chlorine, opioids, and vesicating agents. Finally, funding will continue to support BARDA's technology development programs including Beyond the Needle and ImmuneChip+.

Past pandemic efforts have validated the requirement for the USG to have ready access to domestic, commercial-scale MCM production capabilities, operating under current Good Manufacturing Practices (cGMP), that are positioned to rapidly respond. A lack of ready access to these capabilities is of particular concern and would be addressed by leveraging public-private partnerships to establish and/or capture surge domestic capacities. Requested funding will allow some initial effort to begin to address this gap by supporting nominal access to domestic commercial-scale fill/finish capabilities.

DRIVE and the Medical Countermeasures Innovation Partner (MCIP) - DRIVE (\$76 million): FY 2024 funding will both continue existing DRIVE programs and expand the portfolio of programs. Existing programs include development of the following:

- 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, critical cardiac functions, complete blood counts, and wellness testing markers, such as lipids, hormones and metabolic;
- Digital MCMs that could be immediately deployed at scale in the early phases of a public health emergency;
- Scalable multi-organ, sensor-based micro physiological 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 10-15 investments in FY 2024, with individual investments ranging from \$5-15 million per company. In that scenario and including investments made in FY 2022 and FY 2023, all funds provided to Ventures are expected to be under active investment by FY 2024. In FY 2024, it is also expected that some 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.

Testing of MCMs Against COVID-19 Variants (\$25 million): As part of the COVID-19 response, BARDA supported development and validation of numerous non-clinical and assay testing capabilities, and sample collection and testing efforts. These tools provided continuous support to monitor COVID-19 variants and assess MCM binding (and by inference, effectiveness) against them, as well as determine correlates of protection for vaccines. As COVID-19 continues to evolve, having continuity of these efforts are key to understanding the impact of viral evolution on MCM effectiveness.

Management and Administration (\$170 million): These funds provide support to BARDA's programs for Advanced Research and Development, Project BioShield, Pandemic Influenza, and the COVID-19 Response. These funds also support other offices within the ASPR organization. The BARDA organization has grown significantly over the years and hiring over the last three years has allowed BARDA to come closer to being fully staffed, resulting in a need for increased Management & Administration funding. Funding will be used to bolster scientific staff and other key 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, acquisition policy including Earned Value Management analysis and contract closeouts, 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.

In FY 2020–2023, 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 COVID-19 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, strategic decision making, and public reporting, capabilities that must be maintained going forward to be prepared for future responses.

Program Accomplishments

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 collaborate with product developers more effectively and efficiently and to 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 2022, CARB-X has funded 92 different candidates and currently has 37 active programs for the development of 23 therapeutics, seven vaccines, and seven diagnostics. Twelve 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. In 2022, recognizing the value that preclinical support brings to innovators who seek to combat drug-resistant bacteria, BARDA awarded a new OTA that supports CARB-X for another ten years.

To encourage private sector involvement, minimize development costs and risks, and accelerate product development and approval, BARDA 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, including the 2013 H7N9 avian influenza response, the 2014–2016 Ebola response, the 2016–2017 Zika response, and the COVID-19 pandemic response. The pandemic response effort revealed limitations, including the lack of a trained workforce to perform the necessary manufacturing work. As a result, in FY 2021, BARDA ended the CIADM partnership with one facility, and restructured another to focus on workforce development. BARDA has worked with the partner and countries from Africa to train three cohorts of individuals from multiple countries in Africa in current good manufacturing process. BARDA is supporting the partner in development of an mRNA vaccine manufacturing curriculum, with pilot course delivery anticipated in FY 2023. During 2022, BARDA released a request for information to establish a new consortium of manufacturing partners under a different model that will be referred to as the Biopharmaceutical Manufacturing Partnership. Under this model, BARDA will leverage its Other Transaction Authority to enter into agreements with multiple manufacturing partners and suppliers of raw materials to meet the ambitious goals highlighted in the American Pandemic Preparedness Plan [Sep 2021] and the National Biodefense Strategy and Implementation Plan [Oct 2022]. BARDA anticipates establishing the inaugural consortium of partners in FY 2023.
- ***Fill-Finish Manufacturing Network (FFMN):*** Established in 2013 to assist developers with final drug product manufacturing, the FFMN provides the sterile product formulation and filling capabilities (e.g., vials and syringes) needed for both product development and emergency responses. Previously, the FFMN supported the production of the experimental Ebola therapeutic ZMapp for the 2014–2016 Ebola response, and now is supporting vaccine manufacturing for the ongoing COVID-19 pandemic and mpox outbreak responses. The relationships 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 recent public health emergencies. The CDMO Network expands beyond fill-finish services to other outsourced capabilities that may be needed by BARDA’s partners. The connectivity with these many private service providers is critical for BARDA’s preparedness posture for future public health emergencies.
- ***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 through the FDA Accelerated Program or the FDA Animal Rule Program. 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 supporting data from BARDA-funded nonclinical studies include Anthrasil, BioThrax,

Raxibacumab, Neupogen, Neulasta, Nplate, Anthim, Leukine, TPOXX, Jynneos, Ervebo, Inmazeb, Ebanga, and Tembexa. Since 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. Between 2014 and 2020, the CSN supported ten clinical research projects, including the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) vaccine study during the 2014–2016 Ebola response and 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. These efforts include a master protocol (ACTIV – 1) designed to evaluate multiple investigational agents for the treatment of moderately or severely ill patients infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-1). The CSN performed a nested sub study within the Novavax SARS-CoV-2 vaccine study in subjects less than 18 years old to assess the vaccine efficacy in the pediatric population; data analysis is ongoing. The CSN also initiated a protocol to generate a bank of biological specimens from participants 12 years and older before and after receipt of an authorized or licensed United States Government supported COVID-19 vaccine given as a matter of care. The samples collected may be utilized to determine immunological responses and microbiologic factors, and to develop novel assays, diagnostic tests, vaccines and therapeutic agents. Currently, a clinical research study is being conducted to evaluate the efficacy of half-doses of an anthrax vaccine on immune response and to generate initial data on boost response to inform a pre-exposure prophylaxis clinical study.

Developing Multi-Use Products

BARDA's 2022-2026 Strategic Plan rests on four strategic goals designed to strengthen efforts to ensure that the United States and the public are protected from all national health security threats. These strategic goals include Preparedness, Response, Partnerships, and Workforce. Aligned with these principles, BARDA supports the advanced development and procurement of MCMs targeting known high-priority threats and will invest in innovative technologies to enhance preparedness against unknown threats. BARDA will focus investments on technologies that have the potential to make MCMs faster, safer, and more accessible. It will achieve this goal by developing multipurpose MCMs capable of neutralizing known threats as well as newly emerging threats, investing in platform technologies that can be rapidly redirected against new and emerging threats, stimulating innovation in MCM manufacturing, and

enhancing sustainability by supporting development and repurposing of products and technologies with commercial value.

Building a Robust and Formidable MCM Development Pipeline

In partnership with industry, BARDA 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 36 products that have transitioned to support under PBS, 25 of which have been procured for the SNS. BARDA's efforts have led to 69 FDA licensures, approvals, or clearances of MCMs since 2008, 29 of which focus on countering CBRN threats including those listed below and eight of which have received the Breakthrough Designation under the 21st Century Cures Act. 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 oral formulation 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 mpox vaccine (2019)
- ERVEBO *Zaire ebolavirus* vaccine (2019)
- INMAZEB to treat *Zaire ebolavirus* Disease (2020)
- EBANGA to treat *Zaire ebolavirus* Disease (2020)
- Quick Ebola Rapid Antigen Test to detect Ebola Zaire (2020)
- StrataGraft to treat deep-partial thickness burns (2021)
- NPLATE to treat thrombocytopenia from radiation exposure (2021)
- Lumify Ultrasound functionality of counting B-lines in lung exams (2021)
- TEMBEXA to treat smallpox disease (2021)
- TPOXX intravenous formulation to treat smallpox (2022)
- Silverlon to treat limited cutaneous radiation injury (CRI) and radiation dermatitis (2022)

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, having supported the development and approval of three anthrax antitoxins (Raxibacumab, ANTHIM, and Anthrasil), development and 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. BARDA supported development of the next-generation anthrax vaccine, AV7909 (trade name Cyfendus™) with submission of a Biologics License Application (BLA) in April 2022 and the purchase of more than 30 million doses that have been delivered to the SNS.

Smallpox: Smallpox remains a threat of high concern to both the domestic and international community. BARDA's requirement is to ensure adequate vaccine supply for the public, including at-risk 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.

BARDA supported the late-stage development and procurement of the smallpox vaccine JYNNEOS for immunocompromised patients. In 2019, the FDA licensed the JYNNEOS vaccine to prevent smallpox disease and mpox (formerly monkeypox) disease. BARDA has procured more than 16 million dose-equivalents of bulk vaccine and filled approximately 1.4 million doses into vials, with orders to fill an additional 5.5 million vials. BARDA is prioritizing the replenishment of vaccines used in response to the mpox outbreak with the goal of restoring smallpox preparedness.

BARDA has supported the development of TPOXX, a small molecule antiviral developed by SIGA, for the smallpox indication. The FDA approved the capsule formulation in 2018 for adult and pediatric patients over 13 kg in weight and the intravenous (IV) formulation supported by BARDA was approved in 2022, which expanded access to patients over 3 kg in weight. BARDA is working with SIGA on a third formulation that can be used to treat neonates and toddlers. In 2021, another BARDA-supported product, TEMBEXA, developed by Chimerix, Inc, was approved by the FDA for the treatment of smallpox in adult and pediatric populations. To further increase therapeutic options for healthcare workers, support treatment for 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 treat infections due to both DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders) and healthcare-associated and community-acquired multidrug-resistant pathogens. As of December 2022, BARDA has supported the development of over 125 antibacterial candidates: 92 under CARB-X, 32 in the ARD portfolio, and two with PBS, including

one that transitioned from ARD to PBS in FY 2022. BARDA supported development of three antibiotics to FDA marketing authorization under ARD.

BARDA is actively supporting 18 clinical stage antibacterial candidates, including the following innovative technologies: 1) microbiome-based therapy, 2) phage cocktail, and 3) phage-derived antibacterial candidate. Six antibacterial candidates are currently in Phase 3 clinical development. BARDA is also supporting the late-stage development and procurement under PBS of a novel antibiotic (NUZYRA) for the potential treatment of pulmonary anthrax and community-acquired bacterial pneumonia and an antibiotic (cefepime-taniborbactam) for the potential treatment of melioidosis. In response to the threat of antifungal infections during a public health emergency combined with the rise of resistance to currently available therapeutics, BARDA opened a new Area of Interest within the Broad Agency Announcement to support the advanced development of new antifungal MCMs.

Botulinum Toxin: Botulinum neurotoxins (BoNT) pose a threat to public health as potential weapons that can be disseminated by aerosol, through contamination of food, and as naturally occurring contaminants in food or wounds. Botulinum Antitoxin Heptavalent (BAT) is a licensed polyclonal equine antibody product produced in a vaccinated horse herd. However, BAT production diminishes as the horses age, requiring continuous replenishment of the horse herd and raising concerns about the sustainability of generating BAT using this approach. To establish a more sustainable supply of BAT, BARDA is supporting a next generation pan-BoNT antitoxin development program that aims to produce an antibody cocktail product with efficacy against all seven BoNT serotypes.

Viral Hemorrhagic Fever: Viral Hemorrhagic Fevers (VHF), such as those caused by Ebola viruses (Zaire and Sudan) and Marburg virus, are biological threat agents of concern as well as global emerging infectious disease threats. BARDA has supported, and FDA has licensed or cleared, vaccines, therapeutics, and diagnostics that have been deployed to respond to outbreaks since 2014.

BARDA supported development and procurement of the FDA licensed Ebola vaccine, ERVEBO. BARDA has executed contract options to purchase 1 million doses of the vaccine, more than 300,000 of which have been delivered to date. BARDA continues to seek expansion of the label to include special populations where possible. The BARDA-supported Janssen Ebola vaccine remains in Phase 3 development in the US and is licensed in the European Union.

Regeneron's INMAZEB Ebola therapeutic and Ridgeback's EBANGA Ebola therapeutic were licensed by the FDA in late 2020 for the treatment of Ebola virus disease caused by *Zaire ebolavirus*, and all work for both products is now being supported by BARDA. BARDA is procuring approximately 50,000 treatment courses of INMAZEB to be delivered to the SNS. BARDA also continues to support scale-up manufacturing of EBANGA. Both products were used in the 2021 and 2022 Ebola outbreaks in the Democratic Republic of the Congo and Guinea.

In FY 2019, BARDA initiated programs to address Marburg virus and Ebola Sudan, both threat agents for which there currently are no approved MCMs. BARDA is leveraging vaccine technologies that worked for Ebola Zaire to address these related threats. Sabin Vaccine Institute completed a Phase 1b study for its BARDA-supported adenovirus-Marburg and Ebola Sudan vaccine candidates in 2022 and the vesicular

stomatitis virus-Marburg and Ebola Sudan candidates will enter Phase 1 studies in 2023. BARDA also is supporting a single monoclonal antibody candidate for treatment of Marburg virus disease and a two monoclonal antibody cocktail that targets Sudan virus as well as the related Ebola Zaire virus and Bundibugyo virus. The products exhibited excellent efficacy in nonclinical models of Marburg virus and Sudan virus infection, respectively. Phase 1 clinical trials have been conducted for both products and the Sudan virus product was administered under compassionate use to patients in Uganda during the 2022 *Sudan ebolavirus* outbreak. Continued BARDA support will enable the products to advance rapidly to pivotal studies that will support licensure through the Animal Rule.

Biodosimetry and Biodiagnostics The amount of radiation an individual absorbs greatly affects the recommended course of treatment. 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 transitioned from ARD to PBS in FY 2017, followed by another two candidates in FY 2018. During FY 2022, BARDA down selected three of the candidates based on product verification and validation data and extensive feedback from FDA. This high throughput testing solution is planned for FDA review in FY 2024. Development of a new portable handheld biodosimetry device, which was initiated to facilitate identification of casualties needing further medical evaluation nearer the site of incident, will continue in FY 2024.

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 FY 2019, the FDA cleared the Applied Biosystems anthrax detection test for laboratory use, which was the first BARDA supported molecular diagnostic test for detection of anthrax. In FY 2022, a second anthrax diagnostic was submitted for FDA review. If cleared, this countermeasure will provide testing at the point of care offering an important addition to BARDA's portfolio. In 2019, FDA approved a BARDA supported test to detect Ebola virus in both suspected patients and cadavers. These Ebola tests have been procured by BARDA, WHO, and the Foundation for Innovative Diagnostics (FIND) and have been used during recent Ebola responses. BARDA has since expanded test development to include multiplexed filovirus diagnostics and seeks development of molecular field usable test systems. BARDA continues to seek and support partnerships with key test developers to advance development of multiplexed biothreat diagnostics including anthrax, smallpox, glanders, melioidosis, tularemia, typhus, Q-fever, and plague tests. Currently, BARDA has three biothreat products in review with the FDA with five more working towards submission in the coming years.

BARDA continues investment in diagnostics to inform appropriate use of antibiotics and help curb the emergence of antimicrobial resistant bacteria. BARDA's portfolio includes phenotypic and molecular technologies for antibiotic susceptibility tests (AST), viral vs. bacterial tests, and antimicrobial resistance (AMR) tests. Two products are currently in review with the FDA for 510(k) clearance and another five

products are working towards FDA submission. BARDA continues to focus on products that reduce time to result and get answers to doctors faster.

Radiological and Nuclear Threats: BARDA focuses on developing solutions to address the medical consequences of radiological and nuclear threats and has supported the advanced research and development of over 35 product candidates since 2007 to address this threat, over 20 of which have transitioned from NIH's portfolio. This portfolio includes 12 MCM candidates that target various sub-syndromes of acute radiation syndrome, as well as traumatic injury, and blood products.

BARDA has identified specific host pathways (e.g., coagulation, vascular injury, inflammation, ischemia) that play essential roles in radiation injury and trauma. Repurposing commercially available products that affect these pathways, thereby leveraging commercial development efforts, is a central goal of the program. In FY 2021, a BARDA-supported commercial product to treat thrombocytopenia (low platelet count), 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 (injury to blood vessels). Vascular injury, inflammation (response to infection or injury), ischemia (restricted blood flow), and coagulopathy (excess bleeding or clotting), and our ability to quickly detect and treat these conditions, will continue to be priorities in FY 2024. BARDA's close collaborations with DoD, the National Aeronautics and Space Administration (NASA), and NIH ensure appropriate pipeline development, new biomarker and assay development, and targeted natural history studies. New platform technologies, such as microphysiological systems or organs-on-a-chip, will provide an understanding of commonalities between injuries caused by exposure to different threats. 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 freeze-dried platelet products) and platforms (e.g., pathogen reduction platforms) that will augment the safety and availability of the blood supply that will be essential in mass casualty incidents.

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. Many of these same medical consequences occur in trauma patients treated every day in routine care delivered around the country. The focus of this program has been to identify and resolve bottlenecks caused limited treatment capabilities and inefficiencies in current treatment procedures. Without addressing these limitations in routine care, we would not be able to deliver care in a mass casualty for injuries that would be far too many in number and complications. BARDA is developing a range of next-generation treatments and technologies that not only address these bottlenecks but also can be integrated into routine burn and trauma care. This will provide better return on the investments as BARDA can continually build robust and sustainable preparedness for burn and blast injuries with improved technologies and newer MCMs. Furthermore, this preparedness strategy will immediately improve the quality of routine care, reduce costs, and establish a trained user base that is skilled in the new innovative technology products that enhance our nation's preparedness posture.

Several burn & blast products received FDA Breakthrough Designation, including Spectral MD DeepView burn-depth imaging system, StrataGraft full-thickness off-the-shelf skin substitute and

NovoSorb temporizing wound coverage. In addition, Philips Lumify ultrasound technology is in development as a point of care real-time diagnostic lung imaging device that assists with 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 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 exploring the repurposing of very common Atropine Sulfate for treatment of cholinergic overstimulation, which occurs in response to nerve agent exposure. A BARDA-sponsored clinical study showed that administering these eyedrops sublingually (under the tongue) can achieve blood concentrations sufficient to treat mild-to-moderate nerve agent poisoning. Enabling technologies, such as organ-on-a-chip, are leading to an improved understanding of the injuries caused by chemical agents and to 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, BARDA launched the ReDIRECT program to partner with innovators to repurpose commonly available therapeutics to treat injuries caused by exposure to chemical agents. ReDIRECT will accelerate the development of these and future candidates through preclinical studies and then transition the most promising candidates into the ARD portfolio for advanced clinical development. In September 2022, one project initially funded under ReDIRECT was awarded a contract for clinical development in the ARD program.

Division of Research, Innovation and Ventures (DRIVE): In FY 2018, BARDA established DRIVE to invest in, advance, and de-risk new classes of MCMs and their underlying technologies, to rapidly respond to emerging threats with speed and agility, and to catalyze follow-on funding from private and other public funders. In just a few years, DRIVE investments have led to the creation of four new companies, helped de-risk several new technological approaches including microneedle skin patches for vaccine delivery, and its partners have raised over \$1 billion in follow-on investments and earned three FDA 510(k) device clearances.

DRIVE has established fifteen Research and Development (R&D) programs, each of which has a portfolio of partners and projects that are focused on threat-agnostic approaches to improve the nation's ability to prepare for and respond to any future health emergency. These programs are listed below.

- Beyond the Needle: Transform drug delivery using alternative routes of vaccine and therapeutics administration (partnership with CBRN and NCD).
- Host-based Diagnostics: Inform on health security threat risk to individual patient or a population, agnostic of pathogen.
- Host-directed Therapeutics: Fortify the patient, improve patient outcomes, or restore homeostasis through therapies aimed at modulating host response instead of direct anti-pathogen or -threat action.
- Healthcare Infrastructure, Implementation, and Impact (HI-3): Strengthen clinical impact beyond regulatory approval by building networks of modern healthcare delivery for rapid clinical trials across multiple settings and leveraging analytical insights from private and public health data.
- ENACT (Early Notification to Act, Control, and Treat): Early detection of infection based on physiological signs from commercial wearables and other sensor-based technologies.
- Digital MCMs: First line of defense against health threats with rapidly deployable digital tools and novel data sources.
- ReDIRECT: Repurpose commonly available therapeutics to quickly treat symptoms of chemical agent exposure (partnership with CBRN).
- Immunechip+: Enhance the usability of tissue chips for drug development and personalized medicine through the development of multi-organ microphysiological systems (partnership with CBRN).
- Lab at Home: Bring standard lab assays (e.g., blood panels) into the home through relatable and miniaturized biochemical detection to enable true telemedicine and better health outcomes.
- Home COVID-19 Diagnostics: Innovations in next-generation at-home testing platforms for detection of COVID-19 and other pathogens (partnership with DDDI).
- Agnostic Diagnostics: Develop a first of a kind agnostic clinically approved diagnostic to detect pathogens prior to knowing whether an outbreak has even occurred.
- Healing Lungs: Develop simpler, safer, more widely accessible lung support technologies for severe ARDS patients.
- Vaccines on Demand: Develop flexible, decentralized vaccine manufacturing on demand (partnership with CBRN)
- REBOOT: Repurposing Drugs for Biological Threats, with a focus on Filoviruses (Partnership with CBRN).
- REPAIR: Repurposing and advancing innovations against RAD/NUC threats and prevent acute radiation syndrome (ARS) (partnership with CBRN)

In FY 2024, as part of the HI-3 program, DRIVE plans to expand on a new decentralized clinical studies and healthcare delivery network that will have been established in FY 2023, including with industry leading telemedicine providers, retail clinics, and virtual clinical study organizations. This network is

designed to create entirely new ways to validate and deliver MCMs of the future where people live and work, to keep pace with the rapidly evolving healthcare industry.

Outside of its R&D programs, DRiVe launched the \$500,000 Mask Innovation Challenge through the COMPETES Act prize authority, in partnership with CDC's National Institute for Occupational Safety and Health (NIOSH) and the National Institute for Standards and Technology (NIST). The challenge seeks to develop novel, evidence-based, and user-friendly public-use masks of the future, including against multiple hazards of the future due to climate change.

BARDA Accelerator Network and Blue Knight Partnership: In FY 2018, DRiVe established the BARDA Accelerator Network (BAN), a network of 13 leading life science, medical device, and biotech accelerators across the country, to help BARDA better 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 BAN successfully introduced BARDA to over 568 startup companies in FY 2022, contributing to around 20 percent of DRiVe's contract awards in the same year. The BAN will be reestablished as a next-generation BAN 2.0 in FY 2024 after it expires in FY 2023. In addition to expansion of the national and global footprint to ensure greater diversity and equity among health security innovators, BAN 2.0 will also focus on building the infrastructure for rapid development, testing and validation of MCMs during public health emergencies. In FY 2024, BARDA will continue to operate the Blue Knight partnership, established in FY 2020 with Johnson & Johnson's JLABS to support companies by providing resources and mentorship in one of its global incubator sites, 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 establish a partnership with a Medical Countermeasures Innovation Partner (MCIP) to use venture capital practices, such as equity-based financing, to invest in companies to accelerate development and commercialization of next-generation MCMs and underlying technologies, including manufacturing innovation, to address 21st-century health security threats. In FY 2021, BARDA Ventures formally launched its partnership with the nonprofit Global Health Investment Corporation (GHIC), a long-time 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 \$12.6 million to establish the partnership, followed by an additional \$72.8 million in FY 2022. In FY 2022, GHIC secured its first private investment partner, raising an additional \$50 million beyond BARDA funding. Additionally, GHIC has closed 9 investment deals, investing \$34.6 million from Seed/company formation to Series D/growth stage. The BARDA Ventures – GHIC health security portfolio includes digital and analytical health tools, novel diagnostic modalities, drug, and vaccine delivery platforms, biomanufacturing innovation, and continues to grow to fill critical gaps in public health emergency response. GHIC has built a robust pipeline of mission aligned investment opportunities enabling them to close on 10-15 investment deals each year. In FY 2024, GHIC will continue to operate an up to \$500 million venture capital vehicle or fund that will be established in FY 2023 with combined funding from BARDA and private investors. All previous investments, including the 9 already closed, would be rolled into this fund.

COVID-19 Response: Since FY 2020, ASPR has worked across the government in the fight against the most consequential pandemic in a century. As part of ASPR, BARDA supported development, manufacturing, and/or purchase of MCMs 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 12 and up and authorized for use for ages 6 months to 11 years old, Moderna’s SpikeVax that is licensed for use for ages 18 and up and authorized for use for ages 6 months to 11 years old, Janssen’s Ad26.CoV2.S that is authorized on a limited basis for ages 18 and up, and Novavax’s recombinant spike vaccine 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. The USG also procured an updated bivalent prototype-omicron BA.4/BA.5 vaccine from Moderna and Pfizer in summer 2022 to support a fall vaccination campaign.
- 13 therapeutics, including development, regulatory approval, and procurement of the Regeneron’s monoclonal antibody cocktail REGEN-COV, purchase of four monoclonal antibody products developed by Eli Lilly and Company, GlaxoSmithKline, and AstraZeneca, and antivirals made by Pfizer and Merck; all of these products have been authorized for emergency use by the FDA, though the EUAs for the monoclonal antibodies have since been revoked because they are not effective against currently circulating SARS-CoV-2 variants.
- 17 rapidly deployable and other technologies, including next generation technologies to administer vaccines.
- Over 60 diagnostic tests ranging from high-throughput tests for laboratories to rapid point-of-care and at-home tests, 18 are multiplexed with influenza and other respiratory viruses for more efficient testing strategies, and 30 tests have achieved EUA. One test is 510(k) cleared with several pending applications in review. As of November 2022, BARDA’s private sector partners have shipped more than 290 million tests across the country. Four of 6 expansion projects for domestic diagnostic manufacturing facilities are now complete.

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 DoD, 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.

Key Outputs and Outcomes Table
ASPR: Biomedical Advanced Research and Development Authority

Measure	Year and Most Recent Result / Target for Recent Result ¹ (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
2.4.13a Increase the number of new licensed medical countermeasures across BARDA programs (Intermediate Outcome)	FY 2022: 3 medical countermeasures Target: 3 medical countermeasures (Target Met)	3 medical countermeasures	4 medical countermeasures	+1 medical countermeasures
2.4.13b Increase the number of new countermeasures eligible for consideration by FDA for Emergency Use Authorization (Intermediate Outcome)	FY 2022: 0 medical countermeasures Target: 2 medical countermeasures (Target Not Met)	2 medical countermeasures	2 medical countermeasures	+0 medical countermeasures
2.4.14a Increase the technical assistance provided by BARDA to medical countermeasure manufacturers (Intermediate Outcome)	FY 2022: 65 manufacturers Target: 11 manufacturers (Target Exceeded)	11 manufacturers	16 manufacturers	+5 manufacturers

¹ Results based on both supplemental and base appropriations

Project BioShield

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	780.000	820.000	830.000	+10.000
FTE	-	-	-	-

Authorizing Legislation:

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

Program Description

The Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) program advances medical countermeasure (MCM) research and development and procured life-saving MCMs through public-private partnerships using Project BioShield (PBS) authorities. Disease outbreaks are often naturally occurring, including Ebola outbreaks in West Africa and the Democratic Republic of Congo (DRC), isolated cases of Marburg virus in Ghana, Sudan outbreak in Uganda, mpox outbreak in non-endemic countries, and the ongoing COVID-19 pandemic. Mass casualty incidents are also caused by intentionally engineered or naturally occurring Chemical, Biological, Radiological, and Nuclear (CBRN) threats, which continue to jeopardize national and global health security. As of January 2023, PBS funding has supported 36 products that are critical to the nation’s preparedness and response to these threats. Twenty-five of these MCMs have been delivered to the Strategic National Stockpile (SNS) or procured as vendor managed inventory with commercial stock rotation, with additional products to be delivered in FY 2023 and FY 2024. As of December 2022, 29 MCMs to detect, prevent, or treat CBRN threats have achieved Food and Drug Administration (FDA) approval, licensure, or clearance with additional approvals anticipated in FY 2023 and FY 2024.

The Project BioShield Act of 2004 (P.L. 108-276) provided specific authorities and funding through FY 2013 for late-stage development and procurement of CBRN MCMs. The law also provided the FDA with the legal ability to quickly authorize the 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. As a result of PAHPA, BARDA programs have generated unprecedented progress in the development and acquisition of products necessary to protect health during CBRN incidents and public health crises domestically and globally.

PBS funding purchases and maintains stockpiled products that are sufficiently mature for use under an Emergency Use Authorization issued by the FDA while continuing to support the late-stage development

of product candidates moving towards FDA approval. PBS funding also is 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 SNS programs work closely to align resources and timelines for transition of products.

Funding History	
Fiscal Year	Amount
FY 2020	\$735,000,000
FY 2021	\$770,000,000
FY 2022 Final	\$780,000,000
FY 2023 Enacted	\$820,000,000
FY 2024 President's Budget	\$830,000,000

Budget Request

The FY 2024 President's Budget request for Project BioShield is \$830,000,000, which is +\$10,000,000 above FY 2023 Enacted. The additional \$10 million will support procurement and continued replenishment of smallpox vaccine used during the mpox response. The FY 2024 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, including additional manufacturing requirements due to diversion of product to support the USG mpox response; advanced development and procurement of novel drugs to treat drug resistant bacterial infections; procurement of MCMs to treat injuries resulting from exposure to chemical threats including nerve agents, 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;
- Validation of manufacturing processes, and
- Post-marketing commitment and requirements from the FDA.

The funding amounts listed below reflect the cost of procurement as well as late-stage development activities. The FY 2024 request supports the eight investments listed below, which reflects the highest priority countermeasures for FY 2024.

- 1. New antimicrobial drugs to address biothreat pathogens (\$150 million):** In FY 2024, PBS funds will continue to be used to procure NUZYRA and up to three new antibiotic products. The inclusion of NUZYRA and three additional antibiotics will enhance the US Government's preparedness during public health emergencies and bioterrorism events caused by drug-resistant pathogens. Products may be maintained using vendor managed inventory (VMI) or delivered to the SNS.
- 2. Chemical MCM for nerve agent exposure (\$90 million):** FY 2024 funding will be used to continue procurements of Midazolam and 2-PAM autoinjectors for the SNS CHEMPACK program. Additionally, new and highly effective treatments for seizures resulting from nerve agent exposure that are resistant to currently stockpiled medications, as well as new drugs for

rescue from life-threatening opioid overdose, may become available and will be considered for procurement. Products may be delivered to the SNS, maintained using VMI, or be deployed via new and innovative strategies to ensure timely availability during a chemical emergency.

- 3. Late-stage development and procurement of smallpox antivirals (\$85 million):** PBS funding has supported the development and procurement of the oral antiviral TPOXX, which was approved by the FDA in 2018 for the treatment of smallpox. The IV formulation was approved in 2022. FY 2024 funds will support advanced development and procurement of a pediatric formulation of TPOXX as well as procurement of the IV formulation, which is essential for the treatment of severe disease. The procurement strategy aims to establish a stockpile of TPOXX (oral and intravenous) and develop the pediatric formulation of TPOXX to complement the existing TEMBEXA supply and replenishment activities for oral TPOXX in the SNS. Collectively, the shared PBS and SNS TPOXX procurements ensure that the federal government retains the capability to treat the majority of patients (oral formulation), those who cannot swallow (IV formulation), and patients under the age of 18 (pediatric formulation). In combination with the stockpile of the second antiviral (TEMBEXA), this approach avoids a single point of failure in the supply chain and provides healthcare providers with multiple options for therapeutic intervention.
- 4. Burn and Blast products (\$50 million):** FY 2024 funds will support pivotal validation studies to seek 510(k) clearance from the FDA for a novel imaging technology to aid emergency room and trauma surgeons triage burn victims as well as procurement of 100 devices that will be integrated into multiple burn and trauma centers for use in routine care as well as mass casualty incidents. This would transform the future burn triage using next generation non-invasive burn imaging technologies. Plans are under development to continue to procure allograft (cadaver) skin that will serve as a bridge to bolster preparedness for a mass casualty event involving large numbers of burn victims until next generation MCMs are developed and made available. Similarly, investment in burn care for products that can serve as temporary cover for large and/or deep burns when grafting is not feasible are planned. Funding will support pivotal clinical studies and eventual procurement of synthetic sheets with novel resorbable and biodegradable properties. The investments will ensure that the products remain in routine clinical use and available to well-trained physicians to effectively respond to a mass casualty event.
- 5. Smallpox vaccine (\$140 million):** In FY 2017, PBS funds procured several lots of Bavarian Nordic's IMVAMUNE smallpox vaccine, now referred to as JYNNEOS, in bulk (unviald) form. Significant funding was redirected from other programs to rapidly fill and finish 6.9 million bulk JYNNEOS doses originally designated for the lyophilization program to support the mpox response that began in the summer of 2022, so additional funding is needed to restore our preparedness for smallpox. In FY 2024, continued development is expected of a lyophilized formulation that possesses greater stability and a longer shelf life, and to procure additional vaccine in the liquid formulation if needed. Funds will be utilized to fill bulk substance as either the current liquid formulation or the lyophilized formulation (which have different fill prices) depending on the need and on licensure of the lyophilized formulation that is expected in 2024.

- 6. Therapies for acute ionizing radiation exposure (\$120 million):** Exposure to acute ionizing radiation can induce thrombocytopenia (low platelet count) 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. Additional products are expected to receive approval by FY 2024, which would allow for competitive sourced procurements of new products. Initial FY 2022 procurements only covered approximately 29 percent of the requirement for thrombocytopenia treatment courses, as some of the planned funding was diverted to address the mpox response. Funding will be used to procure additional treatment courses and continue VMI.
- 7. Biodosimetry/Biodiagnostics (\$45 million):** Funds will support late-stage activities for devices to detect ionizing radiation absorption in case of a nuclear detonation or release. Late-stage development, procurement, and manufacturing capacity for biothreat diagnostics needed for response to an outbreak or release of a biothreat agent (such as anthrax and Ebola) will also be supported.
- 8. Filovirus therapeutics (\$150 million):** FY 2024 funding will be utilized to continue the scale up manufacture, expanded clinical safety study, and pivotal preclinical studies supporting MBP134, a monoclonal antibody product developed for Sudan virus, with an aim of achieving BLA approval in 2028. MBP134 is the most advanced product in development for Sudan virus and also has strong efficacy against Ebola virus. Licensure of MBP134 would fill an unmet need in the USG portfolio of countermeasures against Sudan virus and serve as a risk mitigation against failure of either of the licensed Ebola virus therapeutics.

Program Accomplishments

Since FY 2005, BARDA has invested in 36 unique MCMs under PBS. Twenty-seven of these MCMs have been delivered to the SNS or procured as vendor managed inventory, including the MCMs listed below:

- 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 of symptomatic botulism;
- JYNNEOS vaccine for prevention of smallpox infection in people where replicating smallpox vaccines are contraindicated, and for mpox in healthy adults;
- TPOXX (oral and intravenous) for treatment of smallpox infection;
- Seizalam for treatment of status epilepticus (a common effect of nerve agents);
- Seven countermeasures for treatment of the effects of radiation exposure (Nplate, Neupogen, Leukine, Neulasta, Thyroshield, Ca-DTPA and Zn-DTPA);
- Nexobrid, RECELL, and StrataGraft, for treatment of injuries due to thermal burns;
- Silverlon, an antimicrobial wound dressing for treatment of skin injuries due to chemical, radiation, and thermal burns;
- ERVEBO vaccine for prevention of Ebola virus disease (*Zaire ebolavirus*);
- NUZYRA for treatment of anthrax and community-acquired bacterial pneumonia;

- Cefepime-taniborbactam for treatment of complicated urinary tract infections, bacterial pneumonia, and melioidosis, Immazeb for treatment of Ebola virus disease (*Zaire ebolavirus*); and,
- ZENEO-midazolam and ARAI-2PAM for treatment of nerve agent injury.

Based on the successful development of CBRN MCMs under the Advanced Research and Development (ARD) program, the advanced development and/or procurement of new CBRN MCMs under PBS by the end of FY 2024 will be supported. Since the inception of PBS in 2004, BARDA has awarded 36 contracts for late-stage development and procurement of MCMs. In FY 2024, BARDA will support the late-stage development, regulatory approval and initial procurements of MCMs under *existing* contracts to enable the potential use of these products during a declared public health emergency. BARDA will also invest in the late-stage development and procurement of six *new* MCMs, including those transitioning from BARDA's ARD portfolio as well others purchased from manufacturers. These MCMs will address a range of CBRN threats to national health security, including multidrug-resistant bacteria, nuclear and radiological threats, viral hemorrhagic fever viruses including Marburg virus, and opioids. The following promising candidates have the potential to transition to PBS in FY 2024:

- A novel antibiotic to treat multidrug-resistant bacterial infections and infection(s) caused by biothreat pathogens;
- One product to diagnose depth of burn injuries following a nuclear blast;
- A second MCM to treat thrombocytopenia following an ionizing radiation event;
- A monoclonal antibody therapeutic and small molecule drug for treatment of Marburg Virus infections;
- An improved treatment option for reversing the effects of opioid overdose and exposure to other pharmaceutical-based agents; and,
- A novel MCM for treatment of victims exposed to nerve agents.

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

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
2.4.14c Increase the number of medical countermeasures supported under Project BioShield (PBS) (Outcome)	FY 2022: 36 medical countermeasures Target: 30 medical countermeasures (Target Exceeded)	35 medical countermeasures	38 medical countermeasures	+3 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 2022: 25 medical countermeasures Target: 28 medical countermeasures (Target Not Met)	32 medical countermeasures	35 medical countermeasures	+3 medical countermeasures

Pandemic Influenza

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	292.991	327.991	374.991	+47.000
<i>No-year funding (non-add)</i>	265.000	300.000	347.000	+47.000
<i>Annual Funding (non-add)</i>	27.991	27.991	27.991	-
FTE	-	-	-	-

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

The global and domestic impact of the COVID-19 pandemic has been devastating. 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 (PI) 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 show markers of resistance to approved antiviral drugs, restricting therapeutic options for an infection with a case fatality ratio of approximately 40 percent. In the United States (US), Highly Pathogenic Avian Influenza A(H5N1) virus was detected in wild birds sampled in South Carolina in January of 2022. Since then, this virus has spread widely across most of North America and is approaching a record number of birds affected when compared to previous bird flu outbreaks. Avian influenza outbreaks continue in wild birds and poultry, including commercial poultry facilities, with sporadic infections in wild mammals. In April 2022, the Centers for Disease Control and Prevention (CDC) reported the first human infection with A(H5N1) in Colorado. These zoonotic infections with avian influenza signal the need for the US to 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. The unprecedented spread of A(H5N1) among wild birds throughout Canada and the United States will continue to infect backyard and commercial poultry, posing a persistent threat to human health in the upcoming influenza season.

The astonishing speed at which the SARS-CoV-2 virus spread from Wuhan, China and the continuing emergence of variants, demonstrates the immediacy with which Americans expect their government to respond and protect the public from new infectious diseases. The United States Government (USG) must continue to improve medical countermeasures (MCMs), including vaccines, therapeutics, diagnostics, and respiratory protection devices, while sustaining manufacturing capacity and supply chains so that MCMs are available when needed. It is essential that response capabilities are flexible and sustained to ensure an effective response to emerging pandemics. The lessons learned since the emergence of SARS-CoV-2 guide and shape the Pandemic Influenza (PI) portfolio.

Funding History	
Fiscal Year	Amount
FY 2020	\$252,991,000
FY 2021	\$279,991,000
FY 2022 Final	\$292,991,000
FY 2023 Enacted	\$327,991,000
FY 2024 President’s Budget	\$374,991,000

Budget Request

The FY 2024 President’s Budget request for PI is \$374,991,000, which is +\$47,000,000 above FY 2023 Enacted. The request includes \$347 million in no-year funding and \$27.991 million in annual funding for ASPR. The additional \$47 million in no-year funding will support additional investments on BARDA’s mRNA vaccine platform technology to support 2021 American Pandemic Preparedness Plan (APPP) goals and cover increasing sustainment costs for manufacturing capacity for pandemic response readiness.

Funds will be used to support the PI program’s twin pillars, which are: 1) PI preparedness and sustaining current response capabilities and also 2) developing the next generation medical countermeasures needed to significantly improve response capabilities. The first pillar includes sustainment while meeting previous investments in critical domestic influenza vaccine manufacturing facility infrastructure, maintaining and updating the pre-pandemic vaccine stockpile, and determining optimal antigen-adjuvant combinations. The second pillar consists of development of improved vaccines, therapeutics, and diagnostics, driven by lessons learned from COVID-19, and alignment with the Presidential Executive Order 13887, which modernizes influenza vaccines and the 2017 HHS Influenza Plan Update. Importantly, many of these activities, particularly development of platform-based vaccines, diagnostics, and broad-spectrum therapeutics, support the American Pandemic Preparedness Plan, and can be rapidly pivoted to address new and re-emerging infectious diseases.

The 2024 request sustains the preparedness capabilities that maintain domestic manufacturing capacity and operational readiness, pre-pandemic influenza vaccine and adjuvant inventories in the National Pre-pandemic Influenza Vaccine Stockpile as well as therapeutics readiness. Maintaining pre-pandemic influenza seeds, antigen, and adjuvant stockpiles while advancing domestic manufacturing capacity for licensed influenza vaccine platforms (cell-based, recombinant protein-, and egg-based antigen as well as MF59 and AS03 adjuvants) are essential to implement a rapid and effective USG response to control an emerging pandemic.

At the requested funding level, funds will support development and licensure of adjuvanted, next-generation influenza vaccines, therapeutics for pre-exposure prophylaxis and broadly acting, host-targeted therapeutics for acute respiratory distress syndrome and influenza. Recent investments in COVID-19 vaccines will be leveraged to develop nimble platform technologies towards licensure of more effective influenza vaccines that will accelerate the availability of safe and effective vaccines during a PI emergency. The COVID-19 response also emphasized the importance of effective therapeutics for pandemic mitigation. Investments will target therapeutics for pre-exposure prophylaxis that will close a gap in protection of the most vulnerable populations during the earliest phase of the pandemic until pandemic vaccines become available. In addition, funds will be used to initiate development of broad-spectrum, host-targeted therapeutics effective against influenza and Acute Respiratory Distress Syndrome (ARDS). These investments are needed to make more effective pandemic vaccines and therapeutics quickly and widely available, thus transforming our pandemic preparedness and response. The FY 2024 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 lowering transmission.

Annual Funding Request for FY 2024 (\$27.991 million)

Vaccine Stockpiling, Storage and Stability Testing (\$14.991 million): 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 million): Funds will sustain a key pillar of domestic influenza vaccine manufacturing capacity: maintaining a year-round supply of fertile chicken eggs to eliminate seasonality gaps in the supply chain for the egg-based vaccine manufacturing infrastructure. This effort includes a guaranteed year-round egg supply to support domestic manufacturing capacity of a licensed influenza vaccine for response to a pandemic. This annual manufacturing ensures the readiness of this manufacturing facility in Swiftwater, PA.

No-Year Funding Request for FY 2024 (\$347 million)

Facilities and Infrastructure Readiness and Sustainment (\$87 million): The FY 2024 funding will allow for continued sustainment of licensed, domestic manufacturing capacity, including adjuvant production, cell and egg based antigen production, and vaccine filling. The sustainment funding also includes support for annual manufacturing and capability testing of the licensed cell-based manufacturing facility in Holly Springs, North Carolina (NC). Collectively, these investments allow BARDA to maintain the targeted production goal of 660 million bulk antigen vaccine doses (FY 2023) that was achieved with previous investments by BARDA in capacity expansion, and exercise this response capability. Without

the sustainment of this capability, the year-round manufacturing capacity so critical to a PI response will be lost.

Influenza Therapeutics Advanced Development (\$50 million): The COVID-19 pandemic response has shown the importance of having a pre-exposure prophylaxis therapeutic agent to bridge the gap between recognition of a novel influenza pandemic and matched vaccine availability. In FY 2024, BARDA will continue the development of a pre-exposure prophylactic candidate after completion of the ongoing phase 2 study.

Improved Influenza Vaccine Advanced Development (\$185 million): The COVID-19 response validated key risk assessments and assumptions around preferred vaccine characteristics. The requested funds will address current PI response gaps and continue support for key initiatives aimed at producing more vaccine faster, operational improvements to enhance uptake and access, and provide better protection. The advancements include:

- Development of flexible, rapid platforms with smaller manufacturing footprints such as mRNA to allow a shorter time from sequence to first dose ready for vaccination coupled with ability to rapidly scale up and out;
- Development of adjuvants, devices, or other approaches/technologies that allow vaccine efficacy after a single dose instead of the current two-dose regimen);
- Assessment of whether a ‘universal prime’ vaccine could be developed to be used as a first dose while a second dose ‘matched’ vaccine is produced, enabling a mass vaccination campaign to start sooner; and,
- Exploration of improved antigen-adjuvant combinations to allow more doses to be produced faster in emergencies due to other emerging infectious diseases.

Influenza Diagnostics Advanced Development (\$25 million): Funding will be used to continue ongoing activities supporting rapid and specific diagnostic platforms for use in near-patient, point-of-need, and home settings. The goal of these activities will be to move towards fast, real-time, and in-home notification of positive influenza infections. With building on prior influenza investments, during the COVID-19 outbreak great strides were made in bringing diagnostic tests closer to the user, including in-home testing. The requested funds will primarily be utilized to expand the testing capability of those platforms to include simultaneous influenza testing, since during flu season it is important to differentiate influenza infection from COVID-19 infection in a single testing operation, develop additional home-use capable molecular testing platforms with the capability to detect more than three and hopefully four or more analytes in a single testing cycle, and begin further expanding platform manufacturing capacity for these home-use capable molecular testing platform. The end goal of these investments is to expand the availability of home-use capable molecular testing platforms and broaden the menu of tests that can be accomplish in a single testing cycle, to better inform routine disease differentiation and pandemic response.

Program Accomplishments

Strengthening Pandemic Influenza Preparedness

As of January 2023, the PI program has completed the following:

- Built dual-purpose infrastructure and capabilities that were utilized to support the COVID-19 response;
- Expanded the surge capacity of domestic vaccine manufacturing, while increasing its flexibility to help manufacture PI vaccines as quickly as possible;
- Improved technical knowledge and capacity for manufacturing in developing countries in order to increase global PI vaccine production capacity;
- Established, maintained, and continues to update the U.S. National Pre-pandemic Vaccine Stockpile (NPIVS) and implemented a mix-and-match clinical testing program;
- Developed a standard process to rapidly develop vaccine banks for different production platforms. As a result, multiple pre-pandemic influenza virus vaccine seed stocks are readily available for rapid vaccine production as the need arises, including against H5N1, H5N6, H5N8, and H7N9, and more are generated annually;
- Developed and purchased H5N1, H5N6, H5N8, and H7N9 influenza bulk vaccine antigen (the component of vaccine that stimulates the human immune system) for the BARDA-managed US NPIVS;
- Responded to the 2017 H7N9 influenza virus 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;
- Licensed new seasonal and PI vaccines using modern cell- and recombinant protein-based production technologies to expedite and expand domestic production capacity ;
- Supported improvements in assessment of the relative effectiveness of newly licensed influenza vaccines produced in cell culture or recombinant protein platforms as compared to traditional egg-based influenza virus vaccines;
- Developed, tested, and stockpiled 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;
- Established Vendor Managed Inventory of adjuvant in a public-private partnership. This includes ongoing 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 including investigating if early antiviral treatment can inhibit onward transmission of influenza;
- 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;
- Created a new program for the advanced research and development of pre-exposure prophylaxis therapeutic candidates for preventing both seasonal and pandemic influenza infection;
- Supported development of a half-life extended monoclonal antibody for the pre-exposure prophylaxis of both seasonal and pandemic influenza; clinical development is ongoing;

- Worked with the U.S. Food and Drug Administration (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;
- Advanced the development of sensitive diagnostic tests to detect influenza viruses that can be used in near-patient settings;
- Supported FDA clearance of point-of-care and home-use clinical diagnostics and strengthening of the agency's regulatory science capability to speed the approval process for new products;
- Supported the development of technology and processes that promote rapid production of N95 respirators;
- Made the first award to support the development of a pandemic influenza vaccine using a second-generation self-amplifying mRNA-based platform; and,
- Initiated a collaboration with the Department of Defense's Joint Program Executive Office (JPEO) to support the development of Influenza vaccines based on mRNA technologies and also test alternative routes of delivery (e.g., dermal, nasal, mucosal, etc.).

Cell-Based Influenza Vaccines: FDA licensed FLUCELVAX, which is the first cell-based influenza vaccine in the United States. ASPR's investments in the domestic manufacturing capacity for Flucelvax included supporting a facility in Holly Springs, NC. 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. FLUCELVAX is approved for use in persons ages six months and older. BARDA achieved manufacturing efficiencies that double the number of PI 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, CSL Seqirus licensed the first ever adjuvanted, cell-based influenza vaccine to protect against influenza A(H5N1) subtype, AUDENZ, which is indicated for use in persons six months of age and older. In 2023, CSL Seqirus will continue to clinically evaluate the safety, immunogenicity, and antigen-sparing capability of its cell-based and adjuvanted pre-pandemic influenza vaccine candidates, building on the AUDENZ platform technology.

Recombinant Vaccines: The PI program supported the first recombinant protein-based vaccine for seasonal influenza licensed in the U.S. 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. This Quadrivalent Influenza Virus Vaccine was approved by FDA in the winter of 2016. In June 2022, the CDC adopted the Advisory Committee on Immunization Practices' (ACIP) recommendation to preferentially recommend the use of specific flu vaccines for adults 65 years and older, including Flublok Quadrivalent and other higher dose and adjuvanted influenza vaccines. The PI program completed a clinical study to assess the safety and antigen-sparing potential of adjuvanted H7N9 recombinant influenza virus vaccine (Panblok H7) 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. The 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. The efforts laid critical groundwork, enabling the rapid development of the COVID-19 vaccines, which were produced at Sanofi's Pearl River, NY manufacturing facility, established as part of the Flublok program.

RNA-Based Influenza Vaccines: The PI program continues to support advanced development of RNA-based influenza vaccines. In FY2021, CSL Seqirus was awarded a task order to clinically assess the safety, immunogenicity, and dose-sparing capability of its next-generation self-amplifying mRNA pre-pandemic influenza vaccine candidate. The program has awarded a contract to Arcturus Therapeutics for the development of a second-generation RNA-based vaccine for seasonal influenza and for pandemic use. The program has also established a collaboration with JPEO to support the development of RNA-based influenza vaccines along with alternative routes of delivery for these vaccines that may expedite their administration during a mass immunization campaign. The first awards under this collaboration are targeted to be awarded using BARDA funds in early 2023.

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. 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. Adjuvanted formulations represent a major technological breakthrough for pandemic vaccine preparedness and were instrumental in producing an immunogenic vaccine during HHS's H7N9 vaccine responses. The first cell-based MF59-adjuvanted H5N1 influenza vaccine in the world, AUDENZ, was approved in 2020. Furthermore, an HHS Vendor Managed Inventory of MF59 adjuvant was established to include rotation of MF59 adjuvant inventory. Technology transfer of adjuvant production to a United States 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. The PI program is supporting the expansion of U.S.-based MF-59 adjuvant production capacity by 100 percent as part of the vaccine manufacturing expansion project at Sanofi's Swiftwater, PA facility described below.

Expedited Vaccine Availability: Under the Influenza Vaccine Manufacturing Improvement initiative 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 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. As a result, Sanofi has validated 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. The program also awarded a contract to Sanofi to expand domestic manufacturing capacity for the recombinant-based influenza vaccine at its Swiftwater, PA facility. This effort is in direct support of the Presidential Executive Order, “Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health.” Stage two of this effort was funded during 2020 with expansion of adjuvant production capacity, with work continuing on both antigen and adjuvant projects.

Providing New Influenza Antiviral Drugs for use in all populations: In a severe influenza pandemic, millions of Americans may need treatment in an outpatient setting to prevent onward transmission of the virus and prevent severe outcomes such as hospitalization and death. To ensure that efficacious antivirals are available, BARDA continues to support the advanced development of influenza antivirals. In FY 2022, BARDA continued support for one ongoing efficacy trial of a therapeutic candidate to reduce onward transmission of influenza to uninfected individuals. FY 2023 and 2024 funds will support ongoing and new programs to develop novel influenza antiviral drugs with a focus on broadly acting drugs that are active against influenza and potentially other viruses of pandemic potential.

Pre-Exposure Prophylaxis for Seasonal and Pandemic Influenza: There is a gap between recognition of an influenza pandemic and availability of a matched vaccine. Pre-exposure prophylaxis therapeutics that are active against seasonal and pandemic influenza could be used to bridge the gap for the highly exposed, such as healthcare workers, and most vulnerable, such as long-term care facility residents. In FY 2022, BARDA established the pre-exposure prophylaxis portfolio with a half-life extended monoclonal antibody active against both seasonal and pandemic influenza. A phase 2 study was supported through a new Other Transaction Agreement award. In addition, earlier development of novel technologies for pre-exposure prophylaxis such as expression of a broad acting antibody in a viral vector was supported on an existing Other Transaction Agreement. In FY 2023 and 2024, continued support of these platforms is expected with strong data and successful completion of milestones.

Advanced Research and Development of Acute Respiratory Distress Syndrome Therapeutics: In severe pandemics, millions of Americans could be hospitalized with influenza. To improve preparedness, protect health, and save lives during an influenza pandemic, BARDA will support the advanced development of host-targeted therapeutics for the treatment of acute respiratory distress syndrome caused by influenza. In FY 2023 and 2024, BARDA will make an award to establish a phase 2 clinical trial studying multiple drug candidates for the treatment of ARDS. This trial will lay the groundwork for phase 3 study design and establish patient populations most likely to benefit from candidate therapeutics. In

addition, BARDA expects to make one new award for the advanced research and development of an acute respiratory distress syndrome therapeutic ready to advance to phase 3 clinical trials.

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. Four of the platforms are now cleared by FDA, and two have designation that allows easier patient access and faster treatment decisions.

In FY 2020, Emergency Use Authorization was granted, and diagnostic tests delivered in support of the COVID-19 response by key home-use test developers. Though the original FDA Flu test filings were delayed due to exposure risk of medical personnel, one was filed in early FY 2023. During the COVID-19 response significant technical advances in product development and manufacturing capacity were made that accelerated market availability of these home-use tests. In FY 2020, funds were invested in network-based public health surveillance tools to better track disease outbreaks. Also, as part of the COVID-19 response, BARDA has invested in over 18 combination multiplexed COVID-19+Flu A/B diagnostic tests to help improve the nation’s preparedness for co-circulating influenza and SARS-CoV-2 infections. The majority of the tests are molecular based and two are used in home settings. Thus far, 4 products have received EUA from the FDA and three have been submitted for 510(k) clearance. In FY 2023 and beyond, the PI program 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 previous years.

Respiratory Devices and Ventilators: In 2019, FDA approved the Trilogy Evo Ventilator, a next-generation portable ventilator. This 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. The PI program also supported efforts at 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. In 2022, the prototype device was completed and achieved approval from the National Institute of Occupational Health and Safety for their non-cleanable mask.

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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
<p>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</p> <p>(Intermediate Outcome)</p>	<p>FY 2022: 600 million antigen doses</p> <p>Target: 600 million antigen doses</p> <p>(Target Met)</p>	<p>660 million antigen doses</p>	<p>660 million antigen doses</p>	<p>Maintain</p>
<p>2.4.15b</p> <p>Continue advanced research and development initiatives for more effective influenza vaccines manufactured using modern, flexible, agile technologies, and the development of influenza therapeutics for use in outpatient and hospital settings, including pediatric patients</p> <p>(Intermediate Outcome)</p>	<p>FY 2022: 2 programs</p> <p>Target: 2 programs</p> <p>(Target Met)</p>	<p>3 programs</p>	<p>3 programs</p>	<p>Maintain</p>

Strategic National Stockpile

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	845.000	965.000	995.000	+30.000
FTE	329	329	329	-

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

The Administration for Strategic Preparedness and Response (ASPR) Strategic National Stockpile (SNS) program manages and delivers life-saving [medical countermeasures \(MCM\)](#)²⁸ during a public health emergency. It is the largest federally owned repository of pharmaceuticals, critical medical supplies, [Federal Medical Stations \(FMS\)](#),²⁹ and medical equipment available for rapid delivery to support federal, state, and local response to health security threats. If a chemical, biological, radiological, or nuclear (CBRN) event occurred on United States soil today, the SNS is the primary federal resource readily available to respond. During the most recent ASPR reorganization, the SNS was elevated to a standalone office reporting directly to the ASPR to increase its visibility and accountability within the organization.

Strategic procurement and stockpiling of MCMs are necessary to protect the health and save the lives of those impacted by a public health emergency. Medical countermeasures are Food and Drug Administration-regulated (FDA) products (biologics, drugs, and devices) that can be used to diagnose, prevent, protect, or treat conditions associated with CBRN threats or emerging infectious diseases. Some MCMs are not commercially available because of small supplies and limited use. Additionally, United States pharmaceutical supply chains run on a just-in-time model, often containing no more than a 30-day supply of pharmaceuticals under normal conditions. As a result, commercially available products may not exist in necessary quantities or be positioned in ways that allow rapid distribution and use during public health emergencies. For some threats, such as anthrax and botulism, the SNS holds the primary supply of scarce MCMs necessary for effective treatment. The rapid delivery of MCMs from the 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. To operate successfully during nationwide public health emergencies, the SNS, and our state and local partners, must have opportunities to exercise proficiency on smaller scales.

²⁸<http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm>

²⁹<https://aspr.hhs.gov/SNS/Pages/Federal-Medical-Stations.aspx>

SNS 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 collaboration with the FDA, ASPR seeks to maximize the value of SNS funding through the Shelf-Life Extension Program (SLEP) and other methods. 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.

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. 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.

Within ASPR, SNS is responsible for deploying and providing technical assistance to State, Local, Tribal, and Territorial (SLTT) jurisdictions setting up FMS. FMS are traditionally requested in response to natural disasters, like Hurricane Maria, but were also deployed to provide surge hospital capacity during the COVID-19 response. Once set up, FMS are often run by U.S. Public Health Service personnel. 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.

Funding History	
Fiscal Year	Amount
FY 2020	\$705,000,000
FY 2021	\$705,000,000
FY 2022 Final	\$845,000,000
FY 2023 Enacted	\$965,000,000
FY 2024 President’s Budget	\$995,000,000

Budget Request

The FY 2024 President’s Budget request for SNS is \$995,500,000, which is +\$30,000,000 above FY 2023 Enacted. The FY 2024 request prioritizes funding for sustainment of current product lines and procurement of products previously supported by BARDA that lack a significant commercial market. Specifically, the increase included in this year’s request will ensure that the USG is better prepared to respond to a potential radiological or nuclear event occurring on American soil. With the requested increase, SNS plans to procure certain anti-neutropenic drugs necessary to treat acute radiation syndrome which are scheduled to transition from BARDA to SNS procurement in FY 2024.

Product procurement in FY 2024 will be guided by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which was relaunched in February 2022, and related multiyear prioritization as coordinated by ASPR through the development of strategies and implementation of activities to meet the national priorities for federal stockpiling, maintaining SNS capabilities, and addressing 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 for partners on the ground. Using lessons learned during the pandemic, ASPR will maintain training and exercise support in FY 2024 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.

The requested funds will ensure SNS assets are available and ready for use to protect America from 21st century health security threats in FY 2024 by:

- Managing, storing, maintaining, and replacing MCM assets, valued at over \$13.2 billion;
- Supporting PHEMCE with subject matter expertise and data to inform strategic MCM requirements and procurement decisions;
- Establishing and strengthening public-private partnerships to integrate private resources into public health response plans for a fully functioning supply chain for delivery of critical MCMs;
- Providing timely, accurate, and relevant information to clinicians to respond to emerging threats and public health emergencies;
- Improving Tribes, tribal organizations, and urban Indian organizations' access to medical supplies held in the SNS; and,
- Supporting SLTT preparedness through increased training, exercises, and information sharing using lessons learned from the COVID-19 pandemic.

SNS Projected Allocations¹

	FY 2023 Enacted		FY 2024 President’s Budget	
	Requested	Percentage of Total Budget Account	Requested	Percentage of Total Budget Account
Total	\$965.0M	100%	\$995.0M	100%
Product				
Product Total	\$811.7M	84.1%	\$848.8M	85.3%
Procurement Total	\$471.8M		\$701.9M	
<i>Procurement – New²</i>	<i>\$72.2M</i>		<i>\$162.8M</i>	
<i>Procurement – New (above replenishment)³</i>	<i>\$376.2M</i>		<i>\$266.7M</i>	
<i>Procurement – Replenishment</i>	<i>\$23.4M</i>		<i>\$272.4M</i>	
Sustainment Total ⁴	\$339.9M		\$146.9M	
Warehousing Costs	\$277.2M		\$78.8M	
Operations				
SNS Operational Costs ⁵	\$153.3M	15.9%	\$146.2M	14.7%

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 \$13.2 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.

Program Accomplishments

Ongoing COVID-19 Response

The SNS began supporting the federal response to COVID-19 on January 30, 2020. During the early stages of the response, SNS primarily supported the repatriation mission deploying 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 of 2020, SNS began distributing PPE to the 62 Public Health Emergency Preparedness (PHEP) jurisdictions, which included all 50 states, four large metro areas and eight territories and islands. HHS leadership determined the distribution strategy based on a pro rata allocation. Allocations from SNS included N95 respirators, face masks, face shields, gowns, gloves, and coveralls.

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 ventilators and High Flow Nasal Cannulas (HFNC) to 18 states.

In January 2022, in response to a surge of COVID-19 cases related to the Omicron variant, [SNS began deploying NIOSH-certified N95 respirators to the American public](#). These respirators were available for pick-up at retail pharmacies and community health centers nationwide. In total, more than 282 million N95 respirators were distributed through this program.

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 used 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. The ancillary kitting operation required specific product components and configurations for each of the multiple COVID-19 vaccine candidates. SNS and the contractor have configured and built a multitude of unique ancillary kits to support administration of four separate COVID-19 vaccines approved and authorized for emergency use by the FDA. As of December 13, 2022, approximately 8.1 million vaccine ancillary and mixing kits have been produced, enough for 1.3 billion COVID-19 vaccinations. ASPR transferred responsibility for funding, production, management, and distribution of ancillary kits to H-CORE.

Rebuilding SNS's Inventory of PPE to Support Pandemic Threats

SNS continues the replenishment and expansion of the Stockpile through COVID-19 supplemental funding to ensure that national MCM needs are met. This investment has enhanced ASPR's capability to respond to current and future pandemics. As of December 15, 2022, SNS has obligated more than \$11.3 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 expanding 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.

Item	Deployable Quantity
N95 Respirators	537 million
Masks (Surgical/Procedure)	244 million
Eye/Face Shields	18.9 million
Gowns/Coveralls	51.5 million
Gloves	4,486 million
Ventilators	158,000

SNS notes that PPE procured during the COVID response has begun to expire so the table represents the upper limit of what is available for deployment as of December 15, 2022.

Mpox Response

On May 18, 2022, the first case of mpox was confirmed in the US. A public health emergency was subsequently declared on August 4, 2022, and renewed for the final time on November 2, 2022. During the mpox response, SNS worked closely with partners across HHS as well as the private sector to respond to the outbreak. Notably, all Jynneos vaccine deployed by SNS to respond to the mpox outbreak had been procured by Biomedical Advanced Research and Development Authority (BARDA). Additionally, SNS has worked closely with the Centers for Disease Control and Prevention (CDC) to ensure that vaccines and therapeutics are reaching the people who need them. Finally, SNS is working closely with the CDC and FDA to ensure that all medical countermeasures deployed by the SNS are supported by and distributed in compliance with appropriate regulatory guidance.

As part of the Administration's mpox response, the SNS supported efforts to:

- Distribute over one million doses of Jynneos to jurisdictions for vaccination efforts;
- Distribute over 80,000 bottles of oral TPOXX antiviral to treat mpox patients as well as 12,000 vials of IV TPOXX; and
- Distribute limited quantities of VIGIV, Tembexa, and ACAM2000 in support of the mpox response.

All countermeasures were provided to jurisdictions free of charge.

Public health efforts have led to a greater than 95 percent reduction in mpox incidence since the peak of the outbreak and more than one million doses of free vaccine have been administered thus far. Mpox continues to be a priority for HHS, and SNS will continue to support distribution of vaccines and treatments to affected individuals in an equitable manner for as long as necessary.

SNS Support for Small-Scale Events

SNS has demonstrated its ability to simultaneously respond to multiple events by responding to a number of additional smaller events including hurricanes, National Special Security Events, and the Unaccompanied Children Mission, while simultaneously supporting larger missions such as the COVID-19 and mpox responses.

In 2020 and 2021, amid the COVID-19 pandemic response, the SNS responded to three major hurricanes -- Hurricane Laura, Hurricane Delta, and Hurricane Ida -- as part of the overall HHS response and

recovery operations to support people displaced by the storms and affected by ongoing public health concerns.

In July 2021, SNS deployed tecovirimat to treat an internationally traveling patient with a case of mpox. 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.

In August 2022, SNS provided rapid delivery of Inmazed, an Ebola therapeutic MCM, which was used to successfully support post-exposure prophylaxis for a laboratorian.

In December 2022, SNS made additional supplies of Tamiflu available to jurisdictions to respond to an increased demand for the antiviral during this flu season. These efforts continued into 2023.

SNS Support for Tribes, Tribal Organizations, and Urban Indian Organizations

In accordance with EO 14001 SNS is working with interagency partners, including the Indian Health Service (IHS), FEMA, and CDC to improve tribal access to critical medical supplies from SNS and other federal support agencies. During 2022, the interagency workgroup developed a comprehensive set of recommendations outlining multiple alternative routes for tribal and Urban Indian Organizations (UIOs) to access the SNS. SNS hopes to finalize these recommendations in 2023 pending stakeholder review and feedback from tribal leaders. The ASPR has also met with Tribes, tribal organizations, and urban Indian organizations, via the Secretary's Tribal Advisory Committee, to better illuminate how Tribes, tribal organizations, and urban Indian organizations can access supplies and technical assistance from the SNS.

Global Impact

SNS expertise in MCM supply chain optimization and logistics planning is a valued global health resource. In coordination with CDC's Center for Global Health in support of the Global Health Security Agenda, SNS re-engaged with planners from Senegal and Liberia on pre-COVID MCM plans, providing technical assistance to the countries as they seek to finalize national MCM supply chain response plans projected for validation in 2023. Additionally, SNS provided post-validation consultation and technical assistance in supply chain operations and plan development for Sierra Leone, Guinea, and Nigeria.

SNS continues to be in close contact with Ukrainian health officials as they seek medical countermeasure guidance and support.

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 2022, SNS continued to expand web-based and virtual training opportunities, allowing more than 21,000 stakeholders to participate in training opportunities in FY 2022. Growth in the uptake of SNS training materials was due to continued interest in [FMS training videos](https://aspr.hhs.gov/SNS/Pages/SNS-Training-Videos-FMS.aspx)³⁰, posted to YouTube which were viewed more than 18,000 times in FY 2022. In total, SNS provided training for 21,106 SLTT partners during 2022 through the efforts listed below.

³⁰ <https://aspr.hhs.gov/SNS/Pages/SNS-Training-Videos-FMS.aspx>

- 18,838 stakeholders viewed FMS training videos, available on YouTube in both English and Spanish.
- 1,199 stakeholders participated in virtual training on topics including SNS Overview; SNS Risk Communication; Developing MCM Response Plans; Training, Exercise, Evaluating Plans; and other topics.
- 540 stakeholders participated in webinars on topics including SNS Formulary; Introduction to the Strategic National Stockpile; Crisis and Risk Communications; and other topics.
- 529 stakeholders participated in a mix of in person and virtual courses including SNS Operations Response.

In 2021, SNS partnered with the American Association for Respiratory Care (AARC) to develop SNS-held ventilator training for 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 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. 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.

SNS also partnered with the AARC to develop 15 demonstration videos for SNS-held ventilators. Each video offers a demonstration on how to set-up and start mechanically ventilating a patient. The videos are housed on the [AARC SNS webpage](#)³¹ as well as the [ASPR webpage](#)³².

Prior to the COVID-19 pandemic, full-scale exercises were 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 PHEP cooperative agreement. This work was put on hold during the COVID-19 pandemic. As part of the SNS Transformation Plan, SNS is reengaging with jurisdictions using lessons learned during the pandemic in order to improve response capability necessary to respond to future public health emergencies.

SNS Transformation Plan and Related Activities

In accordance with EO 14001, "On a Sustainable Public Health Supply Chain," and the supporting "National Strategy for a Resilient Public Health Supply Chain", SNS is currently working with partners across HHS as well as interagency partners to ensure that the nation is better prepared to respond to future public health threats. ASPR is currently working to finalize the SNS Transformation Plan and hopes to share the final plan with Congress soon. As work to finalize the SNS Transformation Plan continues, SNS began critical implementation work necessary to improve the response capacity of SLTT jurisdictions and private sector partners.

³¹ <https://www.aarc.org/resources/clinical-resources/strategic-national-stockpile-ventilator-training-program/>

³² <https://aspr.hhs.gov/SNS/ventilators/Pages/default.aspx>

Specifically, SNS began work on projected plan initiatives to redefine SNS's support to SLTT partners based on lessons learned during the COVID-19 response. SNS conducted internal SNS After-Action Review workshops to analyze SNS's support to COVID response missions. SNS also developed a Corrective Action Plan with supporting annexes to identify and implement corrective actions, and to update SNS training modules and exercise scenarios to support SLTT partners' preparedness.

Once these initial steps were complete, SNS began work to strengthen its long-standing support to SLTT partners through expanded training and technical assistance drawing upon the lessons of the COVID-19 response. SNS began planning to conduct hands-on training and exercises with SLTT partners on best practices for requesting and receiving medical supplies and devices learned during the COVID-19 response. SNS also began planning and coordination to conduct SNS-SLTT engagement summits to update SLTT partners on the evolution of the SNS mission and operational concepts resulting from lessons learned during the COVID-19 response, and to solicit feedback from partners on potential enhancements to SNS mission capabilities. As of December 15, 2022, SNS has conducted regional summits with two regions. SNS expects to conduct regional summits with the remaining eight regions in 2023.

In addition to work with SLTT partners, significant work is being done with private sector partners in support of the SNS Transformation Plan. This work includes developing collaborations with medical manufacturers and distributors, including McKesson, Cardinal, Becton Dickenson, Medline, Amerisource Bergen, Henry Schein, Concordance, FedEx, United Parcel Service and the United States Post Office. Such collaborations build on the COVID-19 response and enable:

- A more comprehensive understanding of manufacturing capacity;
- The utilization of multiple distribution methodologies; and
- Incorporating more commercial participation with partners that leverage their storage and distribution strengths.

Inventory Management and SLEP

In FY 2022, SNS sustained a 96.75 percent inventory accuracy rate, a significant increase over the 90.04 percent rate achieved in FY 2021. 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 \$13.2 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. This growth continued in FY 2022; as of March 2022, SNS held approximately two and a half times the storage capacity it held at the beginning of the pandemic. In addition to the new and expanded warehouses in the SNS storage network, SNS contracted for a significant number of vendor managed inventory (VMI) pallet positions to hold,

maintain, and distribute Personal Protective Equipment (PPE), ventilators, and pharmaceuticals procured to respond to the COVID-19 pandemic.

ASPR works with FDA to test stability of drugs approaching labeled expiry through SLEP. 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. 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. Working in collaboration with FDA, an additional extension of expiration dates for stockpiled antivirals was granted outside of SLEP in April 2022.

SNS Coordination with Industry Partners

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, HIDA, International Safety Equipment Association (ISEA), Healthcare Distributors Association (HDA), National Association of Chain Drug Stores (NACDS), SMI, and HSCA. These partnerships improve the resiliency of the SNS through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to PPE;
- Improved public access to MCMs;
- Redundant distribution capacity for MCMs, information, and materiel, ensuring 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;
- Education on challenges associated with over-ordering or hoarding of needed materiel during a public health incident;
- Improved situational awareness of inventory levels, shortages, and near real-time product tracking through the ASPR's Supply Chain Control Tower; and
- Collaboration on complex joint distribution problems.

The resiliency of the SNS is closely linked to the resiliency of the commercial supply chain. In 2022, SNS continued work with major industry trade associations. SNS had 84 engagements with industry partners, including Health Industry Distributors Association (HIDA), Healthcare Supply Chain Association (HSCA), and Strategic Marketplace Initiative (SMI), to discuss anticipated challenges and potential opportunities for improved communication, coordination, and continuity between ASPR, SNS, and the commercial sector 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.

As a result of these meetings, SNS is working with HIDA on a project to improve response and manufacturing production as well as identifying key ramp down periods that will improve response times and reduce the need to hold excess inventory as a public health emergency ramps down.

In May 2022, SNS hosted a 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 creating 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. Efforts continue to automate this information in the Supply Chain Control Tower as a single source of information shared across the entire industry leading to better decision making and balancing supply and demand.

Additionally, in 2022 and 2023, SNS and SMI are reviewing best practices at the state level focused on unique and successful distribution of PPE in North Carolina. The review can hopefully be expanded over time and used in other jurisdictions. The goals of this effort include:

- Understanding how the eight separate Healthcare Coalitions collaborated with the healthcare sector and state emergency management to provide status updates, PPE distribution, and support to rural hospitals;
- Exploring the practices and efficiencies of large hospital systems supporting rural and community healthcare by providing PPE and medical materiel they were able to acquire through commercial and federal government stockpiles; and,
- Understanding the role of the commercial supply chain, specifically medical distributors, in triaging, distributing, and coordinating across local providers through the state and federal response.

SNS is committed to continuing work with our commercial partners. In 2023, SNS will attend and present information to our partners during the National Association of County and City Health Officials (NACCHO) Preparedness Summit on resiliency, best practices, data sharing, and collaboration across the entire public/private partnership. The lessons learned during the COVID-19 response show how coordination across the entire commercial supply chain benefits the United States. Interest in partnership remains strong with future commitments from each of these associations and partners to continue to work towards a more transparent and efficient supply chain. The goals of this effort include:

- Standardize the data reporting and situational awareness that can be provided in near-real time;
- Improve supply chain resilience;
- Maximize distribution modalities and the seamless integration with the SNS or other federal agencies;
- Ensure collaboration; and,
- Work to build a Center of Excellence to gather, share, and act as a repository for each of our successes.

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

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
13.4.6 Percentage of inventory accuracies that are attained by using quality inventory management systems. (Outcome)	FY 2022: 96.75% Target: 90% (Target Exceeded)	97%	97%	Maintain
13.4.7 Maintain the safety and efficacy of medical supplies SNS inventory (Outcome)	FY 2022: 100% Target: 100% (Target Met)	100%	100%	Maintain
13.4.8 Maintain the response rate of recall capability (Intermediate Outcome)	FY 2022: 99.9% Target: 95% (Target Exceeded)	95%	95%	Maintain
13.4.9 Increase the number of participants trained by SNS (Intermediate Outcome)	FY 2022: 21,186 trained ¹ Target: 1,500 trained (Target Exceeded)	1,500 trained	1,500 trained	Maintain

¹Total includes more than 18,000 views of FMS training posted to YouTube.

HHS Coordination Operations and Response Element

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	-	75.000	82.801	+7.801
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

Administration for Strategic Preparedness and Response’s (ASPR’s) mission is to assist the country in preparing for, responding to, and recovering from public health emergencies and disasters. The nation faces diverse and ever-changing threats to public health security. Recent events, including COVID-19, Ebola and Marburg outbreaks in Africa, domestic mpox cases, and the threat of use of chemical, biological, radiological, and nuclear agents, all underscore the importance of investing in diverse logistical and response capabilities.

H-CORE was born out of the joint COVID-19 medical countermeasures response led by HHS and the Department of Defense, and transitioned in December 2021 to be permanently housed within the ASPR. The vision and mission for H-CORE is to provide dedicated operational and logistics capability to respond to novel and emerging public health events.

The Consolidated Appropriations Act of 2023 provided annual funding to H-CORE, representing the first annual appropriation for the program, to ensure the organization continues to build enduring operations and logistics capabilities, and is ready to execute missions beyond COVID-19 investments and efforts. H-CORE will support efforts to ensure there is an adaptable, reliable, and resilient public health emergency response in place to aid future efforts, as needed, to address existing and emerging threats to public health.

Funding History	
Fiscal Year	Amount
FY 2020	-
FY 2021	-
FY 2022 Final	-
FY 2023 Enacted	\$75,000,000
FY 2024 President’s Budget	\$82,801,000

Budget Request

The FY 2024 President's Budget request for H-CORE is \$82,801,000, which is +\$7,801,000 above FY 2023 Enacted. The increased funding will:

- Support modernizing and improving H-CORE's operations and logistics architecture and the underlying information technology and analytics infrastructure to enable a resilient and - interoperable, surge-capable ordering, allocation, and distribution ecosystem for public health supplies that can pivot to meet any response.
- Pilot novel/innovative operations and logistics capabilities to enable rapid distribution of materiel required in an emergent public health response.
- Evolve, exercise, and demonstrate data, analytics, and assessment tools to take advantage of rapidly emerging new data sources and technologies that provide information regarding health, health safety, and health security.

In FY 2024, H-CORE's capabilities will pivot to non-COVID-19 priorities with a focus on operations and logistics response capability for a range of new and emerging public health threats. H-CORE's readiness to provide operational and logistics response in this evolving threat landscape relies on modernization, flexibility, and scalability in H-CORE's data and analytics platforms, ordering and inventory management tools, business operations processes, and distribution and partner networks.

The FY 2024 request will be used in four key areas:

1. **Operations and Logistics, Infrastructure, and Modernization:** Will fund sustaining and improving operations and logistics architecture and the underlying IT and analytics infrastructure (such as Tiberius and Health Partner Ordering Portal (HPOP)).
2. **Assessment Capability and Analysis:** Will fund expanding internal and external analysis and assessment capabilities and development of repeatable security, intelligence, and compliance assessments and reviews for H-CORE and, more broadly, for ASPR.
3. **Sustain Readiness and Initiatives:** Will fund steady state efforts including development of repeatable processes for future operations, training and exercising for operations and logistics missions, and sustainment, enhancement, and expansion of partnerships.
4. **Human Capital:** Will fund federal employee salary and benefits, supports contracts, and enhances workforce development and training. H-CORE will invest in its workforce to ensure it can meet future challenges.

Program Accomplishments

Since its inception, some specific H-CORE successes include:

- Conducting allocation planning and execution for 14 COVID-19 vaccine rollouts and campaigns in coordination with Biomedical Advanced Research and Development Authority (BARDA) and the Centers for Disease Control and Prevention (CDC), totaling more than 300 million vaccine doses distributed, and end-to-end management, partner education, and distribution of 8 therapeutics, including more than 13.9 million treatment courses distributed nationwide.

Administration for Strategic Preparedness and Response

- Implementing partnerships with ASPR's Testing and Diagnostics Working Group and the United States Postal Service, leading first-of-its kind efforts to distribute more than 740 million at-home test kits via the U.S. mail, including more than 40 percent of kits sent to vulnerable communities;
- Rapidly developing and continuously improving the functionality of the Health Partner Ordering Portal (HPOP) to enable shipment of twenty different vaccines and at least five different therapeutics to more than 40,000 different locations across the country with a nearly 100 percent successful fulfillment rate; then rapidly modified HPOP within three weeks in support of the mpox response to enable ordering, inventory management and data acquisition of mpox vaccines and therapeutics.
- Providing technical assistance, helpdesk support, and clinical and pharmacy education, in collaboration with other ASPR and CDC subject matter experts, in response to more than 4,200 requests for information regarding the COVID-19 pandemic and mpox;
- Establishing collaborative relationships with hundreds of partners across 14 federal entities, 64 jurisdictions, and nearly 20 retail pharmacy chains to support administration of medical countermeasures. Today, more than 90 percent of U.S. residents live within five miles of at least one of the more than 70,000+ sites where they can receive an updated COVID-19 vaccine, and nearly as many can easily reach the more than 40,000 therapeutics providers across the country.

Policy and Planning

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
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

The Administration for Strategic Preparedness and Response (ASPR) is committed to the highest level of policy development and planning to assist the Nation in preparing for, responding to, and recovering from public health emergencies and disasters. ASPR policy and planning ensures that evidence-based strategy and policy underpin ASPR’s life-saving work. Policy and planning carries out this mission by providing strategic alignment, legislative analysis, and targeted policy implementation and development to ensure programs operate in accordance with ASPR’s wider strategic goals, administrative priorities, and statutory requirements.

ASPR policy and planning oversees a strategic approach to ASPR priorities and provides an anticipatory, long-term perspective on national health security to advance preparedness and response initiatives for the ASPR and the Secretary of the Department of Health and Human Services (HHS). This work includes the development of recurring reports, such as the five-year ASPR Strategic Plan, the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan (PHEMCE SIP), and three statutorily required quadrennial Nation Health Security Strategy (NHSS) documents: the Strategy, the Implementation Plan, and the Evaluation of Progress of the previous NHSS.

ASPR policy and planning ensures that ASPR continues to carry out mission critical work identified in long term strategies such as the 2022 National Biodefense Strategy, the 2020-2030 National Influenza Vaccine Modernization Strategy, the 2021 National Strategy for a Resilient Public Health Supply Chain, the 2022 Biotechnology and Biomanufacturing Initiative, and the PHEMCE SIP.

ASPR policy and planning formulates and implements national health security, biodefense, and public health and medical preparedness and response policy, including the integration and oversight of ASPR policies to achieve national health security objectives. ASPR policy engagements include situational analysis of several established statutory response authorities, such as Public Health Emergency (PHE) declarations, Emergency Use Declarations, and Public Readiness and Emergency Preparedness (PREP)

Act declarations, as well as establishing new policy frameworks through White House policy coordination and National Advisory Committees.

ASPR policy and planning leads and conducts integrated strategic planning in coordination with federal interagency partners to prepare for and respond to future emergent and anticipated health security threats, to limit adverse health impacts of emergencies and disasters. This work includes providing real-time decision support to HHS leadership and guidance to Public Health and Medical Emergency Support Function 8 (ESF-8) partners during responses to national security incidents and public health emergencies. This is accomplished through coordination of strategies, policies, and plans to facilitate effective and efficient response in support of state, local, tribal, and territorial jurisdictions.

ASPR policy and planning establishes capability-based and materiel requirements for development and acquisition of security countermeasures and non-materiel solutions to close critical health security gaps in the ASPR’s national security mission. Development of requirements is not only good practice but is mandated in part by the BioShield Act of 2004 and the Federal Acquisition Regulation. ASPR takes a strategic approach to requirements, focusing not only on security countermeasures, but all aspects of the capabilities that must be developed to meet the ASPR’s national security mission. Through a best-practices approach leveraging experiences from DOD, HHS and PHEMCE, ASPR focuses on capabilities that are flexible and can be broadly applicable to the needs of all components of ASPR’s response mission, including natural disasters, chemical, biological, radiological, and nuclear (CBRN) incidents, and emerging infectious diseases that threaten national security. ASPR reviews and validates approved requirements and develops requirements for capabilities and security countermeasures, equipment, and supplies for future national security threats including emerging infectious diseases (EID) and intentional CBRN threats. ASPR policy and planning also leverages quantitative modeling tools to help ensure ASPR is addressing the most significant threats to health security and implementing the most impactful and cost-effective solutions.

ASPR policy and planning oversees administration of the PHEMCE to assist in ASPR’s mission critical preparedness work. The PHEMCE is statutorily tasked with making recommendations to the Secretary of HHS regarding advanced research, development, procurement, stockpiling, distribution, and utilization of security countermeasures; identifying national health security needs; and supporting development of strategies for logistics, deployment, distribution, dispensing of countermeasures, particularly as it relates to the Strategic National Stockpile (SNS).

Funding History	
Fiscal Year	Amount
FY 2020	\$14,877,000
FY 2021	\$14,877,000
FY 2022 Final	\$14,877,000
FY 2023 Enacted	\$14,877,000
FY 2024 President’s Budget	\$21,417,000

Budget Request

The FY 2024 President’s Budget request for Policy and Planning is \$21,417,000, which is +\$6,540,000 above FY 2023 Enacted.

Within the increase, ASPR will establish quantitative and economics analytics and modeling capabilities to evaluate security countermeasure programs and establish future capabilities-based and materiel requirements for security countermeasures.

We are living in an increasingly interconnected world where diseases and other threats can travel quickly, unnoticed for days. In addition, emerging infectious diseases with national security implications are becoming more frequent and natural disasters more deadly as a result of the increasing changes to our climate. To keep up with the evolving threat landscape, ASPR must remain nimble and ever vigilant while learning from each response it leads. Improved modeling capabilities will allow ASPR to prepare for future national security health threats to the American people – no matter what they might be.

Robust quantitative modeling tools will help ensure ASPR is addressing the most significant threats to national security and implementing the most impactful and cost-effective solutions. The requested modeling capabilities will enable ASPR to (1) estimate and compare the consequences of incidents and attacks involving national security threats such as biological, chemical, radiological, and nuclear agents as well as emerging infectious diseases of pandemic potential; (2) quantify the range of personnel, medical countermeasures, and other resources needed to protect and treat the affected populations, and (3) establish capability-based and materiel requirements for mission capabilities and security countermeasures to respond to future national security threats.

Economics analytics and modeling capabilities will provide early decision support to guide the Department's investments in support of its mission to enhance the health and well-being of all Americans while maintaining the highest standards of fiscal responsibility. These capabilities also support medical countermeasure planning for PHEMCE partners across the federal interagency. Systematic prioritization would allow ASPR to effectively harmonize and direct resources against the highest priority threats and establishing requirements that drive security countermeasure development and procurement for those priorities.

Funding will maintain ASPR policy and planning activities which ensure operational preparedness and response capabilities align with HHS and ASPR's priorities. ASPR will continue developing 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 White House National Security Council, and other leaders. ASPR policy and planning activities will also lead operational planning and requirements setting efforts, in coordination with a broad cross section of public health preparedness stakeholders.

Program Accomplishments

National Health Security Strategy (NHSS)

ASPR policy and planning led the development of three statutorily required quadrennial NHSS documents: the Strategy, the Implementation Plan, and the Evaluation of Progress of the previous NHSS. The *NHSS 2023-2026* presents a unique opportunity to reflect on lessons learned in the ongoing COVID-19 pandemic and focus the Nation's priorities to address evolving public health challenges and be better

prepared for future health security threats. ASPR policy and planning conducted an extensive public engagement effort, including an official Federal Register Notice, to ensure that diverse stakeholder perspectives were used to drive innovative solutions to challenges in public health and medical preparedness, response, and recovery faced across the United States. The *NHSS, 2023-2026 Implementation Plan* serves as a framework to guide federal action and recommend implementation activities for SLTT partners, private industry, and communities. The *NHSS Evaluation of Progress, 2019-2022* highlights activities undertaken by the United States to meet the objectives of the 2019-2022 NHSS.

Response Policies and Authorities

ASPR conducted rapid response policy research and policy analysis to support key decision-making related to issuing any of these declarations or subsequent amendments. ASPR supported HHS in its use of these authorities to address significant national issues.

- From the start of the COVID-19 pandemic through the end of FY 2022, the Secretary of HHS issued over thirty Public Health Emergency (PHE) declarations including COVID-19, mpox, extreme flooding, and the opioid crisis.
- Between early CY 2020 and the end of FY 2022, HHS issued thirteen Public Readiness and Emergency Preparedness (PREP) Act declarations and amendments to facilitate a rapid response to the COVID-19 pandemic.
- Section 564 of the Food, Drug and Cosmetic Act provides HHS greater flexibility to authorize the Food and Drug Administration to issue an Emergency Use Authorization (EUA). In 2020-2022, this authority was used to enhance both the COVID-19 and mpox responses.

White House Policy Engagement

ASPR policy and planning managed a variety of White House policy engagements to ensure appropriate representation and coordination of ASPR's equities in preparedness and response policy actions, and tracked ASPR-wide implementation of Executive Orders related to COVID-19. ASPR provides representatives to over 50 regularly reoccurring engagements, and tracks and monitors ASPR's implementation of Executive Orders and other Administration priorities to ensure strategic alignment.

National Advisory Committees

ASPR policy and planning led 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 in public meetings to advise the HHS Secretary and the ASPR on these important issues. Topics included: improvements to virtual healthcare interactions; mental health responses for children and families; pediatric surge for health care providers; communicating with vulnerable older populations and caregivers to deliver disaster information and resources; strengthening partnerships between state and local emergency management, public health and disability networks; and improving access to durable medical equipment, personal protective equipment (PPE), and medical supplies.

Requirements and the PHEMCE

ASPR policy and planning establishes requirements for the development and acquisition of capability-based materiel and non-materiel solutions that are the most effective and fiscally responsible measures to

close critical gaps in the ASPR mission for 21st Century health security threats. ASPR is strengthening its partnerships with the Department of Homeland Security and across the PHEMCE in support of modeling analysis and development, consequence assessment, and risk analysis to inform decision-making.

**Key Outputs and Outcomes Table
ASPR: Policy and Planning**

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 Target +/-FY 2023 Target
2.4.13 Increase the number of National Health Security Strategy policy tools that support national and health security capabilities (Output)	FY 2022: 85 policy tools Target: 44 policy tools (Target Exceeded)	FY22 Target +4	Prior Target +4	+4
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 ¹ (Intermediate Outcome)	FY 2022: 23 actions Target: 14 actions (Target Exceeded)	Discontinued	Discontinued	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 2022: 130.0 stakeholder engagement contacts Target: 71.0 stakeholder engagement contacts (Target Exceeded)	FY22 Target +3	Prior Target +3	+3
2.4.18 Increase the number of identified ASPR activities designed to implement the National Biodefense Strategy across the entire Biodefense enterprise ¹ (Output)	FY 2022: 12 activities Target: 9 activities (Target Exceeded)	Discontinued	Discontinued	N/A

¹The activity was moved outside of ASPR.

Operations

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	30.938	34.376	69.867	+35.491
FTE	135	142	288	+146

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 Administration for Strategic 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 the 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 prepare for, respond to, and recover from public health emergencies. 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.

Funding History	
Fiscal Year	Amount
FY 2020	\$30,938,000
FY 2021	\$30,938,000
FY 2022 Final	\$30,938,000
FY 2023 Enacted	\$34,376,000
FY 2024 President’s Budget	\$69,867,000

Budget Request

The FY 2024 President’s Budget request for Operations is \$69,867,000, which is \$35,491,000 above FY 2023 Enacted. The increased funding will support ASPR as its overall responsibilities and programs continue to grow. Over the past decade, ASPR has seen its funding increase by \$2.7 billion or over 300 percent, while Operations funding has remained flat. The increase will specifically support the

enhancement of ASPR's financial management, acquisition support, and information technology. These activities provide support across ASPR's programs and will also ensure an optimal infrastructure as ASPR looks to the future.

Within the total increase, the budget includes \$23,980,000 to ensure ASPR can recruit a quality workforce to carry out its responsibilities related to acquisitions, contracting, and financial management. ASPR would add 139 FTE for this effort. Of this total, 130 FTE would support ASPR acquisitions workforce, and the remaining nine FTE would support ASPR financial management. With respect to ASPR's transition to an Operating Division, the budget assumes human capital activities will continue to be supported by HHS centrally in FY 2024.

ASPR programs continue to grow and expand into new mission areas with greater and more complex responsibilities. This gradual expansion was greatly accelerated as a result of ASPR's role in COVID-19 response. New and expanded lines of effort, such as the HHS Coordination Operations and Response Element (H-CORE) and Industrial Base Management and Supply Chain (IBMSC) program, increase the workload for key acquisition support areas, including the need for contract specialists who award, administer, monitor and closeout the contract actions necessary to meet the requirements of vital national programs. To continue to support ongoing mission requirements and prepare for future emergencies, ASPR programs require additional contracting officers and contracting specialists.

A workforce analysis commissioned by ASPR found that the size of its acquisition workforce needs to be increased to manage the growing workload. In partnership with the Department of Defense, ASPR moved nearly \$90 billion in contracts over the course of the COVID pandemic. In benchmarking against comparable agencies such as the FEMA and the Defense Logistics Agency, the study also validates that ASPR does not have sufficient numbers of contracting specialists based on ASPR's annual appropriations, let alone to surge contract support for emergency supplemental funding. The 2024 budget begins to right size this workforce to ensure ASPR is able to successfully execute its mission.

The President's Budget request also includes an additional \$11,511,000 to support ASPR-wide programmatic information technology needs. ASPR's ability to execute its mission depends on a robust, reliable, and resilient information technology and communications infrastructure. ASPR technology infrastructure includes a spectrum of technologies ranging from computers, mobile devices, HF/VHF/UHF radios, and satellite communications devices. A variety of business software applications like Adobe, Microsoft, and Tableau, as well as cloud-based products like ZOOM, Amazon Web Services (AWS), and VMWare, are also essential elements of ASPR's technology infrastructure. Adopting a hybrid approach using both on-site and cloud-based platforms has fostered the development of mission-essential applications and systems like ASPR-Ready and the Geospatial Health System. From the integration of audio-visual technologies in the Secretary's Operations Center to the deployable communications capabilities in National Disaster Medical System, these 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, must be protected. The connection of these systems to the internet introduces significant vulnerability to cyber threats, which

could potentially compromise 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, the Federal Information Technology Acquisitions Reform Act and other directives, standards and policies set for by the federal government and the Department. This includes funding for an additional seven FTE positions to begin to support ASPR's transition to an HHS Operating Division. Additional information technology and cybersecurity professionals will further ensure ASPR is able to maintain the highest level of Confidentiality, Integrity, and Availability, and execute its mission to "Lead the country through public health emergencies," and maintain compliance with departmental and federal policies, laws, and directives.

Program Accomplishments

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 1,073 hiring selections, including 699 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 to 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 messaging and is optimized for mobile devices. This website is the primary platform ASPR uses for sharing information with the public. 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. In FY 2022, the ASPR's contracting enterprise executed over 1,500 contract actions and obligated over \$4.1 billion. ASPR continuously manages its portfolio of acquisition instruments totaling over \$100 billion. In addition, ASPR executed nearly 500 grants actions and obligated nearly \$288 million in FY 2022.

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 developed spend plans to responsibly and efficiently execute emergency supplemental appropriations resulting in over \$100 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.

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 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.

As an Operating Division, ASPR is establishing a new Working Capital Fund (WCF) as a full-cost recovery operating model to recover program expenses through funds collected from all supported customers, both internal and external to the organization. To date, ASPR is developing detailed service costs for finance, human capital, acquisitions, and information technology (i.e., the amount an ASPR program would expect to allocate for different central services). ASPR is working to establish a formal governance structure in FY 2023 and is looking toward implementation in FY 2024.

Preparedness and Response Innovation

Budget Summary (Dollars in Millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Budget Authority	2.080	3.080	3.080	-
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

The mission of the Administration for Strategic Preparedness and Response (ASPR) Preparedness and Response Innovation (PRI) program is to develop, prototype, and procure 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 developing technologies beyond chemical, biological, radiological, and nuclear medical countermeasures (MCMs), and to adapt practical solutions to ensure the availability of the highest standards of care, when needed. The program activities emphasize the advancements in health security products, technologies, tools, and solutions, specifically to invigorate operations, response, recovery, deployment, and dispensing activities.

FY 2021, FY 2022, and FY 2023 PRI funds, as required by Congress, are supporting joint United States (US) and Israeli cooperative research and development. Priorities include development of health technologies, a clinical accelerator network, 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 2020	-
FY 2021	\$2,000,000
FY 2022 Final	\$2,080,000
FY 2023 Enacted	\$3,080,000
FY 2024 President's Budget	\$3,080,000

Budget Request

The FY 2024 President's Budget request for PRI is \$3,080,000, which is equal to FY 2023 Enacted.

Applied (Clinical) Research and Development Projects: These projects will support continued efforts to deploy an accelerator network to advance health technologies. The accelerator network 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 continued 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, 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 continued 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. These funds will be used to continue 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 the technologies involved.

Program Accomplishments

The PRI program has several key recent achievements including:

- An Advisory Panel of key opinion leaders, led by Leadership Co-chairs from the US and Israel was created to assess risks and opportunities, and provide leadership and direction for bi-lateral work involving future health security solutions.
- A research institute from the Technion University in Haifa authored a White Paper highlighting emergent health technologies in Israel and included governmental initiatives and strategies for advancing the fields in Israel and developing appropriate regulatory frameworks and proposed strategies for advancing Israel-US collaboration in these topics. Concurrently, the US Co-Chair and his team from Mass General Hospital identified and connected with more than 95 start-up companies from both countries.
- Information produced and shared between stakeholders during this initial year's effort was presented at a bilateral US-Israeli conference on September 21, 2022, that was broadcast simultaneously in Tel Aviv and Washington, D.C. and featured dignitaries from both Israel and US including the HHS ASPR, Ms. Dawn O'Connell.

SUPPLEMENTAL TABLES

Budget Authority by Object Class

Description	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
<u>Personnel compensation:</u>				
Full-time permanent (11.1)	110.270	133.945	140.642	+6.697
Other than full-time permanent (11.3)	-	-	-	-
Other personnel compensation (11.5)	-	-	-	-
Military personnel (11.7)	13.630	16.550	17.383	+0.833
Special personnel services payments (11.8)	-	-	-	-
Subtotal, Personnel Compensation	123.900	150.495	158.025	+7.530
Civilian benefits (12.1)	47.260	57.405	60.275	+2.870
Military benefits (12.2)	5.840	7.100	7.450	+0.350
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	177.000	215.000	225.750	+3.220
Travel and transportation of persons (21.0)	3.620	4.700	6.000	+ 1.300
Transportation of things (22.0)	5.500	7.000	9.000	+ 2.000
Rental payments to GSA (23.1)	3.670	6.000	7.000	+ 1.000
Rental payments to Others (23.2)	7.490	9.000	9.500	+ 0.500
Communication, utilities, and misc. charges (23.3)	0.980	1.500	2.000	+ 0.500
Printing and reproduction (24.0)	0.060	1.000	1.500	+ 0.500
<u>Other Contractual Services:</u>				
Advisory and assistance services (25.1)	1,506.180	1,685.500	1,997.600	+312.100
Other services (25.2)	83.190	90.000	100.000	+10.000
Purchase of goods and services from government accounts (25.3)	489.080	625.980	785.560	+159.580
Operation and maintenance of facilities (25.4)	20.560	25.000	26.000	+1.000
Research and Development Contracts (25.5)	0.600	3.000	5.000	+2.000
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	12.450	15.000	15.500	+0.500
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal, Other Contractual Services	2,112.060	2,444.480	2,929.660	+485.180
Supplies and materials (26.0)	522.670	650.000	780.000	+130.000
Equipment (31.0)	0.610	1.000	1.500	+0.500
Land and Structures (32.0)	-	-	-	-
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	279.080	290.000	300.000	+10.000
Interest and dividends (43.0)	-	-	-	-
Refunds (44.0)	-	-	-	-
Total Non-Pay Costs	2,935.740	3,414.680	4,046.160	+631.480
Total, Budget Authority by Object Class	3,112.744	3,629.677	4,271.913	+642.236

Salaries and Expenses

Description ¹	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Personnel compensation:				
Full-time permanent (11.1)	110.270	133.945	140.642	+6.697
Other than full-time permanent (11.3)	-	-	-	-
Other personnel compensation (11.5)	-	-	-	-
Military personnel (11.7)	13.630	16.550	17.383	+0.833
Special personnel services payments (11.8)	-	-	-	-
Subtotal personnel compensation	123.900	150.495	158.025	+7.530
Civilian benefits (12.1)	47.260	57.405	60.275	+2.870
Military benefits (12.2)	5.840	7.100	7.450	+0.350
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	177.000	215.000	225.750	+10.750
Travel and transportation of persons (21.0)	3.620	4.700	6.000	+1.300
Transportation of things (22.0)	5.500	7.000	9.000	+2.000
Rental payments to GSA (23.1)	3.670	6.000	7.000	+1.000
Rental payments to Others (23.2)	7.490	9.000	9.500	+0.500
Communication, utilities, and misc. charges (23.3)	0.980	1.500	2.000	+0.500
Printing and reproduction (24.0)	0.060	1.000	1.500	+0.500
Other Contractual Services:				
Advisory and assistance services (25.1)	1,505.760	1,685.000	1,997.000	+312.000
Other services (25.2)	83.190	90.000	100.000	+10.000
Purchase of goods and services from government accounts (25.3)	489.080	625.980	785.560	+159.580
Operation and maintenance of facilities (25.4)	20.560	25.000	26.000	+1.000
Research and Development Contracts (25.5)	0.600	3.000	5.000	+2.000
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	12.450	15.000	15.500	+0.500
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal, Other Contractual Services	2,111.640	2,443.980	2,929.060	+485.080
Supplies and materials (26.0)	522.670	650.000	780.000	+130.000
Total Non-Pay Costs	2,655.630	3,123.180	3,744.060	+620.880
Total Salary and Expense	2,832.630	3,338.180	3,969.810	+631.630
Direct FTE	972	1,246	1,540	+294

¹ ASPR FTE levels may vary from OMB MAX totals due to FTE funded by non-base appropriations (i.e., COVID-19 supplemental appropriations).

Administration for Strategic Preparedness and Response

Detail of Full-Time Equivalent Employment

	2022 Actual Civilian	2022 Actual Military	2022 Actual Total	2023 Est. Civilian	2023 Est. Military	2023 Est. Total	2024 Est. Civilian	2024 Est. Military	2024 Est. Total
Preparedness and Emergency Operations... National Disaster Medical System.....	51	14	65	72	14	86	71	15	86
Health Care Readiness and Recovery.....	135	33	168	115	33	148	127	35	162
Medical Reserve Corps.....	34	4	38	45	4	49	45	4	49
Preparedness and Response Innovation.....	7	0	7	12	0	12	12	0	12
Biomedical Advanced Research and Development Authority (BARDA).....	0	0	0	3	0	3	3	0	3
Project BioShield.....	282	13	295	287	13	300	350	14	364
Pandemic Influenza	0	0	0	0	0	0	0	0	0
Strategic National Stockpile.....	0	0	0	0	0	0	0	0	0
HHS Coordination Operations and Response Element.....	208	18	226	311	18	329	310	19	329
Operations	22	3	25	108	3	111	108	3	111
Policy and Planning.....	110	7	117	135	7	142	281	7	288
Pandemic Preparedness and Biodefense (NEW).....	21	10	31	56	10	66	72	11	83
ASPR FTE Total¹			972			1246			1540

¹ ASPR FTE levels may vary from OMB MAX totals due to FTE funded by non-base appropriations (i.e., COVID-19 supplemental appropriations).

Detail of Positions

ASPR ¹	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Executive level I	-	-	-
Executive level II	-	-	-
Executive level III	-	-	-
Executive level IV	1	1	-
Executive level V	1	1	1
Subtotal Executive Level Positions	2	2	1
Total - Exec. Level Salaries	\$341,600	\$355,600	\$189,310
ES-6	-	-	-
ES-5	-	-	-
ES-4	-	-	-
ES-3	-	18	20
ES-2	-	-	-
ES-1	9	9	-
Subtotal ES positions	9	27	20
Total - ES Salary	\$2,120,400	\$5,630,400	\$3,861,000
GS-15	150	165	206
GS-14	260	311	383
GS-13	290	362	445
GS-12	160	197	246
GS-11	50	74	93
GS-10	30	44	55
GS-9	40	59	71
GS-8	10	14	17
GS-7	18	20	25
GS-6	-	-	-
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	1,008	1,246	1,540
Total - GS Salary	\$109,319,114	\$140,644,670	\$173,932,572
Average ES level	ES-1	ES-3	ES-3
Average ES salary	\$226,300	\$195,000	\$195,000
Average GS grade	13	13	13
Average GS salary	\$108,973	\$112,015	\$112,015

¹ ASPR FTE levels may vary from OMB MAX totals due to FTE funded by non-base appropriations (i.e., COVID-19 supplemental appropriations).

Cybersecurity

Cyber Category	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Cyber Human Capital	-	-	1.400	1.400
Sector Risk Management Agency (SRMA)	0.801	0.708	1.708	1.000
Securing Infrastructure Investments	-	3.800	5.400	1.600
Technology Ecosystems.....	-	-	-	-
Zero Trust Implementation	-	-	0.800	0.800
Other NIST CSF Capabilities.....	-	-	-	-
Detect.....	-	-	0.600	0.600
Identity.....	-	-	-	-
Protect	-	-	0.200	0.200
Recover.....	-	-	-	-
Respond.....	-	-	-	-
Total Cyber Request	0.801	4.508	10.108	5.600

Programs Proposed for Elimination

No programs within ASPR are proposed for elimination.

PROPOSED LAW

FISCAL YEAR 2024 DHHS LEGISLATIVE PROPOSAL Administration for Strategic Preparedness and Response

Working Capital Fund

ASPR seeks language to codify a Working Capital Fund (WCF) within the Public Health Service Act with the authorities equivalent to those provided in 42 U.S.C. 231. ASPR received appropriations via the Consolidated Appropriations Act, 2023 for a WCF. In late July 2022, the Secretary elevated ASPR to an Operating Division within HHS, rather than an office within HHS. As a result of this change, ASPR is seeking WCF authority to ensure the Agency is fully able to establish this fund and utilize its functions fully. ASPR will use the WCF to improve its ability to meet mission requirements to prepare, respond, and recover to public health emergencies and disasters.

Extend Direct Hire Authority for NDMS

The Administration for Strategic Preparedness and Response (ASPR) 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. The hiring authority reduced the hiring time from a year to an average of six months. Extension of this authority will aid NDMS in sustaining a workforce that is integral to public health emergency response, including for COVID-19 in all jurisdictions, as well as for hurricanes and other disasters. 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.

Expand Other Transaction Authority

ASPR seeks to expand its existing authority for Other Transaction Authority (OTA) to include the capability to transition a Prototype OTA to a Production Purpose OTA as a non-competitive follow-on contract as stated under 10 U.S.C. § 4022, except removing the requirement that prototype be completed prior to awarding production OTA (2.B).

During the initial COVID-19 response, ASPR's inability to link product development with procurement caused significant delays, further strained already stretched resources, and increased costs and reduced the government's flexibility in negotiating product procurement contracts. Under the collaboration with the Department of Defense (DoD) for assisted acquisition, the

ability to utilize their existing prototype/production OTA authorities significantly improved flexibility and negotiating leverage. This authority is requested with a modification to not include the requirement to complete the prototype prior to awarding the production OTA. There are often long lead times associated with MCM manufacturing that require the two to overlap to some extent in order to gain maximum efficiencies and minimize timeline from completion of the prototype to delivering of product under the production OTA. By granting ASPR the authority to award Production OTs from Prototype OT without recompeting the requirement in a traditional open competition, ASPR will gain much needed flexibility to expedite and improve the Government's ability to negotiate favorable terms when funding advanced development and manufacturing of medical countermeasures, to prepare for and respond to future health emergencies.

Disasters can impact anyone. However, as has been well-documented during COVID-19, underserved communities are disproportionately impacted by disasters and emergencies. This proposal supports quick and effective contracting actions to aid in current and future response operations and will aid in HHS's capacity to address unmet needs during disasters.

Commercial Solutions Opening

ASPR seeks authority to acquire innovative commercial products, commercial services, processes, and/or methods—including those already in-use outside the USG but for which the USG is seeking first-time or novel application—using general solicitation competitive procedures (similar to DoD Commercial Solutions Opening (CSO) authority made permanent in the 2022 NDAA, Section 803). A CSO is a competitive process to obtain solutions or new capabilities that fulfill requirements (requirements in this case are whatever is determined to appropriately respond to the identified outbreak or disaster (e.g., vaccines, testing components, etc.), close capability gaps, or provide potential technological advances. A CSO is similar to a broad agency announcement (BAA), however, a CSO can be used to acquire innovative commercial items, technologies, or services to directly meet program requirements. Subject to certain limitations, a CSO may also be used for research and development contracting, including advanced component development through operational systems development. For CSO purposes, innovation is defined as any technology, process, or method, including research and development that is new as of the date of proposal submission or any application of a technology, process, or method that is new as of proposal submission. In May 2021, DoD and HHS signed a memorandum of understanding which indicated that HHS required ongoing acquisition services related to COVID-19 vaccines, therapeutics, supplies, technology investments agreements, and other contracting agreements to aid in the response. Throughout the first two years of the pandemic, HHS relied on DoD to perform such acquisitions. With the transition of contracting back to HHS under ASPR, having the authority to acquire innovative products and commercial

services using competitive procedures is critical to continuing success in executing contracts quickly in the future as we continue to support the COVID-19 response and plan for and respond to emerging medical, public health, and health security events.

Disasters can impact anyone. However, underserved communities are disproportionately impacted by disasters and emergencies. For example, throughout the COVID-19 pandemic, the risk of hospitalizations and deaths in black, Hispanic, and American Indian/Alaskan native populations was up to 3 times higher than in the Caucasian population. Increasing access to vaccines across all groups, independent of the ability to pay, helped close this gap and bring the rates of hospitalizations and deaths closer across all groups. This proposal supports quick and effective contracting actions to ensure the availability of both medical and public health countermeasures across the population to aid current and future response operations and in HHS's capacity to address unmet needs during disasters.

Authority for Procurement and Acquisition

ASPR seeks authority to procure supplies, including parts and accessories, and designs thereof necessary for experimental or test purposes in the development of the best supplies that are needed for the national public health and health security (similar to DoD's authority under 10 U.S.C. § 4023). This authority would significantly aid and support a fast and effective response. ASPR could acquire limited quantities of the reagents and other materials necessary to develop diagnostic testing for an emerging public health threat. ASPR could use those materials, and other ancillary supplies procured under this authority, to conduct operational testing of the diagnostics and select candidates most likely to be effective at diagnosing the emergent disease if made more broadly available.

Disasters can impact anyone. However, underserved communities are disproportionately impacted by disasters and emergencies. For example, throughout the COVID-19 pandemic, the risk of hospitalizations and deaths in black, Hispanic, and American Indian/Alaskan native populations was up to 3 times higher than in the Caucasian population. Increasing access to vaccines across all groups, independent of the ability to pay, helped close this gap and bring the rates of hospitalizations and deaths closer across all groups. This proposal supports quick and effective contracting actions to ensure testing and operational and safety assessment across the entire population to aid in current and future response operations and aid in HHS's capacity to address unmet needs during disasters.

Deem Medical Reserve Corps as Time-Limited Federal Employees for the Purposes of Liability Coverage and Medical License Credentials

Modify section 2813 of the Public Health Service Act (42 U.S.C. § 300hh-15) to allow HHS to deploy Medical Reserve Corps (MRC) volunteers as temporary federal responders. These individuals would serve for limited periods of time without compensation but be deemed narrowly as Federal employees for limited purposes of liability coverage and medical license credentials. The MRC program has grown to approximately 760 units and over 300,000 volunteers nationwide – but these volunteers are not used as part of the federal response.

With this requested modification to existing authorities, MRC volunteers would be deemed federal employees for the purpose of liability coverage under the Federal Tort Claims Act (FTCA) and Federal Employees' Compensation Act (FECA)– coverages that they do not currently have unless they are given appointments, which currently entail compensation. They would also be able to provide care within the scope of their state clinical license in any state where they are responding, as is the case with officers of the U.S. Public Health Service Commissioned Corps, National Disaster Medical System (NDMS) responders, and other federal healthcare personnel.

Disasters can impact anyone. However, underserved communities are disproportionately impacted by disasters and emergencies. This proposal supports efforts to strengthen support provided to underserved communities through additional dedicated staff.

SIGNIFICANT ITEM IN APPROPRIATION COMMITTEE REPORTS

SIGNIFICANT ITEM

Cold Chain Technologies.—The Committee recognizes the limitations that are presented by cold chain requirements for vaccine distribution and storage, and supports efforts to address these challenges in the coming years. The Committee directs ASPR to explore opportunities for new technologies such as dry powder 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 in the fiscal year 2024 Congressional Budget Justification on such efforts.

RESPONSE

As outlined in Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority's (BARDA) [2022-2026 Strategic Plan](#), supporting the development and commercialization of alternative delivery technologies that will reduce the need for cold chain distribution remains a priority for the organization.

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. ASPR/BARDA will work with Bavarian Nordic to fill doses as a lyophilized formulation of JYNNEOS in 2023 and a supplemental Biologics License Application for the lyophilized form is tentatively planned for late 2024. In late 2023 and 2024, we expect additional data to become available from past investments in these 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. ASPR/BARDA continues to support and encourage collaborations between antigen manufacturers and developers of new technologies that will reduce vaccine cold chain requirements. ASPR/BARDA will review the data when available to determine whether additional investments are needed to achieve the desired manufacturing scale. Lastly, BARDA has some early investments in on-demand vaccine production that would obviate the need for long-term storage entirely.

In FY 2024, 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, subject to the availability of appropriations and ASPR/BARDA priorities.