DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2025

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) 2025 Congressional Justification for the Administration for Strategic Preparedness and Response (ASPR). The FY 2025 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 86 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, the Industrial Base Management and Supply Chain Office is helping to ensure that critical supplies are manufactured in the United States. The budget invests in the domestic production of medical countermeasures and pharmaceutical ingredients. The budget includes $95 million in new funding to onshore production of medical countermeasures and active pharmaceutical ingredients

that are used in essential medicines. This funding will also be used to deepen HHS's visibility into the medical supply chain to include priority drugs and devices on FDA's essential medicines list.

Preparing for the next threat is more than having the right countermeasures, however. We must also be able to act quickly and nimbly. To meet this mission, ASPR has established the HHS Coordination Operations and Response Element (H-CORE) program which received annual appropriations for the first time in FY 2023. H-CORE now serves as a logistics and operations "Swiss Army knife" for key ASPR missions.

Last year, ASPR deployed NDMS responders in support of the deadly wildfires in Hawaii. ASPR Disaster Mortuary Operations Response Team (DMORT) specialists were deployed to augment Maui's coroner's office and establish a Victim Identification Center (VIC). A Disaster Portable Morgue Unit (DPMU) was airlifted to Maui to facilitate the respectful and dignified identification of remains. 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, continues to support local communities. In FY 2023 MRC volunteers contributed over 248,000 hours of service to their communities. The total economic value of this FY 2023 contribution, which included the efforts of a variety of medical professionals, is estimated at over $9.8 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.

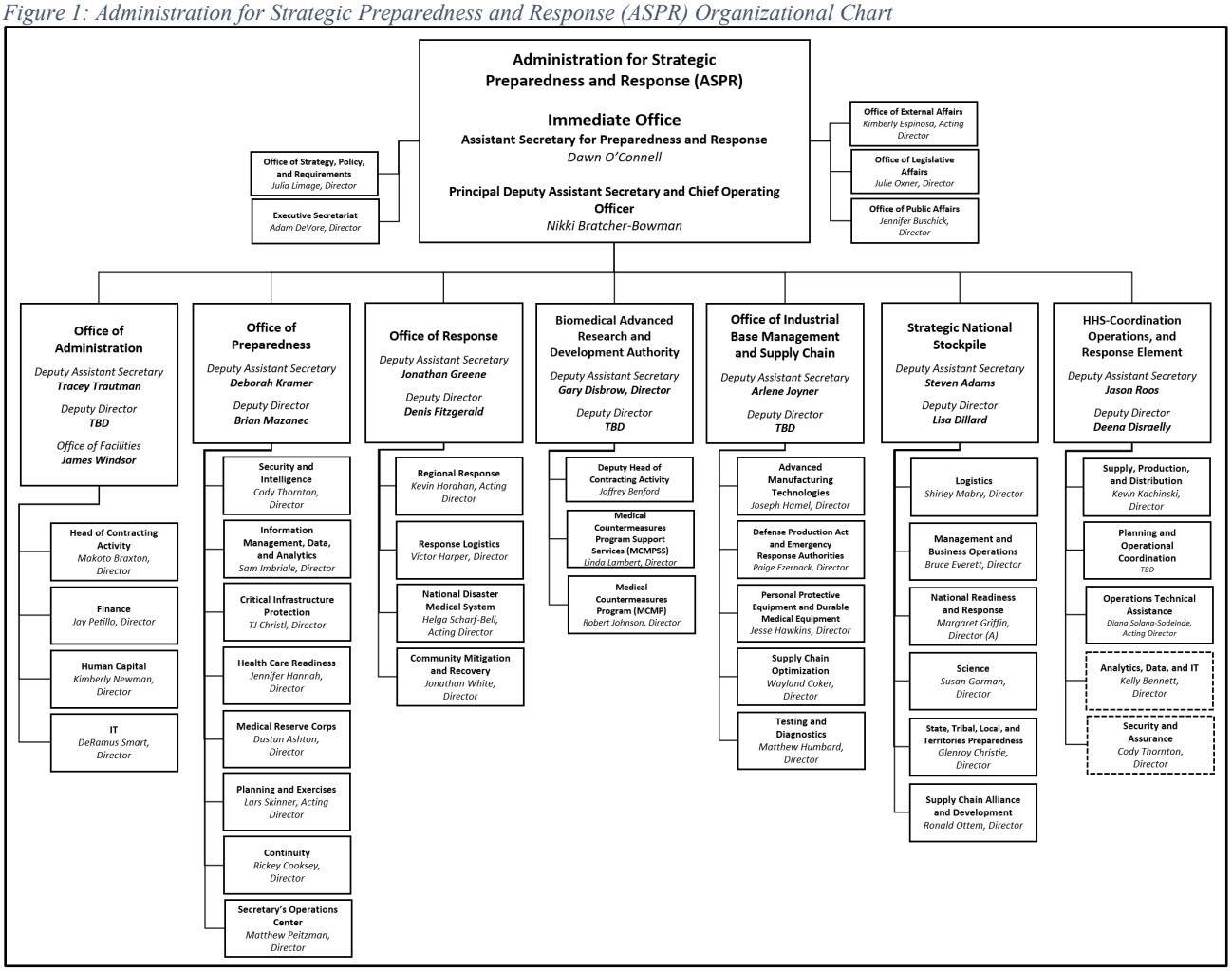
Given the significant work for which ASPR is responsible, I am pleased to present the discretionary FY 2025 President's Budget request for ASPR is $3,768,088,000 which is $138,411,000 above FY 2023 Enacted. The President's Budget also proposes $20 billion in mandatory funding across HHS to strengthen the nation's biodefense capabilities, 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** | Kimberly Espinosa, Acting Director
4. **Office of Legislative Affairs** | Julie Oxner, Director

5. **Office of Public Affairs** | Jennifer Buschick, 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 five (5) offices within the Office of Administration. The Office of the Director includes the Director, Deputy Director, and the Office of Facilities. The Deputy Director position is currently vacant.
    a. **Head of Contracting Activity** | Makoto Braxton, Director
    b. **Finance** | Jay Petillo, Director
    c. **Human Capital** | Kimberly Newman, Director
    d. **IT** | DeRamus Smart, Director

2. **Office of Preparedness:** Deputy Assistant Secretary Deborah Kramer, 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** | Lars Skinner, Acting Director
    g. **Continuity** | Rickey Cooksey, Director
    h. **Secretary's Operations Center** | Matthew Peitzman, 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** | Helga Scharf-Bell, Acting 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, Director
    b. **Planning and Operational Coordination** | TBD
    c. **Operations Technical Assistance** | Diana Solana-Sodeinde, Acting Director
    d. **Analytics, Data, and IT** | Kelly Bennett, 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.

Overview of Budget Request

The FY 2025 President's Budget discretionary request for the Administration for Strategic Preparedness and Response (ASPR) is $3,768,088,000, which is an increase of +$138,411,000 above FY 2023. The budget also proposes $20 billion in mandatory funding across HHS public health agencies to strengthen the nation's biodefense capabilities, 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 FY 2023):

Biodefense Production of Medical Countermeasures and Essential Medicines (increase of +$95 million, $95 million total): Throughout the pandemic, the Industrial Base Management and Supply Chain office supported $17 billion of investments in expanding the domestic industrial base and other critical manufacturing contracts, in addition to critical investments made by the Biomedical Advanced Research and Development Authority and other ASPR components. The President's Budget ensures ASPR can continue its efforts to strengthen the domestic medical supply chain. The Budget includes $95 million to expand and accelerate development and domestic production of medical countermeasures and improve visibility and management of medical supply chains to mitigate potential shortages of priority drugs and devices. Specifically, the President's Budget provides $75 million to onshore production of medical countermeasures (MCMs) and active pharmaceutical ingredients, consistent with Made in America and National Biodefense Strategy (NBS) goals. The Budget also includes $20 million to expand end-to-end visibility and management of the medical and public health supply chain for priority drugs and devices.

Operations (increase of +$45.491 million, $79.867 million total): ASPR uses Operations funding to support the country in preparing for, responding to, and recovering from public health emergencies and disasters. The President's Budget request includes an additional $45.5 million, which will allow ASPR to build a more resilient response organization by improving our human capital, acquisitions/financial management, and IT capabilities. These activities provide support across ASPR's programs and will also ensure ASPR builds and sustains critical agency infrastructure as an HHS Operating Division.

Biomedical Advanced Research and Development Authority (BARDA) Advanced Research and Development (ARD) (increase of +$20 million, $970 million total): The President's Budget proposes to increase BARDA's Broad Spectrum Antimicrobials and Combatting Antibiotic-Resistant Bacteria portfolio by $20 million. The FY 2025 request will support the Combatting Antibiotic Resistant Bacteria Accelerator (CARB-X) and the advanced clinical stage development of novel broad-spectrum antimicrobials to prevent and treat drug-resistant bacterial and fungal infections in both adult and pediatric populations. 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.

Health Care Readiness and Recovery (HCRR) (increase of +$12 million, $317.055 million total): The President's Budget proposes an additional $12 million to support ASPR's Critical Infrastructure Protection (CIP) program, which will improve HHS-wide coordination and response to cyber incidents

affecting the Healthcare and Public Health Sector. A significant portion of the increased funds will be used for acquisition of cybersecurity and risk management expertise.

Discretionary Programmatic Decreases (relative to FY 2023):
National Disaster Medical System (decrease of -$31.000 million, $65.904 million total): The request prioritizes funding for core response programs. The President's Budget discontinues funding for Mission Zero (-$4 million), Public Health Preparedness Equipment (-$20 million), and Pediatric Disaster Care (-$7 million).

Preparedness and Response Innovation (PRI) (decrease of -$3.080 million, proposed elimination): The President's Budget proposes to sunset the PRI program which has supported joint United States and Israeli cooperative research and development, as directed by the Congress. Funding will be prioritized for other higher priority activities described above (see Biodefense Production of Medical Countermeasures and Essential Medicines).

Mandatory Programmatic Increases (relative to FY 2023):
Pandemic Preparedness (increase of $10.54 billion, $10.54 billion total): The FY 2025 request includes a $20 billion mandatory investment, available over five years, across HHS public health agencies to strengthen the nation's biodefense capabilities as outlined in the National Biodefense Strategy. This proposal requests funding within the Public Health and Social Services Emergency Fund (PHSSEF), to be 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 PHSSEF 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 its 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. To drive this improvement, ASPR's work is strengthened by using the best available evidence combined with rigorous performance evaluation. ASPR continuously monitors program effectiveness to improve the most important outcomes for the nation.

Strategic Planning

ASPR's 2022 – 2026 ASPR Strategic Plan aligns with the Department of Health and Human Services' (HHS) Strategic Plan and sets the direction of the organization. ASPR's Strategic Plan (ASP) prioritizes agency actions and facilitates coordination and collaboration with partners. The development and implementation of ASP reflects ASPR's continuing commitment to strengthen the country's ability to prepare for, respond to, and recover quickly from public health emergencies and disasters. The ASP also allows ASPR to build upon past successes while focusing on the current needs of the nation, while promoting innovation, and pursuing excellence. Importantly, this Strategic Plan allows ASPR to clearly measure performance and implement ongoing improvement strategies.

The ASP's implementation plan, called the Roadmap, measures how well ASPR activities align and contribute to the ASP and also monitors progress towards specific ASP goals and objectives. The Roadmap is a 'living' resource that will track, monitor, and report updates on implementation. Using the HHS Strategic Planning tool as a dashboard, each ASPR Office provides updates to their activities in real time. Each of the ASPR Offices proposed activities are based on existing ASPR programs, authorities, and funding. Changes to the respective authorities or resources prompt ongoing revisions to the Roadmap, as well as operational decision making. As a management tool, the Roadmap is used to track initiatives as well as guide leadership prioritization discussions.

During 2023 and 2024, ASPR continues contributions to the HHS Secretary's priorities, as documented in the HHS FY 2022-2026 Strategic Plan, the FY 2025 HHS Annual Performance Plan and Report, the Agency Financial Report, and other requirements of the Government Performance and Results Act (GPRA) Modernization Act of 2010. Within the current HHS Strategic Plan, ASPR contributes data to promote accountability and transparency for the following HHS Strategic Plan objectives: 2.1 Improve capabilities to predict, prevent, prepare for, respond to, and recover from emergencies, disasters, and threats across the nation and globe; 2.2 Protect individuals, families, and communities from infectious disease and non-communicable disease through equitable access to effective, innovative, readily available diagnostics, treatments, therapeutics, medical devices, and vaccines, and, 2.4 Mitigate the impacts of environmental factors, including climate change, on health outcomes. 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, including Objective 4.2 Invest in the research enterprise and the scientific workforce to maintain

leadership in the development of innovations that broaden our understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs.

During 2023, ASPR developed the Data Modernization Initiative (DMI) Strategic Plan to serve as foundational guidance for efforts toward enhancing and optimizing ASPR preparedness, readiness, and response for future all-hazard situations. ASPR Strategic Plan 2022–2026 lays out four overarching strategic goals: Prepare for Future Disasters, Manage the Federal Response, Improve and Leverage Partnerships, and Ensure Workforce Readiness. Each of these strategic goals relies on ASPR being able to use data to understand, evaluate, inform, and disseminate data. The DMI Strategic Plan will support each of ASPR's four strategic goals by defining the data needs for each response mission, making data available at the right time for response decision-makers, making data reliable by standardizing definitions and data formats, and providing rigorous data management and security governance. In parallel, the DMI Strategic Plan seeks to empower an active workforce that considers data as a shared responsibility and asset for making informed decisions.

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. The CDO also leads the ASPR's Data Strategy and Data Modernization Initiative to build foundational capabilities to modernize, strengthen, and unify critical ASPR Data Management.

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 GPRAMA. 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. 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 (APG) and HHS Priorities

APG's are an important tool used by the Department to measure near-term achievements in the HHS strategic plan through regular reviews, documentation of improvements, and public transparency. This helps to ensure focus and efficient allocation of resources across HHS. ASPR's contributions serve as a steppingstone towards long-term objectives in ways that align ASPR with HHS's goals.

For FY 2022 and 2023, ASPR collaborated with HHS partners on an Emergency Preparedness APG. This goal focused on promoting equitable access, strengthening 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. ASPR coordinated part of the Emergency Preparedness APG through its Office of Industrial Base Management and Supply Chain (IBMSC). ASPR's IBMSC continues to build a diverse, agile public health supply chain and working to sustain long-term U.S. manufacturing capability Specific efforts include:

- Transforming the U.S. Government's ability to manage the public health supply chain through coordination and support of manufacturing capacities, enhancing supply chain visibility, and engagement to ensure fair, equitable, and effective allocation of scarce resources;
- Defining acquisition strategies and leveraging enabling authorities to assess supplier risk levels and diversify the domestic manufacturing base to better ensure adequate supplies of critical medical countermeasures during periods of crisis;
- Investing in innovative technologies that will facilitate U.S. Government's ability to meet demands for future public health emergencies; and,
- Establishing a program of activity to assess the public health industrial base's most vulnerable supply chains and develop a range of solutions and alternatives to address those vulnerabilities to ensure an optimized supply chain prepared for the next public health emergency.

During FY 2024 and FY 2025, ASPR is contributing to the Customer Experience (CX) APG. ASPR will be working with those we serve to improve our services to the American people.

ASPR Accomplishments

ASPR's accomplishments during CY 2023 include those listed below.

- As of January 2024, ASPR's Biomedical Advanced Research and Development Authority (BARDA) program received its 86th Food and Drug Administration approval for a medical countermeasure.
- ASPR BARDA, in partnership with the National Institute of Allergy and Infectious Diseases, launched Project NextGen, with an initial investment of $5 billion in supplemental funding, to improve access and enable faster, lower cost, rapid, and flexible production of vaccines and therapeutics.
- The ASPR Office of Preparedness through the Medical Reserve Corps (MRC) awarded $50 million in supplemental funding to 33 states and jurisdictions to strengthen their MRC networks – focusing on emergency preparedness, response, and health equity needs.
- ASPR as part of the Critical Infrastructure Program helped partners better understand their risks and increase their preparedness by developing the enhanced RISC Toolkit 2.0.
- The ASPR Office of Preparedness launched "ASPR Ready" a modernized disaster data

management system which enhances the emergency response capabilities for over 4,000 emergency responders. ASPR Ready serves as a roadmap to bridge the gap between response teams in the field and the essential resources they need, ensuring seamless connectivity. The platform's automation capabilities have expedited workflows for personnel and equipment requests, achieving a remarkable 75 percent improvement in processing time and reducing the personnel tracking time to less than ten seconds. The efficiencies enable swifter and more precise resource allocation in collaboration with Federal, State, and Jurisdictional partners for over 4,200 at risk population since 2022.

- ASPR coordinated the distribution of over 100 million free tests this year alone. Free tests are still available at COVIDTests.gov and invested to improve preparedness for COVID-19 and other future pandemic threats and reduce our reliance on overseas manufacturing.
- The ASPR Office of Response deployed highly trained personnel as part of combined federal, territorial, and state response missions to ease the burden on local health systems for numerous natural disasters, including Guam for Typhoon Mawar; Hawaii for the devastating wildfires in Maui; Florida for Hurricane Idalia; and Maine due to the tragic mass shooting in Lewiston. Our response to the Maui Wildfires was the most significant and extended disaster behavioral health mission in the last decade.
- The Strategic National Stockpile distributed more than 50,000 courses of Tamiflu to respond to flu outbreaks and over one million mpox countermeasures while continuing to stockpile personal protective equipment (PPE) and other countermeasures.
- ASPR’s Hospital Preparedness Program invested $240 million to better prepare hospitals across the country for disasters, emergencies, and new and emerging pathogens.
- ASPR’s Critical Infrastructure Protection Division tracked 285 cyber incidents in the healthcare and public health sectors and released a cybersecurity implementation guide to help the public and private health care sectors prevent cybersecurity incidents.

All Purpose Table

(Dollars in Millions)

Activity	FY 2023 Final		FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	$	FTE	$	FTE	$	FTE	$	FTE
Preparedness and Emergency Operations	31.154	86	31.154	86	31.154	86	-	-
National Special Security Events (NSSE) (non-add)	*5.000*	-	*5.000*	-	*5.000*	-	-	-
National Emergency Tele-critical Care Network (non-add)	*6.500*	-	*6.500*	-	-	-	*-6.500*	-
Health Care Readiness and Recovery	305.055	49	305.055	49	317.055	75	*+12.000*	*+26*
National Special Pathogen System (non-add).	*28.500*	-	*28.500*	-	*28.500*	-	-	-
NETEC (non-add)	*7.500*	-	*7.500*	-	*7.500*	-	-	-
RESPTCs (non-add)	*21.000*	-	*21.000*	-	*21.000*	-	-	-
HPP Cooperative Agreements (non-add)	*240.000*	-	*240.000*	-	*240.000*	-	-	-
RDHRS (non-add)	*7.000*	-	*7.000*	-	*7.000*	-	-	-
Other Costs (non-add)	*29.555*	-	*29.555*	--	*41.555*	-	*+12.000*	-
National Emergency Telemedicine Network (non-add)	-	-	-	-	-	-	-	-
Medical Reserve Corps.	6.240	12	6.240	12	6.240	12	-	-
National Disaster Medical System (NDMS)	96.904	148	96.904	148	65.904	148	-31.000	-
Mission Zero (non-add)	*4.000*	-	*4.000*	-	-	-	*-4.000*	-
Public Health Preparedness Equipment (non-add)	*20.000*	-	*20.000*	-	-	-	*-20.000*	-
Pediatric Disaster Care (non-add)	*7.000*	-	*7.000*	-	-	-	*-7.000*	-
emPOWER (non-add)	*1.565*	-	*1.565*	-	*1.565*	-	-	-
Biomedical Advanced Research and Development Authority (BARDA)	950.000	300	950.000	300	970.000	300	+20.000	-
Advanced Research and Development (non-add)	*780.000*	-	*780.000*	-	*800.000*	-	*+20.000*	-
Program Operations and Management (non-add).	*170.000*	-	*170.000*	-	*170.000*	-	-	-
Project BioShield	820.000	-	820.000	-	820.000	-	-	-
Pandemic Influenza	327.991	-	327.991	-	327.991	-	-	-
No-Year Pandemic Influenza (non-add).	*300.000*	-	*300.000*	-	*300.000*	-	-	-
Annual Pandemic Influenza (non-add).	*27.991*	-	*27.991*	-	*27.991*	-	-	-
Strategic National Stockpile	965.000	329	965.000	329	965.000	329	-	-
HHS Coordination Operations and Response Element	75.000	111	75.000	135	75.000	135	-	*+24*
Operations	34.376	142	34.376	142	79.867	312	+45.491	*+170*
Policy and Planning	14.877	66	14.877	66	14.877	66	-	-
Preparedness and Response Innovation	3.080	3	3.080	3	-	-	-3.080	*-3*
Biodefense Production of MCMs and Essential Medicines	-	-	-	-	95.000	-	+95.000	-
Biodefense Production of MCMs and Essential Medicines (non-add)	-	-	-	-	*75.000*	-	*+75.000*	-
Industrial Base Management and Supply Chain (IBMSC) (non-add)	-	-	-	-	*20.000*	-	*+20.000*	-
Total, ASPR Program Level	**3,629.677**	**1,246**	**3,629.677**	**1,270**	**3,768.088**	**1,463**	**+138.411**	*+217*
Total, ASPR Discretionary Budget Authority	**3,629.677**	**1,246**	**3,629.677**	**1,270**	**3,768.088**	**1,463**	**+138.411**	*+217*

APPROPRIATIONS LANGUAGE

FY 2025 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] *$3,768,088,000*, of which:

(1) [$1,015,132,000] *$970,000,000* shall remain available through September 30, [2025] *2026*, 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] *$820,000,000* 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] *$965,000,000* shall remain available until expended for expenses necessary to carry out section 319F-2(a) of the PHS Act:

(4) [$374,991,000] *$327,991,000* shall be for expenses necessary to prepare for or respond to an influenza pandemic, of which [$347,000,000] *$300,000,000* 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] *$75,000,000* shall remain available through September 30, [2025] *2026*, to support coordination of the development, production, and distribution of vaccines, therapeutics, and other medical countermeasures; and

(6) [$400,000,000] *$95,000,000* shall remain available through September 30, [2025] *2026*, 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, *$65,904,000 shall remain available through September 30, 2026, and* $5,000,000 shall remain available through September 30, *2027*.

Appropriations Language Analysis

Language Provision	Explanation
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, $3,675,168,000, of which:	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.
(1)$950,000,000 shall remain available through September 30, 2026, 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;	This language provides funding for BARDA Advanced Research and Development (ARD).
(2)$820,000,000 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);	This language provides funding for Project BioShield (PBS).
(3)$965,000,000 shall remain available until expended for expenses necessary to carry out section 319F-2(a) of the PHS Act:	This language provides funding for the Strategic National Stockpile (SNS).
(4)$327,991,000 shall be for expenses necessary to prepare for or respond to an influenza pandemic, of which $300,000,000 shall remain available until expended for activities including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools;	This language provides funding for Pandemic Influenza.
(5)$75,000,000 shall remain available through September 30, 2026, to support coordination of the development, production, and distribution of vaccines, therapeutics, and other medical countermeasures; and	This language provides funding for the Health and Human Services Coordination Operations and Response Element (H-CORE).

(6) $95,000,000 shall remain available through September 30, 2026, 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):	This language provides funding for a new program, Biodefense Production of Medical Countermeasures and Essential Medicines. The funding has two-year availability.
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, $65,904,000 shall remain available through September 30, 2026, and $5,000,000 shall remain available through September 30, 2026.	This language provides funding for ASPR National Special Security Events (NSSE) which has three-year availability and the National Disaster Medical System (NDMS) which has two-year availability.

AMOUNTS AVAILABLE FOR OBLIGATION

(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
General Fund Discretionary Appropriation:			
Appropriation (L/HHS, Ag, or Interior).....	-	-	3,768.088
Subtotal, adjusted appropriation.....	-	-	3,768.088
Total, Discretionary Appropriation.....	-	-	3,768.088
Total obligations.....	-	-	3,768.088

Note: For columns FY 2023 and FY 2024, this exhibit does not include ASPR funds which were appropriated to the PHSSEF but made available to ASPR. The FY 2025 column includes ASPR's budget request.

SUMMARY OF CHANGES

(Dollars in Millions)

	FY 2024 CR		FY 2025 President's Budget		FY 2025 +/- FY 2024	
	BA	FTE	BA	FTE	BA	FTE
Increases:						
Built-in:						
Annualization of 2023 commissioned corps pay increase	+10.000	-	+15.000	-	+5.000	-
Annualization of 2023 civilian pay increase	+80.000	-	+125.000	-	+45.000	-
Subtotal, Built-in Increases.....					**+50.000**	**-**
Expanded/New Programs						
Health Care Readiness and Recovery	+305.055	49	+317.055	75	+12.000	+26
Biomedical Advanced Research and Development Authority (BARDA)	+950.000	300	+970.000	300	+20.000	--
Operations	+34.376	142	+79.867	312	+45.491	+170
New Program: Biodefense Production of MCMs and Essential Medicines	--	--	+95.000	--	+95.000	--
Subtotal, Program Increases.....					**+172.491**	**+196**
Total Increases.....					**+172.491**	**+196**
Decreases						
National Disaster Medical System (NDMS)	+96.904	148	+65.904	148	-31.000	--
Eliminated Program: Preparedness and Response Innovation	+3.080	3	-	--	-3.080	-3
Subtotal, Program Decreases.....					-34.080	-3
Total Decreases.....					**-34.080**	**-3**
Decreases:	-	-	-	-	-	-
Net Change.....					**+138.411**	**+193**

BUDGET AUTHORITY BY ACTIVITY

(Dollars in Millions)

Activity	FY 2023 Final[1]	FY 2024 CR[1]	FY 2025 President's Budget
Preparedness and Emergency Operations	31.154	31.154	31.154
Health Care Readiness and Recovery	305.055	305.055	317.055
Medical Reserve Corps	6.240	6.240	6.240
National Disaster Medical System	96.904	96.904	65.904
Biomedical Advanced Research and Development Authority (BARDA)	950.000	950.000	970.000
Project BioShield	820.000	820.000	820.000
Pandemic Influenza	327.991	327.991	327.991
Strategic National Stockpile	965.000	965.000	965.000
HHS Coordination Operations and Response Element	75.000	75.000	75.000
Operations	34.376	34.376	79.867
Policy and Planning	14.877	14.877	14.877
Preparedness and Response Innovation	3.080	3.080	-
Biodefense Production of MCMs and Essential Medicines	-	-	95.000
Total Budget Authority[1]	**3,629.677**	**3,629.677**	**3,768.088**
FTE	**1,246**	**1,270**	**1,463**

[1] ASPR previously received appropriations via the Public Health and Social Services Emergency Fund. The FY 2025 President's Budget requests ASPR be funded directly in a new appropriations account. FY 2023 and FY 2024 CR columns show ASPR funding previously received through the Public Health and Social Services Emergency Fund.

AUTHORIZING LEGISLATION

(Dollars in millions)

Activity	FY 2024 Amount Authorized	FY 2024 Amount Appropriated	FY 2025 Amount Authorized	FY 2025 President's Budget
National Disaster Medical System	57.404	96.904	N/A	65.904
Hospital Preparedness Program	385.000	305.055	N/A	317.055
Medical Reserve Corps	11.200	6.240	N/A	6.240
BARDA	611.700	950.000	N/A	970.000
Project BioShield	710.000	820.000	710.000	820.000
Strategic National Stockpile	610.000	965.000	N/A	965.000
Pandemic Influenza[1]	250.000	327.911	N/A	327.911

[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 2025, the budget proposes a separate appropriations account for ASPR.

APPROPRIATIONS HISTORY

(Dollars in millions)

	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2025				
Annual	3,768.088	-	-	-
Subtotal	3,768.088	-	-	-

Note: For years prior to FY 2024, this exhibit does not include ASPR funds which were appropriated to the PHSSEF but made available to ASPR. The FY 2025 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 2024
Operations	N/A	N/A	N/A	34.376
Preparedness and Emergency Operations	N/A	N/A	N/A	31.154
Policy and Planning	N/A	N/A	N/A	14.877
H-CORE	N/A	N/A	N/A	75.000
Biodefense Production of MCMs and Essential Medicines	N/A	N/A	N/A	N/A

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

Summary of Request

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**3,629.677**	**3,629.677**	**3,768.088**	**+138.411**
Program Level	**3,629.677**	**3,629.677**	**3,768.088**	**+138.411**
Mandatory Pandemic Preparedness (non-add)	-	-	*10,540.000*	*+10,540.000*
FTE	**1,246**	**1,270**	**1,463**	**+217**

The FY 2025 President's Budget discretionary request for the Administration for Strategic Preparedness and Response (ASPR) is $3,768,088,000, which is an increase of +$138,411,000 above FY 2023. The budget also proposes $20 billion in mandatory funding across HHS public health agencies to strengthen the nation's biodefense capabilities, 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 FY 2023):
Biodefense Production of Medical Countermeasures and Essential Medicines (increase of +$95 million, $95 million total): Throughout the pandemic, the Industrial Base Management and Supply Chain office supported $17 billion of investments in expanding the domestic industrial base and other critical manufacturing contracts, in addition to critical investments made by the Biomedical Advanced Research and Development Authority and other ASPR components. The President's Budget ensures ASPR can continue its efforts to strengthen the domestic medical supply chain. The Budget includes $95 million to expand and accelerate development and domestic production of medical countermeasures and improve visibility and management of medical supply chains to mitigate potential shortages of priority drugs and devices. Specifically, the President's Budget provides $75 million to onshore production of medical countermeasures (MCMs) and active pharmaceutical ingredients, consistent with Made in America and National Biodefense Strategy (NBS) goals. The Budget also includes $20 million to expand end-to-end visibility and management of the medical and public health supply chain for priority drugs and devices.

Operations (increase of +$45.491 million, $79.867 million total): ASPR uses Operations funding to support the country in preparing for, responding to, and recovering from public health emergencies and disasters. The President's Budget request includes an additional $45.5 million, which will allow ASPR to build a more resilient response organization by improving our human capital, acquisitions/financial

management, and IT capabilities. These activities provide support across ASPR's programs and will also ensure ASPR builds and sustains critical agency infrastructure as an HHS Operating Division.

Biomedical Advanced Research and Development Authority (BARDA) Advanced Research and Development (ARD) (increase of +$20 million, $970 million total): The President's Budget proposes to increase BARDA's Broad Spectrum Antimicrobials and Combatting Antibiotic-Resistant Bacteria portfolio by $20 million. The FY 2025 request will support the Combatting Antibiotic Resistant Bacteria Accelerator (CARB-X) and the advanced clinical stage development of novel broad-spectrum antimicrobials to prevent and treat drug-resistant bacterial and fungal infections in both adult and pediatric populations. 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.

Health Care Readiness and Recovery (HCRR) (increase of +$12 million, $317.055 million total): The President's Budget proposes an additional $12 million to support ASPR's Critical Infrastructure Protection (CIP) program, which will improve HHS-wide coordination and response to cyber incidents affecting the Healthcare and Public Health Sector. A significant portion of the increased funds will be used for acquisition of cybersecurity and risk management expertise.

Discretionary Programmatic Decreases (relative to FY 2023):

National Disaster Medical System (decrease of -$31.000 million, $65.904 million total): The request prioritizes funding for core response programs. The President's Budget includes discontinues funding for Mission Zero (-$4 million), Public Health Preparedness Equipment (-$20 million), and Pediatric Disaster Care (-$7 million).

Preparedness and Response Innovation (PRI) (decrease of -$3.080 million, proposed elimination): The President's Budget proposes to sunset the PRI program which has supported joint United States and Israeli cooperative research and development, as directed by the Congress. Funding will be prioritized for other higher priority activities described above (see Biodefense Production of Medical Countermeasures and Essential Medicines).

Mandatory Programmatic Increases (relative to FY 2023):

Pandemic Preparedness (increase of $10.54 billion, $10.54 billion total): The FY 2025 request includes a $20 billion mandatory investment, available over five years, across HHS public health agencies to strengthen the nation's biodefense capabilities as outlined in the National Biodefense Strategy. This proposal requests funding within the Public Health and Social Services Emergency Fund (PHSSEF), to be 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 PHSSEF Justification.

Biodefense Production of Medical Countermeasures and Essential Medicines

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**-**	**-**	**95.000**	**+95.000**
Biodefense Production of Medical Countermeasures (MCMs)s and Essential Medicines (non-add)	-	-	*75.000*	*+$75.000*
Industrial Base Management and Supply Chain (IBMSC) (non-add)	-	-	*$20.000*	*+$20.000*
FTE	**-**	**-**	**-**	**-**

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 Administration for Strategic Preparedness and Response (ASPR) will implement the Biodefense Production of Medical Countermeasures (MCMs) and Essential Medicines as a new program that will expand and accelerate development and domestic production of medical countermeasures, including onshoring production of medical MCMs, essential medicines, key starting materials, active pharmaceutical ingredients and finished drug products. The program will also focus on building a resilient domestic medical supply chain by expanding end-to-end visibility and management of medical supply chains for priority drugs and devices. The function of this program is focused on increasing domestic manufacturing and capacity that is critical to bolstering the national supply chain resiliency and ensuring a more robust national health security posture. Recent events have led to the recognition that an extreme reliance on foreign suppliers for critical medical products leaves the nation vulnerable to continued shortages and unavoidable supply disruptions. ASPR is looking to reduce these vulnerabilities with targeted investments. These activities will be led by the ASPR Office of Industrial Base Management and Supply Chain (IBMSC) in collaboration with other ASPR offices as appropriate. IBMSC's goal is to reestablish and maintain a domestic public health supply chain and coordinate the activities related to medical industrial base expansion and sustainment through the use of contracts, grants, other transactions, Defense Production Act (DPA) and ESF-8 authorities.

The Executive Order on a Sustainable Public Health Supply Chain (EO 14001) calls for HHS to provide to the President a strategy to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. Goal 1 of the implementation strategy

for HHS is to build a diverse, agile pandemic supply chain and sustain long-term U.S. manufacturing capability for future pandemics. ASPR leads this effort for HHS. It is critical to establish enduring capabilities that achieve this goal within ASPR. Additionally, the Executive Order on America's Supply Chains (EO 14017) calls out the need to establish resilient, diverse, and secure supply chains to ensure our economic prosperity and national security. To this end, HHS is charged with the establishment of solutions to address risks in the supply chain for pharmaceuticals and active pharmaceutical ingredients. This work is complementary to the ongoing work to secure the supply chains of critical items needed to combat the COVID-19 pandemic, including personal protective equipment, conducted pursuant to EO 14001, but also needs to remain an enduring capacity at ASPR beyond the COVID-19 pandemic.

HHS has also fully implemented the requirements of the Make PPE in America Act. IBMSC continues to maintain a broad portfolio of contracts for the expansion and sustainment of personal protective equipment programs. This helps meet the Make PPE in America Act goal of onshoring PPE manufacturing to ensure American workers, health care professionals, and more have the PPE they need. The IBMSC PPE portfolio is also bolstering domestic production of PPE supplies, creating American manufacturing jobs and ensuring that America is better prepared for the next pandemic.

Furthermore, the National Biodefense Strategy calls out specific goals to 1) Enable risk awareness and detection to inform decision-making across the biodefense enterprise; 2) Ensure biodefense enterprise capabilities to prevent bioincidents; 3) Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents; 4) Rapidly respond to limit the impacts of bioincidents and; 5) Facilitate recovery to restore the community, the economy, and the environment after a bioincident. IBMSC investments in supply chain optimization and supply and demand mapping, testing and diagnostics manufacturing, essential medicine manufacturing and PPE manufacturing enables HHS ASPR to meet all of the above goals.

Funding History	
Fiscal Year	**Amount**
FY 2021	-
FY 2022	-
FY 2023 Final	-
FY 2024 CR	-
FY 2025 President's Budget	$95,000,000

Budget Request

The FY 2025 President's Budget request for Biodefense Production of MCMs and Essential Medicines is $95,000,000, an increase of $95,000,000 above FY 2023. The President's Budget provides $75 million, with two-year availability, to expand and accelerate development and domestic production of medical countermeasures, including to onshore production of MCMs, essential medicines, and active pharmaceutical ingredients, consistent with Made in America and National Biodefense Strategy (NBS) goals. The Budget also includes $20 million, also with two-year availability, to expand end-to-end visibility and management of the medical supply chains for priority drugs and devices.

This program will conduct the necessary industrial analysis to ensure economic feasibility and appropriateness of planned projects, coordinate trade-space for rated contracts, and establish programs dedicated to industrial capacity expansion investment within the public and private sectors. The IBMSC office supported over $17 billion in activities and contracts during the COVID-19 pandemic. The Budget will continue to provide the appropriate oversight and support for contracts initiated during COVID response through their conclusion. The following functions would be gained at ASPR:

- A galvanized, cross-cutting development and commercial transition program that bolsters domestic manufacturing to ensure the availability of medical countermeasures and the highest standards of care when they are needed the most.
    - This includes investments required to commercialize agile and distributed manufacturing of drug substances and drug products and DPA Title III investments in key starting material manufacturing.
    - IBMSC is embarking on a multi-year program to address the shortages of KSMs, and APIs needed for essential medical products that have been identified as critical most especially during a pandemic and or public health emergency. These drugs are typically in significantly higher demand due to increased hospitalizations during a pandemic; thus, their short supply is even more realized during these times of crisis. Onshoring and establishing enduring domestic manufacturing capabilities is a key to mitigating this risk but will require sustained investment to address the 200+ critical medicines identified on the FDA Essential Medicines list.
    - These investments will also sustain manufacturing of diagnostics, PPE and critical stock supplies for both.
    - Funding will also enable broad market analyses that are required to understand current and future demands and inform what investments need to be made to expand and maintain the public health industrial base.
- Oversight of all industry and supply chain management activities throughout ASPR, including supply chain analysis, program management and execution, and execution of DPA Titles I, III, and VII.
- Provide the capability for end-to-end visibility of medical supplies, equipment, devices, and pharmaceuticals, and up-to-date supply chain information to inform industrial base investments and efforts to sustain the medical industrial base.
- Capacities to monitor and analyze medical industrial segments, e.g., personal protective equipment (PPE), diagnostic devices, pharmaceuticals, starting materials and intermediaries.
- Ability to report on market dynamics, market risks, and production status and challenges that affect scalability, so that ASPR and HHS leadership can make informed decisions on investments.

The program will provide consistent and systematic administrative oversight of IBMSC related expansion of industrial base and supply chain capabilities, ensuring these initiatives continue to be properly managed while leveraging the authorities delegated to the HHS Secretary by the President strategically, cohesively, and equitably.

Program Accomplishments

As ASPR BARDA fulfills a unique role in the advanced development of medical countermeasures that private industry will not invest in for the national good, and the Strategic National Stockpile stockpiles medical countermeasures and capabilities to supplement state and local medical supplies and equipment during public health emergencies, so too will an enduring IBMSC capability fulfill an inherently governmental role to support the Public Health Industrial Base. This permanent IBMSC capability will also establish and sustain critical domestic medical industrial capacities to enhance and complement the preparedness and response missions for ASPR and other Federal agencies. This ultimately builds a resilient and responsive domestic public health industrial base that can reduce long-term stockpiling and response burdens on the U.S. Government.

As an office, IBMSC serves two critical roles: 1) support ASPR as a whole in Defense Production Act authorities administration and supply chain landscape surveillance specifically for the public health industrial base, and 2) contribute to supply resiliency through capacity investments to bolster domestic capabilities that further enhance the nations preparedness against public health emergencies. To complement BARDA's medical countermeasure development work, IBMSC addresses the "other" capacity constraints for areas such as PPE, diagnostics and essential medicines that are not direct MCMs but are equally critical during a PHE. Additionally, IBMSC supports the SNS requirements for stocking of PPE that was not previously maintained at larger population scale volumes. ASPR investments in PPE and collaboration with the Make PPE in America team ensure there are domestic products that are compliant and can be purchased by both the SNS and all other HHS groups such as the Department of Veterans Affairs (VA) and Defense Logistics Agency (DLA) that engage in purchasing large quantities of PPE. On the diagnostics side, IBMSC manages the ASPR stockpile of Test kits on behalf of the SNS. This effort included the previous purchases of the test kits, receiving into designated warehouses and then shipment and delivery to thousands of locations such as the underserved communities and also orders through the collaboration with US Postal Service delivery programs.

To meet ASPR's goal to secure, strengthen, and sustain the medical supply chain for the future, from FY 2020 through FY 2023, the IBMSC program invested over $17 billion in medical countermeasures and domestic manufacturing capacities. These investments were across three key areas: personal protective equipment, testing and diagnostics, and advanced manufacturing.

- In FY 2022 and FY 2023, IBMSC met previously unattainable goals for PPE manufacturing and invested $908 million in building PPE production capacities across a wide range of categories, including manufacturing of N95 and surgical masks, gowns and gloves.
- Additionally, IBMSC oversaw the COVID tests procurement and stockpile mission as well as distributed hundreds of millions of tests to tens of thousands of Long-Term Care Facilities, Community Health Centers, Schools, Housing and Urban Development sites, Food Banks and Centers for Community Living. To support this important effort, IBMSC invested more than $3.37 billion in testing and diagnostics manufacturing capacity expansion and more than $9.33 billion in test procurements. Most notably, IBMSC managed the budgets, interagency agreements and operations and logistics activities that enabled the delivery of more than 849 million at-home COVID-19 tests distributed to the American public through the Covidtests.gov program, in conjunction with the United States Postal Service (USPS) and H-CORE.

- When the nation faced an infant formula shortage, IBMSC managed the global operations and logistics to bring in more than 6.2 million powder pounds of baby formula. This involved 33 Airbridge missions, operations support for dozens of ground transport efforts and the management and execution of donation agreements with commercial airlines to ensure parents had access to vital nutrition for their infants. In addition, Defense Production Act – Emergency Response Authorities Office (DPA-ERA) worked directly with domestic infant formula manufacturers and raw material suppliers to ensure they were able to manufacture these critical products at capacity through the use of DPA authorities as necessary.
- With an eye toward pharmaceutical manufacturing and supply chain optimization, IBMSC established drug production capacities that will enable the manufacturing of hundreds of millions of doses of critical drugs in short supply. These projects are focusing on the use of advanced manufacturing technologies specifically to address the availability of essential medicines and increasing the resiliency of domestic Active Pharmaceutical Ingredients (API) supplies. IBMSC also executed efforts that are establishing novel fill-finish technologies and capacities to better make drug products and vaccines at available at population scale and will eventually result in capacity to manufacture hundreds of millions of doses in a dose-sparing, single use format that provides a more economical alternative to traditional glass vial filling and multi-use dispensation formats.
- IBMSC's DPA-ERA has led the Department's use of DPA authorities to respond to the COVID-19 pandemic, issuing over 70 Title I priority ratings to procure or provide a robust supply of COVID-19 countermeasures including PPE, ventilators, vaccines, therapeutics, and diagnostics, as well as other ancillary supplies for administration of medical countermeasures. By exercising its DPA priority rating authority, ASPR ensured that the United States Government was able to develop and secure the quantities of these health resources to meet urgent emergency preparedness requirements. DPA-ERA triaged over 300 requests from private medical manufacturers for assistance due to supply chain constraints and shortages and was able to assist in most cases.
- The DPA-ERA program continues to build out capabilities to leverage DPA Title I, III, and VII authorities consistently, strategically, and equitably (in conjunction with other USG efforts as appropriate) to address vulnerabilities in the domestic public health industrial base that meet the criteria of "national defense." DPA-ERA will maintain open lines of communication developed during COVID-19 response with the private sector to understand current and future supply chain constraints that may be impacting the public health industrial base. Additionally, the combination of investment strategies and authorities captured within DPA enables ASPR and IBMSC to address critical health and medical resources where little (or no) industrial manufacturing exists within the US or its neighboring allies.
- DPA-ERA also leads and coordinates the use of emergency response authorities such as: the Public Readiness and Emergency Response (PREP) Act Declarations for COVID-19 medical countermeasures; and Public Health Emergency Declarations for COVID, wildfires, typhoons, and floods; and Defense Production Act contract ratings for COVID-19 and infant formula response efforts.

Preparedness and Emergency Operations

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**31.154**	**31.154**	**31.154**	**-**
National Special Security Events (non-add)	*5.000*	*5.000*	*5.000*	**-**
National Emergency Tele-Critical Care Network (NETCCN) (non-add)	*6.500*	-	-	-
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
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 disasters, the Preparedness and Emergency Operations (PEO) program leads many HHS preparedness, support, and coordination 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. This program also manages the Department's Continuity of Operations program to ensure HHS can continue its essential functions under a broad range of circumstances, including all-hazard emergencies as well as natural, manmade, technological threats and national security emergencies.

Funding History	
Fiscal Year	**Amount**
FY 2021	$24,654,000
FY 2022	$24,654,000
FY 2023 Final	$31,154,000
FY 2024 CR	$31,154,000
FY 2025 President's Budget	$31,154,000

Budget Request
The FY 2025 President's Budget request for PEO is $31,154,000, which is flat with FY 2023. The request will support strategic and operational planning, the HHS Secretary's Operation Center (SOC) monitoring and alerting, HHS continuity (which includes continuity of the Presidency, Government, and Operations), information management, situational awareness, cybersecurity, intelligence analysis and requirements, personnel security, and exercises.

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

Program Accomplishments
Since its inception, ASPR has led and supported numerous efforts to prepare for, respond to, and recover from the impacts of public health emergencies and disasters. Within this funding line, preparedness efforts, such as the early identification of incidents by the Secretary's Operations Center (SOC) as well as using available situational awareness information and planning documents to help determine response needs, has led to a strong and effective ASPR federal response operation. In 2023, using these tools and programs, ASPR successfully supported a number of declared public health emergencies including: COVID-19; the wildfires in Maui; and hurricanes Lee, Ophelia, Tammy, Idalia, and Typhoons Marwar and Bolaven.

Over the last several years, ASPR also supported non-declared public health emergencies including: expanding the supply chain for personal protective equipment and other deployable assets; managing healthcare surge needs to support significant increases in seasonal influenza and RSV cases; supporting the response to the January 6th Capital insurrection; providing assistance for the Unaccompanied Minor mission along the Southwest Border; supporting 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; supporting Operation Fly Formula to address the shortage of infant formula across the United States; and supporting the mpox Public Health Emergency, including distribution of vaccines.

ASPR continued to support 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 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.

Leading Public Health and Medical Emergency Response Operations

Early detection and communication are critical in responding to and mitigating events that have the potential to significantly impact public health. The HHS SOC is the primary agent for real-time incident detection and response coordination to public health emergencies. The SOC provides uninterrupted

surveillance of emerging threats and critical incidents, nationally and internationally, 24 hours a day, seven days a week, 365 days a year. During the period between July 26, 2022, and July 26, 2023, the SOC Watch Distributed approximately 1,843 notifications, alerts, and reports regarding emergent situations that required a Federal ESF-8 response, HHS coordination, and/or situational awareness.

The SOC provides 24/7 monitoring and communications, as well as ensuring failsafe systems enabling mission shift as needed, to support continuity of HHS missions. ASPR developed protocols to provide 24/7 coverage to ensure mission success, even during evacuation or displacement, through the use of a mobile command center. ASPR maintains $40,000,000 in monitoring and communication assets to guarantee ESF-8 monitoring, which enables ASPR to pre-emptively manage and mitigate issues affecting Americans during public health emergencies and disasters.

This capability ensures that HHS is fully prepared to activate its lead role for ESF-8 and its support role for ESF-6 (for mass care, emergency assistance, temporary housing and human services) 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 coordinates 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 a rapid Federal ESF-8 response.

Throughout the COVID-19 response the SOC was activated and continues to coordinate the federal ESF-8 response to COVID-19 through the deployment of personnel and equipment. The SOC served as the facilitator and conduit for the COVID-19 Temporary Reassignment process 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.

In the last two years, in addition to the ongoing COVID-19 response, the SOC coordinated and supported HHS response activities for incidents, including the emergence of mpox, severe weather systems, mass migration, the repatriation of American Citizens and Afghan allies, and wildfires.

In addition, the SOC serves as the U.S. National Focal Point for World Health Organization (WHO international health regulations communications and reporting, providing situational awareness for Potential Health Emergencies of International Concern, and epidemiological contact tracing for Americans who become ill while in transit internationally. The SOC also supports the HHS Office of the Inspector General through afterhours coverage of their National Tipline for fugitive apprehension.

The FY 2025 ASPR SOC anticipated activities include:

- Maintaining a comprehensive monitoring and detection program that includes all available data sources (including open source and classified) to support enhanced situational awareness, early notification, and decision-support to HHS Senior Leadership;
- Maintaining a support capability for ASPR Response mission activities;
- Strengthening quality assurance, quality control, and quality improvement systems;
- Maintaining the SOC Training program to ensure the preparedness of Emergency Management personnel;

- Reviewing critical policies and procedures; and,
- Planning future information technology improvements.

Intelligence, Information Management, Data, and Analytics
The ASPR information management and intelligence programs serve as the focal point for data management and information collection, analysis, and reporting for ASPR and ESF-8 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. 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. 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, ASPR has produced and distributed more than 35,000 information, intelligence data, and analytic products to support decisions across ASPR, HHS, and the federal sector. The products used during steady-state and responses include senior leader briefs, intelligence books and briefs, open source intelligence briefs, regional deep dive profiles for each of the ten 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 expanded its geospatial and visualization capabilities for information products, which enhanced the ability to identify impacted zones for resource planning and allocation decisions. The program also established a regional presence with information analysts placed in regional offices to facilitate the flow of information. As part of ASPR Ready – ASPR's response and preparedness IT ecosystem – 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 and during response missions. In 2023 a Request for Resources module was launched to modernize and improve how ASPR resources are requested, processed, and tracked. Also, in 2023 ASPR launched the Personnel Accountability Module, which allows for real time tracking and reporting of deployed personnel. In the summer of 2024, ASPR will deploy the Asset Accountability Module, which will allow for modernized tracking of ASPR logistics material/supplies.

Information Technology and Cybersecurity
ASPR's ability to execute its mission depends on a robust, reliable, and resilient information technology and communications infrastructure that is protected from cyber threats. The audio-visual technologies in the SOC, the communications capabilities in the National Disaster Medical System (NDMS), the development of systems like the Geospatial Health System and the Supply Chain Control Tower, and the establishment of an ASPR Common Operating Picture via ASPR Ready 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 of the data collected and shared in these systems, including business proprietary commercially sensitive data. The connection of these systems to the internet introduces significant vulnerability and susceptibility to cyber threats that could compromise the confidentiality, integrity, and availability of critical information during a time of crisis. ASPR provides 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.

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 Secretary and 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 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. ASPR manages the overarching policy and planning portfolio to scope and define the HHS Unified Continuity Program. ASPR ensures daily training and drills for members with mission critical skills. On an annual basis, ASPR develops and facilitates several continuity-focused testing, training, and exercise events to strengthen and assess the HHS COOP program.

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 and diverse path secure and non-secure communications, both internally with our partners. ASPR has restarted the Health Care and Public Health National Radio System (HNARS), which 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.

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.

In FY 2024, ASPR will focus on Federal Mission Resilience, with special attention directed to cyber and power resilience, including the use of renewable energy wherever possible and supporting the Federal fleet electrification initiative. ASPR will continue to lead HHS participation in interagency activities focused on 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, inclusive of locations, systems, and personnel. To protect these assets, ASPR security personnel manage all national security clearance functions, public trust clearance functions, and personnel on-boarding security functions for ASPR, including personnel assigned to the NDMS. 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.

In FY 2023, ASPR processed more than 500 request packages for initial investigations and reinvestigations, and more than 400 security badge requests. ASPR completed initial planning and coordination with interagency partners to build a new Sensitive Compartmented Information Facility (SCIF) to allow authorized ASPR personnel to access and collaborate with partners on classified info and analysis. In FY 2024, ASPR expects personnel security operations to remain at higher-than-normal levels to meet the personnel security process activities necessary to secure ASPR's assets.

In FY 2024 and beyond, ASPR personnel security are responsible for the maintaining and enrolling all ASPR employees into the Trusted Workforce 2.0 program, which is a whole-of-government background investigation reform effort overhauling the personnel vetting process by creating a "one government-wide system" that allows reciprocity across organizations. The intent of Trusted Workforce (TW) is to identify problems within the workforce, allowing managers and security officers to step in and address them, and preventing those small issues from becoming larger issues/risks that result in a shift in someone's reliability and trustworthiness.

In FY 2024 and beyond, ASPR personnel security are responsible for the intake process for all ASPR background investigations and adjudications of all Tier 1, 2, and 4 Public Trust investigations. This is a new function absorbed under the establishment as an HHS operating division. The adjudications branch will allow for a more streamlined resource for ASPR as we continue to onboard and maintain contract, Federal, and Public Health Service (PHS) staff.

Industrial and Physical Security

ASPR is responsible for the assessment and securing of ASPR assets, including personnel, facilities, materiel, information, and equipment required for the performance of research, development,

manufacturing, production, distribution, storage, as well as preparedness and response functions. As a critical lesson learned from the Federal COVID-19 Response, Operation Warp Speed, and the Countermeasures Acceleration Group, ASPR prioritized the strengthening of its industrial and physical security practices and procedures. ASPR established stronger security standards for industrial base expansion efforts, now provides guidance on security-related matters, and enhanced security compliance throughout the complete life cycle of its acquisition process for critical vaccines, therapeutics, diagnostics, and other critical health and public health capabilities and services.

ASPR security is responsible for compliance audits and pre/post site inspections to validate compliance with contract/agreement clauses/requirements, including the review of security language in Requests for Information, Requests for Proposals, and contracts/agreements, at 15 SNS and 56 BARDA-contracted locations, in addition to the expanding portfolio of the Office of Industrial Base Management and Supply Chain (IBMSC) capacity expansion acquisitions. In 2025, ASPR Office of Security and Intelligence will continue to manage the supply chain risk management (SCRM) program to assess the security of the supply chain and recommend and implement mitigation measures, as needed.

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, Organize and Equip, 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 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 led ESF-8 planning and participated 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 2025 (NLE25). 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 at a reduced level in comparison with prior years. ASPR will also continue its Secretary's Quarterly Exercise Series at a reduced level, with one, rather than 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 and funding permits.

Medical Reserve Corps

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025+/- 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

To further 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 disasters, 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 use local volunteers, who donate their time and expertise to prepare for, and respond to public health emergencies and disasters 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 emergency management agencies, local non-profits, and universities also sponsor units.

Funding History	
Fiscal Year	**Amount**
FY 2021	$6,000,000
FY 2022	$6,240,000
FY 2023 Final	$6,240,000
FY 2024 CR	$6,240,000
FY 2025 President's Budget	$6,240,000

Budget Request

The FY 2025 President's Budget request for the MRC is $6,240,000, flat with FY 2023. The MRC is a vital component of our nation's emergency response infrastructure, providing critical support during public health emergencies and disasters. This funding will sustain the minimal level of essential priorities and objectives including limited national and regional coordination efforts, technical assistance for unit leaders, access to the existing set of standardized training materials, and limited collaboration, resource sharing and information exchange to bolster community resilience.

Program Accomplishments

MRC units are active in their communities, as evidenced by the over 14,000 activities reported during FY 2023. According to unit reporting, 100,000 MRC volunteers contributed 248,000 hours of service with an economic value of $9.8 million. MRC units are sustaining their volunteer numbers as the country moves past the peak of the COVID-19 pandemic. Since the beginning of 2022, the number of volunteers across the MRC network grew from roughly 175,000 to over 300,000.

MRC units supported their communities in a wide array of responses to COVID-19, mpox vaccinations, the opioid crisis through harm reduction programs, public health and sheltering support for asylum seekers, public health and medical support to wildland fire survivors in Maui, and responses to severe flooding.

At the national level, the MRC program continued its cooperative agreements with the National Association of County and City Health Officials (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.

ASPR awarded $3.4 million in the Respond, Innovate, Sustain, and Equip (RISE) Awards across an additional 111 MRC units. The MRC COVID-19 RISE awards 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 will 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.

In 2023, the ASPR Medical Reserve Corps awarded $50 million via the State, Territory and Tribal Nations, Representative Organizations for Next Generation (MRC-STTRONG) grants using American Rescue Plan (ARP) supplemental funding. States and jurisdictions will use these funds to strengthen the MRC network – focusing on emergency preparedness, response, and health equity needs.

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.

Health Care Readiness and Recovery

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**305.055**	**305.055**	**317.055**	***+12.000***
Hospital Preparedness Program (HPP) Annual Cooperative Agreement (non-add) /1	*240.000*	*240.000*	*240.000*	-
Regional Disaster Health Response System Cooperative Agreement (RDHRS) (non-add)	*7.000*	*7.000*	*7.000*	-
National Special Pathogen System (NSPS) (non-add)	*28.500*	*28.500*	*28.500*	-
National Emerging Special Pathogens Training and Education Center (NETEC) (non-add)	*7.500*	*7.500*	*7.500*	-
Regional Emerging Special Pathogen Treatment Centers (RESPTCs) (non-add)	*21.000*	*21.000*	*21.000*	-
Other Program Costs (non-add)	*29.555*	*29.555*	*41.555*	*+12.000*
Health Care Readiness and Recovery Enabling Activities and Operations	*22.827*	*22.845*	*22.845*	-
Technical Resources, Assistance Center, and Information Exchange (TRACIE)	*2.710*	*2.710*	*2.710*	-
Critical Infrastructure Protection (CIP)	*1.774*	*1.774*	*13.774*	*+12.000*
Community Mitigation & Recovery (CMR)	*2.244*	*2.226*	*2.226*	-
FTE	**49**	**49**	**75**	-

1/ The Public Health Service (PHS) Act determines the HPP annual cooperative agreement eligibility as the 50 states, Washington, D.C., three high-risk political subdivisions, and all United States territories and freely associated states.

Authorizing Legislation:
Authorization……...Public Health Service Act
Allocation Method……...Formula-based and competitively awarded cooperative agreements; direct federal/intramural; contracts

Program Description

The programs and activities supported by the Administration for Strategic Preparedness and Response's (ASPR) Health Care Readiness and Recovery (HCRR) assist the country in preparing for, responding to, and recovering from public health emergencies and disasters by engaging partners from all 50 states, territories, and freely associated states to prepare the health care sector to provide innovative, coordinated, and lifesaving care in the face of emergencies and disasters.[1] During a disaster, health care delivery occurs at the local level; yet, effective and equitable care delivery during a public health emergency may require additional types of coordination and collaboration among federal, state, local, tribal, and territorial (SLTT) governments, and industry. Public-private partnership, specifically among multiple types of health care, public health, and emergency management entities, is necessary to drive effective coordination and ultimately save patient lives. Furthermore, partnership functions are particularly critical to address gaps in access to clinical sub-specialty care for individuals exposed to chemical, biological, radiological, or nuclear agents, emerging infectious diseases, trauma, and burn injuries.

During surge events – events in which health care entities face sudden, high demands on inpatient beds, workforce, or other resource capacities due to an influx of patients during an emergency – multiple entities must work together to communicate information, share resources, manage patient movement and load-balancing, and make decisions that impact how, when, and where patients receive care and access to services. Investments to strengthen surge readiness, including collaboration to drive patient load-balancing, patient care delivery, deployment of specialty care, and information sharing provide profound, lifesaving impacts for patients during emergencies and disasters.

The national health security threat landscape is more complex and challenging than ever before. Health security threats occur more frequently, creating devastating impacts, both acute and persistent, for individuals, families, communities, health care workforce, and the nation's health care delivery system.[2] When health care is unprepared, these threats exacerbate existing challenges, including health inequities, workforce attrition and burnout, and fragmentation among systems (e.g., among emergency medical services [EMS] and other parts of the health care delivery system) – diminishing capabilities to respond to the novel threats of tomorrow and to our national security.

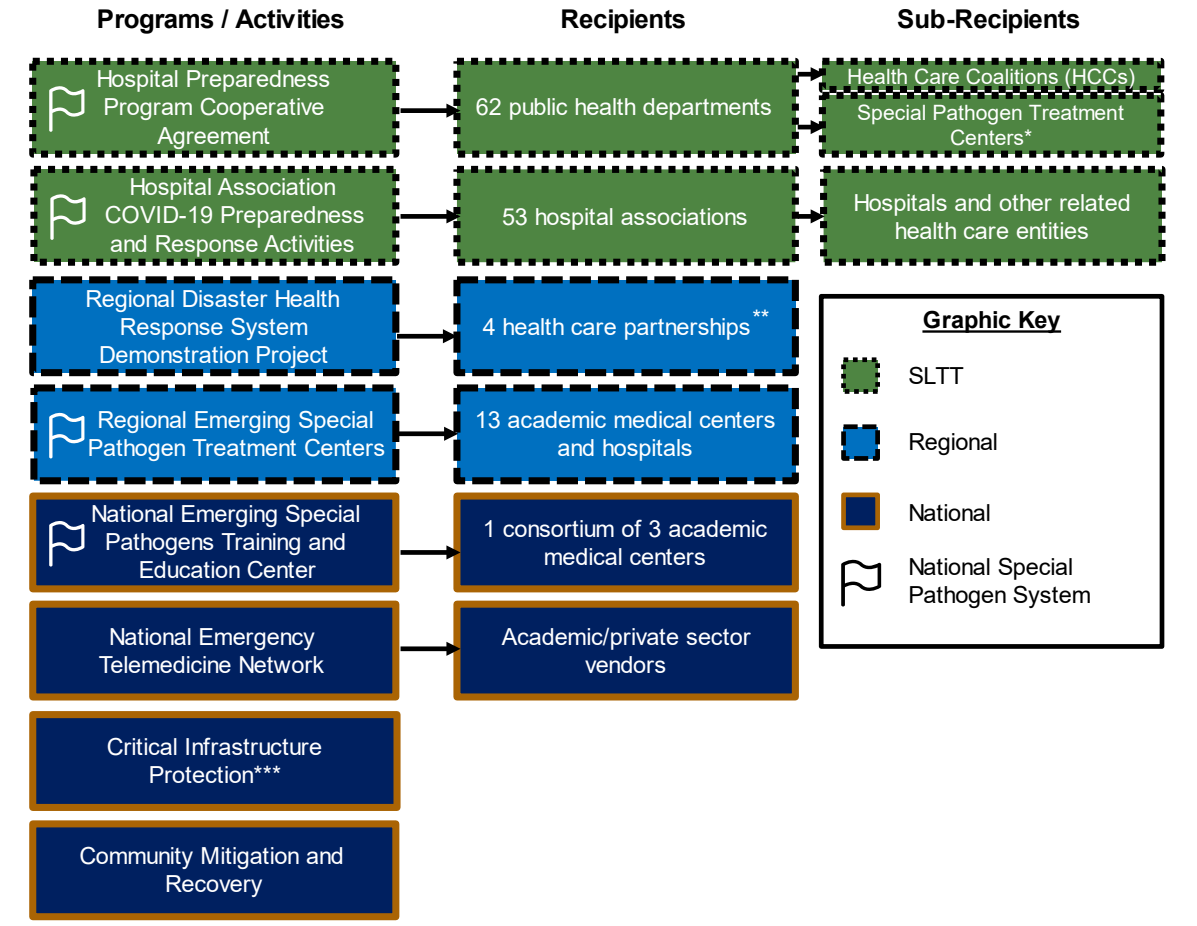
Through HCRR programs and activities, local health care entities can access networks across states and regions, nationally, and globally to use capabilities for lifesaving care and build capacity to prepare against future threats. Health care entities work across all these networks and engage other partners – including critical infrastructure entities, community organizations that support recovery, and more – to coordinate activities before, during, and after public health emergencies and disasters. Altogether, the programs and activities within the HCRR portfolio (**Figure 1**) represent a collection

[1] 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.

[2] For the purposes of this document, the "health care delivery system" refers to all organizations and persons whose mission is to promote, restore, optimize, or maintain health. While there is currently no single national health care system, this document uses "health care delivery system" to capture the broad spectrum of work towards meeting the health care needs of individuals and the population.

of building blocks that strengthen health care emergency preparedness, response, and recovery at all levels to form a comprehensive, national system.

Figure 1: HCRR FY 2024 Programs and Activities



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

** 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.

*** The Office of Critical Infrastructure Protection (CIP) includes ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE).

Funding History	
Fiscal Year	**Amount**
FY 2021	$280,555,000
FY 2022	$295,555,000
FY 2023 Final	$305,055,000
FY 2024 CR	$305,055,000
FY 2025 President's Budget	$317,055,000

Budget Request

The FY 2025 President's Budget request for Health Care Readiness and Recovery (HCRR) is $317,055,000, which is an increase of +$12,000,000 above FY 2023. The additional funding will enhance the ASPR Office of Critical Infrastructure Protection (CIP) to improve HHS-wide responses to cyber incidents affecting the Healthcare and Public Health (HPH) Sector. In its role as the Sector Risk Management Agency designee on behalf of HHS, CIP supports the HPH Sector to prepare for future threats, manage risks, coordinate effective response, and recover from human-caused and naturally occurring threats and hazards. The budget also proposes $240,000,000, equal to FY 2023, to fund the Hospital Preparedness Program (HPP) cooperative agreement. ASPR will distribute this funding across 62 recipients at levels determined by HPP's statutorily required funding formula. With flat funding, HPP recipients will be able to meet and sustain current capabilities. The President's Budget also proposes $7,000,000, equal to the FY 2023 budget, to sustain the four existing Regional Disaster Health Response System (RDHRS) sites. For the National Special Pathogen System (NSPS), the budget proposes $28,500,000, equal to FY 2023. Within this total, $21,000,000 will support the Regional Emerging Special Pathogen Treatment Centers (RESPTCs) 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 the National Emerging Special Pathogens Training and Education Center (NETEC) to continue implementation of the National Special Pathogen System Strategy (NSPS Strategy) and continue building special pathogen preparedness and response capacity across health systems in the U.S. with the goals of driving best practices, closing knowledge gaps, and developing innovative resources.

The FY 2025 President's Budget includes $41,555,000, an increase of $12,000,000 above FY 2023, to support programs and activities in the "Other Program Costs" line. This line includes programmatic funding for Critical Infrastructure Protection (CIP), ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE), and ASPR's Office of Community Mitigation and Recovery (CMR), as well as funding for the HCRR line item's key enabling activities and operations, such as program oversight and technical assistance, workforce capacity building, and Public Health Service Act and program evaluation.

ASPR CIP will use additional funds to ensure health care resources are safeguarded against all-hazard events, including cybersecurity attacks, which have been increasing in frequency and severity. Additional funding will support the continued build out of ASPR CIP's Cybersecurity Division in the form of additional FTEs and program support to:

- Execute the HHS Cybersecurity Strategy as articulated in the Healthcare Sector Cybersecurity Concept Paper released in December 2023, which includes maturing and expanding ASPR's capabilities as the "one stop shop" for healthcare cybersecurity for HHS;
- Implement the Healthcare and Public Health (HPH) Cybersecurity Performance Goals through educational campaigns, implementation guidance, technical assistance, and resource development to support cybersecurity preparedness and resilience across the sector;
- Increase cybersecurity operations to analyze cyber-attack information, assist HPH cyber-attack victims, share intelligence with partners, and inform sector partners of risks and mitigations.

ASPR, as the Health Care Public Health (HPH) Sector Risk Management Agency (SRMA), coordinates with DHS CISA and other federal entities to implement the National Cybersecurity Strategy and defend the nation's critical infrastructure from cyberattacks.[3] Additional funding will enable ASPR CIP to develop innovative models and mechanisms to strengthen collaboration between HPH critical infrastructure owners and operators and ensure private sector partners have the necessary capabilities to rapidly share cybersecurity information and coordinate defensive efforts.[4] ASPR CIP is responsible for uniting HHS cybersecurity entities, facilitating interagency coordination for cyber preparedness and response, and updating incident response plans, supporting a unified, coordinated, whole of government response to cyber threats.[5]

Effective management of cybersecurity risks to the HPH Sector requires a robust cybersecurity function within the SRMA. Additional resources will support significant expansion of HHS's ability to: facilitate and coordinate joint public-private work that directly address cybersecurity concerns, enhance HHS's ability to assess and coordinate activities related to cybersecurity incidents, and conduct robust analysis and integrate analytic outcomes into a range of risk management products to inform the Sector and HHS leadership. A significant portion of the increased funds will be used to support an aggressive hiring initiative targeting acquisition of cybersecurity and risk management expertise.

ASPR TRACIE will use funds to provide direct support to external partners and develop additional resources focused on improving the equitable preparedness, response, and recovery efforts of health care entities and health care coalitions (HCCs). This includes: developing tools and templates to address guidance in the updated Health Care Preparedness and Response Capabilities; maintaining the Disaster Available Supplies Hospitals (DASH) Tool; developing resources to promote patient load balancing or the use of constructs such as Medical Operations Coordination Centers (MOCCs); developing additional resources to address workplace violence; providing technical assistance and developing resources for providers and suppliers affected by updates to the Centers for Medicare & Medicaid Services (CMS) Emergency Preparedness Rule; and supporting initiatives focused on health care disparities, workforce sustainability, cybersecurity, and extreme weather event impacts.

CMR works to integrate community resilience to future extreme weather events and other disasters into recovery operations, supporting the self-determination of local communities and the recovery strategies of states, tribes, and territories. CMR 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. ASPR will additionally use this funding to address the surging demand for disaster recovery assistance for SLTT jurisdictions through coordination of the Health and Social Services Recovery Support Function (HSS RSF), assigned to ASPR under the National Disaster Recovery Framework (NDRF).

Historically, disasters and other public health emergencies exacerbate pre-existing health disparities, overburden local health care and human services systems, and create behavioral health needs that

[3] NSC, "Pillar One: Defend Critical Infrastructure," pg. 7.
[4] NSC, "Pillar One, Strategic Objective 1.2: Scale Public-Private Collaboration," pg. 10.
[5] NSC, "Pillar One, Strategic Objective 1.4: Update Federal Incident Response Plans and Processes," pg. 11.

local systems are typically not resourced to manage. CMR leverages field recovery operations and coordinated interagency supports for affected communities to develop integrated solutions to expand the capabilities of local health care, behavioral health, public health, educational, and human services systems to meet the needs of individuals and families post-disaster.

Funding for key enabling activities will allow ASPR to maintain current infrastructure and technology to support information-sharing, technical assistance, and program evaluation, but ASPR will be unable to expand performance data collection efforts or modernize the existing technology infrastructure. ASPR will continue to provide technical assistance and oversight to HPP, RDHRS, NSPS recipients, sub-recipients, and other health care partners who maintain all-hazards readiness and response capabilities and capacities across the nation. ASPR supports a broad spectrum of health care partners throughout responses to various all-hazards events, including mpox and Respiratory Syncytial Virus (RSV) preparedness and response activities in the U.S. Virgin Islands, multiple hurricanes in Louisiana, and winter storms in Texas.

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. HPP enables the formation of public-private partnerships among multiple types of health care, public health, and emergency management organizations and provides access to a national response network. 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.[6]

An HCC is a network of individual public and private organizations in a defined geographic location that partner to conduct preparedness activities (e.g., exercises, trainings) and collaborate to ensure that each member is equipped to respond to disasters and public health emergencies. HCCs coordinate joint exercises to improve coalition-wide resilience, educate and train health care personnel, distribute and share medical equipment and supplies during a response, and share real-time information to provide situational awareness during a response.

ASPR requires that each HCC funded by the cooperative agreement include, at minimum, the following core members: acute care hospitals, public health agencies, EMS, and emergency management agencies. As of June 30, 2023, there are 47,863 HCC member organizations participating in 318 HCCs nationwide.[7] Through HPP, 98 percent of public health agencies, 94 percent of acute care hospitals, 79 percent of emergency management agencies, and 50 percent of EMS organizations form a part of an HCC. Representation of acute care hospitals and EMS organizations in HCCs nationally increased by three percent each.

[6] 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.
[7] HPP cooperative agreement budget period four (BP 4) end-of-year (EOY) performance data (Period of Performance: July 1, 2022 – June 30, 2023).

HPP improves health care entities' preparedness for emerging, all-hazards threats by strengthening collective response planning and health care capabilities across jurisdictions. During a disaster, transportation services for home health and dialysis patients are often suspended, leaving many without access to lifesaving care. As a result, individuals with End Stage Renal Disease (ESRD) often turn to hospitals in search of care during a disaster, putting additional stress on both hospital staff and resources. In 2022 and 2023, the South Carolina Lowcountry Health Care Coalition (LCHCC), in collaboration with the Island Peer Review Organization (IPRO) and members of its Dialysis Work Group, used HPP funding to develop and use the ESRD Emergency Hub app, which connects individuals with ESRD to resources that can aid them in locating treatment before, during, and after a disaster. As of August 2023, the app is now available to patients in 13 states.[8]

In addition to the COVID-19 surge response, which required coordination across multiple health care partners, HCCs' mechanisms for communication and planning across member types became integral to health care entities' ability to quickly build capacity to respond to other public health response efforts, including multiple hurricanes in Louisiana, power outages caused by winter storms in Texas, and mpox and RSV preparedness and response activities in the U.S. Virgin Islands. 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.

The Medical Response and Surge Exercise (MRSE) is an annual requirement of the Hospital Preparedness Program (HPP) cooperative agreement designed to examine and evaluate the ability of HCCs and their partners to support medical surge. In FY 2022, 93.1 percent of HCCs used the MRSE to test capabilities in a surge scenario demanding equal to or greater than 20 percent of a coalition's bed capacity.[9]

Regional Disaster Health Response System (RDHRS)

To address gaps in regional health care delivery during disasters and to scale public-private partnerships across multiple states, ASPR developed the RDHRS. The RDHRS is a tiered system that builds upon and unifies existing specialty care (e.g., trauma, burn, infectious disease) assets, coordinates resource allocation, and facilitates patient load-balancing within and across multi-state regions, supporting a comprehensive health care delivery system that is more capable of responding to health security threats. The RDHRS also increases medical surge capacity during large-scale disasters or public health emergencies and support regional level-loading and resource allocation efforts to increase quality of patient care during health care emergencies.[10]

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[8] Administration for Strategic Preparedness and Response (ASPR), "HPP-Supported App Now Provides Lifesaving Resources to Individuals with End Stage Renal Disease in 13 States." September 2022. https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/HPP-Supported-App-Provides-Lifesaving-Resources-to-ESRD-Patients.aspx

[9] Due to the strain placed upon the health care delivery system by COVID-19, ASPR provided flexibility for health care coalitions (HCCs) to complete the Medical Response and Surge Exercise in either Fiscal Year 2021 or in Fiscal Year 2022. HCCs were also able to complete the MRSE in both budget periods. As such, results for this measure in Fiscal Year 2022 are compiled across two years, and these results are considered preliminary.

[10] 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. American

Currently, HCRR funds four RDHRS demonstration sites:

- Region 1 RDHRS, based at Massachusetts General Hospital (established in FY 2018)
- 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 (established in FY 2018)
- Region 8 Mountain Plains RDHRS, based at Denver Health and Hospital Authority (established in FY 2020)

The RDHRS establishes and develops multi-state public-private partnerships to meet regional health care delivery needs during an emergency response. As an example, the Region 7 RDHRE supported specialized teams within the multi-state region that provided virtual and in-person assistance, including guidance documents and webinars, to regional partners to enhance COVID-19, mpox, and Ebola readiness. Additionally, the Region 4 SRDRS established the Region 4 Poison Control Center Collaborative (R4PC3) with the goal of increasing surge capacity while enhancing the capability of all 10 Region 4 poison control centers by providing technical and clinical consultation to medical providers, public health, emergency management, and the public during and after chemical disasters.

The RDHRS demonstration sites support health care partners to respond to surge events. For example, at the beginning of the 2022-2023 school year, the Region 7 RDHRE leveraged its assets to enhance situational awareness for practitioners from all major children's hospitals and acute care hospitals with pediatric beds, public health partners, HCC coordinators, and hospital associations by hosting routine calls with pediatric experts. The Region 7 RDHRE also collaborated with all 22 pediatric hospitals and six pediatric transport teams to develop situational reports on hospital capacity, staffing, bed availability, and supply shortages, as well as developed a rapid pediatric bed availability dashboard.[11]

RDHRS sites are also creating tools and teams to build upon, unify, and support the broader existing regional infrastructure. During the 2022 pediatric surge caused by RSV, all four RDHRS sites worked collectively to enhance situational awareness within their regions by standing up patient tracking dashboards, developing and disseminating pediatric surge tools and resources, and hosting meetings with all response partners.[12]

NSPS: National Special Pathogen System (NSPS)

The NSPS is a tiered, national system that promotes, assesses, and assists health care facility infectious disease readiness, educates and trains health care workers, provides technical assistance, supports research, and enables surge mitigation activities through training, exercises, and load

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

[11] ASPR, "Regional Disaster Health Response Systems Demonstration Sites Provide Critical Support by Coordinating Information Sharing Efforts and Technical Assistance Throughout Pediatric Surge." https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/RDHRS-Pediatric-Surge.aspx

[12] ASPR, "Regional Disaster Health Response Systems Demonstration Sites Provide Critical Support by Coordinating Information Sharing Efforts and Technical Assistance Throughout Pediatric Surge." https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/RDHRS-Pediatric-Surge.aspx

balancing efforts. NSPS integrates with other health care delivery systems of care for emergencies, including the National Emerging Special Pathogens Training and Education Center (NETEC), Regional Emerging Special Pathogen Treatment Centers (RESPTCs), HPP recipients and their state and jurisdiction Special Pathogen Treatment Centers (SPTCs), and Hospital Associations (HAs). These components complement and build upon one another to form a national system for special pathogen identification and treatment.

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

NETEC is a consortium of three academic medical centers – Emory University, the University of Nebraska Medical Center/Nebraska Medicine, the New York Health and Hospitals Corporation/ Bellevue Hospital Center – and acts as the national coordinating body for the NSPS. NETEC supports national health care readiness for infectious disease by educating and training health care workers, providing technical assistance, supporting research capacity, and enabling surge activities. Additionally, NETEC regularly serves as a special pathogen response advisor to ASPR and the U.S. government on the country's health care capacity and capabilities to care for patients and protect the health care workforce. During recent outbreaks of mpox, Marburg virus disease, and the emergence of a new COVID-19 variant, NETEC has continued to provide educational materials, situational awareness, readiness status updates, and recommendations on patient care, serving a critical role in coordinating national special pathogen responses.

NETEC engages and provides critical support to the RESPTCs, which work closely with NETEC to improve regional capabilities to prepare for and respond to special pathogens. NETEC annually assesses the readiness of RESPTCs; all RESPTCs that reported receiving services from NETEC used those services to improve operational and clinical outcomes.[13] NETEC also developed an integrated national clinical research network for special pathogens, the Special Pathogens Research Network (SPRN), which consists of research sites at 10 RESPTCs. Centralized resources, including a common rapid response institutional review board, data repository, biorepository, research training protocols, and standardized polices, support the Special Pathogens Research Network.[14]

From January 2023 to February 2024, there have been a total of 12,569 suspected mpox cases reported in the Democratic Republic of Congo (DRC) caused by the Mpox Virus (MPXV) clade I, or the Central African clade. The clade I MPXV is known for more severe clinical manifestations compared to other MPXV clades, characterized by a higher rate of transmission, increased virulence, and a greater potential for causing serious health complications, leading to its classification as a Category A infectious substance. In response to this outbreak, NETEC is working

[13] Regional Emerging Special Pathogen Treatment Center (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.
[14] The SPRN operates at each of the original 10 RESPTC sites. ASPR created three new RESPTC sites in FY 2022 and will be a part of SPRN as they mature. 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/

with federal partners and RESPTCs to ensure proper management of any patient suspected of infection with clade I MPXV should one present in the United States.[15]

NETEC's resources and trainings drive improved capabilities at the local level. Between June 2022 and February 2023, NETEC hosted trainings and events for health care entities that reached a total of 3,750 webinar participants and had 2,500 enrollments in online courses. Additionally, NETEC continues to build out regional medical transport capabilities, such as the Special Pathogens Operational Readiness Self-Assessment for EMS.[16]

As the coordinating body for the NSPS, NETEC is leading health care to implement a strategy that formalizes coordination across these levels through a comprehensive hub-and-spoke system. 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. With the NSPS Strategy, ASPR is in a better position to ready the nation's health care system for special pathogen response by closing knowledge gaps, developing innovative resources, and establishing a national infrastructure to manage special pathogen response safely and effectively.

NSPS: Regional Emerging Special Pathogen Treatment Centers (RESPTCs)

To realize the vision of the NSPS, ASPR provides funds directly to 13 RESPTCs to support a coordinated and standardized health care network of high-quality, patient- and community-centered care for suspected or confirmed special pathogen patients in the U.S. while protecting the health care workforce. As the regional tier of the NSPS hub-and-spoke system, RESPTCs are designed to serve as the regional "hubs" for special pathogen readiness in the U.S. RESPTCs build public-private partnerships to coordinate care delivery, disseminate information, education, resources, and other support across the NSPS.

For example, Massachusetts General Hospital identified the first mpox case in the U.S. and worked with federal and state officials to develop new protocols for exposure investigation. They produced seven peer-reviewed publications from the response, including the most viewed case article in the New England Journal of Medicine for 2022. This response coordination demonstrated significant growth of the region's capability to work with hospitals across New England.

In FY 2024, RESPTCs will continue to mature their regional hub capacity to help formalize the NSPS within their regions while maintaining their special pathogen clinical capabilities. As an example of RESPTCs contributing to regional preparedness, Denver Health and Hospital Authority developed a Virtual Assessment Model in response to the Sudan ebolavirus outbreak. It was approved and drilled

[15] NETEC. "NETEC provides free, ongoing technical support and assistance to health care facilities in response to the outbreak of Mpox disease in the Democratic Republic of Congo." https://netec.org/2023/12/07/press-release-netec-provides-free-ongoing-technical-support-and-assistance-to-health-care-facilities-in-response-to-the-outbreak-of-mpox-disease-in-the-democratic-republic-of-congo/

[16] NETEC, "Readiness Assessment", March 9, 2023. https://netec.org/readiness-assessments/

to be activated for a suspect patient with Viral Hemorrhagic Fever (VHF). They also tested the Ask-Isolate-Call system in outpatient clinics for a suspect VHF patient.

Recent special pathogen responses have highlighted underlying inequities in health care delivery. For example, during the COVID-19 pandemic, racial and ethnic minority groups experienced 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 individuals.[19]

NSPS: HPP and Special Pathogen Treatment Centers (SPTCs)

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 health care delivery system to operate as a cohesive network. When a new highly pathogenic illness emerges and hospitals are experiencing surge events, SPTCS are vital to identify and contain special pathogens while also providing critical care to patients. With their ability to receive a confirmed special pathogen patient within a few hours due to enhanced capability and capacity to care for highly infectious diseases, they serve a crucial role in alleviating burden on surrounding hospitals and health care entities.

An example of how SPTCs operate at the community level is illustrated by their use of COVID-19 supplemental funding to meet the needs created by COVID-19 medical surge. Thirty-two percent of SPTCs who reported their use of COVID-19 supplemental funding reported using staff that had participated in just-in-time trainings to provide surge capacity support and accept COVID-19 patients when other facilities exceeded patient capacity.[20]

NSPS: Hospital Associations (HAs)

HAs serve as a crucial mechanism to distribute funding directly to hospitals and other related health care entities for special pathogen preparedness and response. During the COVID-19 pandemic response, ASPR provided emergency supplemental funding to HAs, which rapidly distributed funds to hospitals and other related health care entity sub-recipients who were significantly overwhelmed with COVID-19 pandemic response activities. HAs communicated health care situational awareness and response needs to ASPR as well as provided hospitals with funding that was used to acquire essential supplies and equipment for local health care organizations. In addition, HA sub-recipients

[17] Stokes EK, Zambrano LD, Anderson KN, et al. . MMWR Morb Mortal Wkly Rep 2020;69:759–765. http://dx.doi.org/10.15585/mmwr.mm6924e2.http://dx.doi.org/10.15585/mmwr.mm6924e2.
[18] Killerby ME, Link-Gelles R, Haight SC, et al. (2020). — Metropolitan Atlanta, Georgia, March–April 2020. MMWR Morb Mortal Wkly Rep. http://dx.doi.org/10.15585/mmwr.mm6925e1.http://dx.doi.org/10.15585/mmwr.mm6925e1
[19] ASPR uses the Public Health Service (PHS) Act definition of "at-risk individuals" as children, pregnant individuals, older adults, individuals with disabilities, or others who may have access and functional needs in the event of a public health emergency, as determined by the Secretary of Health and Human Services: 42 USC 300hh-1(b)(4): National Health Security Strategy; 42 USC 300hh-16: At-risk individuals. https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title42-section300hh-16
[20] HPP cooperative agreement COVID-19 supplemental funding year-end performance data (Period of Performance: March 29, 2020 – June 30, 2021).

conducted COVID-19-specific infection control and triage trainings and implemented improved infection control and personal protective equipment (PPE) practices.

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. As the SRMA for the HPH Sector, HHS is charged with advancing the nation's priorities related to health critical infrastructure, such as implementing the National Cybersecurity Strategy and National Response Framework.[21,22,23] ASPR's CIP carries out its responsibility as the HPH SRMA designee on behalf of HHS, enabling effective and coordinated management of all-hazard incidents, with increasing attention to mitigating Sector cyber vulnerabilities.[24]

Strengthening Cyber Sector Risk Management

ASPR's newly announced Cybersecurity Division strengthens HPH Sector coordination within HHS and across other critical infrastructure sectors. ASPR leads two HPH Sector-wide cyber working groups, engaging closely with over 300 public and private sector partners to enhance threat understanding and improve incident response throughout the HPH Sector. ASPR oversees the HPH Sector Joint Cybersecurity Working Group (JCWG), and in FY 2023, the JCWG established a coordinated strategic approach to HPH Sector challenges. Through this approach, the JCWG is identifying tactical programs and initiatives to align the HPH Sector's cybersecurity approaches, assess key risks, and develop data-driven cyber risk mitigation measures. ASPR also brings together cyber experts from across HHS to align Departmental cybersecurity activities and address critical information requests from HHS leadership, the Department of Homeland Security's (DHS) Cybersecurity and Infrastructure Security Agency (CISA), the National Security Council (NSC), and the Office of the National Cyber Director.

In collaboration with cyber leaders across HHS, ASPR provides cyber response planning and risk mitigation support to the HPH Sector. ASPR partnered with private sector cybersecurity executives and leaders from the private sector through the JCWG to develop the HPH Sector Cybersecurity Framework Implementation Guide and establish a public-private sector partnership playbook to promote collaboration during cybersecurity and all-hazards events.[25] To test and operationalize response plans and playbooks, ASPR participates in cyber-focused tabletop exercises with HPH Sector owners and operations, including DHS's annual CyberStorm exercise.

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[21] Congress, "FY21 National Defense Authorization Act, Section 2215 Sector Risk Management Agencies, Part A." https://www.congress.gov/bill/116th-congress/house-bill/6395https://www.congress.gov/bill/116th-congress/house-bill/6395

[22] White House, "National Cybersecurity Strategy," https://www.whitehouse.gov/wp-content/uploads/2023/03/National-Cybersecurity-Strategy-2023.pdf

[23] FEMA, "National Response Framework," https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response

[24] Congress, "The Pandemic and All-Hazards Preparedness and Advancing Innovation Act," https://www.congress.gov/bill/116th-congress/senate-bill/1379https://www.congress.gov/bill/116th-congress/senate-bill/1379

[25] ASPR, "HPH Sector Cybersecurity Framework Implementation Guide," https://aspr.hhs.gov/cip/hph-cybersecurity-framework-implementation-guide/Pages/default.aspx

During cybersecurity incidents, ASPR leads federal response planning by assessing incident severity, coordinating with federal and SLTT emergency response teams and impacted owners and operators, and sharing critical monitoring and mitigation information with over 8,000 HPH Sector partners. In FY 2023, ASPR partnered with the National Security Council and HHS cybersecurity leaders to develop a novel data collection tool for care delivery centers, improving cyber incident triage planning and enhancing incident tracking for the HPH Sector. Today, ASPR provides HHS leaders with enhanced visibility and data-driven understanding of HPH Sector cybersecurity incidents by working with cyber SRMA partners to conduct outreach to affected organizations, rapidly assess potential impacts to patient care and safety, and determine appropriate response procedures.

Coordinating Partners and Assessing Sector Risk

ASPR engages public and private sector partners to develop and share critical infrastructure expertise and resources, equipping the HPH Sector to prepare for and respond to critical infrastructure challenges. ASPR leads the HPH Sector Partnership (HPH Partnership), uniting more than 300 private sector organizations and federal and SLTT agencies to coordinate and actively partner to protect the nation's HPH infrastructure.[26] The HPH Partnership oversees several working groups addressing the Sector's highest priorities, including cybersecurity and supply chain threats. In FY 2023, the HPH Partnership launched the Joint National Critical Infrastructure Prioritization Working Group (NCIPWG) which created a set of criteria for HPH Sector-specific infrastructure identification and prioritization.

In close coordination with partners, ASPR collects and analyzes information to conduct proactive risk assessments. At the heart of ASPR's HPH Sector risk assessment capability is the CIP-developed Risk Identification and Site Criticality (RISC) Toolkit, which enables ASPR's partners to conduct tailored, data-driven risk assessments. This toolkit includes a cybersecurity module closely aligned with the National Institute of Standards and Technology (NIST) Cyber Security Framework. The launch of RISC Toolkit 2.0 in November 2023 also provides a robust data source for HHS to conduct HPH Sector-wide analysis of critical infrastructure risk and vulnerability. Pairing ad hoc data collection with RISC assessments, ASPR is developing a comprehensive picture of HPH Sector risk and creating planning and mitigation resources for the sector.

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. 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.

Since ASPR TRACIE's launch, the platform has experienced an exponential increase in use and demand, with cumulative visitor volume reaching over 1.75 million as of October 2023. The monthly number of technical assistance requests has also increased, with an average of 118 technical assistance requests per month. ASPR TRACIE experiences spikes in both technical assistance requests and website visitation statistics during times of declared national emergencies

[26] ASPR, "HPH Sector Partnership," https://aspr.hhs.gov/AboutASPR/ProgramOffices/ICC/Pages/HPH/HPH-Sector-Partnership.aspx

and local disasters, and after release of tools and templates. ASPR TRACIE also provides virtual surge assistance and resources during and after incidents to support ASPR staff and local deployed/deployable personnel.

ASPR TRACIE established innovative processes for sharing existing and developing new resources, and since 2015, the team has added over 11,000 resources to the ASPR TRACIE database. The ASPR TRACIE team also:

- Published and maintained over 450 SME-validated resource materials.
- Developed and continuously maintained 60 SME-reviewed Topic Collections.
- Began repurposing resources developed for health care system preparedness and response to COVID-19 to be more widely utilized for other emergencies.
- Published 17 issues of the newsletter, *The Exchange*
- Provided direct support for the Hospital Preparedness Program (HPP) cooperative agreement.
- Collaborated with the Centers for Medicare & Medicaid Services (CMS) to help providers and suppliers comply with the CMS Emergency Preparedness Rule.
- 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.
- Conducted over 100 web-based learning opportunities such as national webinars and speaker series presentations on timely and relevant topics.

Community Mitigation and Recovery (CMR)

The CMR 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. CMR serves as the National Coordinator of the Health and Social Services (HSS) Recovery Support Function (RSF), as assigned in the NDRF.

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, human services, public health/environmental health, and educational systems. In its role as the leading entity, ASPR pays careful attention to ensure that intervention supports the needs of children, youth, and families; integrates older adults and people with access and functional needs; supports climate resilience and sustainability, and; supports equity in post-disaster outcomes.

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

In 2023, CMR saw a 300 percent increase in the number of activations by FEMA of the HSS RSF, compared to the annual average since the National Disaster Recovery Framework (NDRF) was finalized in 2011—from a historical average of 3.1 disasters/year to 12 disasters in 2023. CMR also responded to a record high number of concurrent recovery field activations; prior to 2023, the number of most concurrent recovery missions in a year was four, but in 2023, the number rose to 10 concurrent operations.

Missions in 2023 included recovery operations for hurricanes and typhoons in Florida, Guam, and Louisiana; flooding, storms, and tornadoes in Arkansas, California, the Hoopa Valley Indian Tribe, Kentucky, Mississippi, Missouri, and Vermont; wildfires in New Mexico and Hawaii; train derailment in Ohio; and the COVID-19 pandemic in American Samoa, the Commonwealth of the Northern Marianas Islands, and Guam.

- In Hawaii, following the deadly Maui wildfires, CMR coordinated the largest disaster behavioral health recovery mission in modern American history. Mental health responders working in hotels where survivors were sheltered, public schools, the Lahaina community clinic, and the Lahaina community center provided more than 15,000 behavioral health encounters with survivors of the fires, first responders, and the local recovery workforce.
- In Guam, as part of the integrated recovery mission following Super Typhoon Mawar, CMR developed a health care workforce plan, adopted by the Guam governor's office, to enhance community health care system resilience and make Guam more resistant to future storms.
- In Mississippi, CMR partnered with local community leaders and interagency partners on efforts to keep the local hospital operating as the community recovered from severe storms and tornadoes.

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 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
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 2022 Preliminary Data[1]: 93.1% Target: 90% (Target Exceeded)	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 2022: 98.3% Target: 100% (Target Not Met but Improved)	90%	90%	Maintain

[1] Due to the strain placed upon the health care delivery system by COVID-19, ASPR provided flexibility for health care coalitions (HCCs) to complete the Medical Response and Surge Exercise (MRSE) in either Fiscal Year 2021 or in Fiscal Year 2022. Therefore, results in Fiscal Year 2022 are compiled across two years and are considered preliminary. FY 2023 data will be reported in late December 2024.

Department of Health and Human Services
Administration for Strategic Preparedness and Response
FY 2025 MANDATORY STATE/FORMULA GRANTS

CFDA NUMBER/PROGRAM NAME: 98.899 Hospital Preparedness Program

STATE/TERRITORY	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Alabama	$3,309,964	$3,374,275	$3,374,275	+$64,311
Alaska	$1,207,860	$1,222,975	$1,222,975	+$15,115
Arizona	$4,722,840	$4,736,346	$4,736,346	+$13,506
Arkansas	$2,211,363	$2,247,907	$2,247,907	+$36,544
California	$23,277,698	$22,218,713	$22,218,713	-$1,058,985
Chicago	$2,830,510	$2,561,344	$2,561,344	-$269,166
Colorado	$3,542,915	$3,590,488	$3,590,488	+$47,573
Connecticut	$2,350,090	$2,377,895	$2,377,895	+$27,805
Delaware	$1,197,639	$1,211,436	$1,211,436	+$13,797
District of Columbia	$1,203,349	$1,217,882	$1,217,882	+$14,533
Florida	$11,987,615	$11,304,499	$11,304,499	-$683,116
Georgia	$9,433,528	$9,682,837	$9,682,837	+$249,309
Hawaii	$1,337,512	$1,358,874	$1,358,874	+$21,362
Idaho	$1,467,718	$1,473,698	$1,473,698	+$5,980
Illinois	$8,361,320	$8,177,081	$8,177,081	-$184,239
Indiana	$4,058,614	$4,135,004	$4,135,004	+$76,390
Iowa	$2,132,111	$2,155,801	$2,155,801	+$23,690
Kansas	$2,015,086	$2,050,126	$2,050,126	+$35,040
Kentucky	$2,934,305	$2,980,473	$2,980,473	+$46,168
Los Angeles County	$9,148,955	$8,777,062	$8,777,062	$-371,893
Louisiana	$3,028,717	$3,089,010	$3,089,010	+$60,293
Maine	$1,220,530	$1,236,214	$1,236,214	+$15,684
Maryland	$6,076,325	$6,291,905	$6,291,905	+$215,580
Massachusetts	$4,094,246	$4,081,623	$4,081,623	-$12,623
Michigan	$5,816,519	$5,796,406	$5,796,406	-$20,113
Minnesota	$3,424,146	$3,488,879	$3,488,879	+$64,733
Mississippi	$2,097,775	$2,138,308	$2,138,308	+$40,533
Missouri	$3,725,285	$3,794,404	$3,794,404	+$69,119
Montana	$1,202,609	$1,217,047	$1,217,047	+$14,438
Nebraska	$1,479,301	$1,490,871	$1,490,871	+$11,570
Nevada	$2,968,388	$3,037,916	$3,037,916	+$69,528
New Hampshire	$1,209,450	$1,222,914	$1,222,914	+$13,464
New Jersey	$5,395,339	$5,522,807	$5,522,807	+$127,468
New Mexico	$1,689,996	$1,717,444	$1,717,444	+$27,448
New York	$10,518,499	$11,024,888	$11,024,888	+$506,389
New York City	$7,502,867	$7,468,887	$7,468,887	-$33,980
North Carolina	$6,156,167	$6,281,300	$6,281,300	+$125,133
North Dakota	$1,140,635	$1,147,082	$1,147,082	+$6,447

STATE/TERRITORY	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Ohio	$7,060,825	$7,071,661	$7,071,661	+$10,836
Oklahoma	$2,654,184	$2,695,008	$2,695,008	+$40,824
Oregon	$2,753,157	$2,793,065	$2,793,065	+$39,908
Pennsylvania	$7,761,310	$7,747,180	$7,747,180	-$14,130
Rhode Island	$1,144,760	$1,151,739	$1,151,739	+$6,979
South Carolina	$3,374,105	$3,438,862	$3,438,862	+$64,757
South Dakota	$1,162,368	$1,171,617	$1,171,617	+$9,249
Tennessee	$4,123,510	$4,210,178	$4,210,178	+$86,668
Texas	$15,580,429	$15,634,202	$15,634,202	+$53,773
Utah	$2,384,511	$2,383,699	$2,383,699	-$812
Vermont	$1,141,219	$1,147,742	$1,147,742	+$6,523
Virginia	$8,093,731	$8,313,030	$8,313,030	+$219,299
Washington	$4,668,338	$4,737,712	$4,737,712	+$69,374
West Virginia	$1,419,786	$1,433,771	$1,433,771	+$13,985
Wisconsin	$3,431,589	$3,484,936	$3,484,936	+$53,347
Wyoming	$1,139,432	$1,145,724	$1,145,724	+$6,292
Subtotal	**$235,371,040**	**$235,462,747**	**$235,462,747**	**+$91,707**
Indian Tribes				
Migrant Program				
American Samoa	$279,341	$277,583	$277,583	-$1,758
Guam	$356,709	$357,114	$357,114	+$405
Marshall Islands	$271,796	$271,699	$271,699	-$97
Micronesia	$289,591	$289,175	$289,175	-$416
Northern Mariana Islands	$278,826	$278,044	$278,044	-$782
Palau	$256,623	$256,584	$256,584	-$39
Puerto Rico	$2,590,638	$2,503,784	$2,503,784	-$86,854
Virgin Islands	$305,436	$303,270	$303,270	-$2,166
Subtotal	**$4,628,960**	**$4,537,253**	**$4,537,253**	**-$91,707**
Total States/Territories	**$240,000,000**	**$240,000,000**	**$240,000,000**	**-**
Technical Assistance				
State Penalties				
Contingency Fund				
Other Adjustments (specify)				
Subtotal Adjustments				
TOTAL RESOURCES	$240,000,000	$240,000,000	$240,000,000	-

Note: FY 2024 and FY 2025 award amounts are estimates.

Grant Awards Tables			
	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Number of Awards	62	62	62
Average Award	$3,870,968	$3,870,968	$3,870,968
Range of Awards	$256,623 - $23,277,698	$256,584 - $22,218,713	$256,584 - $22,218,713

National Disaster Medical System

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**96.904**	**96.904**	**65.904**	**-31.000**
Pediatric Disaster Care Program (non-add)	*7.000*	*7.000*	-	*-7.000*
Mission Zero (non-add)	*4.000*	*4.000*	-	*-4.000*
Public Health Preparedness Equipment (non-add)	*20.000*	*20.000*	-	*-20.000*
emPOWER (non-add)	*1.565*	*1.565*	*1.565*	-
FTE	**148**	**148**	**148**	**-**

Authorizing Legislation:
Authorization .....Public Health Service Act
Allocation Method ..... Direct Federal/intramural, contracts

Program Description

When disaster strikes, the Administration for Strategic Preparedness and Response activates a suite of integrated federal medical response capabilities. 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 the Department of 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 2021	$63,404,000
FY 2022	$75,404,000
FY 2023 Final	$96,904,000
FY 2024 CR	$96,904,000
FY 2025 President's Budget	$65,904,000

Budget Request

The FY 2025 President's Budget request for NDMS is $65,904,000, which is $31,000,000 below FY 2023. The request proposes to end the Pediatric Disaster Care, Mission Zero, and Public Health Preparedness Equipment programs. ASPR proposes to discontinue these programs and focus on NDMS's core response capabilities. ASPR will use lessons learned from the Pediatric Disaster Care program in NDMS's care of pediatric patients. In FY 2024, ASPR will plan and prepare for responsible sunset of these programs in FY 2025.

ASPR uses performance measurement to strengthen and continually improve capabilities, coordination, and knowledge for managing programs effectively and efficiently. For NDMS and ASPR's other programs, performance data is one of the tools used for ongoing monitoring and reporting of program accomplishments, specifically progress toward pre-established targets. ASPR is evaluating NDMS's performance measures, interim and outyear targets. During FY 2023, ASPR is undertaking a process to update the connection between the NDMS performance measures and ASPR's base appropriations.

Funding at the FY 2025 President's Budget will be focused to provide a capable, trained, and competent force of medical, veterinarian, behavioral health, and fatality management disaster responders to meet the nation's continually increasing emergency needs.

The FY 2025 budget will be used to meet the following program objectives:

- Modernize the NDMS System to meet 21st century public health and medical challenges. As the nation's safety net for public health and medical infrastructure, NDMS is currently undergoing efforts to modernize the system to be more flexible, modular, and calibrated for the challenges, threats, and hazards of the post-COVID landscape. This includes targeted hiring and training initiatives to meet critical needs across the system.
- 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. As NDMS staff work directly with people, it is critical that some of the training and supervision be in-person. NDMS has utilized courses and delivery methods such as online training and cost-effective trainings with other federal partners (i.e., Anniston CDP, DoD exercises), but these do not consistently address all the training and equipment knowledge that is needed.

- Provide essential training to NDMS partners at the Federal Coordination Centers (FCCs) that are staffed with DoD and VA personnel. Because people are directly impacted by the services provided, the FCC training is necessary to maintain competency and assure that if needed they are functioning at the highest level.

Hiring and Training of NDMS Responders: With the FY 2025 request, NDMS will focus investments to support targeted 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. An in-depth analysis of NDMS was done looking at the last ten years of responses. This review provided insight into the importance of position specific hiring to maintain response capability. In addition, NDMS has an aging workforce and the ability to hire new responders will be critical to maintaining NDMS' current capability.

Mission Essential Infrastructure: To ensure NDMS can rapidly deploy to an emergency, NDMS relies on 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 preposition appropriately in disaster prone locations based on ASPR's risk profile.

State, Local, Tribal and Territorial Planning, Coordination, and Technical Assistance: A critical 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 a disaster response or emergency when required. Developing and maintaining strong relationships enables Regional Operations field representatives to carry out their core objectives on behalf of their stakeholders and partners. The core objectives are connecting partners and stakeholders across the response continuum; generating situational awareness; providing subject matter expertise and technical assistance; and evaluating requirements and mobilizing federal public health and medical resources. Stakeholders and partners, including public health, emergency management, healthcare, critical infrastructure, emergency medical services, and more. Regional Operations collaborates with other ASPR programs (i.e., Healthcare Readiness Program, Medical Reserve Corps, Community Mitigation and Recovery, and Information Management) to identify programmatic and operational objectives to coordinate field outreach and implementation.

The FY 2025 request does not continue the funding for Mission Zero, a decrease of $4 million below FY 2023, Pediatric Disaster Care, a decrease of $7 million below FY 2023, and Public Health Preparedness Equipment, a decrease of $20 million below FY 2023.

Program Accomplishments

Since the beginning of FY 2023, NDMS accomplishments include:

- In August 2023, following the devastating Lahaina wildfires in Hawaii, ASPR Disaster Mortuary Operations Response Team (DMORT) specialists were deployed to augment Maui's coroner's office and establish a Victim Identification Center (VIC). A Disaster Portable Morgue Unit (DPMU) was airlifted to Maui to facilitate the respectful and dignified identification of remains. In addition, ASPR's Maui wildfires mission was the largest and longest-sustained federal field disaster behavioral health in recent history. Over the course of the mission, the team provided 20,892 face-to-face behavioral health contacts, including 15,645 behavioral health support encounters with wildfire survivors and 5,247 force protection encounters with responders and workers serving survivors.
- ASPR Office of Response also responded to the mass shooting in Lewiston, ME by providing a team of four behavioral health specialists and two Regional Emergency Coordinators to support Maine Department of Health and Human Services leadership with expertise and planning assistance."
- Additionally, NDMS was called to support unique missions such as the response to the rise of pediatric respiratory illnesses last winter as a result of RSV, flu, and COVID-19. NDMS also deployed to humanitarian missions at the request of our federal partners.
- In response to large scale weather events, NDMS sent multiple medical teams to Guam for the Typhoon Mawar and Typhoon Bolaven response to support hospital augmentation. They also provided support to Hurricanes Hilary and Idalia added to the deployment of our DMAT teams.
- In 2023, NDMS teams responded to numerous events that provided medical and veterinarian care to our Nation. National Special Security and Special events such as the 2023 State of the Union, multiple Joint Sessions of Congress, the annual Peace Officer Memorial commemoration, the Independence Day Celebration on the National Mall, the United Nations General Assembly, and Asian-Pacific Economic Cooperation.
- In FY 2023, Response Logistics was able to maintain sufficient resources across the Nation to support the preparations for one major and one minor disaster event. This required the deployment of over 600 tons of critical lifesaving and communications equipment to support NDMS NSSE, emergency response and training missions. Both annual budget funds and supplemental funds were used to support this capability.

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. To meet the needs of the various mission sets, NDMS has become more modular. In addition to a full 39 person DMAT team, NDMS can send as few as three medical professionals as part of an assessment team, or seven to 14 medical professionals as a Health Medical Task Force.
- ***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. DMORT also provides assessment teams to help SLTT authorities identify needs to complete a full spectrum of complex mortuary responses.
- ***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 Team

The Response Logistics Team ensures that responders and medical capabilities are synchronized for rapid deployment where they are needed to provide an effective response. The Response Logistics Team encompasses Federal staff and intermittent logistics responders that maintain and coordinate the deployment of vehicle fleet assets, tactical communications, and medical caches prepositioned at forward staged locations throughout the U.S. 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 Special Events (NSSE). It is a highly complex, coordinated effort to rapidly deploy staff and materiel and set up tactical hospitals, communications, and command and control infrastructure in an austere environment. Except for the DoD and the Federal Emergency Management Agency (FEMA), very few federal organizations have this organic response capability and conduct similar operations.

To ensure field responders are properly resourced and logistically supported, ASPR relies on Logistics Response Assistance Team (LRAT) personnel which consists of intermittent federal employees augmented by officers from the US Public Health Service Commissioned Corps, and full-time logistics staff. The LRAT is a rapidly deployable and agile logistics team that deploys to an area of operations to conduct reception, staging, mobilization, onward movement, and integration of HHS response assets into the response. The LRAT can deploy in different team configurations (scalable to the event) to provide critical field services such as Information and Technology (IT), cellular, radio, and satellite communications support, transportation operations services, and materiel management during a disaster, incident, emergency, or special event. The ASPR LRAT can conduct logistics operations supporting all

missions and responses conducted by ASPR. This all-hazards logistics team is trained to an expert level of proficiency on ASPR's response resources through a structured credentialing program. The ASPR LRAT also trains to achieve competency in resource management and logistics areas associated with the FEMA National Qualification System and National Incident Management System (NIMS).

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's 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 ten HHS regions. RECs and their teams have the day- to-day responsibility of developing and maintaining relationships with SLTT public and private partners to prepare for an effective federal emergency response. The Regional Medical Countermeasure Advisors (RMCAs) support the RECs by providing technical assistance to jurisdictions on medical countermeasure operations and they enhance the whole of NDMS in its ability to facilitate coordinated medical countermeasure preparedness activities in each HHS region and to engage with affected SLTT emergency management and public health agencies to determine support and operational requirements during public health emergencies, critical incidents, and disasters. The RMCAs work alongside RECs and have been instrumental in assisting SNS with providing direct technical assistance to jurisdictions on medical countermeasure operations. In addition, the RMCAs have played a central role in assisting H-CORE with logistical operations and coordination for allocating and distributing COVID vaccine and therapeutics.

  A fundamental responsibility of the regional response team is providing technical assistance, direct support, and interagency and intergovernmental coordination in the earliest phases of evolving regional incidents and emergencies. During a response, RECs and RMCAs interface with the affected jurisdiction(s) and federal partners to gain situational awareness and assess the initial level and type of federal support and engagement that may be requested or required by a state. During a smaller-scale regional response, the regional team takes 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.

- ***Regional Operations Coordination Program (ROCP):*** The ROCP, formerly known as the Medical Countermeasures Operations Program (MCOP), provides program management support to the RECs program and serves as a central point of coordination for the regional teams and other ASPR programs that have equities in providing critical information, technical assistance, and medical resources to SLTT to support preparedness and response activities. The ROCP works closely with SNS, H-CORE and other programs to help identify preparedness and operational

gaps 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 resources to help the RECs assist states with improving readiness to respond to a public health and medical emergency. The ROCP also pushes out information and requests from SNS, H-CORE and ASPR leadership to the RECs for sharing with SLTT and gathers critical information about SLTT from the regional teams to allow leadership to make key, and often lifesaving, decisions when allocating resources to jurisdictions.

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.

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.

Special Operations provides ASPR with an invaluable immediate FTE medical response capability, that has been utilized for countless time sensitive short notice or no notice incidents. Among the long list of missions, some of the more notable include initial response to Operations Allies Welcome, COVID Medical Surge Response, Congressional special events, and interagency medical support requests.

International Operations Team

The International Operations team are ASPR's subject matter experts for international operations, response, and deployments. The Office of International Operations works to ensure ASPR's response teams have the ability to deploy internationally, including, overseeing international pre-deployment requirements (training, passports, entry requirements, country background briefs, funding cables, etc.).

The team continues to build relationships with other international partners (i.e., Japan, Canada, Mexico, Taiwan, Australia, Republic of Korea, World Health Organization/PAHO, United Kingdom, etc.) and with the European Union's Health Emergency Preparedness and Response (HERA) and North Atlantic Treaty Organization (NATO)Department of State, aligning closely with the ASPR preparedness and response priorities and mission. The Office of International Operations supports international liaisons to

ASPR such as the Japanese Ministry of Health Labour and Welfare's and HERA's liaisons to ASPR. The team routinely (monthly) meets with Public Health Agency of Canada and the Mexico Ministry of Health to discuss emergency management and to collaborate cross boarder public health and medical issues, and with the Israel Magen David Adom (MDA)—Israel's national EMS organization to collaborate on emergency response.

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:

- ***Community Resilience Team:*** The ASPR Community Resilience team supports recovery field missions through coordination across federal agencies to design assessment and intervention tools and procedures, and develop plans for recovery and behavioral health operations.
- ***Behavioral Health Team:*** The Behavioral Health team coordinates ASPR capabilities and activities 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. The Disaster Behavioral Health team also maintains deployable capabilities to support states, tribes, territories, and local communities to address the psychological effects of disasters in both response and recovery phases.

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 4.5 million individuals who live independently and rely on life-maintaining electricity-dependent durable medical and assistive equipment (DME) and devices[27] and certain essential health care services.[28] Since its inception, emPOWER has continued to expand its at-risk population data and tools based on feedback from its partners. In 2023, emPOWER launched at-risk population combinations data, which provides counts of Medicare beneficiaries who rely on certain essential health care service(s) and electricity-dependent DME and devices down to the ZIP Code level for the HHS emPOWER Map, HHS emPOWER REST Service, and HHS emPOWER Emergency Planning Dataset to help advance target scenario planning. Using Medicare data, emPOWER provides the National Disaster Medical System (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

[27] 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.
28 Essential health care services include outpatient facility dialysis, home oxygen tank services, home health care services, and home hospice care services.

preparedness, response, recovery, and mitigation activities across 13 emergency support functions[29] and 13 sectors[30].

Publicly accessible emPOWER data and tools continue to have a broad reach across 50 states, five territories, and the District of Columbia. In FY 2023, over 19,400 individuals used the HHS emPOWER Map[31]. P and partners consumed the emPOWER data layers via the HHS emPOWER REST Service and used the data over 479,100 times in FY 2023 to inform and support activities across the emergency management cycle nationwide. Additionally, in FY 2023, over 12,600 individuals accessed and downloaded over 4,300 informational resources from the publicly accessible HHS emPOWER Program Platform that provides technical assistance, informational resources, and stories from the field via emPOWER in Action.[5] Communities across the nation have used emPOWER data and tools to anticipate, prepare for, and take action to protect the health of at-risk populations over numerous disasters. For example, from December 21-26, 2022, a prolonged winter storm swept across the nation, resulting in nearly 1.5 million customers without power at the peak of the storm. In the two weeks surrounding the winter storm, 195 users across the country accessed the HHS emPOWER Map and there were over 3,600 uses of the HHS emPOWER REST Service. Additionally, in FY 2023, HHS emPOWER Emergency Response Datasets supported public health authorities in responding to 19 emergencies and disasters that spanned severe winter weather nationwide, extreme heat events , public safety power shutoffs, and wildfires in the Pacific Northwest, hurricanes in Puerto Rico, North Carolina, and California, and critical infrastructure failure events in Utah and Louisiana. Together, emPOWER's meaningful, consumable, and actionable data and tools help federal-to-community responders better address the needs of community-based at-risk individuals, ensure continuity of care, protect the health of at-risk individuals, and reduce health care system surge through multiple incidents, emergencies, and disasters nationwide. Essential health care services include outpatient facility dialysis, home oxygen tank services, home health care services, and home hospice care services.

Pediatric Disaster Care

The Pediatric Disaster Care program, which began in FY 2019, has funded three Pediatric Disaster Care Pediatric Centers of Excellence (COE) multi-state cooperative agreements, and added a new COE in FY 2022, that targeted 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. A specific focus of the COEs has been the management of pediatric care related to trauma, infectious diseases including pandemic influenza, COVID-19, and *Respiratory Syncytial Virus (RSV),* burn, and chemical/biological/radiological/nuclear incidents. The FY 2025 budget proposes to sunset this program.

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

30 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.

31 These data are from October 1, 2022, to September 30, 2023.

ASPR Key Outputs and Outcomes Table
Program: National Disaster Medical Systems

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
1.1 Maintain the percent of new NDMS intermittent staff that complete psychological first aid training	FY 2023: 0 Target: 100 % (Target Not Met)	100%	100%	To be replaced with a new measure
1.3 Increase training and resources to address the access and functional needs of electricity and healthcare service-dependent at-risk individuals who live independently and are impacted by incidents, emergencies, and disasters (Intermediate Outcome)	FY 2023: 515,797 trained Target: 102,150 trained (Target Exceeded)	102,150 trained	102,150 trained	Maintain
1.5 Maintain the number of staff trained in-person[2]	FY 2023: 4% Target: 20% (Target Not Met)	20%	20%	Maintain

[2] Improvement expected for 2024.

Biomedical Advanced Research and Development Authority

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**950.000**	**950.000**	**970.000**	***+20.000***
Operations and Management (non-add)	*170.000*	*170.000*	*170.000*	**-**
FTE	**300**	**300**	**300**	**-**

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 in 2006 as part of the Office of the Assistant Secretary for Preparedness and Response (ASPR), which is now known as the Administration for Strategic Preparedness and Response (ASPR), 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 innovative solutions, advanced research and 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 annual appropriations, under Advanced Research and Development (ARD) 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 2021	$596,700,000
FY 2022	$745,005,000
FY 2023 Final	$950,000,000
FY 2024 CR	$950,000,000
FY 2025 President's Budget	$970,000,000

Budget Request

The FY 2025 President's Budget request for Advanced Research and Development is $970,000,000, which is an increase of +$20,000,000 above FY 2023. The additional $20 million will support BARDA's broad spectrum antimicrobials portfolio.

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[32]. 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, including host directed countermeasures that improve morbidity and mortality associated with viral hemorrhagic fever;
2. New platform vaccine technologies to be applied to CBRN threat agents;
3. New therapeutic for treatment of injuries due to chemical agents (for example, sulfur mustard and opioid exposure);
4. Diagnostic devices to confirm infection with biological agents, some of which will be suitable for use in point-of-care and near patient settings;
5. Innovations for advanced, portable extracorporeal membrane oxygenation (ECMO) devices;
6. Innovations in early stage MCM research and development focusing on sepsis, wearable diagnostics, and distributed manufacturing technologies;
7. New candidate products, including next generation blood products, to address the injuries caused by radiological or nuclear events, including blast injuries caused by nuclear detonation;
8. New diagnostic devices to help reduce the emergence of antimicrobial resistant bacteria by identifying the appropriate treatment sooner;
9. Multi-tissue human microphysiological models that incorporate immune system models for screening of vaccines and therapeutics;
10. Novel patient triage technologies, including phone apps, for rapid patient assessment and

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

information sharing within first responder and hospital networks;
11. Novel host-based therapeutic approaches that are agnostic to pathogen and address severe forms of disease and sepsis;
12. Novel host-based diagnostic approaches to address disease severity and identify health deterioration in a number of clinical settings (pre-hospital, hospital, post-discharge);
13. Novel antibacterial and antifungal drugs, diagnostics, and vaccines;

14. Diagnostic technologies suitable for use in limited healthcare resource settings, such as homes, nursing homes, temporary treatment centers, or tribal clinics, by minimally trained personnel;
15. New technologies to advance detection and treatment of Traumatic Brain Injury (TBI) resulting from nuclear detonation;
16. Threat-agnostic and pathogen family diagnostics for use in the early days of novel disease outbreak; and,
17. Therapeutic platforms that have the potential to pivot rapidly to develop safe and effective treatments for priority pathogens.

Broad Spectrum Antimicrobials/Combating Antibiotic-Resistant Bacteria ($160 million): The FY 2025 request will support the Combatting Antibiotic Resistant Bacteria Accelerator (CARB-X) and the advanced clinical stage development of novel broad-spectrum antimicrobials to prevent and treat drug-resistant bacterial and fungal infections in both adult and pediatric populations. Funding will enable CARB-X to continue to support a pipeline of preclinical and early clinical stage antibacterial drugs, vaccines, and diagnostics to ensure that the early-stage pipeline remains robust and delivers MCMs that are attractive for subsequent investment from BARDA and other organizations. Funding will also continue support across the existing advanced research and development (ARD) portfolio. New funding initiatives in FY 2025 will include the addition of two to three new antimicrobials to the ARD portfolio. 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.

Botulism ($20 million): In FY 2025, BARDA will support a next generation therapeutic for botulism. The current licensed product, Botulinum Antitoxin Heptavalent (BAT), has sustainability concerns based on manufacturing challenges. BARDA will support an innovative therapeutic approach to botulism that, if successful, will improve upon the manufacturability, safety and efficacy of BAT and enable replacement of the existing BAT stockpile so as to provide a long term sustainable alternative MCM for treatment of botulism.

Chemical ($75 million): FY 2025 funding will allow continued support for all the existing candidates, including those identified through BARDA's ReDIRECT (Repurposing Drugs In Response to Chemical Threats) program, and to continue development of non-clinical and organ-on-chip models to support pre-clinical evaluation of candidate MCMs. The goal of the ReDIRECT program is to develop and seek label expansion, if necessary, of FDA approved drugs to treat injuries caused by exposure to chemical threats. In addition, funding will be used to expand use of AI-based 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.

Radiological and Nuclear MCMs ($82 million): FY 2025 funds will be used to support existing programs developing novel and more effective treatment options for acute radiation injury and trauma. Existing programs include development of a self-administration kit for an approved MCM, next generation blood products such as dried plasma, and clinical trials to optimize the use of blood products in pediatric traumatic injury. The portfolio will continue to focus on treatments for vascular injury, inflammation, coagulopathies (impaired blood clotting), and ischemia (inadequate blood supply) that have applicability across several threat areas, including emerging infectious diseases. 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) resulting from both radiation injury and chemical injury, will also be a priority. New therapeutics for the decorporation (removal) of radioisotopes from the body will also be supported.

Biodosimetry and Biothreat Diagnostics ($50 million): In FY 2025, 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) Portable 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 and pathogen family tests for use in the early days of a novel disease outbreak.

Burn and Blast MCMs ($55 million): In FY 2025, funds will support expansion of the burn and blast 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 for blast trauma applications 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.

Smallpox Vaccines and Therapeutics ($20 million): Funds will continue to support a monoclonal antibody cocktail for the treatment of smallpox disease in FY 2025. The product, which is anticipated to be a safe alternative treatment for special populations, provides a risk mitigation strategy for the purposeful or natural development of resistance to approved antivirals for smallpox.

Viral Hemorrhagic Fever ($152 million): FY 2025 funding will focus on development of vaccines and therapeutics for Sudan ebolavirus and Marburg virus. Funds will be used to continue developing vaccine

candidates for both viruses into Phase 2 clinical development and validation of manufacturing. FY 2025 funds will support a Phase 2 clinical trial for a second Marburg virus vaccine and a Phase 2 clinical trial for a second Ebola Sudan vaccine. Funding will also be utilized to scale up and validate manufacturing processes at the intended final scale and to generate additional clinical trial material for future studies. This funding will also enable pursuit of one additional vaccine technology applied to viral hemorrhagic fever that could be pivoted to an emerging threat if needed.

FY 2025 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 or host-directed therapeutic with efficacy against filoviruses will be supported, with a focus on broad anti-filovirus activity, penetration of sites where the virus can remain dormant, and an oral route of administration.

Threat Agnostic MCMs ($50 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 is now applying this strategy toward the development of innovative MCMs against emerging biological threats by prioritizing pathogen-directed therapeutics that are effective against broad classes of pathogens, investing in therapeutic platforms that have the potential to rapidly develop safe and effective treatments, evaluating host-directed approaches that treat the medical consequences of infection, investing in vaccines against current threats built on platforms that can be rapidly redirected to new strains as they emerge, and supporting 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 ($60 million): The Clinical Studies Network (CSN) will continue to develop clinical protocols for evaluation and testing in clinical trials regulated by the U.S. Food and Drug Administration (FDA). 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.

BARDA's next generation Nonclinical Studies Networks were awarded in FY 2022. These networks ensure ongoing available capacity and capabilities necessary for medical countermeasure development addressing CBRN and emerging infectious disease threats. Further, the networks provide expertise supporting innovation and the development of next generation tools within the nonclinical MCM development space. In FY 2025, the Nonclinical Studies Network will continue development of essential

animal models and supportive assays required for licensure, approval or clearance under the FDA Animal Rule or the Accelerated Approval Program. Further, previously established models will be leveraged for efficacy evaluation of MCM candidates in development to treat acute radiation syndrome (ARS) sub-syndromes including gastrointestinal, skin, and pulmonary injury. Product-agnostic models for Sudan and Marburg Virus infections will be used as new MCM candidates are brought into BARDA's portfolio. Next generation therapeutics addressing botulism will be evaluated within the network, and support will be continued for 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 innovation and technology development programs including Beyond the Needle, ImmuneChip+, and other predictive nonclinical tools such as organoids, spheroids, and microphysiological systems.

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 2025 funding will both continue existing DRIVe programs and expand the portfolio of programs. Current and future programs include the following:

- Development and clinical validation of host-based approaches (e.g., diagnostics, algorithms) that can endotype or prognosticate outcomes of disease to better inform therapeutic intervention;
- Addressing the technical challenges in host-based therapeutics for sepsis and ARDS to more readily reduce mortality (e.g., clinical validation of combination approaches, formulation/delivery strategies, rapid repurposing approaches);
- Establishment of a health data ecosystem to ascertain through RWE, pragmatic and other clinical studies, the value of BARDA's medical countermeasures beyond regulatory approval;
- Advancement and validation of novel immunological assays to improve evaluation of immune response to vaccines and subsequently inform future vaccine design;
- On-demand and/or 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 health markers;
- 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, microneedle skin patches) to ease supply and distribution chains and lower barriers to access to lifesaving MCMs;
- Agnostic diagnostic tests using next-generation sequencing that can be available on the first day of an outbreak;
- Innovative technologies that advance the capability for manufacturing vaccines on demand at the point-of-service; and

- Innovative tools and technologies that advance access to existing and new MCMs.

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, provide greater market intelligence to BARDA, and to support early-stage companies developing next-generations MCMs. BARDA Ventures is expected to make 8-12 investments in FY 2024, with individual investments ranging from $5-15 million per company. In that scenario and including investments made in FY 2022 - 2024, all funds provided to Ventures are expected to be under active investment by FY 2025. In FY 2025, 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.

In FY 2025, the Decentralized Clinical Operations for Healthcare and Research will continue to build decentralized capabilities into the network of partners to support clinical readiness to engage patients in more accessible clinical settings (e.g., retail pharmacies, urgent care, mobile labs). Post-regulatory approval of products will be able to be evaluated (e.g., pragmatic, outcomes research) in these real-world settings.

Management and Administration ($170 million): These funds provide support to BARDA's programs for Advanced Research and Development, Project BioShield, Pandemic Influenza, and Project NextGen. 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 and 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 throughout ASPR to support BARDA's mission. These services include information technology, data analysis and modeling, acquisition policy 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 2020–2024, 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) that allows investments in 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 viruses, and COVID-19, among other priority 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. In 2022, recognizing the value this type of support brings to innovators who seek to combat drug-resistant bacteria, BARDA awarded a new OTA that supports CARB-X for an additional ten years. As of July 2023, CARB-X has a portfolio of 33 active projects, including 15 therapeutics, 13 preventatives, and five diagnostics. Eight graduates from CARB-X are currently in clinical development and receiving funding from other sources, including two that are funded by BARDA ARD funding. In addition, the Public Health Agency of Canada and the Novo Nordisk Foundation of Denmark joined BARDA, NIAID, Wellcome Trust, and the Governments of the UK and Germany, as CARB-X funders in 2023. These transitions highlight the success of this program in accelerating early-stage product development to the clinic.

To encourage private sector involvement, minimize development costs and risks, and accelerate product development and approval, BARDA 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 FY 2021, BARDA ended its Centers for Innovation in Advanced Development and Manufacturing (CIADM) partnership with one facility and restructured another to focus on workforce development. BARDA 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 supported the partner to develop an mRNA vaccine manufacturing curriculum, with pilot course delivered in September 2023 with the final BARDA-funded course scheduled for delivery in February 2024. During FY 2023, BARDA established the BioPharmaceutical Manufacturing Preparedness Consortium. The Consortium will enhance the nation's manufacturing preparedness by creating fast and flexible partnerships with the commercial biopharmaceutical industry to leverage manufacturing capacity, platforms, and innovative technologies that can be swiftly transitioned to respond to future public health emergencies. BARDA is leveraging its Other Transaction Authority to enter into agreements with multiple manufacturing partners and suppliers of raw materials services that enable the rapid

availability of vaccines during a public health emergency and support the ambitious goals highlighted in the American Pandemic Preparedness Plan [September 2021] and the National Biodefense Strategy and Implementation Plan [October 2022].

- ***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 supported 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 expanded 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. Future fill/finish capacity expansions and reservations will be executed through the BioMaP-Consortium.
- ***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. BARDA awarded its next generation Nonclinical Studies ID/IQ Networks FY 2022. These networks ensure ongoing available capacity and capabilities necessary for MCM development addressing CBRN and emerging infectious disease threats including robust animal models of disease, key reagents, and supportive assays. Further, the networks provide expertise supporting innovation and the development of next generation tools within the nonclinical MCM development space. Comprised of ten laboratory partners, the network has performed over 220 nonclinical studies under 110 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, Tembexa, and Cyfendus. In addition, BARDA supported the development of a well-characterized model of Marburg virus (MARV) infection that FDA CBER has concurred is suitable for vaccine candidate efficacy studies. This model is now available in an FDA Type V Master File. A similar approach for Sudan virus (SUDV) is underway and achieving concurrence on models for SUDV/MARV therapeutic context of use with FDA CDER is also ongoing. Since 2020, the Nonclinical Development Network accelerated the development of small and large animal models and supportive assays for SARS-CoV-2 infection and completed a study in rhesus macaques using 4 SARS-CoV-2 vaccines to identify immune correlates of protection.
- ***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 2023, the CSN supported eleven clinical research projects, including:
    - 2014-2017: The Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE);
    - 2017-2018 Phase 2 safety and immunogenicity study of a novel influenza H7 vaccine;

- 2016-2017: Collection of clinical samples to accelerate the development of Zika diagnostics;
- 2016-2017: 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;
- 2017-2018: Clinical trial of an investigational anthrax vaccine in older adults;
- 2019-2020: Phase 1 pharmacokinetic study of sublingual atropine as a threat-agnostic treatment for nerve agent toxicity;
- 2020-2023: 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);
- 2021: A nested sub-study within the Novavax SARS-CoV-2 vaccine study in subjects less than 18 years of age to assess the vaccine efficacy in the pediatric population; data analysis is ongoing;
- 2021: A protocol designed to generate a bank of biological specimens from participants 12 years of age 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;
- 2022-Ongoing: 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; and,
- 2023 – In Development: A clinical research study is being conducted to evaluate the safety and immunogenicity of H5N8 influenza vaccine antigen combined with AS03 (full and half dose) or MF59 (full dose) adjuvants in healthy adults to provide data to support use during a public health emergency.

Developing Multi-Use Products

The four goals in BARDA's 2022-2026 Strategic Plan focus on ensuring that the American people are protected from all national health security threats. These strategic goals include Preparedness, Response, Partnerships, and Workforce. Aligned with these principles, BARDA has invested in the advanced development and procurement of MCMs targeting known high-priority threats and innovative technologies to enhance preparedness against unknown threats. BARDA has focused investments on technologies that have the potential to make MCMs faster, safer, and more accessible. BARDA is achieving this goal through development of 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.

In May 2023, BARDA launched the Flexible and Strategic Therapeutics (FASTx) program, which aims to support development of therapeutic platform technologies like siRNA, CRISPR, Vhh, and related biologics. FASTx is investing in innovation and process improvements for promising therapeutic platforms to demonstrate the value of the platform by advancing a product through to licensure. By establishing a repertoire of candidate therapeutic approaches that can pivot rapidly to address new threats, FASTx is improving our ability to respond to future biological threats.

Building a Robust and Formidable MCM Development Pipeline

In partnership with industry, BARDA has built a robust 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 38 products that have transitioned to support under PBS, 27 of which have been procured for the SNS or procured as vendor managed inventory with commercial stock rotation. BARDA's efforts have led to 86 FDA licensures, approvals, or clearances since 2008, 40 of which focus on countering CBRN threats and nine of which received the Breakthrough Designation under the 21st Century Cures Act. Fourteen of these MCMs 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 (2018) and intravenous (2022) formulations to treat smallpox disease
- ZEMDRI to treat complicated urinary tract infections (2018)
- XERAVA to treat complicated intra-abdominal infections (2018)
- RECELL to treat thermal burn wounds (2018) and full thickness skin defects (2023)
- 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) and cutaneous radiation injury and radiation dermatitis (2022)
- Applied Biosystems anthrax detection kit (2019)
- OraQuick Ebola rapid diagnostic test (2019)
- JYNNEOS smallpox and mpox vaccine (2019)
- ERVEBO *Zaire ebolavirus* vaccine for adults (2019) and pediatrics (2023)
- INMAZEB to treat *Zaire ebolavirus* Disease (2020)
- EBANGA to treat *Zaire ebolavirus* Disease (2020)
- StrataGraft to treat deep-partial thickness burns (2021)
- NPLATE to treat thrombocytopenia from radiation exposure (2021)

- Lumify Ultrasound functionality of counting B-lines (2021) and merged B-lines (2023) in lung exams
- TEMBEXA to treat smallpox disease (2021)
- NexoBrid for non-surgical removal of burn wound eschar (2022)
- OPVEE to treat opioid induced respiratory depression (2023)
- Selux Next Generation Phenotyping System – Gram positive panel for AST testing (2023)
- InBios International Active Anthrax Detect Plus Rapid Test (2023)
- Selux Next Generation Phenotyping System – Gram negative panel for AST testing (2023)
- CYFENDUS vaccine for post-exposure prophylaxis of anthrax (2023)
- T2 Biosystem's T2Biothreat Panel for multi-target biothreat testing (2023)
- First Light Diagnostic's Rapid B. anthracis Toxin Test (2023)

Anthrax: BARDA supports the overall preparedness for an anthrax attack or exposure by developing diagnostics, therapeutics, and vaccines to be used in response to anthrax exposure events. BARDA has supported the development, approval, and procurement of three anthrax antitoxins (Raxibacumab, ANTHIM, and Anthrasil) as well as the advanced development and procurement of an antibiotic (NUZYRA) for potential use under EUA. BARDA has also supported the licensure of an anthrax vaccine for post-exposure prophylaxis (BioThrax) and the development, licensure, and delivery of more than 35 million doses of the next-generation vaccine, Cyfendus™. BARDA also supported the clearance of Applied Biosystems' anthrax detection kit, and more recently, the InBios rapid anthrax test.

Smallpox: BARDA's portfolio of smallpox MCMs is another mature program that has supported the development, approval, and procurement of a smallpox vaccine (JYNNEOS) for at-risk individuals to complement smallpox vaccine for the general population held by the SNS. The FDA licensed JYNNEOS to prevent smallpox and mpox (formerly monkeypox). BARDA has supported development, approval, and procurement of two smallpox antivirals, TPOXX and TEMBEXA, as recommended by the National Academy of Medicine of the National Academies of Sciences, Engineering, and Medicine (NASEM) to make available at least two therapeutic agents with different mechanisms of action. BARDA supported the development of TPOXX, a small molecule antiviral developed by SIGA, for treatment of smallpox. The FDA approved the capsule formulation in 2018 for adult and pediatric patients over 13 kg in weight and the intravenous (IV) formulation 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, the FDA approved TEMBEXA, another BARDA-supported product, 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.

As of February 2024, JYNNEOS, TPOXX, and TEMBEXA continue to be deployed in response to the ongoing mpox outbreak.

Broad Spectrum Antimicrobials and Combating Antibiotic-Resistant Bacteria Initiative: BARDA's Broad Spectrum Antimicrobials (BSA) program develops MCMs to treat infections caused by DHS-identified biothreats (anthrax, plague, tularemia, melioidosis, and glanders), healthcare-associated and

community-acquired multidrug-resistant pathogens, and secondary bacterial infections that can occur after any CBRN incident. BARDA has supported the development of over 130 antibacterial MCMs across the CARB-X, ARD, and PBS portfolios, including development of three antibiotics through FDA marketing authorization.

In response to the limited number of approved pediatric antibiotics, BARDA awarded a new contract in July 2023 to support the development and approval of two antibiotics for pediatric indications. In September 2023, BARDA awarded a contract to develop a new oral antibiotic to treat drug resistant infections in adults and children. In addition, BARDA opened a new Area of Interest within the Broad Agency Announcement in late 2022 to support the advanced development of new MCMs to treat fungal infections caused by multidrug resistant *Aspergillus* and *Candida spp*.

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. 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 product, BARDA is evaluating next generation pan-BoNT antitoxins to identify a product with improved sustainability as well as safety and efficacy against all seven BoNT serotypes.

Viral Hemorrhagic Fever: Viral Hemorrhagic Fevers (VHF), specifically those caused by Ebola viruses (Zaire and Sudan) and Marburg virus, are national security threats as well as emerging infectious diseases. BARDA supported development, licensure, and procurement of the Ebola vaccine, ERVEBO, and Merck has delivered more than 700K doses of the vaccine to the U.S. Government. BARDA also supported clinical analyses that enabled expansion of the vaccine to include pediatric populations. The FDA licensed ERVEBO for prevention of Ebola in adults in 2019 and in pediatrics 12 months and older in 2023. The BARDA-supported Janssen Ebola vaccine remains in Phase 3 development in the U.S. 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 Guinea and Democratic Republic of the Congo.

Since 2019, BARDA has supported programs to address Marburg virus and Sudan ebolavirus. BARDA is leveraging vaccine technologies previously applied to Ebola Zaire to support development of three lead vaccine candidates, one of which began a Phase 2 clinical trial for Marburg virus in 2023, and a second initiated a Phase 1 study for Sudan ebolavirus in 2023. Both candidates were recommended for use during the Sudan ebolavirus and Marburg virus outbreaks in 2022 and 2023, respectively. 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 and the related Ebola Zaire virus and Bundibugyo

virus, which was administered under compassionate use to patients in Uganda during the 2022 *Sudan ebolavirus* outbreak. In addition, BARDA launched a program called ReBoot in FY 2023 to support repurposing of late stage or approved host and virus-directed products for the filovirus indication. Products approved or past Phase 1 testing for another indication can be supported under this program for preclinical filovirus efficacy studies, which aims to increase the breadth and depth of our therapeutic arsenal. Through ReBoot, BARDA is currently funding evaluation of a product with the potential to ameliorate vascular damage in VHF infection, which could be administered in conjunction with direct acting antivirals or antibody therapies.

Threat-Agnostic MCMs: BARDA co-invested with the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) in platform vaccine technologies using four different RNA-based vaccine technologies with the goal of advancing them through Phase 1 clinical trials if successful in early research and development. The first clinical trials are anticipated to start in 2024. Current investments in single-domain antibody products (Vhh), multi-specific antibody products, and nucleic acid-expressed antibodies will address gaps in these platform technologies and evaluate these approaches for potential use as rapid therapeutic platforms against infectious threats. The programs will advance a prototype product while investing in platform improvements that could be applied to any target pathogen.

Biodosimetry and Diagnostics: BARDA has aggressively supported the development of biodosimetry assays and detection devices to estimate the amount of radiation that a person has absorbed, essential to effective casualty care following a radiological or nuclear incident. Starting in FY 2010, BARDA supported the development of eleven biodosimetry device candidates, including biomarkers and assays for both point-of-care and laboratory use-cases. These programs have since been down selected based on product verification and validation data and extensive feedback from FDA. Today, two biodosimetry candidate products are in active development. One product is a high throughput laboratory testing solution and is planned for FDA review in FY 2024. Development of a second product, a portable handheld biodosimetry device, was recently initiated to facilitate patient triage near the incident site.

Since FY 2013, BARDA has supported development of diagnostic technologies that detect infection due to biothreat pathogens. Some early successes include supporting pivotal research and nonclinical studies to identify 1) host signs of infection (biomarkers) and 2) host responses to bacterial toxins during disease course for *Bacillus anthracis*, *Burkholderia pseudomallei*, *Burkholderia mallei*, and *Yersinia pestis*. In 2019, FDA approved the BARDA supported OraQuick Ebola Rapid Antigen Test which have been procured by both BARDA, and WHO, and used during recent Ebola responses. The same year, 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 2023, two antigen-based tests were cleared by the FDA: 1) the InBios International Active Anthrax Detect Plus Rapid Test which is well suited for testing outside traditional healthcare settings and 2) the First Light Diagnostics test which offers higher sample throughput. Also in FY 2023, the first BARDA supported Biothreat test panel (a test which targets multiple biothreat agents simultaneously) was cleared by the FDA from T2 Biosystems. These efforts are part of BARDA's successes in preparation for potential future biothreat outbreaks.

BARDA continues to invest in diagnostics to inform appropriate use of antibiotics to help curb the emergence of antimicrobial resistant bacteria. BARDA's portfolio includes phenotypic and genotypic technologies for antibiotic susceptibility tests (AST), viral vs. bacterial tests, and antimicrobial resistance (AMR) tests. Two products received FDA 510(k) clearance in 2023, the Selux Next Generation Phenotyping System – Gram-positive and Gram-negative panels for AST testing, with another six product platforms in development. BARDA's AMR diagnostics development continue to focus on providing results to physicians faster, to better inform appropriate antibiotic prescription.

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 40 product candidates since 2007 to address this threat; more than 20 of these candidates transitioned from NIH's portfolio. The current portfolio includes 15 MCM targeted programs that address various sub-syndromes of acute radiation syndrome, as well as traumatic injury, and blood products. The portfolio has supported seven products through to licensure and incorporation into the SNS and anticipates at least two additional approvals by end of FY 2025.

A central goal of the program is to repurpose commercially available products to treat the injuries caused by nuclear detonation, thereby leveraging commercial development efforts to develop these products for similar injuries. Most of the recent approvals and procurements from the SNS have been repurposed products resulting in cost savings for the taxpayer. In FY 2021, a BARDA-supported commercial product to treat thrombocytopenia (low platelet count) was approved as a MCM to treat acute radiation injury. In FY 2023, BARDA launched an initiative called RePAIR to encourage companies with commercial products with potential for repurposing to address injury caused by radiological or nuclear threats to partner with BARDA for development.

Burn and Blast Threats: Since 2013, BARDA has been investing in the advanced research and development of innovative technologies and approaches to mitigate severe burns and traumatic injuries resulting from a nuclear detonation. The focus of this program has been and continues to be development of a portfolio of next-generation treatments and technologies that address bottlenecks in routine burn and trauma care that will be exacerbated during a mass casualty incident. This strategic approach has led to the FDA approval or clearance of five products between 2018 and 2023. Furthermore, continued investments led to two of those products being approved or cleared for multiple indications in 2022 and 2023, thereby broadening the impact and potential sustainability.

Several burn and 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, two investments in point of care ultrasound technologies from Philips and GE are under development to provide real-time diagnostic lung imaging and aid clinical assessment of lung injury. In 2021 and 2023, BARDA supported two 510(k) clearances of the Philips Lumify for algorithms to help diagnose lung injuries. 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. BARDA made an initial investment in a diagnostic tool for traumatic brain injury in 2022 and will continue to develop MCMs to integrate them in routine care for national preparedness.

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. This strategy has resulted in successes like the FDA approvals of Seizalam (midazolam injection), for seizures including those resulting from nerve agent exposure; Silverlon, a widely available burn and wound dressing that is now indicated for the skin injury resulting from exposure to sulfur mustard; and the FY 2023 FDA approval of Opvee (intranasal nalmefene), an overdose reversal drug particularly suited to fentanyl and synthetic opioids.

Enabling technologies like organ-on-a-chip are leading to an improved understanding of the injuries caused by chemical agents and to identification of available treatments as candidates for repurposing. The organ-on-chip systems have also been used as preliminary efficacy screens for MCM candidates for any injury, saving both time and animals during preclinical development.

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. The goal of ReDIRECT is to accelerate the development of repurposed MCM candidates through preclinical studies. One candidate supported under ReDIRECT has already transitioned into the ARD portfolio for advanced clinical development.

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. DRIVe investments have led to the creation of five new companies, three FDA 510(k) device clearances, and catalyzed additional investment – BARDA's partners have raised over $1 billion in follow-on investments.

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

- Beyond the Needle: Transform drug delivery using alternative routes of vaccine and therapeutics administration (partnership with CBRN and NCD). One partner (Vaxess) was transitioned to a $2.5 million NIH Phase 1 grant.
- Host-based Diagnostics: portfolio of approaches that inform on health security threat risk to individual patient, agnostic of pathogen, supporting regulatory clearance, including FDA clearance of a sepsis diagnostic and a point of care hematology analyzer
- Host-directed Therapeutics: Broad investment in host-directed therapeutics, including small molecules, biologics and devices to advance in clinical development improving patient severe outcomes, or mitigating long term sequelae.
- Decentralized Clinical Operations for Healthcare and Research (D-COHRe): Launched in FY24 to address the challenges with decentralized clinical trials (DCT) and to partner directly with clinical sites delivering healthcare (that is where a patient seeks care) Partnering with

organizations (e.g., retail pharmacies) to enable capability builds to create sustainable DCT infrastructure

- ENACT (Early Notification to Act, Control, and Treat): Early detection of infection based on physiological signs from commercial wearables and other sensor-based technologies, regardless of the presence of any symptoms. One former partner (Sound Life Science) was acquired by Google.
- Digital MCMs: First line of defense against health security threats with rapidly deployable digital tools such as health screening or infection detection apps based on images and audio data.
- ReDIRECT: Repurpose commonly available therapeutics to quickly treat symptoms of chemical agent exposure (partnership with CBRN). One former partner (Enalare) transitioned to the Chemical Medical Countermeasures Branch in CBRN and received an award under their BAA.
- ImmuneChip+: Enhance the usability of 3D human tissue models for drug development and personalized medicine through the development of multi-organ microphysiological systems (partnership with CBRN) and integration of human immune system components.
- Lab at Home: Bring standard lab assays (e.g., blood panels) into the home as well as decentralized health care settings (schools, nursing homes, urgent care sites) through the development of miniaturized biochemical analytical instruments, in order to enable true telemedicine and better health outcomes as well enhanced remote clinical trial monitoring.
- At-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 known as well as emerging pathogens. One of the partners (UCSF) spun off the start-up company, Delve bio.
- Healing Lungs: Develop simpler, safer, more widely accessible lung support technologies for severe ARDS patients, by introducing innovations in the design of life support technologies such as ECMO (Extracorporeal Membrane Oxygenation) as well as development of "shuttle compounds" that deliver oxygen to tissues and simultaneously remove CO2.
- 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, DRIVe established D-COHRe (Decentralized Clinical Operations for Healthcare and Research), a new decentralized clinical studies partnership. D-COHRe will partner with industry leading telemedicine providers, retail clinics, and Clinical Research organizations designed to establish clinical trial infrastructure directly where patients seek care, improving access to diverse patients.

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. Based on the lessons learned from the current BARDA Accelerator Network and the COVID-19 pandemic regarding the importance of having agile and scalable mechanisms to advance rapid product development, BARDA will be launching the next iteration of the network BARDA Accelerator Network (BAN 2.0) in FY 2024. 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. The program currently supports a portfolio of over 40 companies 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 12 investment deals, investing $43.4 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. GHIC is currently raising additional funds from private investors to match BARDA contribution to create a Global Health Security Investment Fund. of up to $500 million venture with combined funding from BARDA and private investors. All previous investments, including the 12 already closed, would be rolled into this fund and in FY 2024, GHIC will continue to operate that fund and make investments and support the portfolio companies.

COVID-19: In addition, with the support of COVID-19 supplemental appropriations, Project NextGen continues the development of new tools that help ongoing management of COVID-19. BARDA, in

collaboration with the National Institute of Allergy and Infectious Diseases, is supporting the development of next generation medical countermeasures, including vaccines and therapeutics, to protect Americans from public health security threats such as coronaviruses. While existing vaccines against COVID-19 are still very effective at preventing serious illness and death, they are less capable of reducing infection and transmission over time. Similarly, previously authorized monoclonal antibody therapeutics critical to treating individuals and protecting some of our most vulnerable populations are not effective against current strains circulating in the country. Through Project NextGen, the Federal government will leverage public-private partnerships to develop new vaccines and therapeutics to better address current SARS-CoV-2 viral strains and prepare for future ones.

Project BioShield

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**820.000**	**820.000**	**820.000**	**-**
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's Biomedical Advanced Research and Development Authority (BARDA) program advances medical countermeasure research and development and procures lifesaving MCMs through public-private partnerships using annual appropriations under 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, Tanzania, and Equatorial Guinea; a Sudan outbreak in Uganda; a global mpox outbreak in non-endemic countries; and the 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 2024, PBS funding has supported 38 products that are critical to the Nation's preparedness to effectively respond to a variety of threats. Twenty-seven 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 2024. As of January 2024, 40 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 2025.

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 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, approval, 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 (EUA) issued by the FDA while continuing to support the late-stage development of product candidates moving towards FDA approval as well as post-marketing activities including label expansion for special populations. 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., JYNNEOS smallpox vaccine and RECELL spray-on-skin device) 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 2021	$770,000.000
FY 2022	$780,000,000
FY 2023 Final	$820,000,000
FY 2024 CR	$820,000,000
FY 2025 President's Budget	$820,000,000

Budget Request

The FY 2025 President's Budget request for Project BioShield is $820,000,000, which is flat with FY 2023. PBS funds support both late-stage development activities and initial procurement of the product. Late-stage activities include the following: (1) Phase 3 clinical studies for biothreat indications; (2) pivotal non-clinical studies for biothreat indications; (3) validation of manufacturing processes; and (4) post-marketing commitment and requirements from the U.S. Food and Drug Administration (FDA). The FY 2025 request supports the following:

1) Continued development and procurement of therapeutics for Sudan and Ebola viruses;
2) Procurement of TEMBEXA, the second therapeutic licensed for smallpox virus infection, to maintain a stockpile in the SNS;
3) Continued procurement of JYNNEOS for prevention of smallpox, including additional manufacturing requirements due to diversion of product to support the United States Government mpox response;
4) Continued procurement of ERVEBO for prevention of disease caused by Ebola virus to include manufacturing optimization;
5) Advanced development and procurement of novel drugs to treat drug resistant bacterial and fungal infections;
6) Procurement of MCMs to treat injuries resulting from exposure to chemical threats including nerve agents;
7) Continued procurement of Allograft to ensure national preparedness for burn injuries;
8) Continued procurement of therapeutics for the treatment of thrombocytopenia (low platelet count) due to acute exposure to ionizing radiation;
9) Initial procurement of newly approved MCMs to treat radiation and blast injuries from nuclear detonation;
10) New intravenous formulations of the currently stockpiled smallpox antiviral drugs for use in special populations or in those who are severely ill;

11) Continued procurement of CYFENDUS, a two-dose vaccine licensed for post-exposure prophylaxis against anthrax;
12) Late-stage development, procurement, and manufacturing capacity for diagnostics to detect biothreat pathogens, such as anthrax and Ebola; during outbreaks and,
13) New vaccine or therapeutic developed using a novel threat agnostic medical countermeasure platform technology.

The funding amounts listed below reflect the cost of procurement as well as late-stage development activities. The FY 2025 request supports the investments listed below, which reflects the highest priority countermeasures for FY 2025.

Anthrax Vaccine ($80 million): In 2023, CYFENDUS became the second FDA-licensed anthrax vaccine for use as a post-exposure prophylaxis in combination with antibiotics. Sustainment of the anthrax vaccine capability is paramount. The FY 2025 funding would enable a low-level pace of vaccine production of approximately two million doses per year.

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, technology transfer to manufacturing, and procurement for biothreat diagnostics needed for rapid response to an outbreak or release of a biothreat agent (such as anthrax and Ebola) will also be supported.

Broad Spectrum Antimicrobials ($135 million): In FY 2025, PBS funds will be used to procure NUZYRA, cefepime-taniborbactam, and up to three new antimicrobial products. The inclusion of these antimicrobials 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.

Chemical MCM for nerve agent exposures and opioid overdoses ($50 million): FY 2025 funding will be used to continue procurements of Midazolam autoinjectors for the SNS CHEMPACK program as well as intranasal nalmefene, a new drug for rescue from life-threatening opioid overdose that was approved by the FDA in 2023. Additionally, new and highly effective treatments for seizures resulting from nerve agent exposure that are resistant to currently stockpiled medications 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.

Filovirus Vaccines ($66 million): In 2019, ERVEBO became the first FDA-licensed Ebola vaccine, developed by Merck, and BARDA executed an agreement to establish a stockpile. FY 2025 funding will support procurement of up to one million doses of the vaccine, including replenishment of expiring doses, over a four-year period.

Filovirus Therapeutics ($47 million): FY 2025 funding will support scale up manufacturing and pivotal preclinical studies for MBP134, a monoclonal antibody product developed for Sudan virus, with an aim of achieving FDA licensure 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. FY 2025 funding will also support scale up manufacturing of Ebanga, a monoclonal antibody licensed for Ebola virus. Ebanga was licensed with a small scale manufacturing approach; the investment BARDA is making in manufacturing of this product will ensure that it is more cost effective and readily available in the future.

Rad/Nuc MCMs ($90 million): FY 2025 funding will support additional procurements to partially fulfill the requirement for MCMs to treat thrombocytopenia (low platelet count) caused by exposure to acute ionizing radiation. Additional products are expected to receive approval for treatment of thrombocytopenia by FY 2024, which would allow for competitively sourced procurements of new products in FY 2025. Funding will be used to procure additional treatment courses of an approved product to treat thrombocytopenia and to continue VMI of that product. Dried plasma products may also be granted FDA approval by FY 2025, thus enabling procurement with VMI.

Smallpox Vaccines ($100 million): In FY 2017, PBS funds procured several lots of Bavarian Nordic's JYNNEOS smallpox vaccine in bulk (unvialed) 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. FY 2025 funding will support licensure of the lyophilized form of the vaccine (currently licensed product is liquid), manufacture of additional bulk substance, and filling of bulk substance as the lyophilized formulation to continue to restore our smallpox preparedness.

Smallpox Antivirals ($82 million): The smallpox therapeutic approach is a layered approach, based on maintenance of oral TPOXX, the first line therapeutic for treatment. This is supplemented by procurement of intravenous (IV) TPOXX for severely ill patients and both tablet and suspension formulations of TEMBEXA, a second line therapeutic that is approved for pediatric patients. Moreover, BARDA continues to support the TPOXX pediatric formulation and, under BARDA base funding, an antibody product for special populations. FY 2025 funding will support advanced development of the pediatric formulation of TPOXX. Funding will also support procurement of tablet and suspension TEMBEXA to replace expiring product. Collectively, the strategy ensures that the US Government retains the capability to treat the majority of patients (oral TPOXX formulation), those who cannot swallow (IV TPOXX formulation), and patients under the age of 18 (pediatric formulation), with the potential for combination treatment with TEMBEXA in cases of severe disease or resistance to TPOXX. This approach avoids a single point of failure in the supply chain and provides healthcare providers with multiple options for therapeutic intervention.

Burn and Blast Countermeasures ($50 million): FY 2025 funds will support additional procurement of allograft (cadaver) skin to bolster preparedness for a mass casualty event involving large numbers of burn victims. Specifically, this funding will support procurement of burn care products that can provide temporary cover for large and/or deep burns when immediate grafting is not feasible are planned. The investments will ensure that the products remain in routine clinical use and physicians remain well-trained to effectively respond in a mass casualty incident.

Rapid Response Capabilities ($75 million): Under Advanced Research and Development, BARDA has long supported the development of threat agnostic MCMs designed to treat the injuries resulting from

chemical, radiological, and nuclear threat agents, rather than targeting the threats themselves directly. BARDA has applied this strategy to the development of innovative MCMs against priority CBRN threats as well as novel emerging biological threats, including pathogen-directed therapeutics that are effective against broad classes of pathogens, therapeutic platforms that can pivot to rapidly develop safe and effective treatments, 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. It is anticipated that at least one product developed using these approaches will be ready to transition to PBS funding in FY 2025. BARDA will advance the late-stage development of multiple threat-agnostic platform technologies such as novel modular therapeutic monoclonal antibody manufacturing capabilities that can quickly pivot to newly emerging threat; RNA-based therapeutic delivery systems that can integrate different payloads; and integrated next-generation RNA-based vaccine discovery, manufacturing, and delivery systems. 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.

Program Accomplishments

Since FY 2005, BARDA has invested in 38 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 and the next-generation CYFENDUS vaccine for post-exposure prophylaxis of anthrax;
- HBAT for treatment of symptomatic botulism;
- JYNNEOS vaccine for prevention of smallpox and mpox infection in adults;
- TPOXX (oral and intravenous) and TEMBEXA (capsule and suspension) 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 (two approvals), 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*) in adults and pediatric subjects;
- NUZYRA for secondary bacterial infections and community-acquired bacterial pneumonia (in development for treatment of anthrax);
- Inmazeb for treatment of Ebola virus disease (*Zaire ebolavirus*);
- Allograft skin (two partners) for treatment of burn wounds; and
- OPVEE intranasal nalmefene for reversal of overdose caused by opioids, including fentanyl.

The following products are part of the PBS portfolio but have not yet been delivered to the US Government:

- Ebanga for treatment of Ebola Virus Disease (*Zaire ebolavirus*);
- Cefepime-taniborbactam for treatment of complicated urinary tract infections and bacterial pneumonia (in development for treatment of melioidosis);
- ZENEO-midazolam autoinjectors for treatment of nerve agent injury;
- MBP134 for treatment of Sudan Virus Disease (*Sudan ebolavirus*); and
- DeepView AI-augmented imaging system for detection of burn injuries.

Key Outputs and Outcomes Table
ASPR: Project BioShield

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 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)	40 medical countermeasures	44 medical countermeasures	+4 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)	26 medical countermeasures	27 medical countermeasures	+1 medical countermeasures

Pandemic Influenza

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025+/- FY 2023
Budget Authority	**327.991**	**327.991**	**327.991**	**-**
No-year funding (non-add)	*300.000*	*300.000*	*300.000*	*-*
Annual Funding (non-add)	*27.991*	*27.991*	*27.991*	*-*
FTE	**-**	**-**	**-**	**-**

Authorizing Legislation:
Authorization .....Public Health Service Act, Sec. 319L; Sec. 2811 42 U.S.C. 247d-7e, 300hh-10
Authorization Status.....Indefinite
Allocation Method ....Direct Federal/Intramural, Contracts, Formula Grants/Cooperative Agreements, Competitive Grants/Cooperative Agreements, Other Direct Federal/Intramural

Program Description

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. This is 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 showed markers of neuraminidase inhibitor resistance, 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, Central, and South America and is approaching a record number of birds affected when compared to previous avian influenza virus 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. Since 2022, there have been 14 cases of influenza A(H5N1) detected in humans. These zoonotic infections with avian influenza signal that the US must continue to remain vigilant and sustain a robust pandemic preparedness posture against influenza viruses with pandemic potential, including but not limited to, influenza A(H7N9), A(H5N1), A(H5N6), and A(H9N2) influenza viruses, as well as other emerging infectious diseases that could cause pandemics. The unprecedented spread of A(H5N1) among wild birds throughout North and South America will continue to affect backyard and commercial poultry,

as well as spillover into marine and land mammals, including, potentially, swine, posing a persistent threat to human health.

The astonishing speed at which the H1N1pdm09 influenza virus spread from Mexico in 2009 and SARS-CoV-2 virus spread from Wuhan, China and the continuing emergence of antigenically distinct virus strains, demonstrates the immediacy with which Americans expect their government to respond and protect the public from new infectious diseases. Specifically, the H1N1pdm09 virus was very different from other H1N1 viruses that were circulating at the time of the pandemic. The United States Government (USG) must continue to improve medical countermeasures (MCMs), including vaccines, therapeutics, and diagnostics, 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 PI portfolio.

Funding History	
Fiscal Year	**Amount**
FY 2021	$279,991,000
FY 2022	$292,991,000
FY 2023 Final	$327,991,000
FY 2024 CR	$327,991,000
FY 2025 President's Budget	$327,991,000

Budget Request

The FY 2025 President's Budget request for PI is $327,991,000, which is flat with FY 2023. The request includes $300 million in no-year funding and $27.991 million in annual funding for ASPR. The no-year funding will support additional investments in BARDA's mRNA vaccine platform technology to support the 2021 American Pandemic Preparedness Plan (APPP)[33] goals, implementation of the *National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (NBS)*[34], and will incorporate pandemic influenza readiness activities including Phase 2 clinical trials in order to test safety and immunogenicity of influenza vaccines targeted to influenza virus strains of pandemic potential and capabilities sustainment of pandemic influenza vaccine manufacturing (e.g., infrastructure readiness, warm-basing domestic adjuvant production).

Funds will be used to support the PI program's twin pillars, which are: 1) PI preparedness and sustaining current response capabilities and 2) developing more effective 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 clinically assessing optimal antigen-adjuvant

[33] https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf
[34] https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf

combinations. The second pillar consists of development of improved vaccines, therapeutics, and diagnostics, driven by lessons learned from the 2009 H1N1- and COVID-19 pandemics. The second pillar will also align with the Presidential Executive Order 13887, which modernizes influenza vaccines, the 2017 HHS Influenza Plan Update, and the NBS. 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 2025 budget request sustains the pandemic preparedness capabilities that maintain domestic manufacturing capacity and operational readiness, and pre-pandemic influenza vaccine and adjuvant inventories found in the US National Pre-pandemic Influenza Vaccine Stockpile (NPIVS). BARDA will also maintain and sustain pre-pandemic influenza virus vaccine 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), which are essential to implement a rapid and effective USG response to control an emerging pandemic. While the AS03 adjuvant is part of a licensed pandemic influenza vaccine, it is not currently a component of seasonal influenza vaccines. Therefore, to maintain pandemic readiness, the USG must ensure that AS03 adjuvant manufacturing remains warm, meaning that a manufacturer maintains expertise and product line capability to ramp up production on demand.

Funds will support development and licensure of more effective influenza vaccines, vaccine platforms capable of producing vaccines faster than currently licensed influenza vaccines, therapeutics for pre-exposure prophylaxis (prevention) and broadly acting, host-directed therapeutics for acute respiratory distress syndrome (ARDS). This includes ARDS caused by 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 that can be used during a PI emergency. Bringing RNA and next generation vaccines to licensure for seasonal and pandemic influenza are major investment areas. Such investments will continue until the capability to manufacture a vaccine dose for every American within 130 days can be achieved. 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 antigen-matched vaccines become available.

The FY 2025 funding request supports ongoing efforts to develop home-use and point-of-need rapid diagnostic tests that empower patients and promote early detection of pandemic virus infections. Efforts are also underway to develop web-connected home-use and near-patient/point-of-need tests that empower patients to receive care more rapidly. These tests will also improve disease surveillance and inform more efficient distribution of critical medicines and healthcare resources, through automatic reporting of de-identified test data. The strategic investments planned for FY 2025 will close important gaps by enabling early detection of emerging influenza viruses, as well as lowering transmission.

Annual Funding Request for FY 2025 ($27.991 million)

Facilities and Infrastructure Readiness and Sustainment ($27.991 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. The annual manufacturing ensures the readiness of this manufacturing facility in Swiftwater, PA. In addition, annual funds will support sustainment and infrastructure readiness of the Holly Springs, NC facility to respond to a pandemic with 150 million licensed, adjuvanted, cell-based influenza vaccine doses within six months of a declared pandemic.

No-Year Funding Request for FY 2025 ($300 million)

Facilities and Infrastructure Readiness and Sustainment ($95 million): The FY 2025 funding will allow for continued sustainment of licensed, domestic manufacturing capacity, including adjuvant production and filling, cell- and egg-based antigen production, and vaccine filling. The sustainment funding includes support for year-round egg supply to support domestic manufacturing capacity at Swiftwater, PA, annual manufacturing and capability testing of the licensed cell-based manufacturing facility in Holly Springs, North Carolina (NC), and annual warm-basing of domestic AS03 adjuvant manufacturing and fill-finish activities at Marietta, PA. Collectively, these investments allow ASPR to maintain the targeted production goal of 660 million bulk antigen vaccine doses that was achieved with previous investments. Such efforts also enable ASPR to exercise the needed response capability. Without the sustainment of this capability, the year-round manufacturing capacity so critical to a PI response will be lost.

Vaccine Stockpiling, Clinical Assessment, and Storage and Analytical Testing ($61 million): The request includes funds to continue support of the risk-based stewardship of the National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS), This includes ongoing stability testing, analytical testing, and maintenance of influenza virus antigens and adjuvant production, including bulk antigen and adjuvant production, fill-finish, and analytical assessments. Testing of this kind is required to ensure these critical components are ready to be utilized as soon as needed in the event of an influenza pandemic. Clinical studies to assess the safety and immunogenicity of vaccines within the NPIVS are required to understand the compatibility of stockpiled antigens and adjuvants. Such studies also investigate heterologous prime and boost vaccination strategies, build the safety database for pandemic influenza vaccines, and otherwise support data driven decisions in a pandemic response.

Influenza Therapeutics Advanced Development ($50 million): Treatment for patients hospitalized because of an influenza infection remains a critical gap in PI response readiness. PI will invest in host-directed therapeutics for the treatment of ARDS. Such efforts will address those infected with ARDS caused by influenza infection. Success will provide a treatment(s) for not only hospitalized influenza-infected patients but potentially any patient suffering from ARDS due to an emerging infectious disease.

Improved Influenza Vaccine Advanced Development ($69 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 effective vaccines, faster manufacturing of vaccines, operational or formulation improvements to

provide better protection, and enhance uptake and access. Specifically, the PI program will invest in advancements that 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,
- Development of improved vaccines with formulations that confer protection against a novel influenza virus with a single dose of vaccine and may include development of adjuvants, devices, or other approaches/technologies.

Influenza Diagnostics Advanced Development ($25 million): Funding will be used to continue support for development of highly sensitive and specific diagnostic testing platforms for use in home and near-patient/point of-need settings. Requested funds will primarily be utilized to expand home testing capability to include simultaneous influenza, respiratory syncytial virus (RSV), and SARS-CoV-2 testing, since during flu season it is important to differentiate infections with similar symptoms in a single testing operation. Similarly, funding will support expansion of the home-use testing platforms capabilities to detect four or more viruses in a single testing action and, to develop lower cost but highly accurate tests to enable sustainment of a robust home-use testing market for routine infectious disease testing. Increasing the nation's ability to move testing closer to the patient and into the home is one important aspect of preparedness for future emerging disease outbreaks, including pandemic influenza.

Home testing is not effective for all people or all situations, however. The Near-Patient/Point-of-Need testing setting proved highly effective during the COVID-19 response in improving access to testing for certain populations including those experiencing homelessness, persons living in community settings, and persons with limited access to testing resources. Improved testing tools are needed for this setting; funding will be utilized to improve the availability, manufacturing cost, ease of use, robustness, and automated reporting capabilities of highly sensitive and specific testing platforms. Specific improvements for use in test-to-treat patient care scenarios and flu viral family tests are needed for response efforts in the early days of a novel disease outbreak. With investments, the available testing capacity in for at home and near patient settings would be expected to increase, thus improving the nations preparedness for emerging disease response.

Program Accomplishments

Strengthening Pandemic Influenza Preparedness

As of December 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 continue 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 virus 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 influenza virus subtypes AH5N1, H5N6, H5N8, and H7N9, and more are generated annually;
- Developed and purchased H2N3, H5N1, H5N6, H5N8, H7N9, and H9N2 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;
- 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 immunogenic;
- 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;
- Completed and initiated new clinical trials that provide the necessary evidence to rapidly deploy stockpiled and newly manufactured adjuvanted H5N1, H5N8, H7N9, and H2N3 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;
- Implemented a phase 2 clinical study investigating 3 host-directed therapeutics for the treatment of acute respiratory distress syndrome;
- 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; phase 2 clinical study was completed in FY 2023;
- 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 510(k) clearance of home-use, point-of-care, and laboratory 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;
- Initiated support of the development of pandemic influenza vaccines using a mRNA-based platforms;

- 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.); and,
- FDA 510(k) clearance of a nasal wash aspirate sample collection and transport device that provides high quality specimens for influenza testing.

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. ASPR 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. Ongoing efforts of this kind are critical to ensure 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) sub-type, AUDENZ, which is indicated for use in persons six months of age and older. In 2025, 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 Protein Vaccines: The PI program supported the first recombinant protein-based vaccine for seasonal influenza licensed in the U.S. This recombinant protein 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 a suitable new influenza virus strain, candidate vaccine viruses, to grow in eggs or cells. In addition, recombinant protein 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 June 2022, the CDC adopted the Advisory Committee on Immunization Practices' (ACIP) recommendation to recommend the use of specific flu vaccines for adults 65 years and older, including higher dose and adjuvanted influenza vaccines. The PI program completed a clinical study that enables selection of the optimal vaccine formulation for pandemic response. Because the adjuvanted vaccine induces a strong immune response, ASPR has critical information to develop a pandemic response strategy that paves the way for both dose selection as well as future new studies that will bring great benefit to Americans.

RNA-Based Influenza Vaccines: The PI program continues to support advanced development of RNA-based influenza vaccines. In FY 2021, 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. Two awards were made to AstraZeneca and

Access to Advanced Health Institute (AAHI) in FY 2023. In FY 2024, RNA vaccine programs will be focused on both near-term licensure of seasonal influenza mRNA vaccines and long-term access to mRNA vaccine platforms.

***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 licensed 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 MF59 adjuvant production capacity by 100 percent as part of the vaccine manufacturing expansion project at Sanofi's Swiftwater, PA facility described below. In FY 2024, sustainment of AS03 bulk and fill-finish manufacturing activities continue.

***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 during 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 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. In FY 2023 and FY 2024, work continues to ensure that operational gaps (including vial puncture studies) are addressed to allow for rapid pandemic response.

***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 2024, BARDA continued support for an ongoing efficacy trial of a therapeutic candidate to reduce onward transmission of influenza to uninfected individuals.

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, ASPR established the pre-exposure prophylaxis portfolio. The phase 2 clinical study has completed, and valuable information was gained to design the next clinical study.

Host-directed therapeutics for the treatment of ARDS: In FY 2024, ASPR 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.

***Diagnostics**:* Accurate, robust influenza tests are needed to inform rapid treatment decisions, patient management, and to assist with public health monitoring. Since 2007, ASPR has supported innovation and development of Influenza diagnostics. To highlight a few successes, 11 BARDA-supported Influenza diagnostics have received Full Market Authorization by the FDA and another 6 combination Flu tests received emergency use authorization over the course of the COVID-19 pandemic.

One important highlight of this portfolio are the early investments in home-use testing. Beginning in 2018, BARDA started supporting novel development efforts for home-use testing of Influenza. These efforts resulted in technological advancements that helped stimulate molecular at-home testing capabilities during the COVID-19 response. As a result, four EUAs for SARS-CoV-2 tests were awarded, two EUAs for SARS-CoV-2 Plus Flu tests were achieved, and the FDA granted the first ever full marketing authorization for an at-home test for any respiratory illness. Without the initial influenza MCM portfolio investments, this type of home-use product may not have been available during the COVID-19 response. FDA Full Market Authorization for an at-home flu test is also undergoing De Novo review. Additional ongoing efforts for the portfolio include the continued advancement and FDA clearance of at-home diagnostic capabilities, combination/multiagent tests, test-to-treat platforms, and support of pathogen family testing.

***Respiratory Devices and Ventilators**:* In 2019, FDA approved the Trilogy Evo Ventilator, a next-generation portable ventilator, the second ASPR funded ventilator to be cleared. 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. In addition, starting in FY 2018, investments were made for development of a reusable elastomeric respiratory protection devise 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. Development and regulatory approval for the cleanable mask is ongoing and clearance is anticipated in coming years FY 2024-25. Each reusable respirator has the potential to replace thousands of disposable N95s masks making them more impactful for stockpiling. For future developments, alternative approaches are being considered, such as ECMO, and additional reusable respirator technologies.

Key Outputs and Outcomes Table
ASPR: Pandemic Influenza

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
2.4.15a Assure that domestic pandemic influenza vaccine antigen manufacturing surge capacity produces desired number of vaccine doses within six months of candidate vaccine virus being delivered to the manufacturers (Intermediate Outcome)	FY 2023: 660 million antigen doses Target: 660 million antigen doses (Target Met)	660 million antigen doses	660 million antigen doses	Maintain
2.4.15b 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 (Intermediate Outcome)	FY 2023: 3 programs Target: 3 programs (Target Met)	3 programs	2 programs	-1 programs
2.4.15c Support pandemic influenza preparedness with manufacturing of pre-pandemic candidate vaccines (Output)	FY 2023: 7 bulk lots of pre-pandemic influenza vaccine Target: 7 bulk lots of pre-pandemic influenza vaccine (Baseline)	2 bulk lots of pre-pandemic influenza vaccine	2 bulk lots of pre-pandemic influenza vaccine	Maintain

Strategic National Stockpile

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**965.000**	**965.000**	**965.000**	**-**
FTE	**329**	**329**	**329**	**-**

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

Program Description
The Strategic National Stockpile (SNS) manages and delivers lifesaving medical countermeasures (MCM)[35] during a public health emergency supporting the Administration for Strategic Preparedness and Response's (ASPR) mission to assist the nation in preparing for, responding to, and recovering from public health emergencies and disasters. The SNS is the largest federally owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations (FMS),[36] 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 chain runs on a just-in-time inventory 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's ability to implement response capabilities for large-scale public health emergencies. To operate successfully during nationwide

[35] http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/ucm431268.htm
[36] https://aspr.hhs.gov/SNS/Pages/Federal-Medical-Stations.aspx

public health emergencies, the SNS, and our state and local partners, must have opportunities to exercise proficiency on smaller scales.

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 jointly managed 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. While SLEP is the most well-known mechanism to extend the shelf-life of pharmaceuticals, there are other methods by which FDA can extend dating of products held by SNS and state, local, tribal, and territorial (SLTT) partners outside of SLEP. For instance, certain influenza antivirals held by SNS and SLTT jurisdictions have been extended by FDA outside of SLEP after FDA's review of scientific data.

ASPR's robust medical logistics capability, which includes H-CORE, 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.

Aiding in the surge response post disaster when health systems become overwhelmed, SNS works closely with SLTTs and can deploy and provide technical assistance to jurisdictions to set up Federal Medical Stations (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 2021	$705,000,000
FY 2022	$845,000,000
FY 2023 Final	$965,000,000
FY 2024 CR	$965,000,000
FY 2025 President's Budget	$965,000,000

Budget Request

The FY 2025 President's Budget request for SNS is $965,000,000, which is flat with FY 2023. The FY 2025 request prioritizes funding for sustainment of current product lines critical for the protection of Americans across SNS's threat portfolios. Product procurement in FY 2025 will be guided by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related multiyear prioritization. The PHEMCE, as coordinated by ASPR, is responsible for 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 response to the COVID-19 pandemic, SNS added additional online and remote learning opportunities for partners on the ground. Now that COVID related travel restrictions have been lifted, SNS plans to restart some in-person training efforts in FY 2024. Specifically, SNS plans to partner with Center for Domestic Preparedness to create a weeklong SNS training and orientation program for public health and emergency management planners and leaders. Using lessons learned and materials developed during the COVID response SNS plans to have both in-person and online/remote training options for partners in FY 2025. These training resources are necessary 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 2025 by:

- Managing, storing, maintaining, replacing, and as needed, distributing MCM assets, valued at over $13.5 billion;
- Supporting PHEMCE with subject matter expertise and data to inform strategic MCM requirements and procurement decisions;
- Establishing and strengthening public-private partnerships to integrate private resources into public health response plans for a fully functioning supply chain for delivery of critical MCMs;
- 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 Allocations[1]

	FY 2024 CR		FY 2025 President's Budget	
	Requested	**Percentage of Total Budget Account**	**Requested**	**Percentage of Total Budget Account**
Total	$965.0M	100%	$965.0M	100%
Product				
Product Total	**$823.7M**	85.4%	**$791.1M**	82.0%
Procurement Total	$661.3M		$564.4M	
Procurement – New[2]	*$39.0M*		*$30.0M*	
Procurement – New (above replenishment)[3]	*$115.3M*		*$68.9M*	
Procurement – Replenishment	*$507.0M*		*$465.5M*	
Sustainment Total[4]	$162.4M		$226.7M	
Warehousing Costs	*$75.1M*		*$157.2M*	
Operations				
SNS Operational Costs[5]	$141.3M	14.6%	$173.9M	18.0%

[1] These amounts are estimates and are subject to change.
[2] Includes items previously purchased by BARDA
[3] This amount supports procurement of additional quantities of products currently held in SNS inventory, purchasing quantities beyond those required for 1:1 replacement of expiring product. The net effect of these procurements is to increase SNS holdings and capabilities in response to PHEMCE requirement goals and procurement recommendations.
[4] This amount supports management costs to sustain the $13.5 billion inventory of SNS assets, including storage, transportation, maintenance, and disposal.
[5] This amount supports work to develop and provide guidance, training, security, and other resources required for effective use of SNS held MCMs at the federal, state, and local level during an emergency.

Program Accomplishments

COVID-19 Response and Transformation Plan

The SNS began supporting the federal response to COVID-19 on January 30, 2020. Throughout the more than three-year response, SNS supported many vital response efforts including repatriation, pro-rata distribution of critical PPE, deployment of more than 25,000 ventilators and 5,000 high-flow nasal cannula to provide respiratory support, and distribution of more ancillary kits that supported more than 1.3 billion COVID-19 vaccinations and booster doses. More recently SNS has focused on:

- Building PPE Inventory - During the COVID response, using supplemental funds appropriated by Congress, SNS greatly expanded its inventory of PPE and ventilators. The recission of supplemental balances in the Fiscal Responsibility Act of 2023 caused ASPR to reevaluate and adjust plans for sustainment of these capabilities.
- The SNS has used supplemental dollars to purchase and maintain a stockpile of PPE throughout the pandemic. With the exhaustion of available supplemental funds to support the continued storage and stockpiling of this PPE, the SNS will lose this capability as the current PPE expires.
- Surge Support - Beginning in January 2022, SNS deployed more than 282 million NIOSH-certified N95 respirators to the American public in response to the Omicron variant. These respirators were available for pick-up at retail pharmacies and community health centers nationwide.

As the nation emerges from the COVID-19 pandemic, ASPR is committed to ensuring that SNS is prepared to respond to the next public health emergency in accordance with EO 14001, "On a Sustainable Public Health Supply Chain," and the supporting "National Strategy for a Resilient Public Health Supply Chain". While much of the work to transform SNS is happening within SNS, it also includes changes to ASPR's structure. Maintaining capacity built during COVID and ensuring that ASPR is prepared for future threats will require sustained support from Congress.

In 2022 ASPR relaunched PHEMCE. PHEMCE is tasked with providing recommendations to the HHS Secretary and communicating medical countermeasure needs to all stakeholders based on the best available evidence combined with situational awareness and field deployment realities. SNS leadership collaborates closely with this group to ensure that SNS's procurement strategy aligns with formal requirements to the extent allowed by available funding.

In February 2023, ASPR was reorganized. As a result of this reorganization, SNS was made its own Office reporting directly to the ASPR. This realignment recognizes the scope of work done by SNS as well as the importance of SNS's mission. As part of this reorganization, various programs within SNS were also elevated, and the Office of SLTT Preparedness was created.

Within SNS, work is ongoing on several key priorities, including the items listed below.

- SLTT Partnerships
- Commercial Partnerships
- Information Technology
- SNS Optimization Initiative
- Supply Chain Control Tower

SLTT Partnerships
In order to increase engagement with SLTT partners, SNS established a new office level organization to coordinate engagement with SLTT in February 2023. The new Office of SLTT Preparedness was tasked with designing and executing a series of engagement meetings in all 10 HHS regions to bring together public health, emergency management, and hospital preparedness leaders from State and local level as well as federal partners to review the COVID experience. These meetings also provided SNS with an opportunity to update SLTT partners of changes and updates to SNS including detailed formulary review as required by the PREVENT Pandemics Act. The regional meetings were completed in CY 2023. SNS is committed to increased engagement with SLTT partners moving forward. These meetings helped to strengthen relationships with SLTT and federal partners; gather information to help advance SNS' capacity to respond to a variety of public health emergencies; and foster complementary projects to improve all levels of MCM response operations. More than 700 representatives from federal, state, local, tribal, and territorial jurisdictions participated in these meetings.

In CY 2023 SNS launched its SNS Planning Resources SharePoint site, a limited-access technical assistance resource to enhance SLTT medical countermeasure (MCM) planning and preparedness efforts. This new site will improve information sharing between SNS and SLTT planners and other external stakeholders. Serving as a communication resource and information repository, the SNS Planning Resources site is targeted toward planners and partners from various disciplines who ensure readiness to distribute and dispense SNS-deployed MCMs in public health and health care settings.

In addition, SNS is seeking to enhance transparency by making formulary information for SNS available to public health, emergency management, and hospital preparedness planners via a limited access website.

Commercial Partnerships
In addition to work with SLTT partners, significant work is being done with private sector partners in support of the SNS's transformation. This work includes developing collaborations with medical manufacturers and distributors. 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.

This work to enhance commercial partnerships has already been exercised during the mpox response. Using a distribution contract, SNS expanded its distribution capacity to better support jurisdictional needs by significantly increasing the number of weekly shipments and delivery locations. Specifically, the contract allowed SNS to go from shipping to five locations per jurisdiction to 2,500 shipments per week of frozen JYNNEOS vaccine and up to 2,500 ambient temperature shipments per week, which can be used for TPOXX distribution.

Information Technology
SNS is in the midst of a significant IT upgrade. Recognizing the deficiencies of SNS's inventory management system at the beginning of COVID, SNS has been working to design and develop and

implement a new information technology inventory management system, which will provide operational efficiencies and enhanced reporting capabilities and allow SNS to respond more effectively during public health emergencies.

SNS Optimization Initiative

With the growth of SNS during the COVID-19 pandemic and SNS's elevation to an Office in early 2023, SNS launched an optimization initiative. Working with experts from Johns Hopkins University, SNS is in the midst of an organizational system improvement optimization initiative. This multi-year collaborative project provides the expertise to conduct a comprehensive assessment of SNS systems to improve SNS' ability to rapidly obtain, process, analyze, and share data to provide faster and more complete situational awareness and interoperability.

The initial project is focused on increasing SNS' ability to:

- Analyze and automate information;
- Become more efficient at managing stakeholder orders;
- Reduce operational steps and response time;
- Provide advanced analytical capability, more accurate and efficient reporting; and
- Gain better insight on, and management of response tools.

Supply Chain Control Tower

The COVID-19 public health emergency reinforced the USG's need for better information about supply chains to support decision making. In response, ASPR developed the Supply Chain Control Tower (SCCT). This advanced tool was instrumental in matching supply and demand imbalances early in COVID-19, providing detailed supply chain system analysis and frequent national level reports on the health of supply chains directly supporting the COVID-19 response. The program, which SNS co-manages, established a more robust supply chain information capability and system to collect data and continually monitor all aspects of the MCM enterprise, from research and development to commercial market availability.

Since early in the pandemic, SNS has devoted significant staff time and funding for development and sustainment of ASPR's SCCT. SNS's support has led to:

- Visibility on end-to-end inventory levels; manufacturer capacity; distribution flows, and point-of-care consumption;
- Insight into demand forecasting, scenario modeling;
- Gap prioritization; and,
- Improved support capacity planning and acquisition strategies; targeted distribution; and strategy and policy refinement during the COVID-19 response.

Moving forward, SNS will continue to provide staff time to support SCCT.

SNS Responses

Mpox
In 2022 SNS worked closely with partners across HHS, the interagency and the private sector to respond to a significant mpox outbreak. By the end of the public health emergency, public health efforts led to a greater than 95 percent reduction in mpox incidence since the peak of the outbreak with over 1.25 million doses of free vaccine having been administered. During the response, SNS collaborated with the Centers for Disease Control and Prevention (CDC) to ensure that vaccines and therapeutics reached the people who need them and with the CDC and FDA to ensure that all medical countermeasures deployed by the SNS were 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.
- Expand distribution capacity approximately ten-fold to take the burden of forward deployment off of our SLTT partners and improve equitable access to critical countermeasures.

Mpox continues to be a priority for HHS. As none of the vaccines and therapeutics for mpox have entered the commercial market, SNS expects to be the only source of these countermeasures. SNS will continue to support distribution of vaccines and treatments to affected individuals in an equitable manner for as long as necessary. Notably, all JYNNEOS vaccine deployed by SNS to respond to the mpox outbreak had been procured by Biomedical Advanced Research and Development Authority (BARDA). All countermeasures were provided to jurisdictions free of charge.

Influenza
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 with more than 50,000 courses deployed to jurisdictions to alleviate shortages throughout the nation.

SNS Support for Small-Scale Events
SNS demonstrated its ability to simultaneously respond to multiple events by responding to episodic events, such as hurricanes and National Special Security Events, while simultaneously supporting larger missions such as the COVID-19 and mpox responses. Other examples include:

- In 2020 and 2021, 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 August 2022, SNS provided rapid delivery of Inmazeb, an Ebola therapeutic MCM, which was used to successfully support post-exposure prophylaxis for a laboratorian.
- In April 2023, SNS deployed raxibacumab to Kenya to treat an anthrax meningitis patient. This

deployment advanced US public health preparedness by obtaining additional data and information regarding use of the product in human anthrax cases.

SNS Support for Tribes, Tribal Organizations, and Urban Indian Organizations
In accordance with Executive Order 14001, SNS is working with interagency partners, including the Indian Health Service (IHS), FEMA, and CDC, to improve tribal access to critical medical equipment and supplies from SNS and other federal support agencies. Beginning in 2022, an interagency workgroup developed a comprehensive set of recommendations outlining multiple alternative routes for tribal and Urban Indian Organizations (UIOs) to access the SNS.

In 2023, the SNS-led interagency EO 14001 Tribal Access working group

- Drafted a comprehensive strategy to streamline tribal nation and UIO access to public health emergency response supplies held in the SNS and other federal medical supply stockpiles (pending ASPR approval).
- Conducted two Zoom sessions - a tribal consultation with tribal leaders and providers, and an urban confer with UIO leaders - for inputs on the draft strategy.
- Initiated communication planning to build tribal and UIO capability to access and utilize federal medical supply assistance during a large-scale public health response.

Global Impact
SNS expertise in MCM supply chain optimization and logistics planning is a valued global health resource. In coordination with CDC's Global Health Center in support of the Global Health Security Agenda (GHSA) and the World Health Organization's International Health Regulations, SNS provides direct technical assistance to public health and emergency management planners from international GHSA Intensive Support partner countries as they seek to finalize national MCM supply chain response plans. In July 2023, SNS conducted a discussion-based exercise with the Senegal Ministry of Health and Social Action and other stakeholders to successfully validate that country's national MCM plan. SNS also provided post-validation consultation and technical assistance in supply chain operations and plan development for Sierra Leone, Guinea, and Nigeria, and continued one-to-one engagement with Liberia to assist that country in developing a national MCM plan projected for validation in 2024.

In addition to one-to-one planning engagements with individual partner countries, SNS supported broader training, technical assistance, and capacity building initiatives with international partners across the globe during 2023. In coordination with CDC's Division of Emergency Operations, SNS conducted two MCM planning workshops as part of CDC's Public Health Emergency Management (PHEM) fellowship program in Atlanta, training 46 public health professionals from 28 countries – including thirteen GHSA Intensive Support countries- on MCM supply chain, operational planning, and response management principles, and partnered with CDC to support in-country PHEM immersion training with a three-day MCM workshop for 60 national and provincial responders in the Democratic Republic of Congo.

SNS continues to support priority ASPR technical assistance and capacity building engagements with international partners, consulting on stockpiling and emergency response issues with the health ministries of Brazil, Japan, Canada, Australia, and the European Union. During the fall of 2023, SNS supported comprehensive subject matter assistance to the European Union's MCM stockpiling effort, hosting a

representative from the European Commission's Health Emergency Preparedness and Response Authority on an extended visit to observe best practices in emergency management and public health preparedness and to learn how the SNS manages the U.S. stockpile. SNS also 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 2023, SNS continued to expand web-based and virtual training opportunities, allowing more than 50,000 stakeholders to participate in training opportunities in FY 2023. Growth in the uptake of SNS training materials was due to continued interest in FMS training videos[37], posted to YouTube which were viewed more than 47,000 times in FY 2023. In total, SNS provided training for 50,994 SLTT and federal partners during 2023 through the efforts listed below.

- 47,940 stakeholders viewed FMS training videos, available on YouTube in both English and Spanish.
- 1,286 stakeholders participated in virtual training on topics including SNS Overview; SNS Risk Communication; Developing MCM Response Plans; Training, Exercise, Evaluating Plans; and other topics.
- 967 stakeholders participated in webinars on topics including SNS Formulary; Introduction to the Strategic National Stockpile; Crisis and Risk Communications; and other topics.
- 801 stakeholders participated in a mix of in person and virtual courses including SNS Overview; Receive, Stage, Store (RSS); Federal Medical Station (FMS); and Chempack.

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 or clinician to prepare for mechanically ventilating patient populations during a large-scale public health emergency or pandemic event.

SNS also partnered with the AARC to develop 15 demonstration videos for each type of SNS-held ventilator. Each video offers a demonstration on how to set-up and start mechanically ventilating a patient. The videos are housed on the ASPR webpage[38]. SNS has again partnered with AARC in FY 2024 to provide additional quarterly webinar trainings for respiratory therapists and clinicians regarding SNS-held ventilators. The first webinar was held in December 2023 with over 800 participants registered and approximately 400 participants attending.

Inventory Management and SLEP

In FY 2023, SNS sustained a 99.44 percent inventory accuracy rate and a 99.99 percent financial accuracy rate across its $13.5 billion inventory. SNS also ensured that no product was lost due to failure to comply with FDA cGMP practices.

[37] https://aspr.hhs.gov/SNS/Pages/SNS-Training-Videos-FMS.aspx
[38] https://aspr.hhs.gov/SNS/ventilators/Pages/default.aspx

In FY 2023, SNS was able to streamline, increase, and relocate a few warehouse locations. These strategic changes strengthened the warehouse portfolio while providing tactical advantages and abilities for a more robust and seamless operation when called upon in an emergency. Throughout this process, SNS increased its Southwest inventory by 45,000 pallet positions in ambient and cold storage allowing more lifesaving medical countermeasures in the immediate area to support a greater section of the U.S. population based on the 2020 census. Also, SNS continues to maintain three warehouses consisting of 143,000 pallet positions specifically designed and outfitted for Personal Protective Equipment. Additionally, the realignment and growth within the portfolio continued with the completion of a new build and complete warehouse renovation in the South and Northeast. Again, these improvements added more diverse capabilities and anchored the ability for rapid sustainable responses.

ASPR works with FDA to test stability of drugs approaching labeled expiry through SLEP and also to extend dating by other mechanisms. In addition to SLEP, select products can be extended after FDA's review of scientific data. FDA also works with manufacturers and stockpilers that seek to initiate expiration date extensions in accordance with FDA protocols including extensions requested by manufactures. Products may be tested and extended multiple times through these programs, 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 manufacturer-labeled expiration. Similarly, these efforts decrease total lifecycle costs for products by reducing the frequency of replacement. Working in collaboration with FDA, an additional extension of expiration dates for certain stockpiled antivirals was granted outside of SLEP in April 2022.

SNS Coordination with Industry Partners

The resiliency of the SNS is closely linked to the resiliency of the commercial supply chain. SNS partners with industry to 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.

In 2023, SNS continued work with major industry trade associations. SNS had 108 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 ASPR, the SNS, and industry trade association partners;
- Discuss medical supply chain issues focusing on CBRN preparedness and response operations; emerging threats; 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.

Additionally, in 2023, SNS and SMI collaborated to review best practices at the state level focused on unique and successful distribution of PPE in North Carolina. The review can be expanded over time and used in other jurisdictions.

SNS is committed to continuing work with our commercial partners. In 2024, 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; and,
- Sustain robust interagency and cross-jurisdictional collaboration.

Key Outputs and Outcomes Table
ASPR: Strategic National Stockpile

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
13.4.6 Percentage of inventory accuracies that are attained by using quality inventory management systems. (Outcome)	FY 2023: 99.44% Target: 97 % (Target Exceeded)	97%	97%	Maintain
13.4.7 Maintain the safety and efficacy of medical supplies SNS inventory (Outcome)	FY 2023: 100% Target: 100 % (Target Met)	100%	100%	Maintain
13.4.8 Maintain the response rate of recall capability (Intermediate Outcome)	FY 2023: 99.7 % Target: 95 % (Target Exceeded)	95%	95%	Maintain
13.4.9 Increase the number of participants trained by SNS (Intermediate Outcome)	FY 2023: 50,944 trained[1] Target: 1,500 trained (Target Exceeded)	1,500 trained	1,500 trained	Maintain

[1] The total includes more than 47,000 views of FMS training posted to YouTube.

HHS Coordination Operations and Response Element

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025+/- FY 2023
Budget Authority	**75.000**	**75.000**	**75.000**	**-**
FTE	**111**	**135**	**135**	**-**

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
The 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.

HHS Coordination Operations and Response Element (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. H-CORE will ensure there is an adaptable, reliable, and resilient public health emergency response infrastructure in place to aid future responses, as needed, to address existing and emerging threats to public health.

Funding History	
Fiscal Year	**Amount**
FY 2021	**-**
FY 2022	-
FY 2023 Final	$75,000,000
FY 2024 CR	$75,000,000
FY 2025 President's Budget	$75,000,000

Budget Request

The FY 2025 President's Budget request for H-CORE is $75,000,000, which is flat with FY 2023. In FY 2025, H-CORE's capabilities will focus on sustaining and evolving operations and logistics response capabilities 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 sustaining the innovative skillsets, tools, and processes developed in its first year, as well as evolving its capabilities through 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 2025 request will be used in three key areas:

1. **Operations and Logistics Readiness and Response:** Funds will be used to sustain a multi-disciplinary workforce able to provide operations and logistics expertise for a range of novel and emerging missions. This includes professional development, exercises, and playbook development to grow workforce skills and ensure their readiness. Funds also will be used to sustain contingency contracts to allow for rapid, end-to-end distribution management of response resources; maintain a volunteer management system to support a 24/7 response-oriented operational capability; and sustain and grow a range of first-of-their-kind public- and private-sector partnerships.

2. **Data and Security Assurance Infrastructure Sustainment:** Funds will be used to sustain and exercise the operations and logistics architectures necessary to rapidly put resource ordering, inventory management, forecasting, situational awareness, and security in place for future operations and logistics responses. This includes activities like the underlying logistics management and information technology and analytics infrastructure (e.g., enhanced Health Partner Ordering Portal (HPOP) and Tiberius) and the security assurance infrastructure necessary for safe and secure operations and logistics activities (e.g., confirmation of authorized trading partners, product tracing, and product security during distribution).

3. **Modernization and Initiatives:** Funds will be used to modernize tools and initiatives driven directly by feedback from partners during previous responses that will reduce demands on both Federal and partner resources (e.g., improved asset tracking, artificial intelligence and machine learning), increase situational awareness and information sharing (e.g., logistics management and information system, pre-established data use agreements), build on novel engagement and education efforts initiated to increase outreach to providers and private-sector partners (e.g., Project Echo); and to establish pilot/proof of concept partnerships to enhance operational data sharing to support coordinated, scalable, and timely responses to public health threats.

Program Accomplishments

Since its inception, H-CORE successes include:

- Procurement, operational planning and coordination, ordering, inventory management and situational awareness of end-to-end distribution of 14 different COVID-19 vaccines across four manufacturers in coordination with the Centers for Disease Control and Prevention (CDC) and Biomedical Advanced Research and Development Authority (BARDA), and continuing the work

of H-CORE's predecessors Operation Warp Speed and the Countermeasures Acceleration Group, totaling more than 980 million vaccine doses distributed nationwide.

- Procurement, operational planning and coordination, ordering, inventory management, management, technical assistance, and situational awareness of end-to-end distribution for eight different COVID-19 therapeutics across six manufacturers, continuing efforts initiated by the Countermeasures Acceleration Group, for more than 24.9 million cumulative treatment courses distributed nationwide.
- Establishment of collaborative relationships with hundreds of partners across 14 federal entities, 64 jurisdictions, and 21 retail pharmacy partners to support equitable access and administration of medical countermeasures. More than 90 percent of U.S. residents lived within five miles of at least one of the more than 90,000 vaccination sites and approximately 40,000 therapeutics providers across the country.
- Procurement, operational planning and coordination, and management of the COVIDTest.gov program, in cooperation with the Department of Defense, U.S. Postal Service and ASPR's Testing and Diagnostics Working Group to provide end-to-end distribution of over 750 million at home test kits that were delivered to 80 million households.
- Extensive coordination between H-CORE and its partners to successfully donate 12,960 doses of bivalent vaccines and 10,800 doses of COVID-19 monovalent vaccines to The Bahamas; to supply Ghana with 2,000 treatment courses of Paxlovid, and to successfully donate 17,000 courses of Paxlovid to Ukraine.
- Finalization of a Tripartite Agreement between HHS, the Global Alliance for Vaccines and Immunization (GAVI), and Pfizer, designating millions of COVID-19 Vaccines for Global Access donations.
- Development, management, and sustainment of enabling information technology and data systems including online ordering, inventory management, data analytics, real-time dashboards, and allocation and forecasting tools.
    - Rapid development and continuous improvement of the functionality of the Health Partner Ordering Portal (HPOP) to enable ordering and shipment of COVID-19 vaccines and therapeutics to more than 40,000 different locations across the country with a nearly 100 percent successful fulfillment rate.
    - Rapid modification of the HPOP system built during COVID-19 within three weeks to support the quick response to the mpox outbreak, enabling electronic ordering, inventory management and data acquisition of mpox vaccines and therapeutics; and further system enhancement to enable ordering of other medical countermeasures and resources for multiple simultaneous responses.
- Development, management, and sustainment of enabling technical assistance, processes, and tools to ensure the security and assurance of COVID-19 response operations.
- Introduction and coordination of novel outreach programs to ensure access to COVID-19 vaccines and therapeutics for rural, elderly, and other underserved populations, including the Long-term Care Booster Administration, in coordination with CDC, and direct to provider treatment distribution.
- Engagement and coordination with HHS and other federal partners, manufacturers, and the full range of administration partners, including webinars and listening sessions with a range of

stakeholders, to ensure that vaccines and therapeutics continue to be available and accessible even after the transition to commercial pathways.

- Provision of technical assistance, helpdesk support, and clinical and pharmacy education, in collaboration with other ASPR and CDC subject matter experts, in response to requests for information regarding the COVID-19 pandemic and mpox.
- Coordination for day-to-day planning, cross-agency activities, and development of guidance and communication related to mpox vaccines and treatments, including the development of processes and reimbursement of vaccines made available for large-scale and equity events.
- Served as subject matter experts to interagency working groups focused on vaccines, therapeutics, and clinical trials to support of White House National Security Council's efforts to implement the National Biodefense Strategy to enhance our ability to prepare for and respond to biological incidents.
- Conducted a foundational assessment to address the capability for Special Pathogen Units/Highly Infectious Disease (HID) patient transport to provide stronger operational and logistical support during response.
- Support for ongoing efforts within the ASPR to transition Department of Defense's assisted acquisition activities to ASPR and supporting efforts to expand the acquisition workforce.

Policy and Planning

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**14.877**	**14.877**	**14.877**	**-**
FTE	**66**	**66**	**66**	**-**

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

Program Description
Policy and Planning activities provide a foundation for the Administration for Strategic Preparedness and Response (ASPR) to assist the nation in preparing for, responding to, and recovering from public health emergencies and disasters. ASPR policy and planning initiatives ensure that evidence-based strategies, best practices, and equitable partnerships underpin ASPR's life-saving work. This program oversees a strategic approach to ASPR health security priorities to advance preparedness and response initiatives for the ASPR and the Secretary of the Department of Health and Human Services (HHS).

Policy and Planning coordinates strategic alignment with the White House and other federal agencies and provides legislative policy analysis and solutions to ensure programs operate in accordance with HHS and ASPR's wider strategic goals, administrative priorities, and statutory requirements. Policy and Planning engages in policy implementation across ASPR for domestic and international health security to address public health and medical preparedness, mitigation, and response; domestic incident response management; biodefense; medical countermeasures; climate change; and meeting the needs of at-risk populations.

ASPR's Policy and Planning 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), the PHEMCE Multi-Year Budget, the quadrennial National Health Security Strategy (NHSS), and the annual threat-based review of the contents of the Strategic National Stockpile. Policy and Planning also continues to support implementation of the National Biodefense Strategy, the National Influenza Vaccine Modernization Strategy, the National Strategy for a Resilient Public Health Supply Chain, and the Biotechnology and Biomanufacturing Initiative, among others.

ASPR policy responsibilities include providing situational analysis of statutory response authorities exercised by the Secretary of HHS, such as Public Health Emergency (PHE) declarations, Emergency Use Declarations, and Public Readiness and Emergency Preparedness (PREP) Act declarations. This work includes real-time decision support for HHS leadership and guidance to National Response Framework's Public Health and Medical Emergency Support Function 8 (ESF-8) partners during responses to national security incidents and public health emergencies.

Additionally, ASPR Policy and Planning oversees administration of the PHEMCE to assist in ASPR's mission critical medical countermeasure coordination 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, and dispensing of countermeasures, particularly in relation to the Strategic National Stockpile (SNS).

ASPR Policy and Planning establishes capability-based and materiel requirements for development and acquisition of security countermeasures and non-materiel solutions to close critical national level health security gaps. Development of these requirements is not only good practice but is mandated in part by the Project BioShield Act of 2004 and the Federal Acquisition Regulation. Through a best-practices approach that leverages relevant experiences across PHEMCE partners, ASPR focuses on capabilities that are flexible and can be broadly applicable to the needs of all components of the response to public health emergencies and disasters, including natural disasters, chemical, biological, radiological, and nuclear (CBRN) incidents, and emerging infectious diseases that threaten national security. As part of the requirements function, ASPR Policy and Planning uses quantitative modeling tools to help ensure that ASPR is addressing the most significant threats to health security while implementing the most impactful and cost-effective solutions.

ASPR Policy and Planning manages and operates four statutorily required federal advisory committees: the National Biodefense Science Board (NBSB), the National Advisory Committee on Children and Disasters (NACCD), the National Advisory Committee on Seniors and Disasters (NACSD), and the National Advisory Committee on Individuals with Disabilities and Disasters (NACIDD). Those four committees provide advice and recommendations to the ASPR and HHS Secretary on a wide range of strategic and operational matters related to chemical, biological, radiological, and nuclear threats as well as naturally occurring infectious diseases and natural disasters. ASPR Policy and Planning also chairs and manages the HHS Biosafety and Biosecurity Coordinating Council, which provides a high-level and formal mechanism to coordinate biosafety and biosecurity issues across HHS, on behalf of the HHS Secretary.

Funding History	
Fiscal Year	**Amount**
FY 2021	$14,877,000
FY 2022	$14,877,000
FY 2023 Final	$14,877,000
FY 2024 CR	$14,877,000
FY 2025 President's Budget	$14,877,000

Budget Request
The FY 2025 President's Budget request for Policy and Planning is $14,877,000, which is flat with FY 2023.

This funding will maintain ASPR Policy and Planning activities, which ensures that operational preparedness and response capabilities align with HHS and ASPR's strategic priorities. FY 2025 funds will primarily support continued development and implementation of a strategic approach to ASPR health security priorities. These activities will continue to include developing ASPR, HHS, and national level strategies, requirements, and policy recommendations - in coordination with a broad cross section of public health preparedness stakeholders. These efforts help ASPR and the broader U.S. Government to most effectively and efficiently address the full spectrum of national health security concerns. Additionally, FY 2025 funding will support independent non-governmental analysis of critical policy issues, as well as development of quantitative modeling tools to help ensure that ASPR is addressing the most significant threats to health security while implementing the most impactful and cost-effective solutions.

Program Accomplishments

National Health Security Strategy (NHSS)
ASPR Policy and Planning leads the development and release 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* includes an enhanced focus on several health care and public health challenges exacerbated during COVID-19 and other public health emergencies, including supply chain resiliency, health care, and public health workforce capacity; risk communication; addressing the needs of at-risk individuals and underserved communities, and equitable access to post-disaster health services. The *NHSS, 2023-2026 Implementation Plan* serves as a framework to guide federal action and recommend implementation activities for *State, Local, Tribal, and Territorial* 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. All three documents were released to the public in March 2023.

Coordination and Alignment of Policy Activities
ASPR Policy and Planning manages a variety of White House policy engagements to ensure appropriate representation and coordination of ASPR's equities in preparedness and response policy actions, and tracks ASPR-wide implementation of Executive Orders. Additionally, Policy and Planning established and uses a hub to coordinate climate change and health equity policy and activities across ASPR.

National Advisory Committees
ASPR Policy and Planning leads the statutorily required NBSB, the NACCD, the NACSD, and the NACIDD. These groups bring together nationally renowned experts in public meetings to advise the HHS Secretary and the ASPR on important issues such as medical countermeasure development, mental health response for children, pediatric medical surge, public health communication with older adults and individuals with disabilities, ensuring equitable distribution of medical supplies, and effective partnerships with disability and aging networks.

Requirements and the PHEMCE
In coordination with PHEMCE partners, ASPR Policy and Planning initiated and completed an initial comprehensive review of all ASPR's approved medical countermeasure and PPE requirements, including

those informing the holdings of the Strategic National Stockpile (SNS). ASPR also strengthened 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. ASPR Policy and Planning led the development of the 2022 PHEMCE Strategy and Implementation Plan (released in October 2022), the PHEMCE Multi-year Budget, and the Medical Countermeasures Preparedness Report which is the threat-based review of the contents of the SNS that includes expanded reporting on broader MCM-related capabilities (transmitted to Congress in May 2023).

Key Outputs and Outcomes Table
ASPR: Policy and Planning

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2024 Target	FY 2025 Target	FY 2025 Target +/-FY 2024 Target
2.4.20 Increase the number of policy coordination actions that strengthen health security (Intermediate Outcome)	FY 2023: 12 coordination actions Target: 12 coordination actions (Baseline)	16 coordination actions	Prior Result + 4	+4
2.4.21 Increase the number of engagements with relevant non-federal PHEMCE partners in accordance with the current PHEMCE Strategy and Implementation Plan (Outcome)	FY 2023: 6.0 engagements Target: 5.0 engagements (Target Exceeded)	15.0 engagements	25.0 engagements	+10
2.4.22 Increase the number of capability-based requirements with updated HHS Target Capabilities (Output)	FY 2023: 64.0 requirement(s) Target: 61.0 requirement(s) (Target Exceeded)	68.0 requirement(s)	Prior Result + 4.0	+4

Operations

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**34.376**	**34.376**	**79.867**	**+$45.491**
FTE	**142**	**142**	**313**	**+171**

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

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. ASPR 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, performance and risk management, 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.

Funding History	
Fiscal Year	**Amount**
FY 2021	$30,938,000
FY 2022	$30,938,000
FY 2023 Final	$34,376,000
FY 2024 CR	$34,376,000
FY 2025 President's Budget	$79,867,000

Budget Request

The FY 2025 President's Budget request for ASPR Operations is $79,867,000, which is $45,491,000 above FY 2023 Enacted. The increased funding will support ASPR as its overall responsibilities and programs continue to grow. Over the past decade, ASPR's funding has increased by $2.7 billion or over 300 percent. Conversely, Operations funding has remained nearly flat. The requested increase will specifically support the enhancement of ASPR's human capital, financial management, acquisition support, and information technology. These activities provide support across ASPR's programs and will

also ensure an optimal, resilient infrastructure as ASPR looks to the future. The requested increase will also provide the necessary capabilities to support the organization as ASPR matures into an HHS Operating Division.

The President's Budget provides $10 million for ASPR to establish its own human capital function in FY 2025. ASPR estimates hiring up to 41 new human capital staff for this function, which will allow ASPR to process its own human capital actions similar to other HHS agencies. Given its mission and activities, ASPR has unique hiring and retention challenges. This in-house capability will allow ASPR to tailor its human capital function to best fit its complex needs.

Within the total increase, the FY 2025 President's Budget includes $20 million to ensure ASPR can recruit a quality workforce to carry out its responsibilities related to acquisitions, contracting, and financial management. ASPR would add 114 staff for this effort. Of this total, 105 staff would support ASPR acquisitions and contracting workforce, and the remaining nine staff would support ASPR financial management. As noted, ASPR's baseline budget has increased by 300 percent, in which has contributed to a large increase in contract and acquisition requirements. 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 executed nearly $100 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 FY 2025 budget request addresses this workforce gap to ensure ASPR is able to successfully execute its mission.

The request also includes $15 million to support ASPR-wide programmatic information technology needs. ASPR's ability to execute its mission depends on a robust, reliable, and resilient information technology platforms and infrastructure. ASPR technology infrastructure includes a spectrum of technologies ranging from computers, mobile devices, cloud architectures and data application platforms. 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 fifteen staff positions to begin to support ASPR's transition to an HHS Operating Division. Additional information technology, data, 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, acquisitions, facilities, and records management 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.

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 2023, the ASPR's contracting enterprise executed nearly 1,700 contract and grant actions and obligated over $11 billion. ASPR continuously manages its portfolio of acquisition instruments totaling over $100 billion.

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.

The FY 2025 budget supports ASPR in establishing a new Working Capital Fund (WCF) as a full-cost recovery operating model to reimburse administrative expenses through funds collected from ASPR programs, projects, and activities that use centrally managed administrative services. To date, ASPR has developed 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 established a formal governance structure in FY 2023 so program leaders have transparency and visibility into the administrative charges and the associated justification. ASPR will continue its preparations to implement the WCF during FY 2024 and FY 2025 while it seeks the necessary authority to operate the Fund. The FY 2025 budget includes a legislative proposal to ensure ASPR has the necessary authorities to fully implement the WCF structure (see the Proposed Law section for more information on this legislative proposal).

Preparedness and Response Innovation

Budget Summary
(Dollars in Millions)

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Budget Authority	**3.080**	**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) is to assist the nation in preparing for, responding to, and recovering from public health emergencies and disasters. New challenges that confront disaster response require new solutions to ensure that the Department of Health and Human Services (HHS) is prepared to protect Americans from national security health threats. Within ASPR, the Preparedness and Response Innovation (PRI) program was designed to develop, prototype, and procure health security products, technologies, and innovations. The PRI program provided funds to develop technologies beyond chemical, biological, radiological, and nuclear medical countermeasures (MCMs), and made it possible to adapt practical solutions to ensure the availability of the highest standards of care.

As required by Congress, FY 2021, FY 2022, and FY 2023 PRI funds were used to support United States and Israeli cooperative research and development. Priorities included development of health technologies, a clinical accelerator network, and establishing a bilateral cooperative program with Israel.

Funding History	
Fiscal Year	**Amount**
FY 2021	$2,000,000
FY 2022	$2,000,000
FY 2023 Final	$3,080,000
FY 2024 CR	$3,080,000
FY 2025 President's Budget	-

Budget Request

The FY 2025 President's Budget request proposes to sunset the Preparedness and Response Innovation program.

SUPPLEMENTAL TABLES

Budget Authority by Object Class

Description	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Personnel compensation:				
Full-time permanent (11.1)	142.302	142.302	236.038	+93.736
Other than full-time permanent (11.3)	11.000	11.000	12.000	+1.000
Other personnel compensation (11.5)	7.000	7.000	8.000	+1.000
Military personnel (11.7)	19.000	19.000	19.500	+0.500
Special personnel services payments (11.8)	-	-	-	-
Subtotal, Personnel Compensation	**179.302**	**179.302**	**275.538**	**+ 96.236**
Civilian benefits (12.1)	48.500	48.500	65.000	+16.500
Military benefits (12.2)	2.500	2.500	3.000	+0.500
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	**177.000**	**215.000**	**225.750**	**+3.220**
Travel and transportation of persons (21.0)	6.000	6.000	7.000	+1.000
Transportation of things (22.0)	16.000	16.000	17.000	+1.000
Rental payments to GSA (23.1)	6.000	6.000	7.000	+1.000
Rental payments to Others (23.2)	4.000	4.000	5.000	+1.000
Communication, utilities, and misc. charges (23.3)	1.000	1.000	1.000	-
Printing and reproduction (24.0)	0.500	0.500	0.500	-
Subtotal, Other Costs	**33.500**	**33.500**	**37.500**	**+4.000**
Other Contractual Services:				
Advisory and assistance services (25.1)	1,522.825	1,522.825	1,525.000	+2.175
Other services (25.2)	150.000	150.000	152.000	+2.000
Purchase of goods and services from government accounts (25.3)	450.000	450.000	455.000	+5.000
Operation and maintenance of facilities (25.4)	25.000	25.000	26.000	+1.000
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	15.000	15.000	16.000	+1.000
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal, Other Contractual Services	**2,162.825**	**2,162.825**	**2,174.000**	**+11.175**
Supplies and materials (26.0)	900.000	900.000	905.000	+5.000
Equipment (31.0)	4.000	4.000	4.000	-
Land and Structures (32.0)	4.000	4.000	4.000	-
Investments and Loans (33.0)	-	-	-	-
Grants, subsidies, and contributions (41.0)	295.000	295.000	300.000	+5.000
Insurance Claim (42.0)	0.050	0.050	0.050	-
Interest and dividends (43.0)	-	-	-	-
Total Non-Pay Costs	**3,399.375**	**3,399.375**	**3,424.550**	**+25.175**
Total, Budget Authority by Object Class	**3,629.677**	**3,629.677**	**3,768.088**	**+138.411**

Salaries and Expenses

Description	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Personnel compensation:				
Full-time permanent (11.1)	142.302	142.302	236.038	+93.736
Other than full-time permanent (11.3)	11.000	11.000	12.000	+1.000
Other personnel compensation (11.5)	7.000	7.000	8.000	+1.000
Military personnel (11.7)	19.000	19.000	19.500	+0.500
Special personnel services payments (11.8)	-	-	-	-
Subtotal personnel compensation	**179.302**	**179.302**	**275.538**	**+ 96.236**
Civilian benefits (12.1)	48.500	48.500	65.000	+16.500
Military benefits (12.2)	2.500	2.500	3.000	+0.500
Benefits to former personnel (13.0)	-	-	-	-
Total Pay Costs	**230.302**	**230.302**	**343.538**	**+113.236**
Travel and transportation of persons (21.0)	6.000	6.000	7.000	+1.000
Transportation of things (22.0)	16.000	16.000	17.000	+1.000
Rental payments to GSA (23.1)	6.000	6.000	7.000	+1.000
Rental payments to Others (23.2)	4.000	4.000	5.000	+1.000
Communication, utilities, and misc. charges (23.3)	1.000	1.000	1.000	-
Printing and reproduction (24.0)	0.500	0.500	0.500	-
Subtotal, Other Costs	**33.500**	**33.500**	**37.500**	**+4.000**
Other Contractual Services:				
Advisory and assistance services (25.1)	1,522.825	1,522.825	1,525.000	+2.175
Other services (25.2)	150.000	150.000	152.000	+2.000
Purchase of goods and services from government accounts (25.3)	450.000	450.000	455.000	+5.000
Operation and maintenance of facilities (25.4)	25.000	25.000	26.000	+1.000
Research and Development Contracts (25.5)	-	-	-	-
Medical care (25.6)	-	-	-	-
Operation and maintenance of equipment (25.7)	15.000	15.000	16.000	+1.000
Subsistence and support of persons (25.8)	-	-	-	-
Subtotal, Other Contractual Services	**2,162.825**	**2,162.825**	**2,174.000**	**+11.175**
Supplies and materials (26.0)	900.000	900.000	905.000	+5.000
Equipment (31.0)	4.000	4.000	4.000	-
Building Improvement (32.0)	4.000	4.000	4.000	-
Grants, subsidies, and contributions (41.0)	295.000	295.000	300.000	+5.000
Insurance Claim (42.0)	0.050	0.050	0.050	-
Total Non-Pay Costs	**3,399.375**	**3,399.375**	**3,424.550**	**+25.175**
Total Salary and Expense	**3,629.677**	**3,629.677**	**3,768.088**	**+138.411**
Direct FTE	**1,246**	**1,270**	**1,463**	**+217**

Detail of Full-Time Equivalent Employment

	2023 Actual Civilian	2023 Actual Military	2023 Actual Total	2024 Est. Civilian	2024 Est. Military	2024 Est. Total	2025 Est. Civilian	2025 Est. Military	2025 Est. Total
Preparedness and Emergency Operations	72	14	86	71	15	86	71	15	86
Health Care Readiness and Recovery	45	4	49	45	4	49	71	4	75
Medical Reserve Corps	12	0	12	12	0	12	12	0	12
National Disaster Medical System	115	33	148	113	35	148	113	35	148
Preparedness and Response Innovation	3	0	3	3	0	3	--	0	--
Biomedical Advanced Research and Development Authority (BARDA)	287	13	300	286	14	300	286	14	300
Project BioShield.	0	0	0	0	0	0	0	0	0
Pandemic Influenza	0	0	0	0	0	0	0	0	0
Strategic National Stockpile	311	18	329	310	19	329	310	19	329
HHS Coordination Operations and Response Element	108	3	111	132	3	135	132	3	135
Operations	135	7	142	135	7	142	305	7	312
Policy and Planning	56	10	66	55	11	66	55	11	66
Biodefense Production of MCMs and Essential Medicines	0	0	0	0	0	0	0	0	0
ASPR FTE Total			**1,246**			**1,270**			**1,463**

Detail of Positions

ASPR	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget
Executive level I	-	-	-
Executive level II	-	-	-
Executive level III	-	-	-
Executive level IV	1	1	1
Executive level V	1	1	1
Subtotal Executive Level Positions	2	2	2
Total - Exec. Level Salaries	**$341,600**	**$355,600**	**$372,810**
ES-6	-	-	-
ES-5	-	-	-
ES-4	-	-	-
ES-3	18	18	19
ES-2	-	-	-
ES-1	3	3	2
Subtotal ES positions	21	21	21
Total - ES Salary	**$4,216,800**	**$4,216,800**	**$6,264,300**
GS-15	181	184	195
GS-14	311	302	354
GS-13	306	304	329
GS-12	135	149	186
GS-11	74	79	101
GS-10	44	49	74
GS-9	59	61	72
GS-8	8	8	10
GS-7	5	5	6
GS-6	-	-	-
GS-5	-	-	-
GS-4	-	-	-
GS-3	-	-	-
GS-2	-	-	-
GS-1	-	-	-
Subtotal	1,123	1,141	1,327
Total - GS Salary	**$122,935,379**	**$138,085,180**	**$229,774,433**
Average ES level	ES-3	ES-3	ES-3
Average ES salary	$200,800	$200,800	$298,300
Average GS grade	13	13	13
Average GS salary	$103,823	$133,692	$117,962

Cybersecurity

Cyber Category	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
Cyber Human Capital.....	-	1.400	2.550	+1.150
Planning Roles and Responsibilities.....	-	1.600	1.800	+0.200
Sector Risk Assessment, Management, and Operations	1.774	1.774	13.774	+12.000
Sector Coordination	-	-	-	-
Other NIST CSF Capabilities:	**-**	**-**	**-**	**-**
Detect.....	-	-	**-**	**-**
Identity.....	-	--	1.200	+1.200
Protect.....	**-**	0.200	0.800	+0.600
Recover.....	-	-	-	-
Respond.....	-	-	-	-
Total Cyber Request.....	**1.774**	**4.974**	**20.124**	**+15.150**
Technology Ecosystems (non-add).....	-	-	-	-
Zero Trust Implementation (non-add).....	-	*0.800*	*1.600*	*+0.800*

Programs Proposed for Elimination

The FY 2025 President's Budget proposed to eliminate the following programs:

- Preparedness and Response Innovation (-$3.080 million)
- Mission Zero (-$4 million)
- Pediatric Disaster Care (-$7 million)
- Public Health Preparedness Equipment (-$20 million)

PROPOSED LAW

FISCAL YEAR 2025 DHHS LEGISLATIVE PROPOSAL
Administration for Strategic Preparedness and Response

Working Capital Fund

The Administration for Strategic Preparedness and Response (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 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.

Proposed legislative language:
SEC.___. WORKING CAPITAL FUND FOR THE ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE.
Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 319L-1, the following:

"SEC.319L-2. ASPR WORKING CAPITAL FUND.

"(a) IN GENERAL.—There is established in the Treasury of the United States a Working Capital Fund (referred to in this section as the "Fund") to be administered by the Administration for Strategic Preparedness and Response (referred to in this section as the "Administration").

"(b) CAPITAL AMOUNT.—The initial capital in the Fund shall consist of such sums as necessary from enacted annual appropriations.

"(c) USE OF FUND.— The Assistant Secretary for Preparedness and Response may use amounts in the Fund, without fiscal year limitation, for the centralized payment of salaries, travel, and other expenses necessary to the maintenance and operation of—

> *"(1) a supply service for the purchase, storage, handling, issuance, packing, or shipping of stationery, supplies, materials, equipment, and blank forms, for which stocks may be maintained to meet, in whole or in part, the needs of the Administration; and*
>
> *"(2) such other services as the Assistant Secretary determines may be performed more advantageously as common services than obligated and expended from separate program lines.*

"(d) REIMBURSEMENT.—The Fund shall be reimbursed from appropriations to the Administration that are available when services are performed or stock furnished, or in advance, on a basis of rates, which shall include estimated or actual charges for personal services, materials, equipment, information technology, and other expenses. Charges for equipment and information technology shall include costs associated with maintenance, repair, and depreciation (including improvement and replacement)."

Expanded Protection for Release of Sensitive, Proprietary Information

ASPR seeks to expand BARDA's Freedom of Information Act withholding authority under section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) to include protection against the release of certain sensitive information of BARDA-funded partners, similar to those provided to ARPA-E, within the Department of Energy, under section 5012 of the America COMPETES Act (42 U.S.C. 16538). Public release of sensitive and proprietary company information, including trade secrets and commercialization plans, can have negative consequences for a company in a highly competitive environment. Specifically, public release of such information may be used by competitors to create an advantage by, for example, modifying their products to improve their performance, offering their product at a lower cost, and targeting previously untargeted customers and territories.

Appropriate "Two-Year" Funding to National Disaster Medical System (NDMS)

ASPR seeks to amend section 2812(g) of the Public Health Service Act (42 U.S.C. 300hh-11(g)) to authorize appropriated funding for NDMS for two years in duration (making annual funding available for the next two fiscal years). As one of the Nation's critical public health and medical emergency response systems, the NDMS operates on a continuous cycle through the year. Annual appropriations that are bounded by the fiscal year result in a break in network operations the beginning of the fiscal year. In recent years, hurricanes and extreme weather have occurred late in the fiscal year, often crossing years. There is increased risk in preparedness potentially limiting pre-deployment of response teams and/or causing a delay in supporting communities post disaster due to the allocation and access of funding. Having more flexible appropriations to support pre-deployment costs for hurricanes and other events that arise before there is a Stafford Act declaration in place would strengthen overall preparedness.

Extend Direct Hire Authority for NDMS

ASPR seeks to permanently extend the National Disaster Medical System (NDMS) direct hire authority. 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 heath 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.