



**U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response**

Strategic Plan for 2020-2023



April 2020



Saving Lives. Protecting Americans.

ASPR

MESSAGE FROM THE ASSISTANT SECRETARY

Colleagues:

In an increasingly complex and dangerous world, being ready and able to protect the health of all Americans is paramount to U.S. national security. Government agencies at all levels, private sector entities, academia, and community organizations must work together to achieve preparedness, save lives, and protect Americans when every minute counts.

The ASPR Strategic Plan 2020-2023 sets a course for the organization and empowers team members to collaborate with our many Department of Health and Human Services colleagues and external partners. Such collaboration is critical to achieving greater effectiveness and efficiency in support of communities across the country.

The development and implementation of this Strategic Plan reflects ASPR's continuing commitment to strengthening our nation's healthcare response systems, capabilities, and capacities. The Plan was developed through a participatory process involving staff across the organization, and it will be operationalized through ASPR's most prized resource – its people. It is intended to be a living document – one that will guide our activities and hold us accountable at every level of the organization. I am confident that using this plan as a common roadmap will allow us to build upon past successes while focusing on the needs of the nation, inspiring innovation, and pursuing excellence.

Robert P. Kadlec, MD, MTM&H, MS



/s/ Robert Kadlec

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EXECUTIVE SUMMARY

The United States faces an array of natural, technological, and human-caused threats and hazards. These threats continually evolve and have potential to cause significant harm or disruption to the general public, critical infrastructure systems, the environment, and the delivery of healthcare and emergency public health and medical services. The *ASPR Strategic Plan for FY2020-23* (the Plan) organizes and identifies how the [ASPR organization](#) will fulfill its mission of saving lives and protecting Americans from 21st century health security threats and achieve its strategic vision – that “the nation’s health care and response systems and the communities they serve are prepared, responsive, and resilient, thereby limiting the adverse health impacts of emergencies and disasters.”

To meet the nation’s current and projected health preparedness, response, and recovery needs, this Plan builds on the successful foundation established by the ASPR strategic plans issued in 2011 and 2014, and aligns with the [HHS Strategic Plan FY2018-2022](#) and other relevant national strategies and legislation. Additionally, it is informed by experience gained and lessons learned from real-world incidents, exercises, and training activities occurring over more than a decade. The Plan organizes ASPR’s efforts under four priority goals and 21 strategic objectives as depicted in Figure 1.

Figure 1: Pictorial Representation of ASPR Strategic Goals and Objectives for 2020-2023



This Plan, particularly the implementation strategies discussed herein, may evolve in response to new policies, challenges, and risks resulting from the fluid nature of health threats and hazards facing the nation. ASPR will evaluate progress of the plan’s implementation and its effectiveness using tailored performance metrics and other forms of feedback.

1.0 INTRODUCTION

1.1 BACKGROUND

This *ASPR Strategic Plan for FY2020-23* builds upon the successful foundation established by the two previous enterprise strategic planning activities undertaken by the Office of the Assistant Secretary for Preparedness and Response (ASPR), including an initial plan issuance in 2011 and an update in 2014. The current Plan reflects specific guidance and key priorities established in the [U.S. Department of Health and Human Services \(HHS\) Strategic Plan, FY2018-2022](#).¹ It is further tailored to the unique and interconnected policy, risk, and fiscal resource environments in which the ASPR organization operates. The Plan also reflects the current and projected health preparedness, response, and recovery needs of ASPR's various key public- and private-sector mission partners, as well as the communities that ASPR and its mission partners collectively serve nationwide. Finally, the Plan has been informed by experience gained and lessons learned from real-world incidents, exercises, and training activities occurring over more than a decade.

1.2 PURPOSE/SCOPE

This Plan highlights the strategic goals, priority objectives, implementing strategies, and feedback processes the ASPR organization will pursue to strengthen mission execution, enhance organizational effectiveness, and enable performance measurement and course adjustments over time. It is also designed to provide ASPR leaders, managers, and employees a common strategic blueprint to guide their important work—including operational, program, and resource planning; workforce development; and performance assessment—across headquarters staff offices and divisions and regional offices. The Plan builds upon ASPR's past strategic planning and related activities, including important previous and ongoing programmatic investments, and its successful history of supporting its many diverse mission partners and communities nationwide across the prevention, preparedness, response, and recovery domains. Finally, this Plan is aligned to and is designed to support the implementation of a number of different higher-order statutes, executive orders, policies, strategies, and plans, including, but not limited to: the [National Security Strategy](#) (NSS)², the [National Health Security Strategy 2019-2022](#) (NHSS)³, the [National Biodefense Strategy](#) (NBS)⁴, the HHS Strategic Plan, FY2018-2022, and the [Pandemic and All-Hazards Preparedness and Advancing Innovation Act](#) (PAHPAIA) of 2019.⁵

1.3 TARGET AUDIENCE

The audience for this Plan includes all ASPR full-time and intermittent staff, temporary employees, and contract support staff. Additionally, the Plan is intended to inform ASPR's many interagency, intergovernmental, and private-sector partners and other key stakeholders, all of whom represent critical components of the ASPR all-hazards mission. Additionally, as a publicly accessible document, the Plan

¹ See HHS Strategic Plan FY 2018 - 2022

² See <https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905.pdf>

³ See <https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf>

⁴ See <https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf>

⁵ See <https://www.congress.gov/bill/116th-congress/house-bill/269/text?q=%7B%22search%22%3A%5B%22monograph+reform%22%5D%7D&r=1&s=1>

can help inform Congress and the general public on ASPR's strategic efforts to enhance and execute its important mission.

Within the overall context of this Plan, it is important to highlight that every member of the organization is critical to ASPR's success. Leaders and staff at all levels should relate their important work to one or more of the strategic goals, objectives, and implementing strategies identified herein. Additionally, leaders and staff will develop and implement a variety of supporting activities, initiatives, and actions aligned with this Plan.

1.4 PLAN DEVELOPMENT METHODOLOGY

The methodology used to develop this Plan encompassed the following key elements:

- Interviews with the Assistant Secretary, ASPR senior leaders, and other office- and division-level leaders and program managers within the ASPR organization;
- Review of principal authorities and references identified in Appendices A & B;
- Review of peer organization strategic plans and best-practices in strategic plan development;
- Draft Plan review/comment iterations with ASPR staff offices and divisions; and
- Final draft Plan review by the ASPR senior leadership and approval by the Assistant Secretary.

2.0 ABOUT ASPR

2.1 ORGANIZATIONAL OVERVIEW

The 2006 Pandemic and All-Hazards Preparedness Act (PAHPA), reaffirmed by the 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) and the 2019 PAHPAIA, established the ASPR to serve as the principal advisor to the Secretary on matters related to federal public health and medical preparedness and response for public health emergencies (PHEs). In addition to important policy-related responsibilities, the ASPR has operational responsibilities both for the advanced research and development (R&D) of medical countermeasures (MCMs), and for coordination of the federal public health and medical response to emergent threats and all-hazards incidents. This includes the federal public health and medical response to PHEs and other incidents covered by the [National Response Framework](#) (NRF) and [National Disaster Recovery Framework](#) (NDRF).

2.1.1 Mission/Vision

The **ASPR mission** is to “*Save lives and protect Americans from 21st century health security threats.*”

The **ASPR vision** is that “*The Nation’s healthcare and response systems and the communities they serve are prepared, responsive, and resilient, thereby limiting the adverse health impacts of emergencies and disasters.*”

Figure 2: The ASPR Mission



2.1.2 Core Values

Core values represent the essence of the organization, and help establish an enduring foundation for this Plan. The core values defined in Figure 3 frame the approach the ASPR organization (including leaders, program managers, and employees at all levels) will apply in interacting with one another and externally with ASPR’s various public- and private-sector mission partners and the general public.



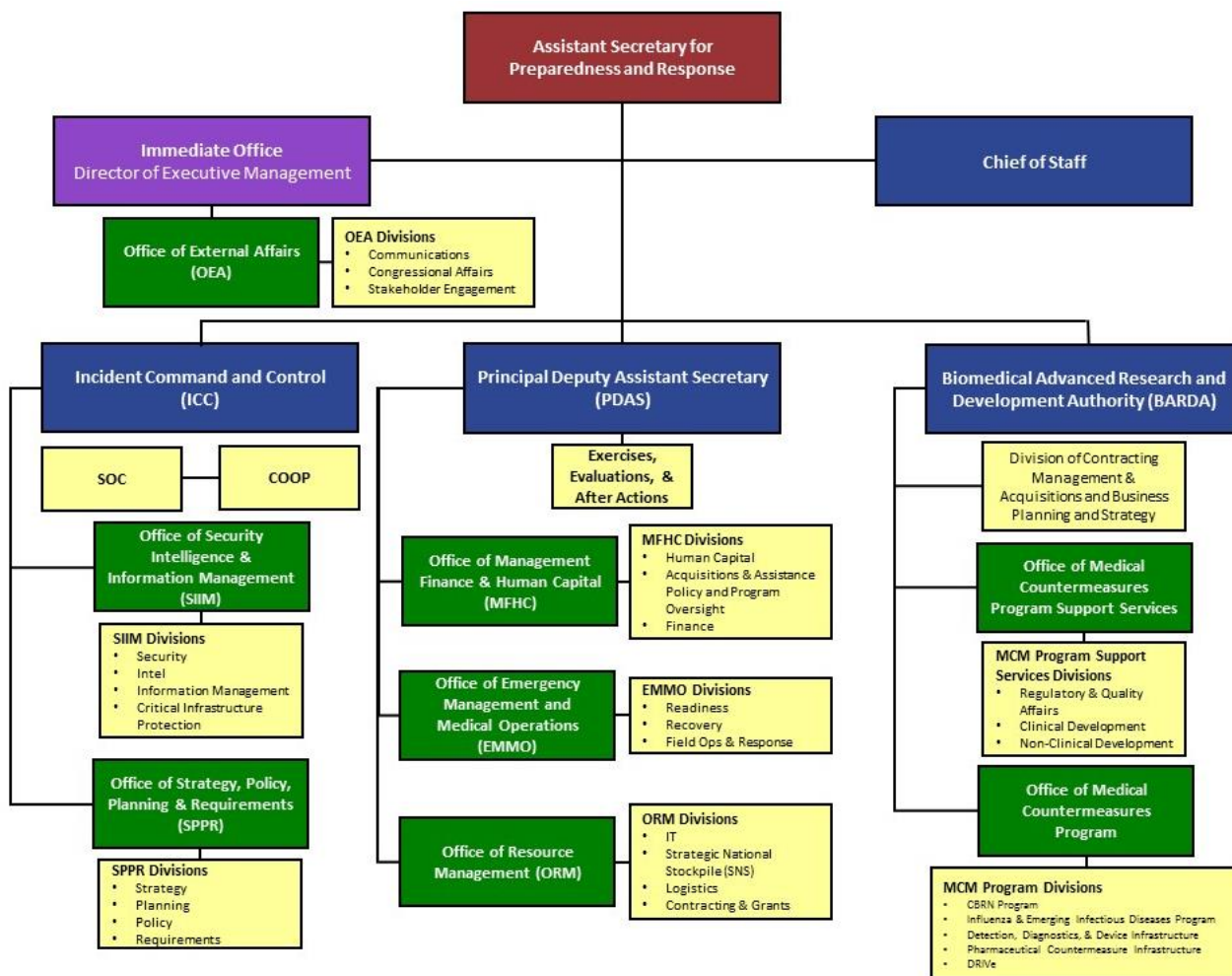
2.1.3 Organizational Structure

The following sub-organizational entities provide policy, operational, and programmatic leadership, management, and support to the ASPR mission:

- Chief of Staff (CoS) and Immediate Office (IO) of the Assistant Secretary
 - ◆ Executive Secretariat, Office of External Affairs (OEA), and Personal Staff
 - ◆ Liaison Officers and Agency Representatives to the interagency
- Office of the Principal Deputy Assistant Secretary (OPDAS) for Preparedness and Response
 - ◆ Management, Finance, and Human Capital (MFHC)
 - ◆ Emergency Management and Medical Operations (EMMO)
 - ◆ Resource Management (ORM)
 - ◆ Exercises, Evaluation, and After Actions (E2A2)
 - ◆ Regional Offices
- Office of the Deputy Assistant Secretary (DAS) for Incident Command and Control (OICC)
 - ◆ Security, Intelligence, and Information Management (SIIM)
 - ◆ Strategy, Policy, Planning, and Requirements (SPPR)
 - ◆ Secretary's Operations Center (SOC)
 - ◆ Continuity of Operations (COOP)
- Office of the DAS and Director, Biomedical Advanced Research and Development Authority (BARDA)
 - ◆ MCM Program
 - ◆ MCM Program Support Services
 - ◆ Contract Management, Acquisitions and Business Planning, and Strategy Division

The following link provides additional detail regarding the [ASPR organizational structure and sub-organizational missions and functions](https://www.hhs.gov/about/agencies/orgchart/aspr/index.html): <https://www.hhs.gov/about/agencies/orgchart/aspr/index.html>

Figure 4: ASPR Organizational Structure



2.1.4 Cross-Cutting Functions

ASPR staff offices, divisions, and programs rely on a core set of cross-cutting functions to facilitate their important work, including: *planning, logistics, operations, external affairs, information management & intelligence, training, and exercises and evaluation* as depicted in Figure 5.

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Figure 5: ASPR Cross-Cutting Functions



2.1.5 Foundational Functions

ASPR could not effectively execute its mission absent the hard work of assigned staff. Daily they provide important foundational functions, such as administration, budget and finance, travel, human capital, and information technology (IT). These foundational functions are known collectively as business operations.

Within ASPR, [Management, Finance and Human Capital](#) (MFHC) oversees conformance with federal fiscal policy, develops and implements program support, and manages the financial resources and talent pipeline needed to support ASPR's mission. MFHC contains the Head of Contracting Authority as well as the Divisions of Human Capital, Acquisition Policy/Support, and Finance.

Additionally, the [Office of Resource Management](#) (ORM) provides a variety of critical support needed to complete ASPR's mission in steady-state and during response operations. This support ranges from ensuring IT needs are met to managing logistics and deployment of people and medical assets to the field. ORM also is home to ASPR's Contracting and Grants Division, which oversees the procurement of

commodities and services needed to support the public health response to and recovery from domestic and international public health and medical threats and emergencies.⁶

2.1.6 Partnerships and Collaboration



Building and sustaining effective intergovernmental and, public-private partnerships and relationship networks is a key element of the ASPR mission. To lead the nation's medical and public health preparedness for, response to, and recovery from disasters, PHEs, and other incidents, ASPR practices and promotes the strategic themes of partnership and collaboration. ASPR collaborates with other federal, state, local, territorial, and tribal (FSLTT) agencies; healthcare coalitions (HCCs), private healthcare system

providers; the national laboratory community; academia; R&D institutions; pharmaceutical manufacturers and biotechnology firms; and other partners across the country and internationally. The goal is to leverage an array of authorities, technical knowledge, capabilities, and resources to enhance collective readiness and response capabilities. Collaboration with these stakeholders provides a shared sense of purpose, broader understanding of the mission, and increased trust and unity of effort, all contributing to enhanced effectiveness.

⁶ In compliance with the 21st Century Cures Act, BARDA has a separate contract management and acquisitions division that solely focuses on the procurement and advanced development of MCMs to address natural and intentional threats to public health.

3.0 STRATEGIC DRIVERS OVERVIEW

3.1 INTRODUCTION

This Plan considers the convergence of the risk, policy, and fiscal resource environments and their respective influences upon ASPR and its external partners. These diverse environmental factors are also taken into account as part of Plan implementation, review and revision, and performance measurement.

3.2 RISK ENVIRONMENT

3.2.1 Introduction

The U.S. faces a wide array of natural, technological, and human-caused threats and hazards. These threats have potential to cause significant harm or disruption to the general public (including large-scale injury and mortality), critical infrastructure systems, the environment, and/or the delivery of healthcare and emergency public health and medical services. The scope and potential impact of these threats and hazards continuously evolves as a function of various factors, including, but not limited to: weather patterns, geological phenomena, land use, population and demographic shifts, construction standards, weapons of mass destruction (WMD) threats, technology proliferation, global socio-economic and ideological tensions, and the increasingly complex international and domestic security environments.

Figure 6: The 21st Century Risk Environment



ASPR's all-hazards approach to mission readiness and execution must account for the broad range of threats and hazards the nation has traditionally faced. ASPR also must prepare for new challenges presented by increasingly severe weather incidents, catastrophic geological disturbances, rapidly spreading emerging infectious diseases (EIDs) and pandemics, acts of mass violence perpetrated by terrorists and domestic violent extremists, widespread and increasingly impactful cyber-attacks, emergent WMD threats, and resurgent threats from nation-state adversaries and rogue actors. The vast scope and shifting nature of these

various threats and hazards call for continuous assessment of realistic scenarios to inform ASPR's preparedness and response activities and investments.

Population and demographic factors such as community-by-community variation in fiscal health, numbers and types of at-risk individuals, levels of training in health security, and availability of MCMs for EIDs, among other factors, complicate consequence management in today's all-hazards threat environment. As the 2014-15 Ebola epidemic in West Africa and the more recent COVID-19 outbreak illustrate, the initial human health consequences of an isolated, geographically-distant incident can evolve quickly, becoming a widespread — even global — crisis. Additionally, as demonstrated by the trio of devastating hurricanes that occurred during the 2017 hurricane season — Harvey, Irma, and Maria — the consequences of an incident can affect services and audiences far beyond the immediate physical impact zone. Moreover, an incident's health-related impacts can focus on a single community, or alternatively, carry with them long-term, cascading consequences for medically vulnerable populations (e.g., those who are prescription-dependent, immune-compromised, elderly, access or functional needs challenged, pregnant or postpartum, or require oxygen or dialysis) on a broader scale and distributed across a wide geographic area.

3.2.2 Threat/Hazard Characterization

Extreme Weather and Other Natural Disasters: As evidenced by the deadly hurricanes that struck Texas, Florida, Puerto Rico, the U.S. Virgin Islands, and North Carolina during the 2017 and 2018 hurricane seasons, extreme weather incidents are becoming more frequent and severe. They also have the ability to significantly impact vulnerable populations and interconnected critical infrastructure systems. These incidents often occur within a very compressed timeframe, with cascading impacts on communities hit repeatedly as they try to recover from a previous incident. The tsunamis and volcanic eruptions that devastated the Pacific Region in 2018 represent further examples of incidents with far-reaching impacts on fragile communities.

Healthcare system integration and interoperability are additional concerns. Health-related systems and services are interconnected geographically, structurally, and programmatically, making the healthcare sector (i.e., facilities, employees, information systems, and supply chains), or important segments thereof, vulnerable to incidents that would otherwise appear isolated. The aftermath of the catastrophic tornado in Joplin, Missouri in 2011, Hurricane Sandy in 2012, and Hurricanes Irma and Maria in Puerto Rico and the U.S. Virgin Islands in 2017 illustrated the immense challenges associated with mitigating operational disruptions in public health and healthcare and emergency medical services. These events occurred concurrently to meeting increased demand in an environment characterized by cascading infrastructure failure and displacement of medically vulnerable populations.

Pandemics and EIDs: The increasing threat of pandemics and EIDs that can quickly cross international borders and affect the global population is clearly evident. Such threats make early detection and a quick response fundamental to saving lives and reducing medical costs and economic impact. The U.S. must be ever vigilant regarding the risk of known EIDs, such as Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), Ebola, and Zika, or the onset of a novel influenza pandemic or unknown disease such as COVID-19. At the same time, long-standing problems, such as increasing antibiotic resistance, pharmaceutical supply shortages, and supply chain vulnerabilities continue to challenge health care systems nationwide. For example, multidrug resistant bacteria are increasingly common, posing a hazard to patients, healthcare workers, suppliers of diagnostic equipment, and health

facilities. In addition, rapid global transportation networks can unintentionally, widely, and with unprecedented speed disseminate diseases, adulterated pharmaceutical supplies, tainted blood products, or contaminated food.

Physical Attacks: The large-scale dissemination of a biological or chemical agent; use of a radiological, nuclear, or high-yield improvised explosive device (IED); or other forms of physical violence can result in mass casualties and fatalities. Such threats could also cause significant damage to the environment and regional economies; lead to mass panic; and spur local, regional, or national disruption of vital services, including significant stress on public health and healthcare and emergency medical services. The already realized and potential future losses of life in the U.S. from violent “lone wolf” threat actors, and the continued risk of potential malicious “insider” attacks on public and private facilities and mission-critical infrastructure in the U.S. is a growing concern to the healthcare sector.

Cyber-Attacks: Public health and healthcare operations are increasingly dependent upon advanced information systems and technologies. This includes the secure storage and transmission of personally identifiable health information to dictate care, maintain patient records, control financial operations, etc. In today’s threat environment, malicious cyber actors (individuals, criminal organizations, terrorists, and nation-state actors) can harvest personal data, corrupt information, directly impact public health and healthcare system operations, or disrupt the provision of critical services. Malware exploits, sophisticated viruses, and “Advanced Persistent Threats” are identified as significant security threats to the pharmaceutical industry and the healthcare sector. Such threats also may target and create cascading impacts for other critical infrastructure upon which healthcare services are critically dependent such as power, water/wastewater, communications, and transportation. Exploitation of cyber vulnerabilities related to advances in Internet-connected synthetic biotechnology represents another significant security concern. Additionally, intellectual property theft through cyber means can threaten competitiveness, innovation, R&D, and strategic capabilities and capacities, particularly in areas where proprietary or national security-related research provides a competitive advantage. Finally, large-scale IT system disruptions or outages in the wake of extreme weather incidents and other natural disasters have far-reaching impacts, including disrupted data access and interruption of service delivery across important elements of the healthcare sector, which, in turn, could impact emergency care and other vital functions directly.

Supply Chain Disruption and Corruption: Highly efficient supply chains have resulted in a “just-in-time” approach regarding day-to-day healthcare capabilities throughout the U.S. and globally, as well as surge medical capacities in an emergency. This situation may leave health-related facilities and systems with limited inventories and the rapid onset of cascading impacts in the event of a supply chain disruption or corruption. Strategically, the biggest risk to healthcare sector supply chains is the U.S. dependency on foreign sources of pharmaceuticals, precursor ingredients or materials, and finished medical products or devices. When such commodities — including ordinary items such as protective masks and surgical gloves — are unavailable, or if reach-back support is significantly affected, patients will be directly impacted by accompanying disruptions and delays in the provision of key medical services. Interruption of foreign supply chains as a result of significant natural disasters, regional military or political conflicts, or trade disputes compounds the risk of disruptions that can directly impact healthcare provision in the U.S.

Space Weather and Electromagnetic Pulse (EMP) Risks: 21st century technologies and infrastructure systems are vulnerable to potentially severe space weather and human-caused EMP threats. In particular, the nation's power grid is at risk of severe damage or significant disruption by the effects of an EMP — a

sudden burst of electromagnetic radiation (pulse) resulting from a natural or manmade incident. Naturally occurring EMPs are produced by magnetic storms that flare from the surface of the Sun. Depending on the impact area, an EMP incident could be catastrophic for healthcare facilities and systems, causing long-term power outages that may overwhelm critical backup power sources.

3.3 POLICY ENVIRONMENT

This Plan operates within the context of a broader federal interagency and HHS policy and planning framework that is designed to promote, sustain, and continuously improve the nation's health, as well as the capability to prepare for, protect against, respond to, and recover from all-hazards emergencies. This overarching policy framework is underpinned and supported by an interconnected set of statutes, executive orders, presidential directives, national strategies, agency-level policies and plans, and other guidance or regulatory documents. This policy environment is dynamic and linked directly to the risk and operational environments discussed above.

This Plan aligns with and supports important national strategies, including the National Security Strategy (NSS), NHSS 2019-2022, and the NBS, which directly address the public health and medical domain. Importantly, the NHSS informs capacity-building activities of ASPR's Hospital Preparedness Program (HPP), the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), and BARDA, as well as ASPR's responsibilities regarding the Global Health Security Agenda (GHSA) and the U.S. Health Security National Action Plan. The three major pillars of the NHSS are:

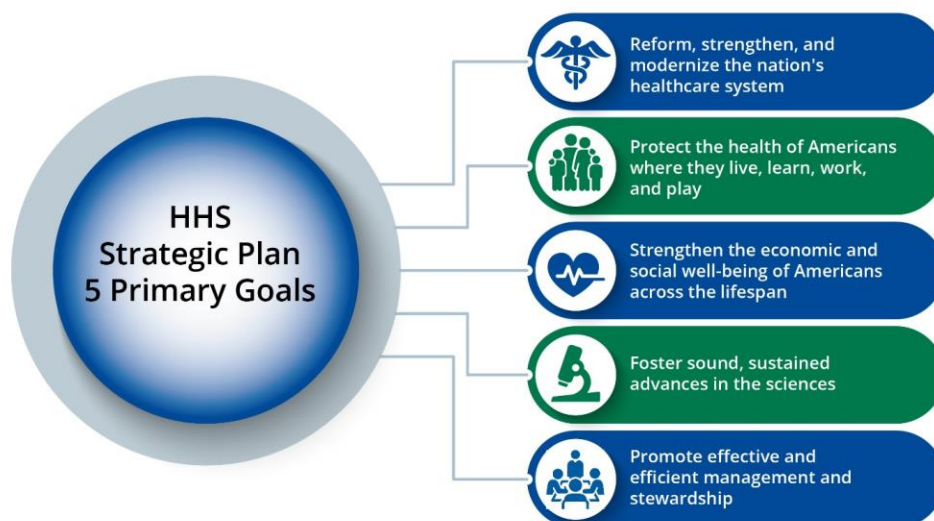
- Mobilize and coordinate the "Whole of Government" to bring the full spectrum of the federal medical and public health capabilities to support FSLTT authorities in the event of a public health emergency, disaster, or attack;
- Protect Americans from the medical effects of emerging and pandemic infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats; and
- Recruit, incentivize involvement, and leverage the capabilities of the private sector.

The NBS informs ASPR's programs and activities in the areas of risk awareness and bioincident prevention, preparedness, response, and recovery. Such programs and activities include advancing MCM development and effective use; optimizing biosafety and biosecurity; and strengthening capacities for health security and countering man-made and natural biological threats. ASPR serves as the overall coordinating authority for implementation of the NBS at the federal level on behalf of the HHS Secretary.

In a similar vein, this Plan also aligns with the National Preparedness Goal and its associated National Mission Area Frameworks, particularly the NRF and the NDRF, as well as the corresponding Federal Interagency Operational Plans (FIOPs). ASPR serves as the overall coordinating authority for the federal public health and medical aspects of each of these frameworks.

At the Department level, this Plan aligns with and directly supports the HHS Strategic Plan, FY2018-2022, which establishes five primary strategic goals, as depicted in Figure 7.

Figure 7: Primary Goals of the HHS Strategic Plan, FY2018-2022



3.4 FISCAL RESOURCE ENVIRONMENT

ASPR's investments are projected to reach approximately \$23 billion during the period Fiscal Years (FYs) 2009 – 2020. Nearly 30 percent of all funding, or almost \$7 billion, was provided via emergency supplemental appropriations. In the years to come, it is likely that emergency appropriations will continue with the emergence of large-scale EIDs, more frequent catastrophic disasters, or both. The experience of the past decade shows that changing weather patterns, viral and bacterial mutations, EIDs, and domestic and international mass murder attacks, along with increased policy-driven responsibilities, will require the efficient application of traditional annual funding, including stable, incremental increases over time as well as significant augmented resource support through supplemental funding when needed.

A resourcing structure reliant on substantial levels of supplemental appropriations presents major challenges. Emergency appropriations are, by definition, a time-limited surge of funding, and often come too late to mitigate the immediate human impacts. As such, the activities and programs identified as urgent and vital in the face of the emergency cannot be sustained financially over the long-term, and, hence, do not systematically contribute to long-term capacity-building, capability sustainment and risk reduction. Without predictable funding, these activities, programs, and assets cannot be properly maintained, nor the contributing vulnerability factors appropriately abated.

Consistency and predictability regarding the resourcing of ASPR's mission and its sustainability over the long term are crucial to future response. ASPR must continue its efforts to educate appropriate audiences on the need for right-sized base funding to ensure stable resources to meet ever increasing demands across the ASPR mission continuum in a dynamic risk environment.

4.0 PRIORITY GOALS, STRATEGIC OBJECTIVES, AND IMPLEMENTING STRATEGIES

4.1 INTRODUCTION

This section discusses ASPR's four (4) priority goals and corresponding strategic objectives and implementing strategies for the multi-year year period of Plan implementation. Their development considered a number of important factors such as legislative and policy mandates, resource availability, known and projected capability gaps, and emerging risks as identified in Section 3. These goals, objectives, and implementing strategies will be reviewed periodically and may evolve to meet new policies, challenges, and risks over the period of this Plan.

Over the long term, the strategic direction pursued through the implementation of the goals and objectives identified will drive collective action broadly across ASPR. This strategic direction is intended to guide and cascade down to performance plans, work plans, initiatives, and activities at all levels of the ASPR organization. ASPR leaders, supervisors, program and project leads, and employees will use this Plan to inform their work efforts and drive the alignment of resources, team and individual performance, and outcomes to advance the ASPR mission and vision. Implementation of the goals and objectives detailed in this Plan also will help inform various forms of interaction between ASPR and its many public- and private-sector partners nationwide.

A synopsis of ASPR's priority goals and strategic objectives, along with Offices of Primary Responsibility (OPRs), is presented in Table 1.

Table 1: Priority Goals and Strategic Objectives

Priority Goals	Strategic Objectives	ASPR Office of Primary Responsibility/Coordination Lead
Goal 1: Foster Strong Leadership	1.1 Lead, Develop, Implement, and Evaluate Federal Public Health Policies and Plans	SPPR
	1.2 Lead Adaptive Planning and Emergency Repatriation Efforts	EMMO
	1.3 Lead/Enhance Emergency Support Function (ESF) – 8	SIIM/EMMO/SOC
	1.4 Develop Effective Leaders	MFHC
	1.5 Build and Sustain a Highly Capable, Empowered Work Force	MFHC
	1.6 Implement Alternative Hiring Practices	MFHC
	1.7 Ensure Responsible Management of Investments in Preparedness and Response	MFHC
Goal 2: Sustain a Robust and Resilient Public Health Security Capacity	2.1 Incorporate Strategic National Stockpile into ASPR Operations	ORM
	2.2 Integrate ASPR Material Management Functions	ORM
	2.3 Strengthen Response and Recovery Operations	EMMO/SIIM/SOC/COOP
	2.4 Improve Situational Awareness	EMMO/SIIM/SOC
	2.5 Manage and Protect the Safety, Security, and Integrity of ASPR Assets	SIIM/ORM
Goal 3: Advance an Innovative Medical Countermeasure Enterprise	3.1 Enhance/Streamline the PHEMCE	SPPR/BARDA
	3.2 Establish Innovative MCM Programs and Enduring, Sustainable Partnerships	BARDA
	3.3 Provide MCM-related Consultation and Technical and Operational Response Coordination Expertise	BARDA/EMMO
Goal 4: Build a Regional Disaster Health Response System	4.1 Modernize NDMS	EMMO
	4.2 Expand Specialty Care Capabilities	EMMO
	4.3 Enhance Private Sector All-Hazards Preparedness	EMMO/SIIM
	4.4 Promote a Resilient Medical Supply Chain	SIIM
	4.5 Integrate EMS into Response Operations	EMMO

4.2 PRIORITY GOAL 1: FOSTER STRONG LEADERSHIP

Setting the Vision

External Focus: *Integrated, multi-level policy, planning, and operational mission execution promoting FSLTT public-private sector unity of effort in preparing for, responding to, and recovering from PHEs and all-hazards disasters.*

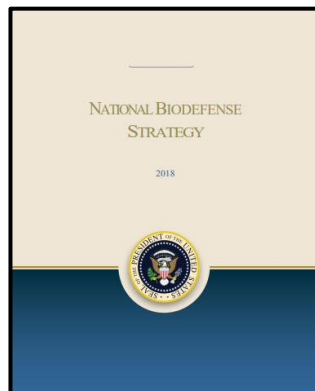
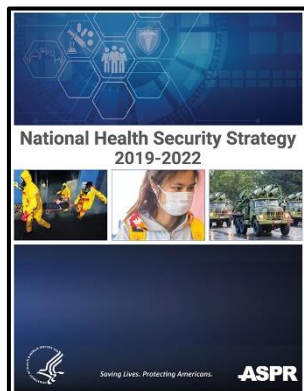
Internal Focus: *An organization based upon a climate of transparency, trust and empowerment; dynamic workforce management including recruiting, hiring, retaining, and recognizing talent; technical and professional development of leaders and employees at all levels; and ensuring the sustainable resources necessary to meet current and future mission needs.*

ASPR provides and promotes leadership in various ways and at various levels internal and external to the Department. ASPR leads and/or supports the development, coordination, and implementation of key federal policies, strategies, and plans related to the public health and medical aspects of emergent threats and all-hazards incidents. In operational terms, ASPR leads ESF-8 under the NRF, as well as the Health and Social Services (H&SS) Recovery Support Function (RSF) under the NDRF. Internally, ASPR fosters the development and continuous improvement of key leaders and managers at various levels of the organization, as well as the professional and technical development and growth of its professional workforce and affiliated personnel, including both full time and intermittent staff. Finally, ASPR provides key leadership for a wide variety of programs that support its external stakeholder base, as well as programs that support the critical foundational and cross-cutting functions of the organization.

Personnel at all levels of the organization – from the Assistant Secretary to the newest hire – are expected to lead and manage within their respective area of responsibility. Leaders perform with excellence, take initiative, and look for innovative solutions to complex problems. Across its broad mission portfolio, ASPR must develop leaders at all levels and demonstrate critical leadership across the federal interagency and among the public health and medical prevention, preparedness, response, and communities nationwide.

Objective 1.1: Lead, Develop, Implement, and Evaluate Federal Public Health Policies and Plans

As health threats evolve, the approaches that government agencies, nongovernmental organizations, and other key stakeholders use to plan and conduct public health and medical prevention, preparedness, response, and recovery activities must also evolve. ASPR enhances a strong, consistent foundation of strategy, policy, planning, and requirements to underpin these efforts. Effective policy and planning at the ASPR level ensure that operational preparedness and response capabilities are aligned with broader federal policy and planning considerations, are adequately resourced to strategic priorities, and are effectively evaluated through data-driven analysis.



Key strategic policy vehicles include the NBS and the NHSS. ASPR leads the coordination of the federal interagency in implementation and evaluation of the NBS, NHSS, and other important national-level public health and medical policies and plans.

ASPR will pursue the following strategies to achieve the stated objective:

- Lead implementation and evaluation of the NBS and NHSS based on established timelines and performance metrics;
- Coordinate public health preparedness and response policy at the interface between national and global health security, such as the International Health Regulations, Joint External Evaluation, U.S. Health Security National Action Plan, Global Health Security Strategy, North American Plan for Animal and Pandemic Influenza (NAPAPI), and the HHS Pandemic Influenza Plan;
- Leverage the Hospital Preparedness Program (HPP) and other ASPR-coordinated programs and lead federal advisory committees and workgroups to mobilize expert analysis, improve readiness, identify gaps, and provide evidenced-based recommendations that inform policy, practice, and leadership;
- Via the HHS Disaster Leadership Group (DLG), provide HHS senior leaders with a forum to deliberate and make recommendations to the HHS secretary and address emergent health security policy issues, including those associated with real-world incident response and recovery;
- Via the HHS Operational Planning Integration Council (HOPIC), engage HHS Operating Divisions (OPDIVS), Staff Divisions (STAFFDIVS), and regional offices to integrate national and regional response plans for catastrophic incidents;
- Provide an anticipatory long-term perspective on national health security threats to identify and advance preparedness, response, and innovation initiatives for consideration by the ASPR and HHS Secretary; and
- Evaluate programs to assess preparedness, identify potential enhancements, and justify resource investment, including an evaluation of HPP benchmarks and targets.

Objective 1.2: Lead Adaptive Planning and Emergency Repatriation Efforts

As of 2016, the Department of State (DoS) estimated that over 9 million American citizens were living abroad. In 2017, a record 38 million Americans traveled abroad on vacation or for business purposes. Historical precedent exists for evacuating American citizens back to the U.S. based on exigent geopolitical factors or the anticipated or realized effects of a wide array of natural or manmade emergencies. Examples include the evacuation of nearly 13,000 American citizens from Lebanon in 2006; 20,000 from Haiti in 2010 following a violent earthquake; 5,000 from the British West Indies during the 2017 hurricane season; and 1,100 from China and Japan as part of the COVID-19 response.

When requested by DoS and/or the Department of Defense (DoD), ASPR provides public health and medical planning and emergency response capabilities to support the repatriation of American citizen evacuees from locations abroad deemed unsafe due to actual or potential danger from natural or manmade disasters, disease outbreaks, civil unrest, or imminent or actual terrorist activities, hostilities, or other similar circumstances. This support includes working with HHS's Administration for Children and Families (ACF) to assist state government officials with domestic planning for the repatriation of American citizens from abroad to locations stateside, providing medical assistance and medical materiel during the evacuation process, and supporting the return of wounded military casualties via coordinated patient movement operations to the National Disaster Medical System (NDMS) healthcare facility (HCF) network. Engagement with a wide array of intergovernmental and private healthcare and hospital systems represents an additional critical aspect of adaptive planning activities.

In March 2018, ACF and ASPR signed a Memorandum of Understanding (MOU) designating ASPR as the lead HHS division for operational planning for the emergency evacuation of American citizens from locations abroad. ACF and ASPR collaboratively review all State Emergency Repatriation Plans (SERPs), which are core documents that articulate state-specific approaches for the response to a mass repatriation event. These reviews involve a combination of technical assistance, physical meetings, and site visits to assist state authorities in completing plans, clarifying information, and identifying potential gaps in plan implementation.⁷

Additionally, ASPR is using scientific research conducted by the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and the National Institutes of Health (NIH) to evaluate specific health concerns that may arise during a mass repatriation event. ASPR provides corresponding recommendations to mitigate such situations, including establishing priorities, developing policy options, providing guidance for SERPs, and directing resources towards areas of need.

⁷ The Emergency Repatriation Program was established in 1935, under Section 1113 of the Social Security Act (42 U.S.C 1313), to provide temporary assistance to AMCITS located abroad who, because of destitution, illness, war, threat of war, or a similar crisis, are without available resources to meet their immediate needs. 24 U.S.C 321-29 expanded the program to include persons with mental illness. In Executive Order (E.O.) 12656 (53 F.R. 47491) as amended, the HHS was given the lead to "develop plans and procedures, in coordination with heads of Federal departments and agencies, for assistance to U.S. citizens or others evacuated from overseas areas." ACF currently oversees the department's overall repatriation activities, while ASPR assists ACF by leading emergency management operations activities when the repatriation event involves more than 500 US citizens.

The following strategies will be utilized to achieve the Adaptive Planning objective:

- Prepare for, plan, mobilize, coordinate, exercise, and improve adaptive planning and emergency repatriation activities utilizing a whole-of-government and public-private partnership approach;
- Complete comprehensive emergency repatriation plans based on identified priority high-risk, geographically-focused scenarios;
- Plan and execute periodic multi-level exercises and conduct after action reporting for completed plans focused on priority high-risk geographic areas;
- Complete SERP reviews and develop strategies to mitigate gaps identified during the planning process;
- Assess and enhance the ability of ASPR logistics to surge to meet identified planning requirements, including the securing of adequate facility space and the rapid mobilization of NDMS and U.S. Public Health Service Commissioned Corps teams, as well as other human resources, equipment, and materiel;
- Develop an outreach approach to leverage the capabilities of the private sector in adaptive planning and emergency repatriation activities; and
- Employ scientific, evidence-based and legal research to inform adaptive planning and evaluate specific health concerns that may arise during a mass repatriation event.

Objective 1.3: Lead and Enhance Emergency Support Function – 8 (ESF – 8): Public Health and Medical Services

ASPR leads the nation’s medical and public health preparedness for, response to, and recovery from all-hazards disasters and PHEs. ASPR utilizes a combination of headquarters and field-based capabilities to coordinate federal ESF-8 activities under the NRF and other authorities. In this role, ASPR provides specialized skills and assets that can rapidly assess, stabilize, and target federal resources to improve the situation in response to FSLTT requests for federal public health and medical support, or at the direction of the President or HHS Secretary, as part of a comprehensive national effort. ASPR’s ability to rapidly respond to these requests across the full range of ESF-8 capabilities is critical to saving lives, minimizing human suffering, protecting the health of affected populations and at-risk individuals, and accelerating community recovery post-disaster.



ASPR cannot meet 21st century health security challenges alone. Success requires that it stay abreast of change, continually adapt to challenges, and become adept at integrating public health and medical capabilities and resources with those of its many FSLTT ESF-8 mission partners. Supporting and enabling FSLTT partners while leveraging their

capabilities and resources to the fullest, working toward common objectives, and building stakeholder capacity are indispensable elements in this endeavor. Achieving this unity of effort will require ESF-8 related strategies, plans, operations, requirements, and future enabling technologies to be closely coordinated with ASPR's nationwide partnership network.

Regarding preparedness, exercises allow ESF-8 partners to validate plans and training activities and practice strategic prevention, protection, response, and recovery capabilities in a no-stress, risk-controlled environment. Exercises are a primary tool for assessing preparedness and identifying areas for improvement, while demonstrating HHS's resolve to prepare for all-hazards incidents. By committing valuable resources to exercises, HHS aims to help departmental and ESF-8 partners gain objective assessments of their capabilities so that gaps, deficiencies, and vulnerabilities are addressed prior to a real-world incident.

ASPR will pursue the following implementing strategies to lead and enhance ESF-8:

- Improve the effectiveness and unity of effort of federal ESF-8 activities, and resolve operational, resource, and policy issues related to interagency response and recovery actions at the national level via active participation in the FEMA-coordinated Emergency Support Function Leadership Group (ESFLG) and Recovery Support Function Leadership Group (RSFLG);
- Develop, maintain, and periodically update national ESF-8 contingency plans and regional ESF-8 support plans that are informed by strategic national/regional threat and risk assessments and gap analyses conducted with FSLTT and nongovernmental partners;
- Lead the ESF-8 Senior Leader Advisory Council to provide strategic guidance, direction, coordination, and integration for federal public health and medical preparedness, response, and recovery activities;
- Lead the ESF-8 partnership in the update of Federal Interagency Operations Plans (FIOPs) and FIOP annexes to address the whole community response to a wide array of threats and hazards, including EIDs, CBRN-focused incidents, and catastrophic disasters;
- Develop multi-level ESF-8 processes, procedures, operating guides, position task books, and other key training aids based on the structures and processes detailed in the ASPR Incident Response Framework and supporting functional annexes;
- Develop and administer a comprehensive, fully resourced ESF-8 rostering, qualification, and training program (including in-advance and "just-in-time" training, as well as technical training on FEMA IT system access and operations for applicable personnel) and monitor training status for ASPR headquarters and field personnel (including regional staff and intermittents) and other HHS and federal interagency personnel who are pre-designated to staff/support key ESF-8 coordination nodes during an incident response;
- Develop a comprehensive protocol covering all aspects of the ESF-8 mission assignment process including a complete process mapping of how requirements are identified and resulting mission assignments are developed, validated, coordinated, approved, sourced, tracked, and reported out;
- Establish an Integrated Process Team (IPT) with FEMA to determine how to best achieve data and IT system interoperability and better leverage FEMA systems, products, and capabilities supporting the ESF-8 mission assignment process and National Response Coordination Center (NRCC), Regional Response Coordination Center (RRCC), and Joint Field Office (JFO) operations during a response;

- Lead/coordinate ESF-8 engagement in National Level Capstone exercises and develop/conduct multi-level ESF-8 exercises and after action reporting processes that present complex and realistic scenarios requiring critical thinking, rapid problem solving, and effective responses by trained personnel; and
- Convene and administer an annual ESF-8 training forum to discuss the future risk environment, identify potential solutions to known/anticipated preparedness gaps, provide a discussion forum for new developments (i.e., doctrine, operating concepts, new technologies, R&D activities, etc.), and disseminate best practices based on real-world incident response situations.

Objective 1.4: Develop Effective Leaders

ASPR must have strong, innovative, and effective leaders and program managers at all levels of the organization. Such leadership is particularly critical during dynamic incident response operations where ASPR staff must lead large teams; coordinate effectively with interagency, intergovernmental, and nongovernmental partners; and adapt to changing environments. Within ASPR, leadership is not limited to one's current supervisory status or scope of duties. Rather, all members of the organization, from the assistant secretary to the newest hire, must see themselves as leaders and operate as such. ASPR has a responsibility to encourage and support leadership development for all employees across the organization, while also developing and growing the organization's next generation of leaders.



ASPR employees must have a clear understanding of the skills and competencies that enable professional growth and effective leadership at their levels of the organization. For example, there are certain competencies that all leaders should exhibit (e.g., customer service, accountability, influencing and negotiating, etc.). However, as leaders rise within the organization, they will require additional higher-order skills

(e.g., strategic visioning and thinking, external awareness, management of large, high-dollar programs, etc.).

Developing effective leaders requires a multi-faceted approach, in turn allowing employees to follow distinct technical and/or managerial career pathways. ASPR will create and implement a standardized, sustainable professional development program organized according to three major components:

- A common set of universally applicable leadership skills, as well as specialized skills based on type/level of position and scope of duty;
- Technical skills and managerial/supervisor training and professional development aligned to the effective and efficient management of organizational resources; and

- Ongoing leadership training and professional development activities that allow all employees to excel in their current competencies and develop new leadership skills aligned to their individual career pathways.

ASPR will pursue the following strategies to attain the stated objective:

- Define the required leadership competencies development to meet both current needs and future professional growth;
- Develop and conduct assessments/surveys to provide information on current employee leadership developmental status versus identified leadership competency targets;
- Establish individual professional development plans for all employees who are interested in pursuing further leadership development;
- Develop and implement a sustainable training program that includes internal/external on-line technical and managerial training and other professional courses;
- Develop a variety of additional structured learning opportunities managed by the MFHC Career Development Team, including rotational assignments, cross-training activities, courses, webinars, reading lists, speakers, discussions, and on-the-job training;
- Leverage and enhance the existing ASPR formal mentoring program — via improved guidelines and tools — based on goals and objectives mutually developed by mentor-mentee pairings;
- Strengthen the performance management process, including better ensuring critical elements are directly linked to work being performed; and
- Conduct supervisory training sessions to ensure supervisors are aware of the tools available to engage employees, recognize performance, and strengthen accountability.

Objective 1.5: Build and Sustain a Highly Capable, Empowered Workforce

ASPR's most important resource is its people. The ASPR mission attracts driven, highly capable individuals who want to make a difference within their chosen professions, within their communities, and across the nation. Service and professionalism represent the heart and soul of the organization.

ASPR must continue to recruit, hire, support, nurture, and retain highly talented staff across an array of disciplines and skill areas to execute its mission to greatest effect. ASPR also must implement policies, practices, and programs to ensure its ability to maintain a highly-skilled workforce shaped to today's challenges and tomorrow's needs. This workforce must be flexible, agile, responsive, and adaptable to change — in discipline-specific knowledge and technology, workforce demographics, society, risk environment, and internal/external expectations, etc.



Accordingly, ASPR must ensure staff have the acquired skills and resources they need to succeed, are appropriately recognized for excellence in performance, are empowered to effect change, and are encouraged to come forward with ideas and identify problems in an environment of openness. ASPR also will continue to promote cultural practices and initiatives that ensure its employees are respected, engaged, and fulfilled in a quality work life.

Finally, ASPR will continue to refine its focus on performance management, educating employees, and ensuring goals and expectations are aligned to job series and grade. These activities are informed and shaped by collaborative goal-setting, coaching, providing appropriate feedback, and conducting and documenting fair and objective evaluation of employee job performance. This approach is designed to foster an environment in which employees are entrusted and empowered to do their duties while being held accountable to objective performance standards developed jointly between managers and employees.

ASPR will pursue the following strategies to build and sustain a high quality, empowered workforce:

- Develop a sustainable process for workforce management from on-boarding to departure, including administering the new employee program “*From Yes to Success*,” conducting training needs assessments and meeting technical and managerial training needs, ensuring employees develop attainable standards, and aligning expectations appropriately to position-specific responsibilities;
- Increase opportunities for cross-training and cross-detailing activities to address mission critical requirements, drive employee retention, help shape professional development opportunities, and manage knowledge transfer within ASPR and its critical mission space;
- Foster diversity and inclusion activities to create an environment where employees feel valued and can effectively contribute their talents to the mission;
- Build an environment of trust, learning, and problem-solving between managers and employees;
- Encourage a positive and supportive work environment through frequent “all-hands” meetings and open communication channels at all levels that provide opportunities for ASPR employees to collaborate, stay informed, and offer creative ideas to improve the organization;
- Conduct comprehensive and objective employee evaluations;
- Use employee feedback and best practices from across the federal government to identify and develop strategies to act on employee input and increase engagement, including continued use of the annual Federal Employee Viewpoint Survey;
- Ensure robust programs exist to appropriately recognize and reward employees who demonstrate high levels of performance and significantly contribute to achieving organizational goals; and
- Ensure ASPR human capital activities account for U.S. Public Health Service Commissioned Officer Corps personnel and that ASPR leaders and managers receive appropriate training on the Corps’ personnel and awards system.

Objective 1.6: Implement Alternative Hiring Practices

Recruiting and hiring top talent in the most effective and efficient manner possible is a key ASPR priority. In fact, ASPR's recruitment and retention program must seek to identify, hire, and retain the most qualified and diverse candidates at all levels of the organization. Additionally, more than 20% of ASPR employees are currently eligible to retire, and 32% are either currently or become eligible within the next five years. This situation reinforces the need to conduct robust succession planning and knowledge management activities, particularly within ASPR's intermittent work force and specialized response teams. This will require new independent hiring authorities, innovative hiring strategies to target prospective employees, training programs to get them up to speed and maintain mission proficiency, and engagement/retention strategies to hold on to ASPR's best talent. As older workers retire and younger workers become a larger proportion of the overall workforce, ASPR will have to adapt how it recruits and retains these new workers whose skills, expectations, and preferences can differ substantially from those of older generations. Greater flexibilities and work/life balance initiatives will become increasingly important as recruitment and retention tools.

MFHC leadership is pursuing various strategies to maximize hiring options, including enhanced collaboration between office-level hiring managers and MFHC's Human Capital Team to meet their resource needs. Options include a variety of flexibilities that could be leveraged to get quality candidates on board faster than via the traditional hiring process, including independent hiring authority and comprehensive human capital process management. Other strategies involve streamlining and targeting recruitment and on-boarding activities, as well as fostering expanded external partnerships with potential sources of recruitment.

ASPR will pursue the following strategies to meet its recruiting and hiring priorities:

- Pursue establishment of independent hiring authority, along with a robust internal capacity to write and classify position descriptions, conduct security screening, hire, and onboard qualified candidates;
- Deploy strategic recruitment strategies to target talent to fill mission-critical occupations and positions, including global recruiting and sharing vacancies and certificates to reduce recruiting time;
- Build out ASPR's Talent Acquisition Program/Portfolio and leverage data to make informed decisions regarding recruitment and retention strategies;
- Increase the efficiency and effectiveness of recruitment efforts via partnerships between hiring managers and program staff;
- Expand collaboration with universities, colleges, and associations, and initiate sponsorship of quarterly hiring fairs;

- Utilize existing flexibilities and pursue new retention incentives to ensure ASPR retains the highest caliber workforce, including seeking direct hire authorities for qualified full time and intermittent staff in critical mission areas;
- Improve workforce planning efforts by integrating succession management activities into efforts to retain employees and manage knowledge transfer within government-wide and agency-specific mission-critical occupations and other shortfall areas; and
- Develop and launch a program to actively recruit medical professionals into NDMS and build response capacities in critical mission areas.

Objective 1.7: Ensure Responsible Management of Investments in Preparedness and Response

Responsible financial management provides the foundation for prudent financial stewardship. ASPR staff provide full acquisition, grants management, and oversight services for a diverse R&D, emergency response, and operational program support portfolio of 500-plus active contracts and 100-plus Grants/Cooperative Agreements; incorporate full lifecycle management techniques from concept/inception, administration through closeout and A-133 audits; ensure integrity and oversight through consistent adherence to statutory, regulatory, and administrative policy, which includes auditing and facilitating Earned Value Management System (EVMS) processes; support industry outreach; and provide expert capabilities in the conduct of acquisition strategies, requirements, and grants solutions.

The Government Performance and Results Modernization Act (GPRMA) holds federal agencies accountable for using resources wisely and achieving programmatic results. ASPR currently issues an annual multi-year budget forecast for the HHS agencies that comprise the PHEMCE. This report spans five years and includes out-year forecasts for the basic and advanced research, procurement, regulatory science, storage and sustainment of MCMs to respond to CBRN and EID threats. This approach helps ensure continuity in program management and provides direct linkages between strategic planning, programming, and resource allocation processes across a 5-year year trajectory. ASPR will look to extend this proven multi-year approach to other aspects of its planning, programming, and resource allocation enterprise, including healthcare preparedness and the NDMS.

ASPR utilizes financial resources that are unique to the mission of preparedness, response, and recovery. This includes the National Special Security Special Event (NSSE) contingency fund account, which is appropriated annually at the level of \$5 million available for a period of three years. This fund supports known NSSEs such as the State of the Union Address, July 4th Celebration on the National Mall, and United Nations General Assembly, as well as other significant unanticipated events where identifying preparedness requirements occurs in a timeframe shorter than the annual budget process can accommodate. ASPR also relies on contingency-driven, time-limited supplemental funding to response needs in support of major disasters or large-scale incidents.

Regarding grants and contracts, ASPR has achieved exceedingly high rates of obligation for annual funds. Once funds are obligated, they may be available to vendors and grantees for a multi-year period of execution, or may be approved for carry over or extensions. The utilization of these funds by vendors, grantees, and other ASPR partners has significant impact on preparedness. Through an aggressive approach to enterprise risk management, including review and execution of contract close-outs, ASPR has helped to

ensure that contracts, grants, and other agreement-type financial mechanisms are fully expended by its mission partners.

ASPR will pursue the following strategies to optimize its investments in preparedness and response:

- Maintain and continually review processes to ensure all ASPR programs and resource investments are driven by validated requirements and enterprise strategic planning;
- Utilize finance and acquisition best business practices with enhanced emphasis on best value to the taxpayer through focused MFHC teaming and partnerships with all ASPR program offices;
- Expand ASPR's multi-year requirements forecasting to include non-MCM capabilities in the areas of preparedness, response, and recovery using programs such as the NDMS, HPP, and Medical Reserve Corps as focal points for this activity;
- Assess the potential benefits of a dedicated contingency fund for large-scale PHEs, including rapid onset EIDs, as well as additional authorities to rapidly transfer funds within HHS to address rapid onset health emergencies across all hazards;
- Optimize contract and grant award funds utilization by conducting additional post-award analysis to help ensure the highest percentages of funds utilization; and
- Expand business operations staff training and development efforts to strengthen the competencies of all personnel with responsibilities that impact ASPR's fiscal stewardship.

4.3 PRIORITY GOAL 2: SUSTAIN A ROBUST AND RESILIENT PUBLIC HEALTH SECURITY CAPACITY

Setting the Vision

Responding to and recovering from threats to health security through the effective, efficient, and timely delivery of public health and medical capabilities and resources in an integrated way across FSLTT and public-private sector partnerships nationwide.

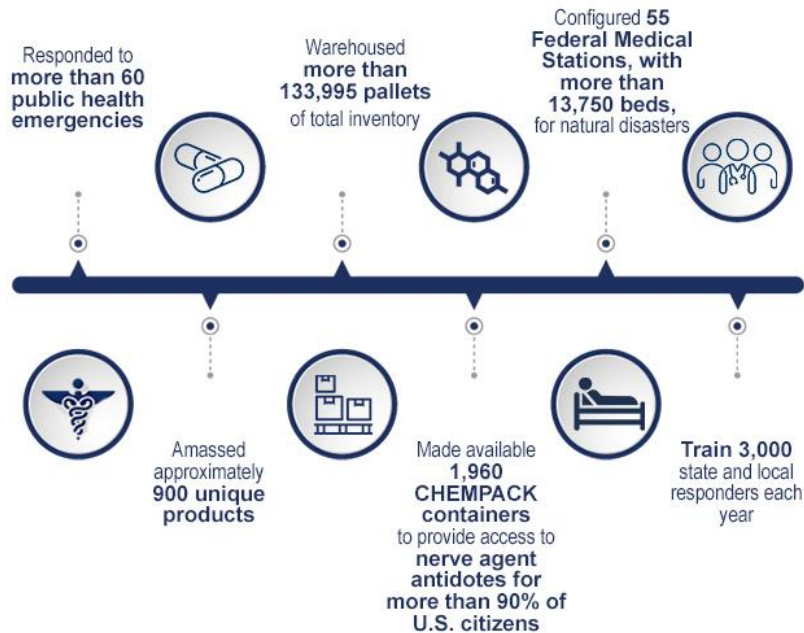
The ASPR organization must be ready to execute public health and medical missions in response to a wide variety of human-caused and naturally occurring threats and hazards. This includes catastrophic incidents that may severely impact vulnerable populations and/or cripple public health and healthcare systems and interconnected lifeline infrastructure on a regional or national scale. ASPR's overall mission is achieved through people, processes, systems, and capabilities that enable ASPR to effectively and efficiently lead, manage, and coordinate federal public health and medical response and recovery operations. The ASPR recently issued a comprehensive Incident Response Framework that describes the organizational structure and coordination process through which the organization's human, physical, and IT resources and partnership networks will come together to achieve its important mission.

ASPR must develop and maintain internally- and externally-focused mission capabilities and operational and logistics processes that are streamlined, easily understood, less manpower-intensive, technologically-smart, and compatible with published national-level incident response and recovery doctrine. Such processes must be fully compatible and interoperable with comparable processes and systems used by ASPR's diverse FSLTT and non-governmental partners. Finally, ASPR's response mechanisms are comprised of a robust, secure, and resilient set of human resources and physical facilities, along with IT capabilities that ensure appropriate functionality and cybersecurity for the IT backbone that underpins the ASPR response and recovery mission.

Objective 2.1: Incorporate the Strategic National Stockpile (SNS) into ASPR Operations

The HHS Secretary transferred the SNS to ASPR from the CDC, effective October 1, 2018. As cited in the [*HHS Congressional Justification for Fiscal Year 2019 Budget*](#), this decision was made to increase operational effectiveness and efficiencies and strengthen integration with ASPR's existing MCM program.⁸ Further, the transfer was designed to enhance domestic preparedness by optimizing MCM development, acquisition, stockpiling, sustainment, response, and utilization, while also strengthening the nation's response to 21st century health security threats.

⁸ See FY 2019 Congressional Justification at <https://www.hhs.gov/sites/default/files/fy-2019-phssef-cj.pdf>

Figure 8: DSNS Operational Accomplishments to Date

ASPR has rapidly integrated Division of the Strategic National Stockpile (DSNS) staff and operational capabilities, while ensuring that all FSLTT partners continue to receive the same exceptional service and support during the transition. Early assessments indicate the integration of DSNS operational capabilities provides ASPR with new flexibility and scalability necessary to respond more effectively and efficiently to mission-related needs.

The DSNS integration has included enhanced information sharing and operational collaboration between the Secretary's Operations Center (SOC) and the DSNS Operations Center. ASPR will work to further engage the DSNS' strong supply chain management and operations functions along with other public health and medical preparedness and response capabilities under ASPR to improve the efficiency of emergency responses, strengthen and streamline the MCM enterprise, and leverage synergies in supply chain logistics.

ASPR will pursue the following implementing strategies to integrate the DSNS into its operations:

- Continue to integrate DSNS support functions, including human resource services, IT services and infrastructure, safety, security, and asset management into OS and ASPR processes, systems, and enterprises;
- Achieve further integration of DSNS response structures and coordinating processes into the ASPR Incident Response Framework and supporting SOPs and operational checklists;
- Further synchronize DSNS Operations Center and material management functions with corresponding SOC and ASPR/ORM operations to support enhanced threat awareness, a common operating picture, and the rapid mobilization, deployment, and tracking of response and recovery resources;
- Continue the integration of DSNS resources and processes into the end-to-end MCM enterprise managed by ASPR; and

- Further integrate ongoing technical assistance, guidance, training, and exercise support activities conducted by the ASPR E2A2 and DSNS focusing on the identification of gaps in operational continuity, MCM response capabilities, and supporting processes and procedures.

Objective 2.2: Integrate ASPR Materiel Management Functions

ORM performs overall logistics functions for ASPR. In concert with a recent organizational restructuring, ORM is leveraging the DSNS' extensive supply chain management capabilities and operational experience to consolidate the management of ASPR materiel inventories under proven DSNS storage, inventory management, and quality control systems. The integration of common ASPR material management functions under DSNS management reduces overall material storage and management costs, minimizes redundant facilities, streamlines deployment processes, and ensures strict accountability and quality control, while further improving the efficiency of ASPR's emergency response capabilities and strengthening the MCM enterprise.

Since its establishment in 1999, the DSNS has borne responsibility for managing the nation's largest



repository of emergency MCMs. Over that time, the management of SNS inventories has been refined and streamlined to minimize overhead costs and optimize deployment capacity, while maintaining strict accountability and quality controls. The SNS inventory is currently valued in excess of \$8 billion. Over the last decade, there was less than 1 percent product loss due to regulatory compliance issues and sustained

annual inventory accuracy of more than 99.7%. DSNS uses well-documented inventory management policies and standard operating procedures. The division performs operational compliance reviews with internal and external audits annually at each storage location in the SNS network.

Integration of common ASPR material management functions under the DSNS logistics portfolio has resulted in improved management, operational efficiencies, and projected long-term cost savings. Continuing the consolidation of redundant storage facilities and inventories into the SNS warehouse network will greatly reduce ASPR's overall material storage and management costs. Moreover, through leveraging economies of scale in the acquisition of ASPR material, DSNS is able to negotiate lower prices to meet and sustain ASPR MCM requirements and inventories. Furthermore, integration of the NDMS materiel inventory into a single ASPR materiel management system enables rotation of common items into deployable caches, thus facilitating product use before expiration and savings on disposal costs.

In addition, consolidation of ASPR medical material under a single independent quality program enables more effective and efficient management of materiel, validation of materiel safety, regulatory compliance, and adoption of best practices. This consolidation also increases accountability and enhanced

reporting and visibility on ASPR resources, promoting improved and more rapid decision making during responses and in PHEMCE deliberations.

Finally, the integration of ASPR material management functions affords new opportunities for improved management of the MCM enterprise. The transfer of the SNS to ASPR was made in anticipation of more effective contract negotiations and more productive relationships with the manufacturers of stockpiled products or potential products. These expectations are coming to fruition as DSNS and BARDA collaborate on mutually beneficial contracting, supply chain, and sustainability approaches that better meet the requirements of the government, while simultaneously providing manufacturers with more certainty and reduced operational risk.

ASPR will continue to pursue the following implementing strategies to achieve optimal integration of its critical material management and logistics functions:

- Consolidate all ASPR and SNS medical materiel, equipment, and supplies under a single network of storage sites, independent quality control function, and automated inventory management system;
- Consolidate all ASPR warehousing and inventory and financial management functions under a single system of documented policies, processes, and audits;
- Integrate NDMS cache material management functions into DSNS;
- Consolidate ASPR product acquisition requirements under a joint contract mechanism;⁹ and
- Consolidate the transportation function for all ASPR supplies and equipment.

Objective 2.3: Strengthen Response and Recovery Operations



ASPR continually strives to improve delivery of public health and medical assistance to communities impacted by disaster throughout the mission continuum. Successful preparedness for, response to, and recovery from PHEs and other incidents requires accurately identifying gaps, and subsequent planning and preparedness activities to address them. ASPR, through its regional staff, engages in detailed planning with FSLTT partners to ensure roles and responsibilities are

clearly defined, gaps and seams are identified, and regional federal public health and medical support plans

⁹ To the extent that SNS and BARDA-administered PBS funds are separately appropriated, contract funding may require discernment, even if coordinated under a single award.

are developed to support the response to FSLTT partner requests for federal support. Further action is necessary to develop and maintain plans that are up-to-date and routinely and thoroughly exercised, ensuring the ASPR organization is fully ready to execute them. Additional approaches that strengthen this critical mission area include the adoption and implementation of the ASPR Incident Response Framework; training ASPR headquarters and field-level response and recovery personnel to appropriate conditions and standards; maintaining personnel readiness to deploy and conduct operations in forward environments; building an enhanced regional response capability; developing other new capabilities where required; and coordinating closely with partners to deliver success.

ASPR will pursue the following strategies to strengthen its disaster response capabilities:

- Fully implement, test, and validate the various components of the ASPR Incident Response Framework, including development, implementation and ongoing exercising of all functional annexes (Information Management, Planning, Resource Coordination, and Finance & Administration) and other supporting annexes, operational doctrine, and SOPs;
- Develop position task books, job action sheets (JAS), operational checklists, incident-specific playbooks, and other job aids for all headquarters and IMT-level positions defined under the Incident Response Framework;
- Establish a formal Federal Health Coordinating Official (FHCO) training program and selection criteria;
- Develop and implement an ASPR responder qualification, training, and automated training management system for headquarters and field response organizations and staff (including permanent and intermittent staff and augmentees), including the capability to support Type I incident management requirements;
- Support the development and implementation of a near real-time resource management system and common operating picture to improve transparency of resource readiness, enhance situational awareness, and improve decision support capabilities at all levels of the ASPR incident response structure;
- Conduct a comprehensive review of the SOC Emergency Management (EM) Portal from a content, access, and functionality perspective, implement recommendations for enhancement, and develop a comprehensive training program for portal users;
- Conduct and implement priority recommendations based on a comprehensive assessment of crisis communications (including social media) staffing and training requirements needed to support all key nodes of the ASPR incident response structure, as well as ESF-15 operations in a Joint Field Office (JFO) and/or Joint Information Center (JIC), if established;
- Provide enhanced program management regarding standardized requirements, inventory, configuration, maintenance, update, inspection, replacement, service provider contracts, etc. for all deployable IT systems, computers (including mobile computing), printers, radios, phones, and other deployable cache items used to support key nodes of the ASPR incident response structure;
- Establish a financially sustainable, multi-year and multi-level exercise program designed to test policies, plans, and capabilities and achieve and sustain national preparedness to prevent, respond to, and recover from all-hazards disasters;
- Develop an interagency accessible database to warehouse exercise outcomes, including after action reports, and facilitate trends analysis to inform preparedness improvement across the ESF-8 community.

- Strengthen international partnerships and mechanisms to enhance U.S. public health security capacities and incident response.

ASPR's roles and responsibilities for disaster recovery, as the federal coordination lead for the H&SS RSF, are organized along nine core mission areas: public health, health care services impacts, behavioral health impacts, environmental health impacts, food safety and regulated medical products, long-term health issues specific to responders, social services impacts, referral to social services and disaster case management, and children and youth in disaster. H&SS recovery support actions are focused on "shortening the distance" between recovery needs and resources, to include: information; knowledge and knowledge transfer through technical assistance, communications campaigns, or other interventions to share and diffuse knowledge; or funding to gain or ensure access to needed services for eligible populations.

The H&SS RSF mission starts with the response and involves proactive measures to describe, understand, and mitigate challenges and barriers to recovery progress for H&SS providers, individuals, families, and communities. Disaster recovery issues are temporal in nature – they change over time, and so too do the necessary interventions to support SLTT recovery activities. As time progresses, the complexity of the issues related to H&SS become increasingly interdependent. ASPR plays a critical role in working with FSLTT, private, and non-profit partners to identify courses of action to support locally-driven disaster recovery. These courses of action must be designed as more than simply "one off" interventions where a large swell of resources are rapidly delivered and just as rapidly demobilized. Instead, recovery operations must derive courses of action that will eliminate barriers to recovery, address specific disaster-related issues, and build local capacity to sustain the recovery effort for the long haul.

In implementing the H&SS RSF since 2011, ASPR cultivated a broad array of experience assisting communities, hospitals, healthcare systems, school systems, and human services providers in how to endure the "marathon" of recovery. ASPR will continue to work with these partners to pursue the following strategies to improve its ability to support disaster recovery operations:

- Develop recommendations for HHS senior leadership consideration to allow for a more effective and efficient utilization of authorities, programs, resources, and capabilities across department OPDIVS and STAFFDIVS to meet H&SS-related recovery needs;
- Engage the HHS DLG to foster continued monitoring and engagement and address policy issues that emerge in the recovery mission over time;
- Complete and promulgate H&SS-related, all-hazards recovery planning, cost recovery guidance, and decision support tools for FSLTT, non-governmental, and healthcare coalition partners;
- In collaboration with FEMA, explore more effective, efficient, and sustainable approaches/mechanisms to recovery related to resource funding, management, and reporting, as well as travel reimbursement for recovery personnel;
- Establish qualification standards and develop qualified and trained ASPR internal staff and NDMS intermittent staff with the skills necessary to conduct post-incident recovery assessments, coordinate federal assistance to support recovery planning and mitigation strategies, and work with impacted communities to develop relevant recovery and resilience measures;
- Revise recovery-related concepts of operation, plans, SOPs, etc. to incorporate detail regarding the transition from response to recovery for critical headquarters and field nodes of the ASPR Incident Response Framework, where relevant;

- Utilize recovery operational best practices, decision-making, issue analysis, and technical assistance to augment response operations throughout deployed and headquarters-based staff; and
- Establish a department-wide recovery volunteer cadre in coordination with ASA/OHR to support H&SS-related recovery operations.

Objective 2.4: Improve Situational Awareness

Situational awareness spans the spectrum of all-hazards incident prevention, response, and recovery. It involves the intake, compilation, and assessment of various types of threat/hazard data and other pertinent information from various sources, including, but not limited to: law enforcement threat information; national security intelligence; CBRN-related information including atmospheric, ground, and water toxic dispersal analysis; human, animal, and plant surveillance data; environmental monitoring data; syndromic surveillance data; critical infrastructure data; media and social media information; etc. ASPR's mission requires an integrated, all-hazards approach to situational awareness that leverages the capabilities of FSLTT agencies (including the CDC as the federal lead for public health surveillance and situational awareness), foreign governments, and domestic and international non-governmental entities, including private-sector organizations across the healthcare industry.

Situational awareness begins with the determination and validation of the all-hazards informational needs of the ASPR, HHS senior leadership, and the White House, as well as the varied needs of ASPR's nationwide inter- and intragovernmental and public-private sector partnership networks. This comprehensive understanding of information needs underpins the subsequent collection, fusion, and analysis of timely, relevant, and accurate information. The final component of situational awareness involves the ability to appropriately share assessed data with relevant partners using a variety of technologies, systems, electronic displays, and products that inform decision-making at various levels of the government and private sectors.



ASPR will employ a wide range of techniques, technologies, and methodologies to improve its situational awareness capabilities. The path forward involves improved coordination of domestic and international public health and healthcare-related information sharing activities in partnership with the CDC. It also includes expanded collaboration with the intelligence community, law enforcement, the military, academic and R&D communities, and other relevant sectors to rapidly characterize new and evolving threats. ASPR also will work to improve the timely and accurate flow of information with international public-private sector partners to support the coordination and management of incidents that may constitute a PHE of International Concern (PHEIC). Finally, ASPR will assist its many domestic and international partners in expanding their resources and capacities through coordinated training and exercises that are focused on identifying gaps in maintaining and sustaining enhanced and shared situational awareness across the incident life-cycle. The desired outcome is active and timely situational awareness that informs responsible decisions and actions that, in turn, promote improved resource utilization, effective mitigation of emerging threats, and enhanced health outcomes among impacted populations.

ASPR will pursue the following strategies to enhance its situational awareness capabilities:

- Coordinate with the CDC, other HHS OPDIVS/STAFFDIVS, and other federal partners to maintain situational awareness and inform preparedness and response capabilities based on a wide range of threats and hazards;
- Develop and implement an intelligence concept of operations designed to integrate ASPR information management and situational awareness products and processes that inform ASPR senior leader decision-making;
- Refine and revise ASPR's Critical Information Requirements (CIRs) and Essential Elements of Information (EEIs) associated with a wide range of naturally occurring and human caused threats and hazards as defined in national-level risk analyses;
- Implement the following specialized information management capabilities:
 - ◆ ASPR Ready, a consolidated IT platform designed to integrate disparate ASPR data sets and information systems into a unified architecture;
 - ◆ ASPR Common Operating Picture (COP);
 - ◆ ASPR personnel and logistics tracking and reporting tool (in coordination with ORM);
 - ◆ Improved healthcare facility status reporting; and
 - ◆ Catalog of information management reporting products.
- Develop and implement an ASPR data implementation strategy, including enhanced data management, analytics, and visualization for situational awareness and decision support;
- Implement and test all situational awareness-related process and information system requirements detailed in the ASPR Incident Response Framework and supporting functional annexes;
- Develop new or leverage existing advanced public health and medical modeling capabilities to support senior decision maker needs across a wide range of all-hazards scenarios;
- Promote a more robust integration of healthcare and public health sector partners into the national network of Joint Terrorism Task Forces (JTTFs), fusion centers, and emergency operations centers to foster the timely and comprehensive gathering, assessing, and sharing of relevant information; and

- In coordination with FSLTT, nongovernmental, and international partners, plan, execute, and conduct after action reporting for a series of multi-level and multi-sector drills, tabletop exercises, and functional exercises focused on identifying situational awareness capability gaps and recommendations for improvement.

Objective 2.5: Manage and Protect the Safety, Security, and Integrity of ASPR Assets

ASPR's overall incident response posture is critically dependent on the organization's ability to effectively manage, maintain, and safeguard its highly distributed array of human, physical, and cyber assets and resources. These assets, capabilities, and resources provide the critical foundation for all aspects of the ASPR mission from steady-state administrative activities through complex incident response and recovery operations. In exigent circumstances, their continuity is accounted for via the Mission Essential Function (MEF) identification process, and department and ASPR-level Continuity of Operations (COOP) plans.

Executive Order 13327 and federal management regulations requires federal agencies to promote the efficient and economical use of federal real property resources and ensure proper accountability, use, care, and protection of all personal property in their possession, custody, or control. Via the Government Services Administration and other federal warranted leasing officers, ORM leases an extensive portfolio of real property and manages approximately \$8 billion of property and SNS assets to support the execution of ASPR's public health and medical preparedness, response, and recovery missions. ASPR has made significant strides in improving its asset management planning process; determining asset requirements; optimizing and measuring asset performances; and leveraging assets to reduce the federal footprint and disposal of assets that no longer meet ASPR needs.

ORM will pursue the following strategies to enhance asset management in coordination with ASPR's resource management partners:

- Collaborate with ASPR offices in developing and executing a long term facility strategy that adopts innovative workplace solutions and technologies, and provides a real estate portfolio that more effectively and efficiently meets the needs of the ASPR mission and staff;
- Optimize ASPR's headquarters and regional office space utilization by providing decision-makers with high quality data analysis, space planning strategies, and facility plans; and
- Pursue innovative approaches to property accountability and asset management by deploying improved technology, and providing education, processes, and procedures to reduce loss and damage of government property.

These strategies will allow ASPR to maintain asset management compliance requirements and achieve potential cost savings by reducing loss and damage of government property while evaluating and optimizing asset utilization. They also will deliver workspace solutions that will provide ASPR staff the opportunity to focus more time and resources on their mission-related operations.

While asset management generally is the domain of a specialized cadre of ASPR staff, the safety, security, and integrity of ASPR assets is the responsibility of all ASPR employees. Safeguarding physical and cyber assets is a critical function that spans all ASPR offices and divisions, and applies to all aspects of ASPR operations, including, but not limited to, day-to-day administration, MCM end-to-end supply chain management, procurement and acquisition, preparedness initiatives, operational planning, and all-hazards incident response.

ASPR's Security Division is responsible for personnel suitability, national security clearance management, and physical security activities regarding BARDA and SNS assets. In fact, in coordination with other federal and private-sector partners, the physical security mission ensures the comprehensive protection of ASPR's MCM program at all levels. From conceptual and advanced development of MCMs through stockpiled and delivered products, facilities access and control, protection, surveillance, monitoring, and related exercises are essential duties performed by ASPR's Security Division. The Security Division currently is developing a comprehensive set of physical security policies and procedures, risk assessment methodologies, and specific risk management appropriate for broader application across the ASPR enterprise.

During incident response operations, ASPR's newly formed Division of Intelligence acts in support of the Information Management Section within the SOC. In coordination with the HHS Office of National Security (ONS), the Division of Intelligence also supports the Physical Security Manager, IT Systems Security Specialist, and Communications Specialist within the SOC and deployed ASPR Incident Management Teams (IMTs) to provide up-to-date threat information and inform operations security (OPSEC), information security (INFOSEC), and communications (COMSEC) postures and risk management strategies, as needed.

ASPR will pursue the following implementation strategies to strengthen ASPR's security culture and more effectively protect ASPR's human and physical resources.

- Develop and implement an ASPR physical security strategy and Insider Threat program, including appropriate policies, protocols, and workforce and supervisor training;
- Develop and implement ASPR-wide physical security standards based on federal best practices and other applicable guidelines;
- Facilitate the conduct of comprehensive physical security assessments of all ASPR real property assets, whether owned or leased; and
- Implement headquarters and field-level physical security protocols, security staffing, and general and specialized training programs based on requirements established in the ASPR Incident Response Framework, regulation, or statute.

On the IT front, the [NSS](#) charges every federal agency with ensuring that the systems it owns and operates meet the standards and cybersecurity best practices it recommends to industry.¹⁰ It is imperative that ASPR maintain an adequate level of security for both internal and interconnected IT systems. ASPR will undertake a systematic effort to assess its information systems at greatest risk, and ensure that appropriate protective capabilities and methodologies are in place to secure sensitive information while enabling critical mission functions. Through its Information Technology Advisory Council, ASPR will adopt a more unified approach to securing its internal information systems and, where appropriate, deploy standardized, cost-effective, and cutting-edge capabilities across high-value information systems. As ASPR increasingly explores and leverages cloud and shared services, it also must develop and pilot emerging capabilities,

¹⁰See <https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905-2.pdf>

tools, and practices to more effectively detect and mitigate evolving threats and vulnerabilities in a timely fashion and ensure that cybersecurity approaches are flexible and dynamic enough to counter determined and creative adversaries.

ASPR will pursue the following strategies to enhance the security of its IT assets and guarantee their functional resilience in support of incident response and recovery operations:

- Via HHS/ONS and HHS/Office of the Chief Information Officer (OCIO), maintain continuous connectivity to the cyber threat assessment community to stay abreast of emergent threats and recommended prevention and mitigation strategies;
- Conduct comprehensive risk and gap assessments across ASPR information systems based on consistent methodology and government and industry best practices; and
- Pursue innovative and agile approaches to acquisition and technology procurement to deploy cutting-edge capabilities that facilitate protected use of current technologies, as well as future cloud and shared services.

The activities identified above will allow ASPR to maintain an appropriate level of cybersecurity, commensurate with assessed risks, to ensure the confidentiality, availability, and integrity of critical ASPR information systems and information.

Finally, during certain exigent circumstances, the continuity of the ASPR mission—including the integrity of mission essential resources—is provided for via department and ASPR-level COOP plans, processes, and operational structures. The HHS COOP staff, physically and functionally situated within ASPR, provides direction and guidance for continuity planning, exercises, and operational implementation to all HHS OPDIVS, STAFFDIVS and Regional Offices, based on the “Assess, Distribute, and Sustain” methodology established in Executive Branch policy.

ASPR will pursue the following strategies to ensure continuity of its MEFs and corresponding human, physical, and IT resources in a COOP environment:

- Define planning parameters and procedures to prepare the department and ASPR for a high consequence, no-notice incident;
- Procure, maintain, and test the department’s continuity communications and information technology capabilities, in accordance with OMB/OSTP Directive 16-1;
- Review and/or update or develop new HHS and ASPR continuity policies to address changes in the COOP policy, risk, operating, and fiscal environments, and to ensure a consistent and efficient approach to satisfying common requirements;
- Conduct an assessment of the OS continuity site to determine continued suitability and address emergent needs;
- Conduct an annual senior leader tabletop exercise to discuss continuity-based policies and procedures and the coordinated HHS-ASPR response to a high consequence, no-notice incident; and
- Incorporate requirements corresponding to future updates of Presidential Policy Directive-40 (or equivalent) into HHS and ASPR COOP plans and operations.

4.4 PRIORITY GOAL 3: ADVANCE AN INNOVATIVE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE

Setting the Vision

A comprehensive MCM development, procurement, and delivery program that ensures a national capability to rapidly respond to public health security threats and emergencies and fosters innovation, mitigates risk, and leverages a whole-of-government approach with the end user and the patient as the priority.

Led by ASPR, the PHEMCE is an interagency coordinating and integrating framework for enabling the timely provision of safe and effective medical products (i.e., vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures) to protect or treat affected or potentially affected populations. The PHEMCE focuses on PHEs arising from naturally occurring incidents, such as pandemic influenza or EIDs,



as well as CBRN threats or the deliberate or unintentional release of CBRN agents/materials. The PHEMCE framework comprises a variety of complex and interdependent efforts, including early detection of EIDs and pandemics; developing, manufacturing, procuring, and stockpiling medical products against potential threats; distributing and administering MCMs to affected populations; and evaluating the effectiveness of the MCMs utilized.

ASPR's role within the PHEMCE includes developing and coordinating national policy and associated requirements; overseeing the advanced development, acquisition, stockpiling, and sustainment of medical products that address the requirements of at-risk populations; and managing operational coordination to ensure that MCMs are deployed and administered effectively when needed. ASPR's accomplishes these responsibilities in a collaborative manner with the support of other HHS OPDIVS and STAFFDIVS, FSLTT agencies, international public health partners, private health care providers, and other healthcare public health sector partners.

Objective 3.1: Enhance and Streamline the PHEMCE

The PHEMCE comprises interdependent groups of federal senior officials and subject matter experts with equities in MCM-related activities, including early- and late-stage product development, regulatory approval, acquisition, stockpiling, distribution, dispensing, sustainment, and use and efficacy monitoring. The PHEMCE coordinates and prioritizes the acquisition, maintenance, and use of MCMs throughout their lifecycle to meet the nation's public health and national security needs in an operational setting. The PHEMCE, established in 2006, was codified through the PAHPAIA of 2019 (P.L. 116-22).



ASPR initiated a PHEMCE restructuring in 2019 to streamline and strategically drive deliberative processes, enabling a quicker and more efficient response to emerging threats. This restructuring expands representation to include DoD, enabling engagement with key aspects of DoD's MCM investments from early research through field testing and Food and Drug Administration (FDA) approval. It also will enable a more effective partnership between HHS and DoD on MCM development, including increased resource-sharing and

alignment of activities to ensure investments with minimal redundancy.

A further key aim of this restructuring effort is to protect national security-sensitive or proprietary information, regardless of classification level, in the context of aggregation of data that can blur distinctions based on classification guidelines. Assessments conducted by the Intelligence Community continually inform the PHEMCE regarding threats, MCM capability gaps, and risks. To protect such information, PHEMCE leadership meetings involving discussion of aggregated information that may present security risks are held at the SECRET or higher level. Additionally, ASPR critically examines information that is meant for public dissemination, including congressionally mandated documents, to determine whether the information strikes an appropriate balance of informing stakeholders while protecting the federal MCM enterprise and the American public against potential threats. ASPR takes steps to mitigate potential security risks in all cases.

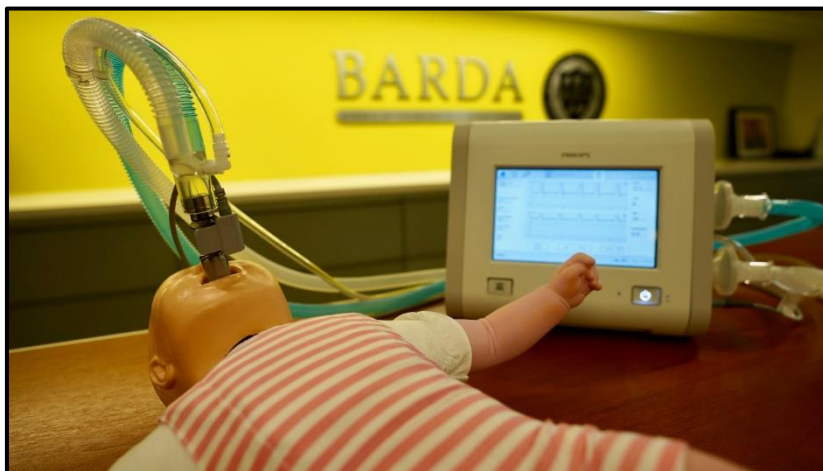
The following high-priority strategies will help fully implement the PHEMCE restructure and advance ASPR's goals for enhancing the federal MCM enterprise:

- Strengthen relationships among senior leaders and subject matter experts from key departments and agencies, particularly DoD and HHS, to align MCM priorities and activities;
- Develop and implement whole-of-government plans that outline the near- and long-term R&D and procurement strategies for MCMs to address high-priority threat areas. Such plans will include means to assess whether investment in new or enhanced MCMs within a particular portfolio would yield significant improvement over existing MCMs and, hence, require prioritization by PHEMCE members;
- Solicit priorities from non-federal stakeholders regarding activities and priorities of the PHEMCE to include SLTT officials, industry, and representative healthcare sector associations;
- Develop the PHEMCE Strategy and Implementation Plan and SNS Threat-Based Review and clearly articulate within these documents the cross-threat priorities and corresponding priority activities required to adequately protect national security;
- Identify gaps and provide recommendations to ensure the safety, security, and reliability of supply chains to provide necessary MCMs and other materiel support during CBRN incidents;

- Develop improved business models for MCM development and acquisition to address the strategic risks posed by supply chain disruptions and foreign ownership of MCM production and distribution;
- Work with SLTT partners to develop and implement strategies to maximize effective utilization of MCMs through clinical guidance and public health communications;
- Work with federal partners to identify and segment, compartmentalize, or otherwise limit the potential aggregation of unclassified but sensitive information regarding MCMs and associated activities over electronic networks;
- Support domestic and international partners in their activities to improve regulatory science, translational research, concepts of operation, and the manufacturing, procurement, and dispensing of MCMs; and
- Foster the ASPR Priority Medicines on Demand effort to help ensure the availability of saline for all patients (particularly end state renal disease patients), as well as small molecule and biologics products at point-of-use.

Objective 3.2: Establish Innovative MCM Programs and Enduring, Sustainable Partnerships

ASPR BARDA oversees and manages the development and acquisition of MCMs, working with industry partners to facilitate the transition of promising MCM candidates from early research through advanced development to potential licensure. To date, 52 FDA licenses for unique products have been supported by BARDA. While these successes represent significant advances towards more robust national health security, critical gaps remain that require innovative thought and entrepreneurial approaches that occur commonly in the private sector, coupled with market incentives to drive change and improvement in science and technology solutions.



The 21st Century Cures Act, signed into law on December 13, 2016, authorized the Secretary, acting through the Director of BARDA to enter into an agreement with an independent, nonprofit entity – a Medical Countermeasures Innovation Partner (MCIP) – to foster and accelerate the development and innovation of MCMs and technologies that may assist advanced R&D for MCMs,

including through the use of strategic venture capital practices and methods. BARDA must direct and oversee work conducted under the agreement and ensure transparency and accountability. Accordingly, the Secretary of HHS directed BARDA to create and develop a sustained and ongoing bilateral partnership with a third party nonprofit entity for the development and innovation of MCMs and related tools, technologies, data, and techniques using joint capital venture partnership agreements.

BARDA has established a new division, the Division of Research, Innovation, and Ventures (DRIVE) to enhance its ability to respond to CBRN threats, pandemic influenza, and EIDs. A major component of

DRIVE, DRIVE Launch, is designed to spur and support innovative and entrepreneurial activities not commonly addressed under traditional MCM development. The goal is to push innovative technologies forward for potential transition to other components of DRIVE or to traditional non-dilutive funding under advanced R&D.

To foster innovative and enduring partnerships that support a sustainable MCM enterprise, BARDA will:

- Provide overarching leadership in the end-to-end scope of product development, technologies, and tools to help improve ASPR's overall response capability and capacity in addressing 21st century threats to national health security;
- Continue to advance and sustain robust public-private partnerships for MCM development and production;
- Provide the MCIP with priorities for the conduct of market research and opportunities via targeted investments and capital funding;
- Provide accelerator services to quickly develop and adopt tools and technologies to address gaps and transition them to BARDA's advanced R&D pipeline or transfer them to other government partners for continued development, deployment, or their exit and release for commercial adaptation;
- Push technologies forward for additional future investments by other venture capital groups or their transition to other components of DRIVE or traditional non-dilutive funding under advanced R&D;
- Identify additional incentive mechanisms to engage MCM developers and stimulate private sector investment and innovation across the range of the MCM technology base;
- Provide seed and start-up capital to innovative entrepreneurial companies working in the field of health security solutions or related technologies to attract private sector funding for continued support and development;
- Provide awareness of specific products, tools, and technologies developed through the advancement of the MCM enterprise;
- Review and improve processes governing the solicitation, review, and award of MCM contracts; and;
- Ensure that BARDA, its accelerators, and MCIP utilize best business practices with public/private partnerships to emphasize the best value to the taxpayer through the use of innovative acquisition methods and increased cost sharing.

The activities identified above will include development and/or manufacturing of diagnostics, vaccines, therapeutic drugs, and other innovations including the nontraditional use of computer and data science to improve health security. Also included are solutions that enhance the distribution and administration of tools and technologies following threat exposure and provide a quick means to implement processes to provide assistance on the ground at the SLTT level.

Objective 3.3: Provide MCM-related Consultation and Technical and Operational Response Coordination Expertise

SLTT elected and appointed decision-makers, emergency managers, first responders, public health officials, and clinicians need tools that guide the effective integration of MCMs into a response. This includes concise and easy-to-follow guidance developed and issued by the CDC that SLTT and other public health and healthcare stakeholders can use to inform the development of MCM response plans and crisis communications strategies. Effective MCM guidance and plans enable decision-makers to take time-sensitive action and select MCMs and MCM deployment strategies that correspond to the threat and dynamics of at-risk communities, particularly those with significant specialty care or access and functional needs. In coordination with the CDC, ASPR will support SLTT partners in developing and exercising their MCM plans and logistics protocols based on operational realities and inclusive of relevant stakeholders. Similarly, ASPR will work in coordination with the CDC and FSLTT partners to enhance deployment, distribution, and dispensing capabilities and capacities needed to ensure effective provision of MCMs to all segments of the population, including pediatric and other medically vulnerable populations and individuals with access and functional needs. ASPR support of MCM operational response plans will be coordinated with CDC Operational Readiness Review assessments that are focused on state capabilities to effectively receive and deliver MCMs in a response.



The DSNS is engaged with the Urban Area Security Initiative (UASI) jurisdictions to improve nationwide access to MCM necessary for the management of disease threats through improving managed inventory delivery times, sustaining distribution velocity, and incorporating lessons learned. This UASI improvement cycle starts with updating jurisdictional MCM-related response plans and expectations for SNS delivery,

evaluating jurisdictional capacities to implement plans through tabletop exercises, delivering targeted trainings to address identified gaps or opportunities for improvement, and validating capabilities through full-scale exercises in the UASI jurisdictions. ASPR also holds meetings with private sector partners to maintain and enhance public-private partnership activities that reduce the burden on SLTT officials in incidents requiring an MCM response. These private-sector partners include important commercial supply chain companies as well as trade organizations and their members.

Additionally, ASPR incorporates strategies and identifies opportunities to advance the MCM enterprise in innovative ways by leveraging international partnerships to contribute to the development of strategies and identify opportunities that can protect and promote U.S. public health security. ASPR leverages the NAPAPI framework and identifies activities within the Global Health Security Initiative (GHSI) in the promotion of rapid sharing of biological samples, MCM development and regulatory approval, and deployment to contribute to the advancement of the MCM enterprise and the promotion of both regional and U.S. public health security.

Through the coordinating leadership provided by DSNS and the Medical Countermeasure Operations Program (MCOP), ASPR will work with federal partners to help SLTT partners improve their operational readiness to rapidly receive, distribute, dispense, administer, and monitor the safety of MCMs during a PHE.

ASPR will pursue the following implementing strategies to achieve the stated objective:

- Foster collaboration between the CDC, DSNS, MCOP, ASPR Regional Emergency Coordinator (REC) cadre and other regional staff, and SLTT partners to conduct/facilitate pre-incident planning for receipt, distribution, and dispensing of MCM to ensure such activities can be accomplished in a timely manner, are informed by appropriate guidance, and can be supported operationally by federal and SLTT agencies during a response.
 - ◆ Integrate the needs of at-risk populations and individuals with access and functional needs into planning for MCM distribution and dispensing; and
 - ◆ Facilitate the capability to monitor the safety and effectiveness of deployed MCMs.
- Provide assistance and consultation on all topics pertaining to MCM logistics planning and execution, including distribution and points of dispensing (POD) operations;
- Provide specialized subject matter expertise to optimize the MCM logistics chain and assist with necessary planning, training, and exercises;
- Work to build specialized capabilities and capacity in accordance with strategies as described in HHS's Last Mile Initiative, and in conjunction with DSNS programmatic priorities; and
- Integrate ASPR Critical Infrastructure Program (CIP) and DSNS coordination with public and private partners and participants in the MCM supply chain to ensure communities are prepared and key medical supplies are available during PHEs.

4.5 PRIORITY GOAL 4: BUILD A REGIONAL DISASTER HEALTH RESPONSE SYSTEM

Setting the Vision

A ready, capable, and sustainable network of regionally-based FSLTT public health, private healthcare, and emergency medical capabilities ready and able to support SLTT partners during PHEs and all-hazards disasters.

Naturally occurring and human-caused incidents that span large geographic areas and create population displacement and infrastructure disruption for extended periods of time require specialized planning, resources, and mutual aid. Response resources may be extended well beyond the jurisdictional boundaries of individual states and major metropolitan statistical areas. The capabilities of individual partners alone will not be sufficient to meet all of the public health and medical needs that undoubtedly will surface in the wake of a large-scale or catastrophic incident impacting a large geographic area. Accordingly, a unified, regional approach to improving healthcare readiness and medical surge capabilities and capacity that can be tailored to address specific regional risk profiles around the country is needed. This approach can be accomplished most effectively and efficiently by integrating and expanding preparedness capabilities within the already-existing healthcare delivery and emergency response infrastructure across the public and private sectors nationwide. Medical surge capacity may be further coordinated and supported through improved alignment across NDMS, HHS CIP, HPP, Medical Reserve Corps, U.S. Public Health Service Commissioned Corps, RECs, and other HHS regional staff.

ASPR will leverage and expand upon established investments in healthcare preparedness and all-hazards response capabilities, including HPP and NDMS, to serve as the foundation for a forward-looking Regional Disaster Health Response System (RDHRS). This regional system will be built upon a tiered framework that emphasizes collaborative capacity building among FSLTT partners in both the public and private sectors. The RDHRS will promote enhanced surveillance and health security-related information sharing amongst regional partners; increase preparedness for uniquely challenging incidents such as IEDs and CBRN incidents; expand access to specialty clinical care expertise; and increase medical surge capacity during incident response.

Figure 9: Achieving a Regional Disaster Health Response System



Objective 4.1: Modernize NDMS

A key departmental aim is to ensure the nation’s all-hazards disaster healthcare system is integrated with the day-to-day healthcare delivery infrastructure — hospitals, emergency medical services, emergency management, and public health agencies — to provide safe and effective healthcare during PHEs and other disasters. ASPR is strengthening the NDMS to better prepare the nation for situations that may be unprecedented, require significant surge capacity, or could overwhelm hospitals and other healthcare facilities. The NDMS focuses on synchronizing the enhancement of NDMS HCFs and associated capabilities with those maintained by NDMS partners — including DoD, Homeland Security (DHS), and Veterans Affairs (VA) — through its Definitive Care Program.



The NDMS Definitive Care Program consists of a current network of over 1,800 HCFs nationwide with various capabilities to support populations affected by a major disaster or other contingency in which DoD and VA medical facilities become overwhelmed. HCFs are a key component of the support NDMS provides to the nation as hospitalized and home care patients are relocated from a

disaster impact area to NDMS HCFs outside of the impacted area and returned when conditions are appropriate. Each participating NDMS HCF signs a Memorandum of Agreement (MOA) with the federal government ensuring reimbursement to the facility at an established rate for NDMS patient acceptance.

In support of the RDHRS concept, ASPR will pursue the following strategies, in partnership with VA and DoD, to modernize the NDMS HFCs:

- Identify and develop a set of guidelines to enable HCFs to provide appropriate patient care during, in advance of, or immediately following, a PHE resulting from an EID or CBRN incident;
- Develop an approach to integrate NDMS partners into hospital, HCC, and SLTT planning on a regional scale;
- Outreach to a full range of traditional and non-traditional partners, including trauma centers, burn centers, poison control centers, pediatric hospitals, public health laboratories, outpatient services, behavioral health, and home and community-based health and human services, among others;
- Strengthen collaborative partnering activities with HPP to align grant programs focused on health system readiness;
- Increase focus on recruitment activities that develop a stronger business case for civilian health care facilities to become a NDMS HCF; and
- Enhance training and exercise support for NDMS HCFs, including preparedness for catastrophic disasters, EIDs, and CBRN incidents.

ASPR is not only working to deepen its NDMS partnerships and expand the capacity of its many public health and medical organizational partners. It is also working to improve its hiring processes and enhance its own internal NDMS team capabilities so that NDMS professionals maintain the appropriate skill sets and are ready to meet the emergent challenges of complex disaster response. Specifically, NDMS is developing new ways to enhance existing training and develop new training incorporating a wider range of specialized capabilities to provide a seamless, strategic, and coordinated response. The NDMS program office within ASPR also is modernizing system caches designed to support federal public health and medical team response missions under ESF-8, taking into account the dynamics of the current and projected risk environments and operational needs. To implement these cache upgrades, DSNS has integrated all of ASPR's NDMS caches into DSNS facilities and overall logistics operations. This move includes both the warehoused supplies and the staff who manage them and is expected to decrease overall materiel management costs. Having all NDMS materiel under one centrally DSNS-managed line of control further streamlines ASPR logistics operations and better postures ASPR to execute its mission.

To implement this aspect of the RDHRS, ASPR NDMS program and regional staff will:

- Conduct a review of NDMS to assess and identify gaps regarding current staffing, specialty care skills, capacity, training, and readiness of the intermittent work force to respond to PHEs and other all-hazards disasters, including multiple, simultaneous PHEs or other incidents, as well as a national-level PHE.
- Work in concert with ASPR's Division of Intelligence to ensure that NDMS program staff and operational teams stay abreast of emergent public health threats and related trends;
- Factor public health threat and risk information into NDMS capabilities planning, operational concept development, and equipment and materiel acquisitions;
- Coordinate with FSLTT partners to determine the need for additional NDMS enterprise and regionally-focused capabilities and capacity, along with corresponding training, equipment, and materiel needs;

- Coordinate with FSLTT partners to identify requirements and operating concepts for new caches/kits to support future missions, including catastrophic disasters, EIDs, and CBRN incident response;
- Identify potential pre-staging locations for newly developed resources; and
- Establish contracted wrap-around field support capabilities to support NDMS planning, training, and emergency response missions.

Objective 4.2: Expand Specialty Care Capabilities

In today's risk environment, responding effectively to a wide range of potential threats and hazards requires affected communities to not only provide general public health and medical services in an emergency setting, but to be able to readily access clinical specialists and technical services in diverse areas such as pediatrics, dialysis, trauma care, burn care, hazmat exposure, and EIDs. Such capabilities are not uniformly distributed across the country, leaving some state and local areas underprepared for certain medical and public health threats. For example, not every community has a Level I trauma center, a burn center, or a pediatric hospital. Nor does every community have quick and reliable access to specialty care providers proficient in radiation treatment or infectious disease. While the daily demand for these specialty care capabilities may be very low in a given community, demand could change very rapidly in a disaster or PHE.



Establishing mechanisms for building specialty care capacity, providing clinical expertise, and ensuring the prompt delivery of specialty medical services is key to addressing critical gaps in patient care as related to a wide range of potential risk vectors. Additionally, as demonstrated during the 2017 hurricane season response, at-risk populations or individuals with access and functional needs may have greater challenges accessing services or may be displaced for longer

periods of time as a result of complex or catastrophic incidents. ASPR and SLTT response planning, concepts of operation, and operational capabilities must account for the ability to provide health and medical services to important populations of at-risk individuals and those with access and functional needs (e.g., small children and infants, older adults, individuals with disabilities, individuals with limited English proficiency, people relying on home-health care, etc.).

Advanced planning in support of potential specialty care and access and functional needs should account for capabilities that already exist on a regional scale, as well as the identification of new capability providers and additional capabilities to meet needs associated with a catastrophic disaster scenario or unique incident type (i.e., EID or CBRN incident).



ASPR will pursue the following strategies to enhance specialty care and access and functional needs capabilities, with a priority on those scenarios that represent catastrophic consequences and/or long-term population displacement or inability to access regular specialized medical care:

- Utilize Centers for Medicare and Medicaid (CMS) data to provide SLTT health officials with situational awareness of medically vulnerable and access/functional needs populations in their communities to inform and enhance preparedness planning, capabilities development, and incident response operations;
- Review regional and SLTT catastrophic disaster plans, and develop recommendations to address potential large-scale specialty care needs across various high-consequence scenarios;
- Identify regional “hub-and-spoke” constructs to create a deliberately planned and more effective division of labor among initial intake/assessment centers, concentrated regional HCFs, and specialty care providers (e.g., hazmat and burn care);
- Identify risk-based, cost-effective recommendations to expand specific specialty care capabilities within ASPR’s NDMS teams, either individually or based on likely region of deployment/employment;
- Integrate ASPR situational awareness, data analytics, and modeling capabilities to provide near real-time support to SLTT public health agency activities to rapidly identify specialty care and access/functional needs populations to accelerate triage, transport, and provision of required medical services or treatment; and
- Work with SLTT and HCC partners to expand the use of telemedicine, portable, and in-home care options during disasters to increase the availability and efficiency of pediatric critical care, dialysis, and other specialty care services.

Objective 4.3: Enhance Private Sector All-Hazards Preparedness

Central to the RDHRS vision are the frontline providers and facilities who care for the ill and injured every day. The nation depends on the continuity of its healthcare systems, particularly during disasters with significant population and critical infrastructure impacts. Private industry plays a large role in maintaining that continuity of service, as over 92% of health-related infrastructure is privately owned and operated.¹¹ Within the healthcare sector, private-sector owners and operators are primarily responsible for pre-incident readiness, timely response to all-hazards incidents, and restoration of their assets post-incident, as reinforced by recently implemented Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (particularly with regard to emergency preparedness and risk assessment activities). Without strong emergency preparedness foundations, the private sector may be less ready and able to continue to provide critical services operations during disasters, potentially creating new challenges and exacerbating existing ones.

¹¹ See CRITICAL INFRASTRUCTURE PROTECTION: Progress Coordinating Government and Private Sector Efforts Varies by Sectors' Characteristics. GAO Report. (2006.) <https://www.gao.gov/assets/260/252603.pdf>

HPP is the only source of federal funding for health care system readiness. HPP helps prepare the health care system nationally to address the all-hazards risk environment through the development and nurturing of HCCs. HCCs are in-state regional groups of healthcare and response organizations that collaborate to prepare for and respond to incidents requiring medical surge. Core members of HCCs include hospitals, emergency medical services (EMS) (including inter-facility and other non-EMS patient transport systems), emergency management organizations, and public health agencies. Many other facility and provider types also participate. HCC partners serve an important communication and coordination role within their respective jurisdictions and actively contribute to strategic planning, operational planning and response, information sharing, and resource coordination and management. HCCs also may collaborate with one another to ensure individual HCCs the support and resources they need to respond to emergencies and prepare for planned events, including medical equipment and supplies, real-time information, communication systems, and trained health care personnel.

ASPR developed the [2017-2022 Health Care Preparedness and Response Capabilities](#) to describe what the health care delivery system — including HCCs, health care organizations, and emergency medical services (EMS) – must do to effectively prepare for and respond to emergencies that impact the public’s health. These capabilities illustrate the range of health care preparedness and response activities that represent the ideal state of readiness in the U.S. HPP also requires all HCCs to exercise to specific response plan annexes that focus on identified surge requirements and scenarios (e.g., pediatric, burn, infectious disease, radiation and chemical). This helps HCCs and their 34,000 members to prepare for a variety of incidents, including those that may require highly specialized clinical expertise, and work towards a response-ready health care system.

ASPR/HPP will pursue the following strategies to support the implementation of a RDHRS:

- Encourage multi-state collaboration and participation when designing and executing exercises and training activities required under cooperative agreements;
- Identify opportunities for synergy across federal government activities to prepare clinical facilities via close collaboration with other departments and agencies;
- Award grants to a select number of eligible high-acuity trauma centers to enable military trauma teams to provide, on a full-time basis, trauma care and related acute care at such facilities;
- Determine and clearly communicate the estimated return on investment and overall value of specific preparedness activities; and
- Work with HCCs, RDHRS partners, and other stakeholders to identify and promote guidelines, standards, and best practices for the creation and implementation of a RDHRS.

ASPR, via the ASPR SIIM CIP Division, is the lead for executing the Sector-specific Agency (SSA) responsibilities assigned to HHS in Presidential Policy Directive 21, “Critical Infrastructure Security and Resilience.” In this capacity, the CIP Division is responsible for a variety of efforts to promote the physical security, cybersecurity, and resilience of the nation’s health infrastructure by leading a dynamic public-private partnership under the National Infrastructure Protection Plan (NIPP). It also works with private sector partners during incident response and recovery operations to develop an understanding of HPH Sector-specific impacts and response and recovery priorities which, in turn, is used to inform restoration and recovery planning and operational activities at various levels. During steady state, the CIP Division fosters implementation of the NHSS among ASPR’s private sector partners and works collaboratively to

assess gaps and challenges and provide risk mitigation recommendations regarding physical and cyber-related supply chains.

ASPR will pursue the following implementing strategies to enhance private sector preparedness:

- Expand the HPH Sector Government Coordinating Council membership under the NIPP partnership framework;
- Establish the CIP Division as the HHS private-sector lead interface for cybersecurity issues, including prevention, response, recovery, and mitigation coordination;
- Develop external private sector outreach and communication mechanisms and information products to facilitate strategic outreach amongst HHS regions and healthcare subsectors;
- Work with relevant FSLTT public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of those aspects of the Healthcare and Public Health (HPH) Sector that need to be maintained through any emergency or disaster situation, including entities capable of assisting with, responding to, and mitigating the effect of a PHE;
- Fully integrate the HPH Sector partnership into the newly established ESF-14 (Cross-sector Business and Infrastructure) under the NRF to improve public-private collaboration, information sharing, and decision making at the SLTT, regional, and national levels during incident response and recovery;
- Continue use of the CIP Division's Risk Identification and Site Criticality (RISC) toolkit to enhance end-user functionality, streamline the data ingest process, facilitate the identification of HPH Sector critical infrastructure, and enable agile, multi-level reporting; and
- Expand private sector participation in FSLTT-sponsored exercise activities, both nationally and regionally.

Objective 4.4: Promote a Resilient Medical Supply Chain

The continuity of healthcare and public health services on a local, regional, and national basis depends on a robust and resilient series of interdependent service- and materiel-oriented supply chains. These supply chains represent very complex and sophisticated systems, with private-sector partners working across a global market and relying on just-in-time delivery of necessary services and medical materiel. In specialty areas such as pharmaceuticals, healthcare industry supply chains are further challenged by the realities of a consolidated pharmaceutical marketplace with key interdependencies and a limited number of manufacturers. Disruptions to these supply chains — even on a small scale — can have critical impacts on patient care during steady state and in complex incident response situations.



In collaboration with private-sector partners, ASPR works to identify potential courses of action to both better understand and address public health and medical supply chain issues, foster connections across public and private sector partners during both steady state and incident response/recovery situations, and promote the adoption of resilience measures that make sense for healthcare sector partners.

ASPR will pursue the following implementing strategies to help increase supply chain security and resilience within the healthcare sector:

- Establish a private and public sector functional working group under the HPH Sector partnership framework with a focus on supply chain risk issues, including, but not limited to, the following:
 - ◆ Identify key in-sector and out-of-sector dependencies/interdependencies and approaches to reinforcing medical product supply chains;
 - ◆ Explore different approaches to domestic and geographically-dispersed production of healthcare equipment and supplies;
 - ◆ Identify and address challenges in transporting and receiving health care equipment and supplies, including across national, state, local, and territorial borders and outside the continental U.S; and
 - ◆ Explore approaches to address supply chain-related risks corresponding to EIDs and catastrophic human-caused and naturally occurring disasters.
- In collaboration with FSLTT and industry partners, factor healthcare supply chain risks and mitigation strategies into local, regional, and national preparedness efforts, including multi-level risk assessment, contingency planning, and exercise activities;
- In collaboration with FEMA, factor supply chain issues into the ESF-14 planning, decision making, and resource allocation processes at the national, regional, and SLTT levels during incident response operations; and
- In collaboration with industry partners, leverage the analytical capabilities of the DHS National Risk Management Center to conduct targeted studies and analysis of HPH Sector physical and cybersecurity supply chain risks on a sector, subsector (e.g., direct patient care, health IT, pharmaceuticals, blood supply, medical materiel and logistics, etc.), and regional basis.

Objective 4.5: Develop Regional Response Consortia & Exercise Regional Capabilities

Disasters do not occur neatly within the boundaries of any given jurisdiction. Therefore, SLTT communities must collaborate with one another in order to share resources, expertise, and information; safely move patients; and provide quality medical care. Achieving the RDHRS vision necessitates robust multi-state regional collaboration and coordination. This capability will be realized through the development and maturation of regional response consortia that are comprised of FSLTT partners in health care, public health, and emergency management. These consortia will include both federal (military and civilian) and non-federal (governmental and non-governmental) partners to ensure that all available health care resources and expertise are brought to bear during a catastrophe.

Regional response consortia will be responsible for identifying and inventorying health care assets in their regions, understanding and working to mitigate regional limitations in readiness and response, and building the specialized capabilities required to provide health care during medical surge scenarios. The regional consortia also will be responsible for ongoing cross-state partnerships within their own region, as well as region-to-region partnerships with other consortia across the country.

ASPR will pursue the following implementation strategies in support of the stated objective:

- Establish a pilot project as a proof of concept to validate this activity;
- Via HPP cooperative agreements, encourage the development of multi-state regional centers of excellence that are capable of collaborating and coordinating across state boundaries to improve clinical response capability and capacity;
- Identify and test viable models for state- and/or hospital-based medical teams with highly specialized clinical capabilities that can deploy to disasters in their own state as well as to other states within a region;
- Determine the essential elements of information (EEI) and minimum technical standards required to safely and effectively exchange clinical information with healthcare providers/systems and FSLTT medical response personnel; and
- Identify and address existing legal, regulatory, and policy barriers to effective multi-state clinical response in disasters and PHEs (e.g., through the drafting and dissemination of model language).

A related activity critical to the development of an effective RDHRS is the establishment of a financially sustainable, multi-year exercise program designed to validate enhanced or newly developed regional capabilities. This exercise program should maintain an appropriate mix and frequency of exercises and related activities to maintain preparedness across regional whole-of-community partners while accounting for advances in science, capability, and policy. Such a focus will help ensure that a regional PHE will be managed by continuously trained and practiced staff resources and other operational capabilities across the public health and medical response domain.

Specific implementing strategies supporting this activity include the following:

- Developing or enhancing existing exercise programs, planning, and conduct of regional scale activities nationwide;
- Creating an exercise after action reporting requirement and a whole-of-community accessible database to analyze exercise outcomes in order to inform progress and status reports on the development of a RDHRS; and
- Producing an annual analysis of biodefense preparedness on a regional scale to be included in the National Preparedness Report.

Objective 4.6: Integrate EMS into Response Operations

EMS is an integral part of the overall public health and medical response to any natural or human-caused disaster or PHE. Local EMS is a recognized member of the public safety community, along with police, fire, and emergency management. Much of the nation's EMS capabilities are operated and delivered by private companies, including for-profit ambulance providers and hospital-based systems. There are also

more than 6,000 9-1-1 call centers across the country, typically managed by police, fire, county or city government, or other entities.



A key objective of any EMS system is to ensure each patient is directed to the most appropriate setting consistent with their acuity and medical condition. Coordination of the regional flow of patients is essential to ensuring the quality of pre-hospital care. It is also integral to addressing system-wide issues related to hospital and trauma center crowding, particularly in the context of mass casualty incidents. Regional coordination requires effective synchronization and communications across the many elements that

comprise a regional system. Community hospitals, trauma centers, and, particularly, pre-hospital EMS must work together effectively to achieve this common goal.

ASPR takes a lead in coordinating federal activities to help ensure that EMS organizations nation-wide are better prepared for day-to-day operations, surge effectively during response, and support mass casualty operations in the context of both traditional and nontraditional risk vectors. ASPR engages its key federal interagency partners through the Federal Interagency Committee on EMS (FICEMS), advocating for enhanced integrated preparedness and incident response planning, providing leadership in the areas of tactical medicine training and operations in concert with interagency and intergovernmental partners, and maintaining strong partnerships with national and SLTT EMS organizations.

A range of issues affects the delivery of pre-hospital EMS, including interoperable communications at the local level; coordination of the regional flow of patients to hospitals and trauma centers; reimbursement for EMS response activities; national training and credentialing standards; innovations in triage, treatment, and transport; integration of all components of EMS into disaster preparedness, planning, and response actions; and the need for additional clinical evidence to support EMS care delivery.

An important enabler of integrated EMS activity during disaster response is the FEMA National Medical Transport and Support (NMTS) contract. This vehicle provides contractor-managed, multi-functional transport and medical support resources and capabilities, established in conjunction with a forward operating base or staging area, as needed, in support of Federal assistance, evacuations, or other medical support activations for incidents covered under the Stafford Act. Support resources include staffed transport and EMS as well as licensed and certified medical personnel for augmentation beyond medical transportation. This support is primarily intended to supplement a State response to any incident in which federally provided medical transportation and support capabilities are needed.

ASPR will lead and/or facilitate the coordination of the following implementing strategies to better integrate EMS into response operations:

- Engage HCC organizations; SLTT public health, law enforcement, and emergency management agencies and EMS partners to:

-
- ◆ Use cooperative agreements and other funding sources to more fully integrate pre-hospital EMS participation in HCC and other SLTT preparedness activities, including regional-level all-hazards planning, training, and exercise activities;
 - ◆ Address gaps in EMS capabilities related to high-consequence response scenarios, including the capacity to support specialty care and access/functional needs populations; and
 - ◆ Support the integration of EMS organizations into local level “Rescue Task Force,” “Mass Casualty Task Force,” and “CBRN Task Force” concepts of operations, plans, and training and exercise activities.
- Collaborate with HCC organizations, FICEMS member agencies, SLTT agencies, and EMS partners to promote standardization and quality improvement of pre-hospital data and the adoption and implementation of National EMS Information System-compliant systems;
 - Engage DHS, FICEMS member agencies, and SLTT partners to improve all-hazards situational awareness provided to EMS personnel, along with up-to-date threat/hazard data, to help ensure the protection of EMS personnel during a response;
 - Advocate for the expanded scope of practice of EMS via community para-medicine and mobile integrated healthcare initiatives in support of PHE response and recovery activities;
 - Convene a working group with FEMA (including appropriate legal, legislative, contracting, fiscal, policy, program and operational representation) to determine the feasibility of and requirements for transferring the responsibility for oversight of the NMTS contract from FEMA to HHS to streamline and better integrate the public health and medical aspects of incident response operations requiring federal support.
 - ◆ Assess potential modifications to the current contract to better serve all communities through well-planned and highly coordinated emergency care services;
 - ◆ Account for greater interconnectivity for dispatchers, EMS personnel, medical providers, public safety officers, and public health officials to enable each patient to receive the most appropriate care, at the optimal location, with minimum delay;
 - ◆ Establish a mechanism for evaluation of the delivery of services and facilitation of the development and adoption of best practices; and
 - ◆ Conduct a federal assessment to identify any gaps, shortfalls, and redundancies; identify challenges to the implementation and execution of the transfer of EMS and the NMTS contract; and recommend any necessary updates or modifications.

5.0 ACHIEVING RESULTS AND MEASURING PERFORMANCE

5.1 INTRODUCTION

Measuring performance against established goals and objectives is a critical aspect of this Plan. Performance measurement involves the systematic and, where possible, quantifiable tracking of progress of Plan implementation. It also includes assessing the effectiveness of the implementing strategies that form a core part of the Plan on a goal-by-goal, objective-by-objective basis. Individual performance metrics provide a basis for ASPR to establish accountability, document actual performance, facilitate diagnoses, promote effective risk management, and provide a feedback mechanism to leaders and managers at various levels across the organization. Where appropriate, performance metrics developed to support the goals, objectives, and implementing strategies identified in this Plan should also align with those used by the HPP and CDC Public Health Emergency Cooperative Agreement to help ensure a synergistic approach to improvement between HHS/ASPR and its SLTT and nongovernmental partners.

5.2 MEASURING ORGANIZATIONAL PERFORMANCE

ASPR will evaluate the implementation progress and effectiveness of this Plan based on achievement of the priority goals and strategic objectives identified in Section 4, as well as additional supporting activities and initiatives instituted at the staff office and division level across the organization. ASPR's performance management activities are integral to achievement of its mission, and, therefore, are grounded in an inclusive culture in which staff at all levels participate. ASPR will follow the direction provided in [Public Law 111-352](#), GPA Modernization Act of 2010, in the development and implementation of performance measures to evaluate Plan progress.¹²

Measurement of Plan implementation progress and effectiveness will be conducted via a set of core performance metrics developed by the designated OPR/coordination lead (see Table 1) for each objective-implementing strategy pairing identified in Section 4. The Office of SPPR will assist these OPRs in the development and subsequent analysis of these core performance metrics, and will facilitate tracking of activities accomplished as well as those in progress. The core metrics may be reinforced by additional metrics developed to support priority activities related to Plan implementation at the staff office and division level.

Using these initial performance metrics and other forms of feedback, ASPR, in conjunction with its various external partners, as required, can adjust and adapt its approaches to account for progress achieved, as well as for changes in the policy, risk, and resource environments. Metrics-based assessments also can be used to focus attention on specific areas that warrant additional resources, plan modifications, enhanced partner collaboration, or other improvements. For example, if an evaluation reveals insufficient progress toward a given objective, identified ASPR OPRs (including subordinate staff offices, divisions, and/or regional offices) can act to identify and address deficiencies.

¹² See <https://www.govinfo.gov/content/pkg/PLAW-111publ352/pdf/PLAW-111publ352.pdf>

5.3 IMPLEMENTATION GOVERNANCE

The ASPR IO will provide direct oversight and guidance to facilitate Plan implementation, and, supported by the Office of SPPR, will track and monitor the execution of priority implementing strategies across ASPR. The ASPR staff office, division, and/or regional office leadership designated as the OPR for specific objectives and implementing strategies identified in Section 4, assisted by the Office of SPPR, will develop and provide quarterly and annual progress/outcome reports to the ASPR and ASPR Senior Leadership Team. Progress and outcome reporting will clearly articulate implementation status along with evidence to support evaluation of the successes achieved via the implementation of each priority assigned. This reporting process also will address internal and external challenges, risks, resource gaps, etc., which may have affected or may have the potential to impact desired outcomes, as well as options to mitigate those risks and challenges. Such evaluation also will support the periodic review and refinement of this Plan across its life cycle.

The Office of SPPR staff will work with the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) staff to identify an appropriate collaborative information management approach to support Plan implementation, tracking, and reporting requirements. This approach should include a centralized capability to track, report, and evaluate implementation progress and performance achievement.

6.0 ONGOING PLAN MANAGEMENT AND MAINTENANCE

The ASPR IO is designated as the overall OPR for the ongoing management and maintenance of the ASPR Strategic Plan for 2020-23. This responsibility includes the following principal activities: (1) exercising general oversight of ASPR-wide Plan implementation; (2) leading the conduct of an annual Plan review and the development/issuance of any corresponding updates, including updates to priority implementation strategies and performance metrics, as required; and (3) leading out-of-cycle Plan reviews and update issuances based on an analysis of real-world incidents; exercise after-action reports and lessons learned; changes in mission/organizational structure; changes in the policy, fiscal, and/or risk environments, etc. The Office of SPPR will assist the ASPR IO in the execution of these responsibilities.

7.0 CONCLUSION

The vision, core values, priority goals, strategic objectives, implementing strategies, and performance feedback mechanisms detailed in this Plan define the path forward to enhance execution of the ASPR mission. Through implementation of this Plan, ASPR is committed to fulfilling its responsibilities under various higher-order statutes, policies, and plans to save lives and help protect the American people against all hazards. To do so, ASPR will work diligently to enhance its capabilities and develop its workforce while also leveraging and reinforcing the diverse authorities, capabilities, expertise, and resources resident within its vast partnership network nationwide. Through the initial feedback processes and performance metrics established in this Plan, ASPR will track and measure progress against the achievement of stated goals, objectives, and implementing strategies.

The continuously evolving nature of the policy, risk, and resource environments in which ASPR and its many public- and private-sector partners operate requires an equally dynamic approach to risk management as this Plan is implemented. The priority goals, strategic objectives, performance metrics, and partnership approaches identified herein, therefore, are intended to be flexible in their application to account for the continued evolution of these interconnected environments. This means accommodating modifications, updates, and re-prioritization as necessary, as well as maintaining sustainability in the face of emergent challenges and/or resource issues. Although ASPR's external environment will no doubt continue to evolve in various dimensions — some predictable and others in unknown ways — the organization's mission and vision, as stated in this Plan, help provide a consistent focus throughout.

Moving forward, the ASPR organization will build upon its previous accomplishments, successes, and investments and fully leverage the renewed strategic foundation provided via this Plan. Mission success will be achieved and measured as a function of the priority goals and strategic objectives established herein, as well as through important supporting activities and initiatives undertaken and continuously evaluated at the staff office and division levels. The overarching governance structure described above will help ensure that the strategic priorities identified in this Plan remain relevant over time and are adapted to account for future opportunities and challenges.

APPENDIX A: ACRONYMS

ACF	Administration for Children and Families
AMCIT	American Citizen
ASA	Assistant Secretary for Administration
ASPA	Assistant Secretary for Public Affairs
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CBRN	Chemical, Biological, Radiological, Nuclear
CDC	Centers for Disease Control and Prevention
CIP	Critical Infrastructure Protection
CIR	Critical Information Requirement
CMS	Centers for Medicare and Medicaid Services
COMSEC	Communications Security
COOP	Continuity of Operations
COP	Common Operating Picture
COS	Chief of Staff
CUI	Controlled Unclassified Information
DLG	Disaster Leadership Group
DOD	Department of Defense
DOS	Department of State
DRIVE	Division of Research, Innovation, and Ventures
DSNS	Division of the Strategic National Stockpile
E2A2	Exercise, Evaluation and After Actions
EID	Emergent Infectious Disease
EM	Emergency Management
EMMO	Emergency Management and Medical Operations
EMP	Electromagnetic Pulse

EMS	Emergency Medical Services
ESF	Emergency Support Function
ESFLG	Emergency Support Function leadership Group
EVMS	Earned Value Management System
FEMA	Federal Emergency Management Agency
FHCO	Federal Health Coordinating Official
FICEMS	Federal Interagency Committee on Emergency Medical Services
FIOP	Federal Interagency Operations Plan
FSLTT	Federal, State, Local, Tribal, Territorial
FY	Fiscal Year
GHSA	Global Health Security Agenda
GHSI	Global Health Security Initiative
GIS	Geospatial Information System
GPRMA	Government Performance and Results Modernization Act
H&SS	Health and Social Services
HCC	Healthcare Coalition
HCF	Healthcare Facility
HHS	Department of Health and Human Services
HOPIC	HHS Operational Planning Integration Group
HPH	Healthcare and Public Health
HPP	Hospital Preparedness Program
IHR	International Health Regulations
IM	Information Management
IMT	Incident Management Team
INFOSEC	Information Security
IO	Immediate Office
IPT	Integrated Process Team
IT	Information technology
JAS	Job Action Sheet

JEE	Joint External Evaluation
JIC	Joint Information Center
JFO	Joint Field Office
JTTF	Joint Terrorism Task Force
LES	Law Enforcement Sensitive
MCIP	Medical Countermeasure Innovation Partner
MCM	Medical Countermeasure
MCOP	Medical Countermeasure Operations Program
MEF	Mission Essential Function
MERS	Middle East Respiratory Syndrome
MFHC	Management, Finance, and Human Capital
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NAPAPI	North American Plan for Animal and Pandemic Influenza
NBS	National Biodefense Strategy
NDMS	National Disaster Medical System
NDRF	National Disaster Recovery Framework
NHSS	National Health Security Strategy
NIH	National Institutes of Health
NIMS	National Incident Management System
NIPP	National Infrastructure Protection Plan
NMTS	National Medical Transport and Support
NPS	National Preparedness System
NRCC	National Response Coordination Center
NRF	National Response Framework
NSPM	National Security Presidential Memorandum
NSS	National Security Strategy
NSSE	National Special Security Event
OCIO	Office of the Chief Information Officer

OEA	Office of External Affairs
OICC	Office of Incident Command and Control
OMB	Office of Management and Budget
ONS	Office of National Security
OPDAS	Office of the Principal Deputy Assistant Secretary
OPDIV	Operating Division
OPSEC	Operational Security
OPR	Office of Primary Responsibility
ORM	Office of Resource Management
OS	Office of the Secretary
OSTP	Office of Science and Technology Policy
PAHPA	Pandemic and All-Hazards Preparedness Act
PAHPAIA	Pandemic and All-Hazards Preparedness and Advancing Innovation Act
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act
PHE	Public Health Emergency
PHEIC	Public Health Emergency of International Concern
PHEP	Public Health Emergency Preparedness
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PIO	Public Information Officer
PPD	Presidential Policy Directive
PL	Public Law
POD	Points of Dispensing
PSC	Program Support Center
PTB	Position Task Book
R&D	Research and Development
RDHRS	Regional Disaster Health Response System
REC	Regional Emergency Coordinator
RRCC	Regional Response Coordination Center
RSF	Recovery Support Function

RSFLG	Recovery Support Function Leadership Group
SARS	Severe Acute Respiratory Syndrome
SERP	State Emergency Repatriation Plan
SIIM	Office of Security, Intelligence, and Information Management
SLT	Senior Leadership Team
SLTT	State, Local, Territorial, Tribal
SNS	Strategic National Stockpile
SOC	Secretary's Operations Center
SPPR	Office of Strategy, Policy, Plans, Requirements
SSA	Sector-specific Agency
STAFFDIV	Staff Division
TBD	To Be Determined
UASI	Urban Area Security Initiative
USC	United States Code
VA	Department of Veterans Affairs
WHO	World Health Organization
WMD	Weapons of Mass Destruction

APPENDIX B: AUTHORITIES

The Public Health Service Act (PHSA), as amended, including but not limited to, Sections 311, 319, 319F-2, 2801, 2811, and 2812 (42 U.S.C. 201 et seq. §§ 243, 247d, 247d-6b, 300hh, 300hh-10, and 300hh-11).

Public Law 111-352, GPA Modernization Act of 2010, January 4, 2010

Section 319C-2 of the PHS Act, 42 USC 247d-3b

Section 319L of the PHS Act, 42 USC 247d-7e

Homeland Security Presidential Directive 5 (HSPD-5), “Domestic Incident Management” (HSPD-5), 2003.

Presidential Policy Directive 8 (PPD-8), “National Preparedness,” March 30, 2011.

PPD-25 (Classified).

PPD-44 (Classified.)

National Biodefense Strategy, 2018.

National Health Security Strategy, 2019-2022.

National Security Strategy of the United States of America, December 2017

National Response Framework (NRF) (third edition), June 2016.

National Disaster Recovery Framework (NDRF) (second edition), June 2016.

U.S. Department of Health and Services, Strategic Plan, FY2018-2022.

APPENDIX C: ADDITIONAL REFERENCES

Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5121 et seq).

Post-Katrina Emergency Management Reform Act (PKEMRA) of 2006 (Public Law 109-295), October 4, 2006.

Sandy Recovery Improvement Act of 2013 (SRIA), (Public Law 113-2).

National Preparedness Goal, September 2011.

National Preparedness System, November 2011.

National Incident Management System (NIMS) (third edition), October 2017.