National Health Security Strategy 2019-2022

Saving Lives. Protecting Americans.

ASPR

TABLE OF CONTENTS

INTRODUCTION

Our nation faces diverse and evolving health security threats that have the potential to disrupt our public health and health care systems and inflict injury and loss of life on our people. Significant progress has been made in improving capabilities to address the immediate public health and medical consequences of anticipated and actual public health threats, such as extreme weather and infectious disease outbreaks. However, to save lives and protect the nation[i] from other 21st century risks, we—the collective group of stakeholders with responsibilities for national health security—must advance our preparedness and response capabilities to address the realities of our immediate and future threat landscape.

This landscape includes threats we have faced before—such as natural disasters and human-caused incidents, emerging and pandemic infectious diseases, and acts of terrorism—as well as growing, potentially catastrophic risks posed by nation-state actors, revisionist powers, and rogue regimes. To protect our nation's health security we must ensure our people are prepared and resilient.

U.S. National Health Security actions protect the nation's physical and psychological health, limit economic losses, and preserve confidence in government and the national will to pursue its interests when threatened by incidents that result in serious health consequences whether natural, accidental, or deliberate.

We must continue to strengthen U.S. public health and health care systems to effectively and swiftly confront the devastating consequences of risks, such as the use of chemical, biological, radiological, and nuclear (CBRN) weapons; cyber warfare; emerging infectious diseases that could lead to a pandemic; and catastrophic natural disasters and human-caused incidents.

As our nation's health threats evolve, the way governments and stakeholders work together and carry out missions must evolve as well. Ensuring a health-secure nation is a collective responsibility among federal, state, local, tribal, and territorial (SLTT) governments and public and private partners, non-governmental organizations, academia, professional associations, communities, volunteers, families, and individuals. The National Health Security Strategy (NHSS) provides a vision for strengthening our nation's ability to prevent, detect, assess, prepare for, mitigate, respond to, and recover from 21st century health security threats.

NATIONAL HEALTH SECURITY OBJECTIVES

The 2019-2022 NHSS is focused on three overarching objectives. As health security threats continue to emerge and evolve, these objectives are intended to be flexible and adaptable.

1. Prepare, mobilize, and coordinate the Whole-of-Government to bring the full spectrum of federal medical and public health capabilities to support SLTT authorities in the event of a public health emergency, disaster, or attack.

Areas of focus for this objective include, but are not limited to:

- Providing the leadership to improve national preparedness and convene a unified, national response to public health emergencies and disasters;

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[i] The term nation in the context of national health security is inclusive of American citizens, non-U.S. citizens, and visitors who may be at risk of adverse health effects in event of a public health emergency or disaster.

- Mobilizing, coordinating, and directing the medical and public health assets of the U.S. Government;

- Promoting sustainable enhancements to SLTT medical and public health infrastructure and response capabilities and capacity; and

- Evaluating the effectiveness and viability of regional disaster health response capabilities to better identify and address gaps in coordinated patient care during public health emergencies and disasters.

2. Protect the nation from the health effects of emerging and pandemic infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats.

Areas of focus for this objective include, but are not limited to:

- Continuing efforts to improve early detection of emerging and potential pandemic infectious diseases;

- Rapidly identifying, developing, producing, and making available safe, effective medical countermeasures (MCMs)[ii];

- Maintaining the capacity to produce enough vaccines and other necessary MCMs to provide protection from pandemic influenza and CBRN agents that represent a strategic health security threat to the nation; and

- Supporting SLTT authorities' efforts to stock, and rapidly obtain, distribute, dispense, administer, and monitor the safety of MCMs.

3. Leverage the capabilities of the private sector.

Areas of focus for this objective include, but are not limited to:

- Developing and sustaining robust public-private partnerships for MCM development and production;

- Fostering the creation of a resilient medical product supply chain; and

- Incentivizing and sustaining private sector health care surge capacity for large-scale incidents.

Cutting across these three objectives is the need to ensure a holistic view of public health and health care, which includes behavioral health and social service needs. We will take into account and plan for the access and functional needs of at-risk individuals, including children, individuals with disabilities, and older adults. We will engage across the whole community to ensure citizens are empowered to participate in preparedness efforts, reduce or mitigate their

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[ii] Medical Countermeasures are pharmaceutical products, such as vaccines, antimicrobials, and antitoxins, and nonpharmaceutical products, such as ventilators, diagnostic tests, PPE, and patient decontamination materials, that may be used to prevent, mitigate, or treat the adverse health effects from a public health emergency.

risks from public health emergencies, disasters, or attacks, and build individual and community resilience.

In addition to the NHSS, the 2019-2022 Implementation Plan (IP) provides the roadmap for advancing health security capabilities, while the 2015-2018 Evaluation of Progress (EOP) assesses the nation's efforts to achieve the health security goals of the prior quadrennial NHSS. The statutory requirements for these documents are detailed in Appendix A.

The NHSS aligns with and supports national strategies such as the National Security[1], Defense[2], and Biodefense[3] Strategies. The NHSS informs capacity building efforts of the Hospital Preparedness Program (HPP), the Public Health Emergency Preparedness (PHEP) program, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the Biomedical Advanced Research and Development Authority (BARDA), the Global Health Security Agenda (GHSA), and the U.S. Health Security National Action Plan.[4] Furthermore, the NHSS aligns with the National Preparedness Goal[5] and its associated frameworks such as the National Mitigation Framework[6], the National Response Framework[7], and the National Disaster Recovery Framework.[8]

STRATEGIC ENVIRONMENT AND THREAT LANDSCAPE

"Competition among countries will increase in the coming year as major powers and regional aggressors exploit complex global trends while adjusting to new priorities in U.S. foreign policy. The risk of interstate conflict, including among the great powers, is higher than at any time since the end of the Cold War. The most immediate threats of regional interstate conflict in the next year come from North Korea and from Saudi-Iranian use of proxies in their rivalry. At the same time, the threat of state and non-state use of weapons of mass destruction will continue to grow."
Statement for the Record: Worldwide Threat Assessment of the U.S. Intelligence Community, Daniel Coats, Director of National Intelligence, February 13, 2018[9]

Our nation is not a sanctuary against external and internal threats. The events of 9/11, the subsequent anthrax attack in 2001, and recent domestic "lone wolf" terrorism attacks demonstrate that America remains a target. However, the nature of the threat is changing. According to the 2018 National Defense Strategy, "inter-state strategic competition, not terrorism, is now the primary concern in U.S. national security."

Technologies that enable cyberwarfare and the development of CBRN weapons have proliferated internationally, fostering concerns from the intelligence community about threats from state-based actors. Whether these adversaries are affiliated with nation-states, revisionist powers, rogue regimes, or terrorism, they pose a lethal threat to the nation from anywhere in the world.

In destabilized areas around the globe, deteriorating social cohesion exacerbated by poverty, crime, migration, and violence spur recruitment to militant groups. Increasing interconnectedness allows violent ideologies to be swiftly promulgated via social media leading to the proliferation of homegrown extremists. Conflict and destruction perpetrated by malign actors become more likely to occur within U.S. borders and affect the nation's health security.

While the U.S. public health and health care infrastructure has matured over the past decades, it continues to struggle to maintain funding and response capabilities and capacities for known threats such as extreme weather and infectious diseases, and has been severely tested by new and emerging threats. As these threats to the nation evolve, we must continually assess what realistic scenarios should inform our preparedness efforts. We must prepare for these threats rapidly, continuously, and comprehensively. These preparedness efforts require an assessment

of the 21st century threat landscape and strategic environment as well as the vulnerabilities in our public health and health care infrastructure.

Extreme Weather and Natural Disasters

Extreme weather events are becoming more frequent and severe (Figure 1). Multiple devastating events can occur in a short timeframe—as witnessed with consecutive major hurricanes that affected Texas, Florida, Puerto Rico, and the U.S. Virgin Islands in 2017—repeatedly challenging communities trying to recover from the last storm. Extreme weather events, geologic activity (e.g., earthquakes and volcanic eruptions), and space weather/solar flares can expose vulnerabilities within our critical health infrastructure.
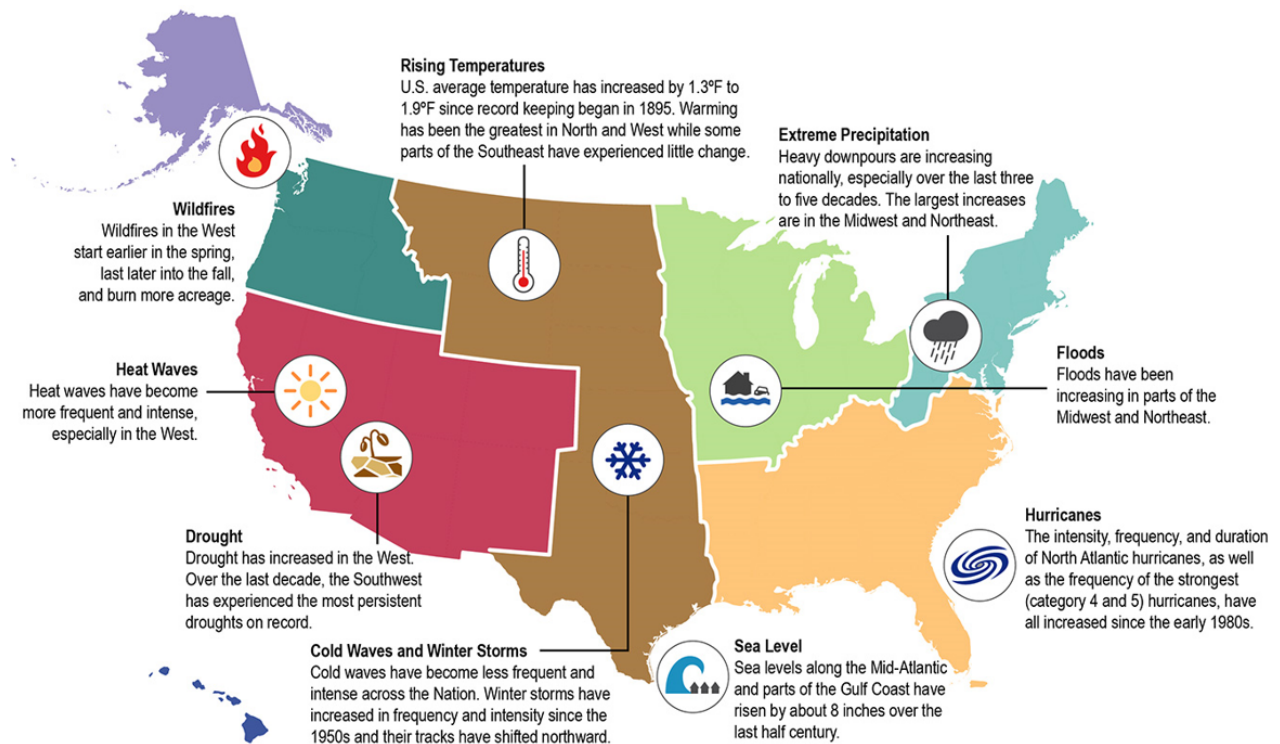

Rising Temperatures
U.S. average temperature has increased by 1.3°F to 1.9°F since record keeping began in 1895. Warming has been the greatest in North and West while some parts of the Southeast have experienced little change.

Wildfires
Wildfires in the West start earlier in the spring, last later into the fall, and burn more acreage.

Extreme Precipitation
Heavy downpours are increasing nationally, especially over the last three to five decades. The largest increases are in the Midwest and Northeast.

Heat Waves
Heat waves have become more frequent and intense, especially in the West.

Floods
Floods have been increasing in parts of the Midwest and Northeast.

Drought
Drought has increased in the West. Over the last decade, the Southwest has experienced the most persistent droughts on record.

Hurricanes
The intensity, frequency, and duration of North Atlantic hurricanes, as well as the frequency of the strongest (category 4 and 5) hurricanes, have all increased since the early 1980s.

Cold Waves and Winter Storms
Cold waves have become less frequent and intense across the Nation. Winter storms have increased in frequency and intensity since the 1950s and their tracks have shifted northward.

Sea Level
Sea levels along the Mid-Atlantic and parts of the Gulf Coast have risen by about 8 inches over the last half century.

Figure 1: U.S. national and regional climate trends[10]

Public health and emergency management organizations regularly respond to such natural incidents, but the increasing intensity of weather can act as a threat multiplier. Emergency response can be further complicated as extreme weather may exacerbate poverty, environmental degradation, emerging infectious diseases, vector-borne diseases, epidemics, chronic health problems, and social and political unrest.

Frequent, wide-scale, or acutely devastating incidents can:

- Result in surge for services that can overwhelm public health and medical resources;

- Damage or destroy health infrastructure further limiting access to life-saving or life-sustaining products and/or services; and

- Result in damages to communities' public health and health care systems resulting in loss of services and economic impact.

Pandemic and Infectious Diseases

"The increase in frequency and diversity of reported disease outbreaks—such as dengue and Zika—probably will continue through 2018, including [the potential] for a severe global health emergency that could lead to major economic and societal disruptions, strain governmental and international resources, and increase calls on the U.S. for support. A novel strain of a virulent microbe that is easily transmissible between humans continues to be a major threat."
(Worldwide Threat Assessment, 2018)

Globalization, population density acceleration, urbanization, and increased proportion of immunocompromised and/or unvaccinated individuals are all powerful trends of the 21st century, which have the ability to reshape human interaction and society at large. Interconnectedness spans national boundaries, remote areas, and long distances, affecting travel, trade, and the distribution of people. Unintended consequences include hastened disease transmission (through increased mobility and access to remote areas) and increased health risks for the nation and U.S. citizens living abroad. Destabilized areas abroad may pose shared risks in critical global supply chains or raw materials, affecting health in the United States.
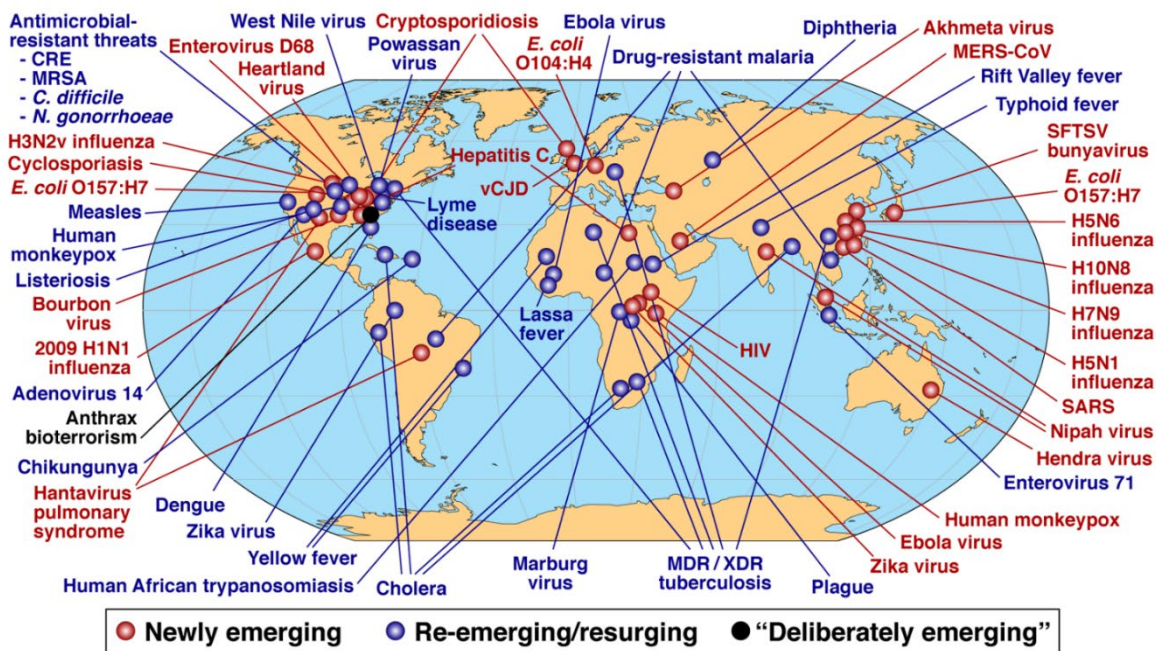

Figure 2: Global Examples of Emerging and Re-Emerging Infectious Diseases[11]

The increasing threat of infectious diseases crossing international borders and affecting our population is already evident. New strains of the influenza virus with pandemic potential continue to emerge globally, making early detection and response fundamental to saving lives and reducing medical costs and economic impact. Not all emerging infectious diseases can result in a global pandemic. However, some pathogens represent a dual threat of having pandemic potential and utility as a bioterrorism or biological warfare agent.

Additionally, the growing resistance to antibiotic medicines and other antimicrobial compounds increases the threat of infectious diseases. The Centers for Disease Control and Prevention (CDC) has estimated that drug-resistant bacterial infections kill approximately 23,000 people and cause 2 million infections in the United States annually, resulting in estimated annual costs of $20-$35 billion in excess healthcare expenditures and lost productivity[12]. While antibiotic resistance (AR) threats vary globally, AR exists in every part of the world. Germs with unusual resistance genes that are resistant to all or most antibiotics tested are constantly developing

and spreading. The ability to exploit AR for malicious purposes with today's molecular biology tools is not a difficult task. The growing incidence of AR has both public health and national security consequences. In addition to preparing for AR in potential bioterrorism agendas, the diminishing number of effective antimicrobial compounds against naturally circulating pathogens increases the likelihood that, in the future, common infectious diseases may be resistant to available antimicrobial therapies. Expanding the antimicrobial arsenal is a real and immediate requirement to avoid an era of untreatable infectious diseases.

Technology and Cyber Threats

"The risk is growing that some adversaries will conduct cyberattacks—such as data deletion or localized and temporary disruptions of critical infrastructure—against the U.S. in a crisis short of war."
(Worldwide Threat Assessment, 2018)

Technological advancements in health care continue to save lives. However, increased use and dependence on information technologies such as electronic health records and connected medical devices potentially puts sensitive patient data at risk. As our health delivery systems become more networked, incidents like the 2017 WannaCry cyberattack remind us that technological advancements have trade-offs in the form of new vulnerabilities and risks. Technology can produce consequences by:

- Creating dependency on technology that pervades society, requiring investments in defensive backup, anti-virus, and security systems; awareness training; and vigilance;

- Introducing cyber threats characterized by the exploitation of systems for monetary or political gain;

- Accelerating development and availability of various types of weaponry for malicious purposes; and

> The **2017 WannaCry cyberattack** disrupted over 200,000 computers in more than 150 countries. One of the largest agencies affected was the National Health Service with hospitals in England and Scotland, impairing 70,000 devices including computers, MRI scanners, blood-storage refrigerators, and surgery theatre equipment. The WannaCry cyberattack caused some services to turn away non-critical emergencies and divert ambulances the day of the attack.

- Generating opportunities for misuse of scientific research and sensitive or classified public health intelligence or information.

Similar to a physical attack, a cyberattack could broadly damage critical infrastructure that affects public health and health care, such as power grids, or specifically target public health and medical infrastructure, severely impacting patient treatment.

Biotechnology presents new vulnerabilities and opportunities in the current threat landscape. Synthetic biology (which combines biology and engineering with the goal of designing new organisms or re-designing existing cellular processes) and new gene editing technologies have enormous potential to improve diagnostics, MCMs, and other aspects of public health, agriculture, plant, and animal health.

The field of synthetic biology has advanced rapidly in recent years, and several experiments have generated security concerns. For example, Clustered Regularly Interspaced Short Palindromic

> **CRISPR/Cas9** is a multifunctional gene-editing technology that can be used to disrupt, replace, or regulate (turn expression on/off) genes. The power, low cost, and growing ubiquity of this technology has raised concerns that it could be misapplied to make more effective bioweapons.

Repeats (CRISPR) technology has tremendous potential to reduce disease transmission, enhance resistance to disease, improve disease diagnostics, create novel MCMs, and advance basic research. Effective oversight of "dual-use" research and a strong culture of biosafety, biosecurity, and responsible scientific conduct are critical for mitigating the risks of synthetic biology while encouraging beneficial research and commercial applications.

Chemical, Biological, Radiological, and Nuclear Threats

> *"Both state and non-state actors have already demonstrated the use of chemical weapons in Iraq, Syria, and the UK. Biological and chemical materials and technologies—almost always dual-use—move easily in the globalized economy, as do personnel with the scientific expertise to design and use them for legitimate and illegitimate purposes."*
> (Worldwide Threat Assessment, 2018)

Rapid technological advancements interact with the changing character of hostile actions, making human-caused incidents, especially CBRN incidents, imminent possibilities. A CBRN incident has the potential to cause mass casualties and fatalities, as well as damage to infrastructure, the environment, and the economy. Intentional attacks such as the large-scale release of a biological or chemical agent or the detonation of a nuclear device, or accidents such as a nuclear power plant meltdown, would stress U.S. public health and health care systems in extraordinary ways, including:

- The initial release of a hazardous substance could go undetected until the onset of disease in humans or animals, creating a sudden influx of patients and possibly loss of life;

- Incidents that result in impairment or loss of power, food, and water supplies as well as transportation and communication barriers may affect or cripple public health and health care services;

- Trauma of a CBRN attack and subsequent fears of exposure or contamination may inhibit the health care workforce, strain behavioral health providers, and cause civil disorder;

- First responders and health care workers will risk exposure and contamination in the undetected phases of a CBRN attack and during early response operations;

- Secondary infections with antibiotic resistant organisms may further complicate care for people exposed to specific agents; and

- Challenges in monitoring long-term health status and environmental impacts may complicate recovery operations.

The National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases maintains prioritized biodefense organism lists, commonly referred to as Category A, B, and C Priority Pathogens. These lists are updated annually and include pathogens or toxins thought to pose the highest risk to U.S. national security and public health.

Category A (highest risk)	Category B (second highest risk)	Category C (third highest risk)
• Can be easily disseminated or transmitted from person to person • Result in high mortality rates and have the potential for major public health impact • Might cause public panic and social disruption • Require special action for public health preparedness	• Are moderately easy to disseminate • Result in moderate morbidity rates and low mortality rates • Require specific enhancements for diagnostic capacity and enhanced surveillance	Include emerging pathogens that could be engineered for mass dissemination in the future because of: • Availability • Ease of production and dissemination • Potential for high mortality rates and major health impact

Table 1: Category A, B, and C Priority Pathogens[13]

Furthermore, the 2017-2018 PHEMCE Strategy and Implementation Plan lists high-priority CBRN threats which either the Secretary of the Department of Homeland Security (DHS) has determined pose a material threat sufficient to affect national security or PHEMCE leadership [HHS, DHS, Department of Defense (DoD), Department of Veterans Affairs (VA), and Department of Agriculture (USDA)] has determined have the potential to threaten national health security.

Even during steady state periods, our public health and health care systems operate amid major challenges. To meet the threats in this new landscape, we will confront the capability gaps in the systems that operate at the intersection of health and national security. We will continue work to strengthen—and, where needed, reimagine—public health infrastructure, health care systems, and MCM capabilities. We will better support SLTT disaster risk reduction, preparedness, mitigation, response, and recovery efforts to overcome this new era of health security challenges.

STRATEGIC APPROACH

We will pursue an approach which emphasizes one of America's greatest strengths—our nation is made up of communities and networks of stakeholders that can act collectively to safeguard and improve the lives of our people. We will also capitalize on the advanced biomedical research and biopharmaceutical manufacturing infrastructure to promote innovation and improvements in the MCM enterprise. We will build on our efforts to bridge health care, public health, and emergency management to create a more integrated, networked, and resilient system. This national health security enterprise will be built upon operationally sound principles and with the strength to handle routine emergencies as well as potentially catastrophic incidents.

We will bring in new partners across the government, in the private sector, and in Non-Governmental Organizations (NGOs). We will create distributed networks to incentivize the nation's dispersed health care system to work together and function efficiently in matters of national health security. We will integrate diverse stakeholders into these networks and create touchpoints between networks. We will empower communities, family units, and individuals with preparedness and response information that will improve their resilience to health security threats.

As we continue work to build the most effective health response system in the world, increasing risk trends prompt us to improve preparedness to prevent emergencies and, when unforeseen events arise, act. We will guide stakeholders to understand the causal factors of risks,

vulnerabilities, and the hazards which exacerbate them. We will work to apply practical, real-world strategies to reduce and mitigate health security risks.

We will foster a competitive mindset that drives innovation and streamlines processes and efficiencies. We will apply this approach to the challenges facing public health and health care in today's world. We will help stakeholders and decision-makers understand the real risks from health security threats. We will address vulnerabilities in a fragile medical product supply chain and will swiftly prepare for the threats that may arise from rogue regimes and revisionist powers.

To forward this strategic approach we will focus on three objectives:

1. Prepare, mobilize, and coordinate the Whole-of-Government[iii] to bring the full spectrum of federal medical and public health capabilities to support SLTT authorities in the event of a public health emergency, disaster, or attack;

2. Protect the nation from the health effects of emerging and pandemic infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats; and

3. Leverage the capabilities of the private sector.

Objective 1: Prepare, Mobilize, and Coordinate a Whole-of-Government Approach

"In the event of a disaster, federal, state, and local agencies must perform essential functions and have plans in place to ensure the continuation of our constitutional form of government."
U.S. National Security Strategy (NSS), December 2017[14]

A successful whole-of-government approach starts with providing leadership in domestic and international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response. At the federal level, this approach is a shared mission carried out by multiple agencies across government.

Departments that support national health security efforts include, but are not limited to, HHS, DoD, DHS, VA, USDA, the Department of Justice, the Department of Energy, the Department of Education, Department of State, and the Environmental Protection Agency. Agencies within HHS that support national health security include the Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, NIH, the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), the Administration for Community Living , the Health Resources and Services Administration, and the Substance Abuse and Mental Health Services Administration, among others.

A constantly changing threat landscape requires the nation to remain flexible and actively adapt our operational capabilities. The U.S. Government understands that many stakeholders work together and share a collective responsibility for national health security. These include SLTT governments and public and private partners, NGOs, academia, professional associations, communities, volunteers, families, and individuals.

All relevant partners in the U.S. Government will continue to be at the forefront of these changes and provide the leadership, direction, and support to combat whatever threats arise. To provide

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[iii] Whole-of-Government refers to public service agencies working across portfolio boundaries to achieve a shared goal and an integrated government response. Approaches can be formal and informal and include government partners at federal, state, tribal/territorial, and local levels.

strong leadership and mobilize a whole-of-government approach, we will target the following areas.

Convene a Unified, National Response and Recovery to Public Health Emergencies and Disasters

ASPR, in coordination with HHS and federal partners, leads the nation's public health and medical preparedness and response and its health and social services recovery efforts, as delegated by Emergency Support Function #8, and the Health and Social Services Recovery Support Function. These efforts provide unified national leadership and guidance to public health and health care stakeholders before, during, and after disasters. We recognize that SLTT stakeholders are on the front line during response and may need timely and appropriate federal support to augment their resources and capacity. Therefore, it is critical to improve situational awareness and coordination across the federal interagency and with regional and SLTT partners.

In addition, we will continue work with international partners to make sure our preparedness and response efforts are aligned with those of the global community. We will sustain efforts to organize, train, equip, and exercise response capabilities. We will identify health care readiness standards to assess coalition readiness status and ensure exercises test system resilience against routine and catastrophic threats.

Improve Threat and Situational Awareness

Improving awareness of threats will help define the capabilities and requirements the nation needs to better prepare for, respond to, and recover from emergency events and disasters. We must be prepared to adjust our strategies rapidly based on lessons learned as we respond to threats in real time. We will implement an integrated approach to situational awareness that leverages the capabilities of multiple federal agencies, SLTT governments, foreign countries, and domestic and international non-governmental entities. We will continue to improve coordination of domestic and international public health surveillance and detection systems. We will work with the intelligence community, law enforcement, the military, research and development (R&D), academic, and other relevant sectors (e.g., animal health, environmental health, agriculture) to rapidly characterize new and evolving threats.

> The HHS **emPOWER Map** helps community partners better anticipate, plan for, and respond to the needs of electrically dependent populations in each community. emPOWER data enhances situational awareness and provides actionable information for assisting areas and at-risk individuals that are impacted during a disaster.

Enhance Partnerships and Engagement at the Federal and SLTT Levels and Among Communities, Families/Family Units, and Individuals

Emergency preparedness, mitigation, response, and recovery benefit from strategic partnerships among all levels of government and the private sector. Building on the successful efforts of key programs such as PHEP and HPP, we will:

- Identify and use expertise inside and outside all levels of government to identify critical challenges;

- Continue to support public health and health care organizations to improve their capacity and resiliency;

- Provide SLTT stakeholders with a clear point of contact during public health emergencies and offer practical guidance and communication;

- Inform communities, families/family units, and individuals about threats and response strategies/tactics to improve their resiliency to public health emergencies and disasters.

- Enhance PHEMCE actions by engaging with SLTT governments to inform the MCM enterprise and distribute, dispense, monitor, and assess the safety and efficacy of MCMs provided to the public;

- Promote disaster risk reduction and mitigation approaches to build resilience at the federal and SLTT levels, in communities and families/family units, and among individuals; and

- Build on partnerships with behavioral health and human services programs to ensure support is available to affected victims, disaster incident survivors, and first responders, including volunteers.

Enhance Partnerships and Engagement at the International Level

Sustaining and strengthening global partnerships and international response coordination policies and plans is critical to prepare for and respond to Public Health Emergencies of International Concern that may, or do, affect the United States. Through the U.S. Health Security National Action Plan and the GHSA, we will:

- Continue work with select international partners to help build international and U.S. capacities to prevent, detect, communicate, and respond to public health emergencies, under the framework of International Health Regulations (IHR) (2005);

- Seek to enhance strong relationships and rapid communication mechanisms with the World Health Organization's Health Emergencies Programme and international partners in order to better coordinate with global activities and in response to infectious disease threats; and

- Align and develop jointly with our national health security partners the appropriate preparedness policies, plans, and tools for a faster, more efficient response to public health emergencies of international concern.

Coordinate with Non-federal Partners and the Private Sector

While the U.S. health care system has made advancements in developing coalition networks, it faces new vulnerabilities involving cyberattacks, fragile medical product supply chains, and other systemic challenges. These vulnerabilities require a different kind of network; one based on a distributed system of coordination, integration, mutual aid, and specialization. We will work through public-private partnerships to:

- Promote a One Health approach to collecting situational awareness data across human, animal, plant, and environmental health;

- Prioritize bi-directional communication with partners;

- Leverage medical equipment and supplies and the assistance of volunteers;

- Ensure medical response is coordinated through mutual aid agreements that include regional jurisdictions; and

- Prioritize incentives toward critical infrastructure mitigation and preparedness and cybersecurity.

> **One Health** is defined as "a collaborative, multisectoral, and transdisciplinary approach—working at local, regional, national, and global levels—with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment."

As federal assets, the National Disaster Medical System (NDMS)[15] and the U.S. Public Health Service Commissioned Corps can work with state, local, and private health care systems to ensure continuity of care, decompress health care system stress, and support pre-hospital, in-patient, out-patient, behavioral health, home, and community-based health and human services.

Build Regional Disaster Health Response Capabilities

Risks disrupting larger geographic areas for longer durations require specialized capabilities and mutual aid to extend well beyond state lines. Federal capabilities alone cannot meet all of the needs following a large-scale or catastrophic incident. The nation needs a unified, regional approach to improve national health care readiness and medical surge capacity. This may be accomplished by integrating preparedness within the already-existing health care delivery infrastructure across the public and private sectors.

Building regional disaster health response capabilites may be accomplished through collaboration among local health care coalitions, trauma centers, public and private health care facilities, and emergency medical services. Regional collaboration may optimize health care delivery capabilities and capacity by enhancing coordination across local, state, regional, and federal health care response assets, and improving bidirectional communication and situational awareness of medical needs and issues in a response.

> **NDMS (a partnership among HHS, DHS, DoD, and VA)** provides patient care, patient movement, and definitive care; veterinary services; and fatality management to support SLTT authorities during a public health emergency or disaster. NDMS teams such as **Disaster Medical Assistance Teams (DMAT)** work with patient care in hospitals, health care facilities, medical sites and shelters, and provide mass prophylaxis during a disease outbreak.

Furthermore, medical surge capacity may be coordinated and supported through NDMS, the HHS Critical Infrastructure Protection program, HPP, the Medical Reserve Corps, the U.S. Public Health Service Commissioned Corps, and ASPR's Regional Emergency Coordinators, among others.

Communication and planning before a catastrophe will ensure patients arrive at the right place and receive the appropriate level of care, irrespective of their starting location. The U.S. Government will provide guidance and support to the public and private sectors to integrate public health, emergency management, emergency medical services, NDMS, regional coalitions, and other non-traditional health care providers. Other elements of planning and coordination may:

- Include other partners such as 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;

- Involve real-time, real-world training for all types of incidents, including CBRN and cyber threats; and

- Integrate NDMS teams into hospitals, coalitions, and SLTT planning.

Figure 3: DMAT providing patient care

Enhance Delivery of Specialized Care

In addition to preparing for natural disasters for generally healthy populations, responding effectively to incidents such as CBRN requires access to clinical specialists in areas such as pediatrics, trauma and burn care, and infectious disease. Building regional health response capabilities will further develop specialty care expertise critical to unusual hazards or catastrophic incidents. Establishing mechanisms for sharing clinical expertise can address critical gaps in patient care following a catastrophic incident.

Coordination of specialty care could include a hub and layered-spoke system that does not require all hospitals and health care facilities to have the same advanced level of care, but rather centralizes expertise and increases capabilities for education and consultation. For example, regional centers can provide specialized care to patients, assessment hospitals can safely isolate a patient while diagnosis is underway, and other centers can address specific population needs such as pediatric or geriatric trauma.

The 2014-2015 Ebola outbreak resulted in the creation of a **regional network for caring for patients with Ebola and other highly infectious diseases**. This network consists of 10 regional Ebola and other special pathogen treatment centers, more than 60 state-based Ebola Treatment Centers, and more than 150 Assessment Hospitals. This innovative approach has resulted in a national, regional, and local capability to respond to future outbreaks.

Objective 2: Protect the Nation from Emerging and Pandemic Infectious Diseases and CBRN Threats

"We will strengthen our emergency response and unified coordination systems to rapidly characterize outbreaks, implement public health containment measures to limit the spread of disease, and provide surge medical care—including life-saving treatments." (NSS, 2017)

Deepen Interoperability

All levels of government and society have roles to play to improve the nation's ability to actively respond to and recover from 21st century threats and reduce illness, injury, and loss of life to first responders and victims. Changing threats require the combined strength of all of our capabilities, including intelligence, law enforcement, and homeland security, military and veteran stakeholders. We will organize partners across the government, the private sector, NGOs, professional associations, and academia to improve interoperability to quickly and effectively detect disease outbreaks and CBRN threats. This multi-sectoral approach will include the following:

- Improved communication and planning among public health, disaster response, and intelligence communities; the military; law enforcement; and other relevant sectors;

- Greater coordination with non-government entities, including private sector hospitals and the full array of health care providers, the R&D community, NGOs, and academia; and

- Greater integration of partners, including local agencies in affected areas, into fusion centers to rapidly gather, assess, and share information and surveillance data.

Support and Sustain a Robust and Reliable Public Health Security Capacity

A strong public health system is a cornerstone of national security. We will further develop the interoperability of our federal, SLTT, and global public health security partners to quickly and effectively identify and counter public health threats whether they originate at home or abroad. We will support a robust and reliable public health security capacity by continuing:

- Disease situational awareness domestically and abroad, including detection, identification, and investigation;

- Disease containment, including capabilities for isolation, quarantine, prevention, diagnostics, and treatment;

- Risk communication and public preparedness; and

- Strong domestic public health policies, plans, and capabilities and capacity to mitigate disease impact.

> **The Global Health Security Agenda (GHSA)** is a multi-sectoral and multilateral effort launched in 2014 to accelerate progress toward compliance with IHR (2005) and other relevant international frameworks and agreements. More than 60 countries have joined the GHSA making commitments to build capacities to detect, prevent, and respond to emerging infectious diseases at the national, regional, and/or global levels.

Modernize Key Public Health Security Capabilities

We must be prepared for newly emerging and re-emerging infectious diseases (such as pandemic influenza, Ebola virus, and Zika virus) and the potential for these diseases to be animal-related or have factors exacerbated by the environment. These health threats—and others like antimicrobial resistance and the potential use of CBRN weapons by adversaries—present imminent and evolving risks to national health security. We must modernize key areas such as cybersecurity, agile logistics, command and control, surveillance, laboratory testing and diagnostics, and decontamination capabilities to keep pace with an increasingly complex threat environment.

As the lead federal agency for disease detection, investigation, and response, CDC's expertise in research, surveillance, clinical guidance, monitoring and reporting, as well as the development and distribution of diagnostic tests and safety guidelines, will remain pivotal before, during, and after public health emergencies. In conjunction with CDC, interagency partners will continue to marshal the best science and tools for health surveillance, epidemiological investigation, and disease detection. Efforts such as developing new antibiotic therapies are complemented by national actions to improve detection, prevention, and antibiotic use.[16]

We live in a highly-interconnected world and must rely on surveillance capabilities abroad to identify threats before they reach the homeland. Human health is also connected to the health of animals, plants, and the environment. We will continue surveillance across the One Health spectrum to provide early warning detection and diagnosis.

Strengthen the Nation's Ability to Expedite the Development and Availability of MCMs

MCMs remain our most effective approach toward mitigating the health consequences of CBRN and naturally-caused, emerging infectious threats. PHEMCE partners collaborate to conduct research and develop MCMs, with NIH conducting basic research through early clinical research, and BARDA supporting advanced development. In addition, as home to one of only two laboratories in the world that can work with live variola virus, CDC plays an important role in basic research through clinical research for smallpox MCMs. Strategic plans from these agencies such as the BARDA Strategic Plan and the annual PHEMCE Strategy and Implementation Plan provide a vision for R&D to stockpile and replenish the Strategic National Stockpile (SNS) and ensure our MCMs remain at the cutting edge of technology. Additionally, these plans prioritize effective, rapid production and dissemination of MCMs that will most significantly reduce morbidity and mortality from public health emergency threats.

To address the challenges of MCM R&D, we must accelerate our efforts to pursue innovative approaches to development, and use MCM public-private partnership models. We must also pursue approaches to accelerate MCM licensure. While these efforts continue, we must pivot toward enabling a faster response. We will progress toward a rapid-development posture by improving MCM response platforms that can transition quickly between MCM products. A faster response is not defined solely by the scientific advancements in the development process. It is also defined by the pursuit of novel public-private partnerships with industry and streamlined processes.

HHS and DoD collaboration builds on their respective longstanding research programs to accelerate identification of potential MCM candidates against a range of diseases. This cooperation has already led to successful development of monoclonal antibodies (mAb), which represent a potential and powerful technology, and may allow us to create products quickly to treat both known and novel threats.

> **mAbs** currently in the SNS, and those under development by BARDA, are specific to anthrax, botulism, and Ebola. Ongoing efforts at CDC also include work on smallpox, and research at NIH includes a range of pathogens, such as Ebola, MERS-CoV, Zika, and antibiotic-resistant bacteria. Additionally, DoD has information on mAbs for diagnostic purposes in a variety of viral diseases such as Rift Valley, dengue, and yellow fever.

Address 21st Century Threats, Maintain 21st Century Posture

We acknowledge that 21st century threats must drive our research choices—and that these threats are both known and unknown. This shift in thinking means a conversion from the development of a single "known bug, known drug" approach to a multifaceted approach that prepares for the known threats while scaling up development based upon novel threats. The components of increased speed and flexibility to the nation's production of MCMs include:

- Conducting 21st century threat analyses and integrating these risks into ongoing planning and preparedness activities;

- Analyzing the drug production process to identify steps that can be expedited;

- Streamlining internal federal processes to promote fast, flexible decision-making and funding;

- Prioritizing dedicated MCM production facilities;

- Promoting innovation and capitalizing on advances in science and biotechnology;

- Making evidence-based and timely decisions to prioritize MCM candidates; and

- Revitalizing the PHEMCE with enhanced collaboration, coordination, streamlining and transparency of processes and decision making.

In order to ensure the nation has additional capacity to respond to pandemics or other threats, HHS entered into novel public-private partnerships to establish manufacturing and response capacity through a coalition of government-sponsored facilities known as the **Centers for Innovation in Advanced Development and Manufacturing (CIADM)**. The CIADMs were utilized during the Ebola and Zika responses.

Develop the Public Health Workforce to Address 21st Century National Health Security Threats

We must train and equip our public health and medical workforce to rapidly adapt to new threats. Evolving risks—including the potential for CBRN threats brought about by adversaries—requires modernization of the skill sets of public health professionals to address the physical and psychological health of first responders and victims. A highly mobile, globalized population could enable an infectious disease to arrive within our borders in less than a day. We will continue to work with the public health and health care communities to update needed competency areas, train the workforce, and recruit subject matter experts to address imminent and potentially catastrophic national health security risks.

The **National Center for Disaster Medicine and Public Health (NCDMPH)** is strategically situated within the federal interagency to help advance the readiness of the public health and medical workforce through enhanced collaborative efforts in disaster health research and education. NCDMPH leads federal efforts to develop and propagate core curricula, training, and research related to medicine and public health in disasters

We will continue to develop response and recovery plans. We will also prepare for high-impact events such as pandemics and CBRN attacks by:

- Planning for widespread incidents that require aggressive social distancing measures (domestic and international);

- Improving training in use of personal protective equipment and capabilities for decontamination, isolation, quarantine, and fatality management; and

- Conducting research, and developing scientifically based decontamination processes, techniques, training, and capabilities for human and animal (e.g., service animals/pets) CBRN decontamination.

Advance Laboratory Safety, Security, and Capacity

Scientific research is critical for protecting the nation and developing national capabilities (including MCMs) to mitigate the risks of infectious diseases. Biorisk management systems mitigate the potential for an accidental or intentional release of biological material from a

laboratory. We must ensure the benefits of scientific research are effectively realized, while the potential for misuse is minimized by:

- Strengthening biosafety and biosecurity by improving programs, policies, training, and practices, conducting basic and applied biosafety research, and encouraging pre-incident response planning;

- Supporting responsible conduct in the life sciences through promoting a culture of responsibility, effective oversight of dual-use research, and engagement with nontraditional and amateur research communities; and

- Working with national and international stakeholders to implement and strengthen biosafety and biosecurity risk management frameworks.

Strengthening public health infrastructure by ensuring appropriate laboratory capacity and biocontainment is critical. The Laboratory Response Network, established by CDC, is a national security asset tasked with maintaining an integrated network of SLTT, private, academic, military, and international laboratories with the capacity to respond to biological incidents and other public health emergencies. It is important to promote and protect laboratory infrastructure, continue to improve interoperability of laboratory reporting systems, and address timely sharing of sample agents and data with other laboratories, government agencies, and key law enforcement agencies.

Mitigate Disease Impact

The U.S. population, as well as U.S. citizens traveling abroad, deserve to know the health risks they face during all phases of natural disasters, CBRN incidents, disease outbreaks, and other incidents. We will provide risk-informed, accurate, timely, and actionable health information. We will continue to take advantage of our progressive communication platforms such as CDC's Crisis and Emergency Risk Communication to reach all individuals, including those with access and functional needs.

We will continue to build our arsenal of public health measures (e.g., public messaging and when indicated, social distancing) to provide a "cushion" of time to develop MCMs against 21st century health threats. Effective use of communication to the public, personal protective equipment for frontline health care workers, and non-pharmaceutical interventions will reduce exposure and infection with the goal of providing time to develop an MCM.

We will continue to safeguard against the risks posed by influenza. The influenza virus regularly mutates, in some cases becoming resistant to treatment and/or increasingly harmful. We will continue efforts that seek to expand domestic vaccine production capacity, enhance real-time data, respond faster, and deter the spread of the virus through public messaging and community mitigation measures such as social distancing, personal protective equipment, and isolation and quarantine if indicated.

> After the 2009 H1N1 pandemic, the United States moved to expand domestic manufacturing capacity for pre-pandemic vaccines. Under ASPR support, we have **increased pre-pandemic vaccine antigen manufacturing capacity** from 60 million doses to 600 million doses.

Since many of the disease threats we face are global in nature, we will continue to engage with the international community across sectors to strengthen global health security through

17

information sharing, strategic and operational planning, training and exercising, and capacity building. We will work with our partners around the world to protect the nation against these threats, regardless of their source.

Effective and rapid dissemination of MCMs

It is essential that we provide on-the-ground decision-makers, first responders, emergency management and public health officials, and clinicians with tools that guide the effective integration of MCMs into a response. We will provide clear and easy to follow guidance that SLTT and public health and health care stakeholders may use to inform their development of MCM response strategies. Effective MCM guidance and plans will allow decision-makers to strategically select the right actions and MCMs to go with the threat and the population dynamics of the community. We will support SLTT partners to develop and exercise MCM plans that are based on operational realities and include critical players, such as first responders. We will develop and maintain the federal and SLTT deployment, distribution, and dispensing capabilities needed to ensure effective provision of MCMs to all segments of the population, including pediatric and other vulnerable populations.

Objective 3: Leverage the Capabilities of the Private Sector

"The U.S. Government will use private sector technical expertise and R&D capabilities more effectively. Private industry owns many of the technologies that the government relies upon for critical national security missions….[The U.S. Government will] establish strategic partnerships with U.S. companies to help align private sector R&D resources to priority national security applications." (NSS, 2017)

Develop Partnerships to Create MCMs

A cornerstone of our MCM approach will remain partnering with industry. The U.S. Government will continue efforts to develop more flexible, nimble, and stable partnerships with the domestic and international pharmaceutical industry. We will implement partnership strategies to ensure MCMs can quickly traverse advanced R&D when no stable commercial market exists. We will leverage innovative public-private partnership models for use for MCM development. Past partnerships have resulted in dozens of stockpiled and multi-purpose products. New partnerships will continue to emphasize these qualities while also:

> HHS, in collaboration with the Wellcome Trust of London, the Bill and Melinda Gates Foundation, and the U.K. government, is involved in the **Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)**. This innovative public-private partnership was launched in just one year and is showing early signs of success. To date, CARB-X is supporting 33 antibacterial products including novel classes, non-traditional products, and diagnostics.

- Focusing on the speed of contracts and the flexibility of different types of contracts, such as Other Transaction Authorities;

- Allowing industry to pivot research appropriately; and

- Creating partnership models that are based on response needs and intertwined with speed and flexibility for MCM development and licensure.

Foster a Resilient Medical Product Supply Chain

To shore up the medical product supply chain, the government will partner with industry at home and abroad to plan around real-world considerations, such as a consolidated pharmaceutical

marketplace with interdependencies and a limited number of manufacturers. We will work with our partners to:

- Reinforce medical product supply chains;

- Explore approaches to domestic and geographically-dispersed production of health care equipment and supplies; and

- Address challenges in transporting and receiving health care equipment and supplies, including across national, state, county, local, and territorial borders and outside the continental United States.

Incentivize Preparedness

The U.S. health care system is predominately owned and operated by the private sector. Therefore, incentivizing the private sector is crucial to promote adoption and integration of preparedness as a normal part of operations. The all-hazards risk assessment, planning, and training approach of CMS's Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers rule[17] was a good first step toward continuity of operations. We must continue to address preparedness, mitigation, response, and recovery at the federal, regional, and SLTT levels by ensuring:

- Preparedness includes primary care and health care systems that are not Medicare-certified;

- Measures of preparedness are integrated into standards of care;

- Crisis standards of care are clearly described and readily understood by health care providers;

- States are encouraged to adopt portability of health professionals' licensure and reciprocity to ensure medical professionals can seamlessly provide care across state and territorial lines; and

- Pre-hospital emergency medical services are integrated into health care coalitions and preparedness activities.

In addition, during response and recovery individuals with access and functional needs may have greater challenges accessing services or may be displaced for longer periods of time. Effective national health security requires planners, emergency responders, health professionals, public health specialists, educators, community organizations, families, and individuals to work together to address the needs of at-risk individuals (such as older adults, individuals with disabilities, individuals with limited English proficiency, people relying on home-health care, and children).

Streamline Processes and Increase Efficiencies

We must always remain focused on the mission to save lives and protect our nation. We will continuously identify ways to streamline processes to deliver efficient services, including:

- Reducing administrative burdens and providing more flexibility to federal grant recipients so they can better adapt to threats and challenges;

- Reducing barriers to increase the health care workforce's ability to respond to incidents, such as streamlining cross-state/territory recognition of medical licensure to allow out-of-state professionals to practice and easing barriers for quickly hiring personnel during a response; and

- Clearly defining roles and responsibilities in public health emergencies and developing efficient interagency and SLTT integration to enhance capabilities and eliminate duplication of effort.

CONCLUSION

Our nation faces real—and potentially imminent—health security threats. Threats are evolving every day, so we cannot wait to build a robust response. To safeguard the health and well-being of our people, the strategies outlined in the NHSS must be brought to bear swiftly and effectively. This will require the involvement of the American people, their government, and the public health and health care systems that serve them.

The execution of the NHSS must be adaptable and nimble to prepare for and address rapidly evolving health threats in the current and projected strategic environment. All levels of government and society have roles to play to improve the nation's health security. We must strategically strengthen our partnerships with the aim of improving operational effectiveness and building needed capabilities. We must marshal our best minds and best practices to spur innovation to counter emerging risks, some of which we have not faced in our lifetimes.

These challenges to our nation's health and well-being—whether naturally occurring or human-caused—are significant. But history has shown that the American people can meet any challenge when there is the collective will to do so.

APPENDIX A: NHSS STATUTORY REQUIREMENTS

Every four years, Congress directs HHS to prepare three closely related documents: the EOP, which evaluates progress made from 2015-2018 (including an evaluation of HPP, PHEP, and vaccine tracking activities), the NHSS Strategy document, and the IP, which operationalizes the Strategy. Throughout all three documents are specific preparedness goals, identified earlier by Congress, which each of the three documents address in their respective contexts.

The NHSS shall include provisions in furtherance of the following:[iv]

1. **Integration** – Integrating public health and public and private medical capabilities with other first responder systems, including through: (A) the periodic evaluation of federal, state, local, and tribal preparedness and response capabilities through drills and exercises, including drills and exercises to ensure medical surge capacity for events without notice; and (B) integrating public and private sector public health and medical donations and volunteers.

2. **Public Health** – Developing and sustaining federal, state, local, and tribal essential public health security capabilities, including the following: (A) disease situational awareness domestically and abroad, including detection, identification, and investigation; (B) disease containment, including capabilities for isolation, quarantine, social distancing, and decontamination; (C) risk communication and public preparedness; and (D) rapid distribution and administration of MCMs.

3. **Medical** – Increasing the preparedness, response capabilities, and surge capacity of hospitals, other health care facilities (including mental health and ambulatory care facilities and which may include dental health facilities), and trauma care, critical care, and emergency medical service systems, with respect to public health emergencies (including related availability, accessibility, and coordination), which shall include developing plans for a number of specified medical considerations (see actual statute for full text of all noted details).

4. **At-Risk Individuals** – Taking into account the public health and medical needs of at-risk individuals, including the unique needs and considerations of individuals with disabilities, in the event of a public health emergency. (For the purpose of this section, the term ''at-risk individuals'' means children, pregnant women, senior citizens, and other individuals who have access and functional needs in the event of a public health emergency, as determined by the Secretary).

5. **Coordination** – Minimizing duplication of, and ensuring coordination between, federal, state, local, and tribal planning, preparedness, and response activities (including the State Emergency Management Assistance Compact). Such planning shall be consistent with the National Response Plan, or any successor plan, the National Incident Management System, and the National Preparedness Goal.

6. **Continuity of Operations** – Maintaining vital public health and medical services to allow for optimal federal, state, local, and tribal operations in the event of a public health emergency.

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iv Section 2802 of the Public Health Service Act (42 U.S.C.300hh-1)

7. **Countermeasures** – Promoting strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, chemical, radiological, or nuclear agent or agents, whether naturally occurring, unintentional, or deliberate.

8. **Medical and Public Health Community Resiliency** – Strengthening the ability of states, local communities, and tribal communities to prepare for, respond to, and be resilient in the event of public health emergencies, whether naturally occurring, unintentional, or deliberate by optimizing alignment and integration of medical and public health preparedness and response planning and capabilities with and into routine daily activities; and promoting familiarity with local medical and public health systems.

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