## National Health Security Strategy Evaluation of Progress

# 20192022











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## Executive SUMMARY

This Evaluation of Progress, as mandated by the Public Health Service Act, examines the actions taken by the United States between 2019 and 2022 to meet the three objectives of the <u>2019-2022 National Health Security Strategy</u> (NHSS).<sup>1,2</sup> From 2019 to 2022, the United States faced numerous health security threats. Novel threats like coronavirus disease 2019 (COVID-19) emerged, while known threats persisted.

The COVID-19 pandemic presented immense health security challenges for the United States. Congressional action was instrumental in mitigating these challenges. The release of supplemental funding to federal departments and agencies enabled them to invest in a wide range of critical activities to combat the effects of COVID-19. For example, supplemental appropriations helped federal entities fortify the U.S. supply chain, expand domestic manufacturing, increase medical countermeasure (MCM) stockpiles, and improve health data sharing capabilities. These appropriations also supported state, local, tribal, and territorial (SLTT) response activities, vaccination efforts, and provided funds to healthcare facilities to purchase critical supplies and hire additional surge support staff. Additionally, these funding streams included financial support for healthcare providers and businesses, as well as direct payments to individuals experiencing economic hardships due to the COVID-19 pandemic. In addition, Congressional action was instrumental in enabling rapid and effective U.S. action internationally, keeping Americans safe, saving lives around the world, and rebuilding the U.S. and global economies. A breakdown of COVID-19 supplemental appropriations is outlined in Figure 1.

This Evaluation of Progress is a retrospective look at efforts made by the United States to meet the three objectives of the 2019-2022 NHSS.



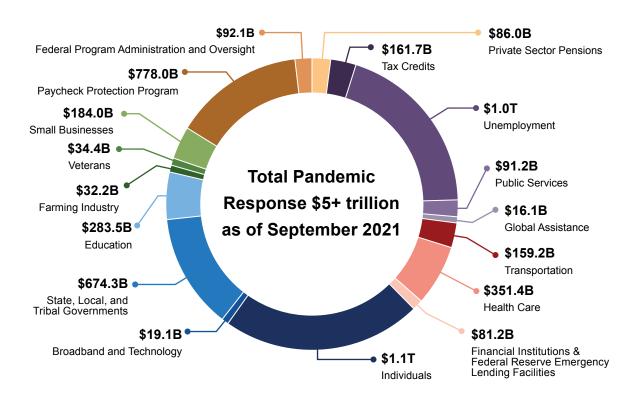


Figure 1: Pandemic Relief Funds from Six COVID-19 Congressional Supplemental Appropriations<sup>3,4,a</sup>

The progress made due to these investments and other activities across federal, SLTT, and private entities in response to COVID-19 strengthened national health security capabilities. The United States is committed to ensuring that these investments and measures to end COVID-19 contribute to sustainable improvements in domestic and global health security and resilient and responsive public and animal health systems, enabling the United States and partner countries to effectively respond to future infectious disease threats. Sustained investments that build upon the investments made thus far are critical to further advancing the health security capabilities of the United States.

Between 2019 and 2022, the United States took significant steps to counter national health security threats. Efforts are ongoing and there remains room for additional progress. Therefore, continued attention toward protecting national health security is warranted in the years to come. A summary of this report's findings is included below. These findings are categorized by thematic area within the three overarching objectives of the 2019-2022 NHSS.

a A description of what is covered under each sector in Figure 1 can be found at the Pandemic Oversight website.



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.

Situational awareness and information sharing platforms were modernized and adapted during the COVID-19 response: At times during the COVID-19 response, real-time information collection, analysis, and sharing proved challenging. As a result, the federal government created and/or augmented existing programs to strengthen information sharing. This included strengthening information exchange between immunization systems, increasing partnerships to share patient data during emergencies, and establishing a near-real-time data sharing system to provide situational awareness for healthcare system metrics such as hospital capacity, therapeutic distribution, and testing and vaccination data.5

The federal government took action to help alleviate both immediate and long-term healthcare and public health workforce shortages: Staffing shortages and workforce burnout resulted in deficiencies in critical expertise and disruptions in care for chronic disease patients. Federal medical response teams deployed to jurisdictions across the country to aid in the COVID-19 response by helping hospital staff care for patients, setting up alternate care sites, and assisting with vaccination efforts.<sup>6</sup>, <sup>7,8</sup> To begin addressing long-term workforce challenges, the United States announced plans to provide

\$7.4 billion in funding to recruit and train public health professionals with essential public health skills, including expertise in epidemiology and data science. Additional funding was dispersed to increase workforce capacity in underserved communities 1.10 Creating a larger public health workforce that is resilient, well-trained, and diverse will benefit U.S. health security.

The United States took steps to build regional health response capabilities: A regional response network enables healthcare facilities to share information and transfer supplies, expertise, and patients between care sites during emergency responses. Between 2019 and 2022, the United States engaged in activities to build regional response capabilities. The U.S. government created two pilot programs focused on providing pediatric-specific care during public health emergencies.<sup>11</sup> Additionally, Regional Disaster Health Response System (RDHRS) demonstration sites were launched in four of the Department of Health and Human Services (HHS) defined regions, improving clinical collaboration and engagement across each region's healthcare sector.

b According to Executive Order 13985, underserved communities refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, such as: Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Objective 2

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

Accelerated MCM development and approval for the COVID-19 response: MCM development is pivotal to protecting the nation from health security threats. The emergence of COVID-19 exposed shortages in certain MCMsc and demonstrated the importance of rapid and adaptable MCM research and development to respond to novel threats. The federal government established Operation Warp Speed which transitioned into the Countermeasures Acceleration Group and later into the HHS Coordination Operations and Response Element (H-CORE)—to accelerate the rigorous clinical trials essential to showing that rapidly developed vaccine candidates were safe and effective. 12, <sup>13</sup> Two COVID-19 vaccines have received full approval for adults from HHS's Food and Drug Administration (FDA) and FDA Emergency Use Authorization EUA) for younger age groups. 14,15,16 In addition, 641 other MCMs to combat COVID-19 have active EUAs as of November 21, 2022, which include vaccines, drugs and non-vaccine biological products, and medical devices.17

The United States leveraged existing, and developed new, surveillance and detection mechanisms: The United States' response to the COVID-19 pandemic showed the nation could benefit from further modernizing data collection and reporting, expanding laboratory capacity, and improving surveillance system interoperability. It also highlighted the importance of quickly developing accurate diagnostics for novel threats and the need for public and animal health laboratories to accommodate large influxes of samples during health emergencies. The nation leveraged existing disease surveillance and detection efforts while also developing new surveillance mechanisms to address COVID-19. Specifically, the U.S. government launched new initiatives to implement SARS-CoV-2 genomic sequencing efforts across SLTT authorities to better identify variants and developed new frameworks to increase surveillance across the human-animal interface. 18, 19 The U.S government also developed multiple innovative diagnostic tests and technologies for COVID-19 and future health threats.20 These efforts have not only aided the COVID-19 response but also provided a foundation that the United States will build on to allow for earlier detection of infectious disease threats in the future.

c Medical countermeasures include both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins) and non-pharmaceutical interventions (e.g., medical devices—including diagnostics—ventilators, personal protective equipment, and patient decontamination) as well as other needed medical products that may be used to prevent, mitigate, or treat the adverse health effects of an intentional, accidental, or naturally occurring public health emergency. They include (but are not limited to) qualified countermeasures as defined in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. § 247d–6a(a)(2)); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the Public Health Service Act (42 U.S.C. § 247d–6d(i)(7))), and security countermeasures as defined in section 319F–2(c)(1)(B) of the Public Health Service Act (42 U.S.C. § 247d–6b(c)(1)(B)).



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

The use of non-pharmaceutical interventions slowed the spread of COVID-19: The federal government shipped millions of units of N95 respirators, face masks, gloves, and nonsurgical gowns across the country during the COVID-19 pandemic.21 In addition, government public health experts worked with academia, healthcare personnel, health departments, and other public health partners to study the efficacy of these interventions and regularly updated guidance.<sup>22,</sup> <sup>23, 24, 25</sup> Federal health officials also continuously updated recommendations for implementing these interventions in high-risk settings, such as nursing homes and other healthcare facilities.<sup>26</sup>, <sup>27, 28</sup> As the understanding of COVID-19 and its spread evolved, health officials continued to update guidance and recommendations. However, updated guidelines, combined with misinformation, disinformation, and malinformation, and different guidance across jurisdictions, contributed to public confusion and led to varying levels of adherence to non-pharmaceutical interventions.

The United States continues to enhance biosafety and biosecurity and promote a culture of responsibility among life science researchers: As availability and use of synthetic biotechnologies increases, so too does the risk of laboratory accidents or intentional misuse of these technologies for malicious purposes. The U.S. government released several biosafety and biosecurity guidance documents between 2019 and 2022, including guidance for managing waste contaminated with Category A agents, and coordinated a framework for laboratories to selfassess their organizational culture through the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences.<sup>29,</sup> 30, 31, 32, 33 Additionally, the U.S. government continued to support biosafety and biosecurity efforts domestically and through international partnerships.34

## Objective 3

#### Leverage the capabilities of the private sector.

Public-private partnerships were critical to accelerating MCM development and increasing the availability of medical supplies for COVID-19 and other health security threats:

Streamlined collaboration between the federal government and the pharmaceutical industry accelerated the research and development of COVID-19 treatments and vaccines. These collaborations allowed for the swift development of COVID-19 treatments and vaccines and provided a partnership model that can be built upon to combat future threats. The importance of publicprivate partnerships in protecting the United States from health security threats was evident before the emergence of COVID-19 and they continue to strengthen national health security for a variety of health threats. For example, the U.S. government continued to partner with the private sector through the Combating Antimicrobial Resistance Accelerator (CARB-X).35 CARB-X has 62 active projects aimed at developing diagnostics, therapeutics, and preventatives to counter antimicrobial resistance (AMR).36

### The United States' worked to reduce its reliance on foreign sourcing for supplies and materials:

From 2019 to 2022, the United States worked to reduce its reliance on foreign supply chains through investments in domestic manufacturing and executive actions to create a more resilient and sustainable public health supply chain. <sup>37, 38</sup> To meet this directive, the U.S. government released the *National Strategy for a Resilient Public Health Supply Chain* in July 2021 to drive investments and to expand the U.S. public health industrial base and the Strategic National Stockpile. At least \$11 billion in COVID-19 emergency supplemental funding is devoted to expanding domestic manufacturing through 2025. <sup>39</sup> Additionally, the U.S. government

employed the Defense Production Act, the Defense Priority and Allocation System (DPAS), and the Health Resources Priority and Allocations System (HRPAS) to produce over 165,000 ventilators, 600 million N95 masks and other essential personal protective equipment (PPE), 315 million needles and syringes, and 20 million swabs.<sup>40, 41</sup>

Steps were taken to mitigate risks associated with health technology: Cyberattacks on healthcare systems have led to canceled or delayed surgeries and cancer treatments, closed COVID-19 test collection sites, and disrupted communication between hospitals. This threat continues to grow as telehealth service use increases, and cyber criminals become more sophisticated. In 2021, the federal government developed several recommendations and tools to improve healthcare cybersecurity, including guidance to mitigate software vulnerabilities, risk assessments to better protect patient electronic health data, and resources for supply chain vendors to better prevent cyberattacks.<sup>42, 43</sup>

The United States is working to combat the continued stresses on public health critical infrastructure: The United States must have systems in place to maintain a resilient healthcare and public health and critical infrastructure capable of preparing for, responding to, and recovering from health security threats. Several federal programs have been working to meet this need. These programs supply technical expertise to SLTT entities and provide funding for them to purchase medications and medical supplies and to prepare for public health emergency responses.44 They also provide resources, sector-specific training, and hospital toolkits to reinforce healthcare and public health critical infrastructure across U.S. jurisdictions.45

#### INTRODUCTION

This Evaluation of Progress examines actions taken by the United States between 2019 and 2022 to meet the objectives of the 2019-2022 NHSS. The 2019-2022 NHSS provided a strategic vision to strengthen the United States' ability to prevent, detect, assess, prepare for, mitigate, respond to, and recover from health security threats.<sup>2</sup> It has three overarching objectives, which are outlined in **Figure**2. The Evaluation of Progress is a quadrennial requirement mandated by the U.S. Public Health Service Act.<sup>1</sup> This requirement was reauthorized as part of the 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act.<sup>46</sup>

Figure 2: The Three Objectives of the 2019-2022 National Health Security Strategy



#### **Objective 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.



#### **Objective 2**

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



#### **Objective 3**

Leverage the capabilities of the private sector.

From 2019 to 2022, the United States faced many significant health security threats. The emergence of SARS-CoV-2, the virus that causes COVID-19, posed challenges on a scale not experienced in modern times.<sup>47</sup> COVID-19 has resulted in the worst pandemic in over a century, exerted tremendous strain on healthcare systems across the country, and had enormous economic ramifications.

COVID-19 highlighted areas where the United States must continue to improve to meet an evolving health security threat landscape. The pandemic tested the public health workforce, the nation's surveillance systems, domestic manufacturing capabilities, risk communication and community engagement processes, and MCM innovation, research, development, production, and stockpiling capacity. It also demonstrated the importance of coordinating resources across jurisdictions, modernizing the country's public health infrastructure, and real-time information exchange. Collaboration across federal and SLTT entities, as well as with private industry, is critical to protecting the health security of the nation.<sup>48</sup>



COVID-19 was not the only health security threat that impacted the United States between 2019 and 2022. Events spurred by climate change and extreme weather, cybersecurity breaches, AMR, and concerns related to biosafety and biosecurity remain significant threats that the United States is working to address even as the COVID-19 pandemic continues. For example, the United States recorded its most active Atlantic hurricane season on record in 2020 and drug-resistant infections plagued states like New York, New Jersey, and Illinois.<sup>47, 49</sup> Increased use of synthetic biotechnologies also increases the risk of accidental releases and deliberate misuse, making proper biosafety and biosecurity oversight more important than ever. Similarly, as telehealth service use increased, so too have cybersecurity concerns related to protecting patient health data.

Though COVID-19 and other health security threats exposed areas where improvements can be made, they also pushed the United States to create innovative solutions to further safeguard the health security of the nation.

#### **National Health Security in Review:**

## 2019-2022



#### **Objective 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.

The United States uses a whole-of-government approach to prepare, mobilize, and respond to disasters and public health emergencies. This approach works to ensure a unified, national response to public health emergencies and disasters where the federal government can support SLTT healthcare and public health capabilities and address potential challenges. As such, the 2019-2022 NHSS set out to:

- Improve national preparedness and convene a unified, national response to public health emergencies and disasters.
- Mobilize, coordinate, and direct the healthcare and public health assets of the U.S. government.
- Promote sustainable enhancements to SLTT healthcare and public health infrastructure and response capabilities and capacity.
- Evaluate the effectiveness and viability of regional disaster health response capabilities to better identify and address challenges in coordinated patient care during public health emergencies and disasters.

#### **PROGRESS AND KEY FINDINGS**

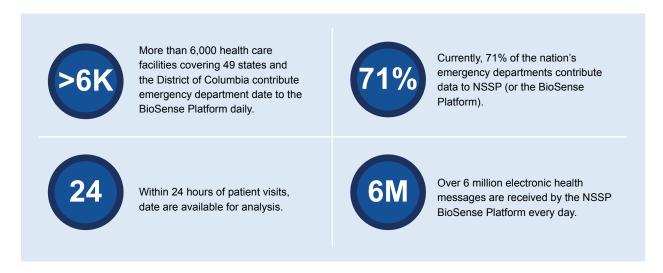
Since 2019, U.S. healthcare and public health systems have been strained by the increased frequency and severity of natural disasters caused by climate change, the COVID-19 pandemic, and other public health emergencies. However, COVID-19 and other public health emergencies have introduced opportunities for collaboration between SLTT authorities, non-governmental organizations, and the private sector.

#### Situational Awareness and Information Sharing

Timely healthcare and public health situational awareness, information collection, and sharing capabilities provide the foundation for thoughtful decisions and deliberate actions. Information sharing results in better use of resources, successful mitigation of domestic and international emerging threats, and improved patient outcomes.

Increasing partnerships and coordination promotes enhanced situational awareness efforts to address critical threats at the national and SLTT levels. HHS's Centers for Disease Control and Prevention (CDC) operates the National Syndromic Surveillance Program (NSSP) and BioSense Platform, which enables the sharing of emergency patient health data to allow federal and public health officials to detect, understand, and monitor events of public health concern in an efficient manner.<sup>50</sup> States have used the NSSP partnership to monitor and inform enhanced overdose surveillance, identify a *cryptosporidium* outbreak, and identify e-cigarette- and vaping-associated lung injury.<sup>51, 52, 53</sup>





Situational awareness is critical to ensure patients with existing health needs can continue to receive proper care during and after a disaster. Through HHS's Office of the National Coordinator for Health Information and Technology and private sector partners, the Patient Unified Lookup System for Emergencies (PULSE™) initiative allows health responders to securely access medical records so people can continue to receive the care they need during an emergency.⁵⁵ For example, PULSE™ was deployed at local disaster recovery centers in the wake of the 2019 California wildfires. The system allowed providers to access lists of patients' prescribed medications and subsequently fill prescriptions for patients who had left their medications at home while fleeing the affected area.⁵⁶

While the COVID-19 pandemic illuminated challenges in public health situational awareness and information sharing, it also highlighted promising practices. It spurred investments to increase and modernize information sharing between health information exchanges and immunization systems. The Immunization Data Exchange Advancement and Sharing program increased access of patient data to track COVID-19 vaccination progress and measure post-vaccination health outcomes.

The COVID-19 pandemic necessitated the development of new situational awareness data sharing systems and processes. HHS Protect is a secure data ecosystem that provides near-real-time data sharing on healthcare system metrics such as hospital capacity, therapeutic distribution, and testing and vaccination data. HHS Protect offers a holistic view of the U.S. healthcare system by integrating more than 200 disparate data sources across federal, state, and local governments, as well as the healthcare industry.

Effective situational awareness and data sharing can only occur when information is efficiently and reliably gathered from, and shared among, relevant domestic and international sources and used to make timely, well-informed decisions. 2019 to 2022 demonstrated the need for flexible information sharing mechanisms across federal, SLTT, and private sector partners that can be employed to address a variety of health security threats. Improving partners' situational awareness can lead to operational advancements at all levels of the public health and medical system, including surveillance, pre-hospital care, and hospital patient and resource management.



#### Healthcare and Public Health Workforce Surge Capacity

Ensuring adequate patient care and maintaining critical management responsibilities in major medical and public health incidents requires medical system resiliency, protection of healthcare professionals, information management, and coordination of diverse operating systems. COVID-19 caused staffing shortages and workforce burnout resulting in deficiencies in critical expertise and disruptions in continuity of care for chronic disease patients. The surge of ill patients outpaced the number of available healthcare workers in many parts of the country. This resulted in providers working extra hours to meet the demand of persons requiring care.

Several federal programs were vital to expanding surge capacity for COVID-19 testing, treatment, and vaccination.

- The Department of Homeland Security (DHS), through its Federal Emergency Management Agency (FEMA), expanded medical support services and mass care assistance by providing funding, supplies, and personnel to augment COVID-19 testing, treatment, and vaccination.<sup>58</sup>
- In 2020, the Medical Reserve Corps (MRC), housed within HHS's Office of the Assistant Secretary for Preparedness and Response—known as the Administration for Strategic Preparedness and Response (ASPR)<sup>d</sup> as of July 2022—contributed more than 800,000 MRC

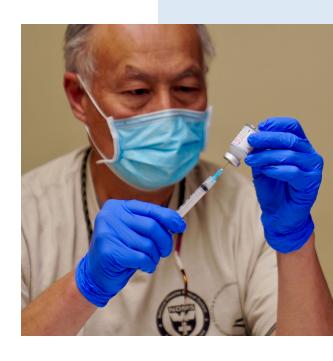
d ASPR transitioned from the Office of the Assistant Secretary for Preparedness and Response to the Administration for Strategic Preparedness and Response on July 20, 2022. ASPR activities in this report prior to that date reflect the Office of the Assistant Secretary for Preparedness and Response, while activities from that date onward reflect the Administration for Strategic Preparedness and Response.

volunteer hours assisting with community screening and testing operations, medical surge support at long-term care facilities, healthcare facilities, and alternate care sites, patient case and contact investigations, call center operations, community education and logistics, and provided technical expertise.<sup>6</sup>

- Between January and May of 2021, more than 700 MRC units staffed by up to 290,995 volunteers were stood up in all ten HHS regions of the United States and provided more than 460,000 hours to COVID-19 vaccine support.<sup>7</sup>
- The National Disaster Medical System (NDMS) conducted 735 COVID-19 response missions in 38 U.S. states and territories.<sup>59</sup> The Department of Defense (DOD) deployed active-duty military personnel to assist civilian medical staff at hospitals and support state-level across the country to combat COVID-19.<sup>60</sup> DOD also supported state-led COVID-19 vaccination sites, as well as other COVID-19 federal response missions.
- Health care coalitions used funding from ASPR's Hospital Preparedness Program (HPP) to ramp up hospital surge capacity to respond to the COVID-19 pandemic.<sup>61</sup>
- On July 28, 2022, DOD, on behalf of and in coordination with HHS, awarded a \$1.74 billion agreement to purchase over 65 million doses of Moderna's COVID-19 vaccine for a fall vaccination campaign. The vaccine will target the SARS-CoV-2 Omicron subvariant viruses, as recommended by FDA.<sup>62</sup>
- In March 2022, DOD, in coordination HHS, awarded contract modifications to private sector partners allowing for the purchase of an additional 176.8 million over-the-counter COVID-19 test kits. This effort supports the president's plan to deliver one billion free at-home COVID-19 tests to the nation in response to the Omicron variant.<sup>63</sup>
- The Department of Agriculture (USDA) had 25 laboratories in its National Animal Health Laboratory Network gain needed approvals that enabled them to test over six million human samples for COVID-19 to support state public health partners.<sup>64</sup>

The COVID-19 pandemic highlighted the consequences of underinvestment in the healthcare and public health workforce and the critical need for a workforce that is robust and diverse. By the end of fiscal year (FY) 2020, 43 states plus the District of Columbia increased funding for public health activities and staff.<sup>47</sup> However, workforces were still strained during the pandemic. Healthcare executives indicated that staffing shortages are worse since 2019, including nurses, physicians, advanced practitioners, and behavioral and mental healthcare providers. In addition to shortages, health workers reported higher rates of burnout and mental health conditions.<sup>65</sup>

To help mitigate this challenge, the U.S. government can build on recent actions to provide more sustainable funding to grow the healthcare and public health workforce. In May 2021, the United States announced its plan to invest \$7.4 billion to recruit, hire, and train public health workers such as epidemiologists,



data scientists, and school nurses.<sup>9</sup> HHS's Administration for Community Living provided additional funding to community-based healthcare organizations that support people with disabilities and older adults.<sup>66</sup> Additionally, HHS's Centers for Medicare and Medicaid Services funded new training to increase the number of physicians in underserved communities and rural areas.<sup>67</sup> This workforce expansion allows qualifying hospitals in rural and underserved areas to establish 1,000 new Medicarefunded physician residency slots, with an additional 200 positions added annually beginning in 2023 for five years.<sup>10, 68</sup>

The pandemic also highlighted challenges with moving non-federal healthcare providers across state lines to meet surge needs in other parts of the country. A public health emergency declaration by the HHS Secretary does not waive state licensure requirements for non-federal healthcare workers. <sup>69</sup> Rather, this decision resides at the state level. Actions have been taken by states to meet this challenge. For example, 35 states implemented the Nurse Licensure Compact, which allows registered nurses and licensed practical nurses to receive a multistate license, permitting them to administer care in other participating states. <sup>70</sup> At the federal level, a Public Readiness and Emergency Preparedness (PREP) Act declaration was issued, which in part authorized licensed or certified healthcare providers



and pharmacists and pharmacy interns to administer countermeasures across state lines regardless of more restrictive state requirements. While the federal government also assisted SLTT workforces through funding mechanisms and programs such as NDMS and MRC, additional mechanisms would allow non-federal providers to better assist other parts of the country during emergencies. Continuing to grow the healthcare and public health workforce can foster a more diverse and capable workforce that is better prepared to respond to future health threats.

#### Regional Response Capabilities

Regional response capabilities are critical to national health security because they allow for flexible responses, management of hospital surges, and resource sharing within a region. Disasters, especially those caused by natural hazards, may cause healthcare facilities to shut down select services or evacuate. Using a regional health response model, jurisdictions impacted by a disaster or resource shortages can coordinate with unaffected neighboring areas to share information, such as hospital operating status and bed capacity, and transfer patients as needed.

Using disaster health response capabilities at the regional level has augmented surge capacity during widespread emergencies like the COVID-19 response. ASPR's RDHRS is a tiered system that builds

upon and unifies existing assets within states and across regions.<sup>71</sup> As a complement to this project, ASPR created a pilot program for two Pediatric Disaster Care Centers of Excellence.<sup>11</sup> The centers' model programs are designed to decrease the impacts of exposure to trauma, infectious diseases, and other public health threats on children by providing pediatric-specific care during public health emergencies.

By October 2021, ASPR launched four RDHRS demonstration sites in Massachusetts, Nebraska, Colorado, and Georgia. The RDHRS demonstration sites address healthcare preparedness, establish promising practices, and explore the effectiveness and viability of an RDHRS across the United States. These sites worked to establish and mature multistate partnerships, build on local health care coalitions and trauma centers, and integrate local medical response capabilities with emergency medical services, burn centers, pediatric hospitals, laboratories, and outpatient services. During COVID-19, these demonstration sites shifted focus to support preparedness and response efforts by:

- Leveraging stakeholder engagements developed during year one of the pilot program.
- Developing state-wide information sharing platforms.
- Coordinating and providing subject matter expertise across the region.
- Using lessons learned and promising practices to better prepare for future COVID-19 cases.

Figure 4: The Three Goals of the RDHRS



Improve communication
and situational awareness
of medical needs during
responses between health
care organizations and local,
state, regional, and federal
partners.



Leverage, build, or augment highly specialized clinical capabilities critical to unusual hazards or catastrophic events.



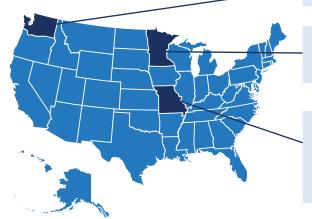
Augment the vertical and horizontal (whole of community) integration of key stakeholders that comprise health care coalitions with readilty accessible clinical capabilities that are missing from the current structure of the coalitions.

The National Special Pathogen System also augments regional response capabilities. It is a nationwide systems-based network approach that builds on existing infrastructure and investments in preparing for infectious disease outbreaks.<sup>72</sup> As shown in **Figure 5**, The National Special Pathogen System supports the urgent preparedness and response needs of hospitals, health systems, and healthcare providers related to treating patients with special pathogens.<sup>73</sup>

Figure 5: The National Special Pathogen System in Action<sup>73</sup>

NETEC has hosted 20 webinars to date in its COVID-19 webinar series, which highlights subject matter experts' experience and response to the challenges presented by COVID-19.

Washington's designated RESPTC, the Providence Sacred Heart Medical Center, applied its expertise as a first responder to the COVID-19 pandemic and hosted 4 COVID-positive passengers from the Diamon Princess Cruise ship.



The **Minnesota Department of Health** created a COVID-19 toolkit to help lon-term care facilities prepare for the respond to COVID-19 cases.

The **Missouri Hospital Association** released a new report. "Mid-Resonse Assessment: Missouri Hospitals' Reponse to the COVID-19 Pandemic," highlighting the clinical and operational lessons learned from the COVID-19 pandemic response among Missouri hospitals.

ASPR is building a new system for catastrophic disaster medical care. Existing healthcare preparedness investments will be the foundation for this new system. These investments include the HPP, NDMS, MRC, and the National Special Pathogen System.<sup>73</sup>





#### **Objective 2**

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

Preparing for and responding to infectious diseases and CBRN threats requires robust public health security capacity and swift development of MCMs. To achieve this objective, the 2019-2022 NHSS set out to:

- Continue efforts to improve early detection of emerging and potential pandemic infectious diseases.
- Rapidly identify, develop, produce, and make available safe and effective MCMs.
- Maintain the capacity to produce enough vaccines and other necessary MCMs to protect from pandemic influenza and CBRN agents that represent a strategic health security threat to the nation.
- Support SLTT authorities' efforts to stock and rapidly obtain, distribute, dispense, administer, and monitor the safety of MCMs.

#### **PROGRESS AND KEY FINDINGS**

The United States faced complex and emerging health security threats between 2019 and 2022, specifically related to pathogens with pandemic potential and biological threats. Protecting the nation from infectious diseases and biological threats presents complex challenges, and these challenges were magnified by the COVID-19 pandemic.

#### MCM Development

Safe and effective MCMs that combat an array of health security threats must be available in adequate quantities to meet the needs of the U.S. population. The COVID-19 pandemic exposed weaknesses in federal and SLTT stockpiles and highlighted U.S. reliance on foreign supply chains. The pandemic also demonstrated the unparalleled capacity of the U.S. research and development infrastructure to create and validate novel MCMs in an emergency; at the same time, it highlighted areas where improved domestic and international coordination might have resulted in more effective MCM development and distribution.

In October 2022, the United States released the National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security. The strategy sets forth a comprehensive plan and bold actions to achieve the vision of a world free from catastrophic biological incidents. The strategy aims to transform the federal government's ability to prevent, detect, prepare for, respond to, and recover from outbreaks, in partnership with our international, SLTT, and private sector partners.



As COVID-19 began to spread rapidly across the country in 2020, it became apparent that existing stockpiles held insufficient quantities of PPE for healthcare workers. There were also early concerns with having enough ventilators available for critically ill patients. In addition, the emergence of SARS-CoV-2 demonstrated the importance of continued development of threat agnostic MCMs, such as ventilators, disinfection technologies, and PPE. It also highlighted the critical need to maintain a domestic-based manufacturing capacity capable effectively of producing vaccines, therapeutics, and diagnostics, while also being able to secure adequate raw materials to produce these MCMs in surge events.

A whole-of-government response was initiated to mitigate these challenges. The federal government employed the Defense Production Act to drive the production of ventilators and PPE and allow for expedited manufacturing of machinery, equipment, and supplies required for COVID-19 vaccine production.<sup>40, 41</sup> The United States also funded MCM development projects, partnered with nonfederal research institutions, and collaborated with pharmaceutical companies to develop and distribute safe and effective MCMs against SARS-CoV-2.

HHS and DOD worked with private industry to capitalize on existing platforms to speed up the development and production of MCMs. This was most apparent in response to the COVID-19 pandemic. Operation Warp Speed supported multiple existing vaccine platform technologies—specifically messenger RNA (mRNA) and replication-defective live-vector platforms—to produce three vaccine candidates were investigated in clinical trials coordinated by HHS's National Institutes of Health (NIH) and FDA and granted EUAs by FDA. 12,14 Two of these candidates were ultimately licensed by the FDA. 15,16 COVID-19 vaccines are undergoing extremely intensive safety monitoring. This monitoring includes using both established and new government safety monitoring systems to make sure that COVID-19 vaccines are safe. 74

In February 2022, ASPR announced the relaunch of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE is a critical multisectoral partnership focused on combating infectious diseases and CBRN threats. Nimble and flexible response operations during incidents depend on robust and integrated capabilities among the federal and nonfederal partners that share the MCM preparedness mission. The PHEMCE's relaunch will build on lessons learned by using a flexible model for engaging partners to facilitate collaboration and drive strategic development and use of MCMs to protect the nation from health security threats.



Figure 6: COVID-19 Vaccine Doses at a Tennessee Hospital

While these platforms had not previously been employed to develop an FDA-licensed vaccine in the past, they had been studied for years leading up to the pandemic and had the potential to be scaled-up quickly, allowing them to be leveraged to accelerate development of COVID-19 vaccines. Some Operation Warp Speed-supported companies also conducted vaccine clinical trials concurrently with mass production to enhance the speed at which vaccines were available to the public. In 2021, Operation Warp Speed transitioned into the HHS-DOD COVID-19 Countermeasures Acceleration Group, which subsequently became known as H-CORE in 2022. Under these new names, this group continued to support COVID-19 MCM development, including production of COVID-19 vaccines.

Aside from vaccines, 641 other MCMs have active EUAs from the FDA to combat SARS-CoV-2 as of November 21, 2022.17 These include 419 in vitro diagnostics (277 molecular, 53 antigen, 85 serologic, and four other in vitro diagnostics), 68 PPE products, 87 ventilators, 21 ventilator accessories, four ventilator tubing connectors, 14 therapeutics, and 28 other medical devices. 75, 76, 77, 78, 79, 80 The HHS Secretary also issued a PREP Act declaration to provide liability immunity for manufacturing, development, distribution, administration, and use of COVID-19 MCMs and to expand individuals authorized to prescribe, dispense, and administer those countermeasures.81 This declaration helped address some of the challenges associated with the mass administration of MCMs to the U.S. population. Additionally, some U.S. companies diverted from standard production activities to manufacture products that were in high demand during the COVID-19 pandemic, such as PPE and sanitation supplies.

Federal agencies also made significant strides to develop MCMs for an array of other infectious disease and CBRN threats. Several HHS components, including CDC, NIH, and ASPR's Biomedical Advanced Research and Development Authority (BARDA), in coordination with DOD, contributed technical support and funding to pharmaceutical companies to develop and manufacture a vaccine for the ebolavirus. In 2019, the Merck ERVEBO vaccine became the first FDA-approved ebolavirus vaccine.<sup>82</sup>

BARDA also supported the development of the JYNNEOS® vaccine and Seqirus AUDENZ H5N1 avian influenza vaccine. The former is the first FDA-approved, non-replicating vaccine for smallpox and the first licensed vaccine for monkeypox. The latter is the first cell-based adjuvanted H5N1 pandemic vaccine licensed in the United States.<sup>83</sup>

As of July 2022, H-CORE has helped distribute more that 732 million vaccines to adult and pediatric populations across 90,000 care sites in the United States.



The National Influenza Vaccine
Modernization Strategy 2020-2030
outlines the nation's vision for
an influenza vaccine enterprise
that more effectively reduces the
impacts of seasonal and pandemic
influenza.

Additionally, BARDA support contributed to the development of several other MCMs for health security threats that received FDA approval, clearance, or licensure between 2019 and 2022. These include MCMs for Zika, influenza, sulfur mustard, and radiation exposure. Specific details about these MCMs are outlined in Table 1 and Table 2 (see *Promising Practices: Select National Health Security Highlights from HPP, PHEP, NDMS, BARDA, and Vaccine Tracking Activities* section below).

The National Institute of Standards and Technology (NIST), a component of the Department of Commerce, developed a reference material with genetic fragments for monkeypox that allows for the accurate development of monkeypox diagnostic tests.<sup>84</sup> Building on lessons learned in the generation of a similar SARS-CoV-2 material, NIST researchers were able to provide this reference material to manufacturers in only 30 days, a rapid response that will help to prevent community spread and slow the next health emergency.

In addition to MCM development activities, the federal government also worked to improve equitable access to MCMs. For example, HHS's Health Resources and Services Administration's Health Center COVID-19 Response Programs were stood up to distribute COVID-19 vaccines, at-home self-tests, point of care tests, oral antiviral therapeutics, and N95 masks to community health centers and Rural Health Clinics serving the nation's most vulnerable individuals and families, including people experiencing homelessness, agricultural workers, residents of public housing, and veterans. As of October 12, 2022, 217 Rural Health Clinics have enrolled in the Rural Health Clinic COVID-19 Vaccine Distribution program, while 1,742 Rural Health Clinics have enrolled in the Rural Health Clinic COVID-19 Testing Supply Program, and 119 Rural Health Clinics have enrolled in the Rural Health Clinic COVID-19 Therapeutics Program.

The United States' role in international efforts was also critical in mitigating the global impact of COVID-19. In December 2021 the U.S. government launched the Initiative for Global Vaccine Access, or Global VAX. This initiative, led in partnership by the United States Agency for International Development (USAID), CDC, and other federal entities builds on existing U.S. government efforts and in over 120 countries to mitigate challenges with vaccine delivery and

In 2022, BARDA released a new five-year strategic plan. A critical component of the *BARDA Strategic Plan 2022-2026* focuses on the rapid development of safe MCMs and ensuring those MCMs are readily available to the American public. BARDA will work to achieve this goal through several actions, including promoting the development of agile MCMs that can be quickly scaled in response to new threats and catalyzing innovation across the MCM development pipeline.



e Numbers provided by HHS's Health Resources and Services Administration.

uptake. <sup>85</sup> USAID also provided funding through its American Rescue Plan Act to increase equitable access to MCMs globally and further the development of the next generation of COVID-19 vaccines designed to protect against newly emerging variants and for use in low-income settings.

The MCM development actions taken by the United States served not only to address health security threats faced between 2019 and 2022 but to better position the United States to combat future health security threats. For example, mRNA vaccine technologies and other programmable platforms can be adapted to rapidly develop new MCMs for the next emerging pathogen. Additionally, central coordination of the emergency research agenda and research resources—including government, academic, private sector—to implement the agenda was shown to be essential for optimal response. The process of scaling up manufacturing concurrent with ongoing clinical trials can be re-examined to improve flexibility in production based on trial results and new pathogen variants, and to more efficiently deliver safe and effective MCMs to the public. Furthermore, the nation now has experience employing the Defense Production Act in response to a public health emergency and will be ready to use it in a similar fashion if required in the future.



#### Disease Detection and Surveillance

Accurate and timely surveillance data is critical to detecting disease emergence and assessing its spread throughout the population. Several factors, including real-time data gathering, public health laboratory capacity, accurate testing and diagnostics, and surveillance system interoperability influence the nation's ability to monitor and detect diseases effectively. While all 50 states, U.S. territories, and the District of Columbia reported having at least one public health laboratory, the COVID-19 pandemic initially placed a significant burden on these laboratories as they worked to test the large influx of samples received. This problem was further complicated by validation issues with the initial batches of COVID-19 testing kits. Public health laboratories' surge capacity improved as the challenges with the testing kits were resolved, testing was expanded to include assistance from USDA's diagnostic laboratory network and private laboratories, and rapid at-home tests were authorized. By the end of 2020, public health laboratories in all 50 states plus the District of Columbia had a six-to-eight-week surge capacity plan in place.<sup>47</sup>

The COVID-19 pandemic also revealed that U.S. surveillance systems could be improved to communicate more effectively. Though the United States has several long-standing surveillance systems in place that are designed to enable disease detection, these systems can be modernized to facilitate electronic data sharing in a timely manner. Additionally, the United States can build out its surveillance capabilities to better integrate data across the human, plant, animal, and environmental sectors. This integration is key to detecting diseases that can spillover between these populations.

Despite these challenges, the United States has made significant progress in disease surveillance and detection between 2019 and 2022. The nation leveraged existing efforts while also developing new and innovative surveillance mechanisms to combat health security threats. These efforts have not only aided in detecting COVID-19 cases, but also provided the necessary frameworks that can be built upon to detect future infectious disease threats earlier.

HHS entities collaborated with professional associations to train U.S. hospital personnel and assist hospitals with the reporting of COVID-19 laboratory tests. CMS also released guidelines for hospitals related to laboratory test reporting. As a result, hospital COVID-19 laboratory test reporting increased, which facilitated modeling and forecasting while also improving federal and state decisions for placement of COVID-19 public health and medical response capabilities.

The U.S. Department of Agriculture (USDA) released a <u>Strategic Framework</u> to conduct surveillance of SARS-CoV-2 and build an early warning system to detect future zoonotic threats. This framework aims to expand the types of animal species actively surveilled to better detect emerging diseases and prevent their potential spillover into human populations. USDA will implement this framework by collaborating with CDC and other One Health partners to prioritize animal health strategies, prevent transmission to humans, and safeguard the food supply.<sup>86</sup> Additionally, USDA used its National Veterinary Services Laboratories and its National Animal Health Laboratory Network to detect SARS-CoV-2 in animal populations.<sup>87</sup>

During the early stages of the COVID-19 pandemic, the United States lacked a comprehensive, national capability for timely surveillance and detection of virus variants. 88 As SARS-CoV-2 variants of concern began to arise, it became increasingly important to track and analyze these new variants. As of mid-2022 the majority of SARS-CoV-2 infections have been caused by variants. The essential work of surveillance to identify new variants and to correlate genomic changes in the virus with phenotypic ones like transmissibility and severity has required considerable adaptation of existing surveillance systems and establishment of new capabilities.

Federal agencies unveiled initiatives to better understand SARS-COV-2 variants and increase genomic sequencing surveillance activities. The NIH Tracking Resistance and Coronavirus Evolution initiative, for example, aims to prioritize which viral variants should be studied to determine the effectiveness of vaccines and therapeutics currently in late stages of development, coordinate data sharing, and confirm testing and periodic public reporting of results. This effort allows confident decision making by the U.S. government, health professionals, and pharmaceutical organizations. Additionally NIH formed the SARS-CoV-2 Assessment of Viral Evolution (SAVE) Program,



the National COVID Cohort Collaborative (N3C), and the Rapid Acceleration of Diagnostics (RADx) initiative. 89, 90, 91 The SAVE Program provides a comprehensive, real-time risk assessment of emerging mutations in SARS-CoV-2 that could impact transmissibility, virulence, and susceptibility to infection- or vaccine-induced immunity. N3C compiles COVID-19 clinical data to create a repository researchers can use to learn more about the virus and its effects to improve patient outcomes. RADx works to enhance the development, commercialization, and implementation of COVID-19 testing technologies.

CDC launched the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) and the National SARS-CoV-2 Strain Surveillance (NS3) program. SPHERES is a consortium of federal, state, and local public health laboratories, academic centers, and research institutes. It works to accelerate real-time SARS-CoV-2 sequencing data, coordinates and supports sequencing efforts at SLTT laboratories, and improves genetic data sharing between laboratories.18 The NS3 program collects up to 750 SARS-CoV-2 samples per week from public health laboratories across the nation for advanced genomic sequencing and viral characterization.<sup>19</sup> CDC also partnered with commercial diagnostic laboratories and universities to increase genomic surveillance of SARS-CoV-2. These programs and collaborations allow for enhanced surveillance of viral evolution to better inform the performance of vaccines, therapeutics, and diagnostics.

#### **Federal Surveillance and Detection Highlights:**

- The Department of Veterans Affairs (VA) established its National Surveillance Tool.
- DHS's <u>National Biosurveillance Integration Center</u> aided in COVID-19 disease tracking and information sharing between public and private entities.
- NIST and CDC collaborated on the <u>National</u>
   <u>Wastewater Surveillance System</u>, a new public health
   tool aimed at monitoring viruses and other infectious
   diseases in wastewater. Development of standards to
   detect viruses and a connected system that collects
   reports from regional communities provides early
   warning systems of potentially infected communities
   and can reduce community spread.
- CDC launched the <u>Center for Forecasting and</u> Outbreak Analytics.
- DOD's <u>Sigma+ program</u> is developing sensors to detect CBRN threats and is investigating whether this technology can be used to detect SARS-CoV-2.
- BARDA's COVID-19 detection efforts resulted in 29 EUAs for diagnostic tests and over 243 million diagnostic test kits shipped by BARDA-supported partners as of October 21, 2022.
- USAID announced a <u>\$125 million project</u> to detect unknown viruses with pandemic potential.
- HHS formed the <u>SARS-CoV-2 Interagency Group</u>, which includes several HHS components, DOD, and USDA, to better understand COVID-19 variants to inform decisions about development and use of MCMs.
- NIST researchers collaborated on a multiorganizational study to use reference materials with known amounts of SARS-CoV-2 to help standardize polymerase chain reaction tests for COVID-19.

For future threats, a systematic approach is needed to strengthen and link global genomic surveillance and timely assessment of the phenotypic characteristics of novel variants, which will support the development and updating of diagnostics, vaccines, therapeutics, and non-pharmaceutical interventions. Using medical intelligence and better integrating surveillance data from across the human, animal, plant, and environmental sectors globally also contribute to enhancing these capabilities.

#### Non-pharmaceutical Interventions

Non-pharmaceutical interventions, such as PPE, social distancing, and good hygiene practices, were vital in mitigating the spread of COVID-19 especially in the early days of the pandemic before vaccine development and while therapeutic efficacy was being researched. Efforts across the U.S. government focused on investigating which interventions worked best, promoting widespread adoption of these interventions, and communicating their importance to mitigating the transmission of COVID-19.

Federal agencies conducted a series of studies to better understand the level of protection provided by various non-pharmaceutical interventions. For example, the Environmental Protection Agency (EPA) studies on face coverings provided insight about the varying filtration capacities across mask types, which disinfectants were most effective at killing viruses present on common mask materials, and possibilities for sanitizing masks in the event of a PPE shortage, and demonstrated the fit and filtration benefits of wearing two facial coverings.<sup>22, 23, 24</sup> CDC officials collaborated with academia to model exposure reduction of SARS-CoV-2 through physical distancing while aboard aircrafts.<sup>25</sup> The findings from this study were intended to serve as a resource to inform considerations about passenger proximity and filling middle seats.

Researchers at NIST conducted studies on the best fabrics for non-medical-grade masks, providing some clarity to the public on how best to protect themselves and others while medical masks were difficult to find. 93, 94 Additionally, NIST established a program to accelerate the development and use of germicidal ultraviolet disinfection technologies to inactivate pathogens, including SARS-CoV-2. NIST, along with industry, academia, and health organizations, released a collection of open-access peer-reviewed articles providing the necessary information for establishing ultraviolet standards. 95 It was demonstrated that N95 masks could be effectively and safely disinfected for reuse should PPE supply chains be strained again in the future.

NIST and DOD collaborated to determine which ultraviolet wavelengths work best for COVID-19 virus inactivation, and NIST developed documentary standards for how to evaluate ultraviolet efficacy for microorganism removal or inactivation in test and real-world scenarios, including operating and patient rooms. <sup>96</sup> By engaging with multiple stakeholders in industry, government, and the public, NIST demonstrated the capabilities of ultraviolet disinfection to be a major tool for the control and prevention of pathogens and could be used during future health emergencies.

EPA published List N:

<u>Disinfectants for Use Against</u>

<u>SARS CoV-2</u>, which is a searchable list of publicly available disinfectants that are effective against SARS-CoV-2.

HHS agencies released extensive guidance documents about non-pharmaceutical interventions and recommendations for when and how to use them. They continued to update guidance and recommendations as scientists learned more about COVID-19. A few examples include:

- CDC regularly updating its recommendations for use of non-pharmaceutical interventions by medical providers and nursing home personnel to limit COVID-19 infections in healthcare and nursing home facilities.<sup>27, 28</sup>
- CDC posting <u>mask guidance</u> describing how to wear masks properly, how to clean reusable facial coverings, criteria to consider when choosing a mask, and special considerations when selecting masks for children.
- CDC posting information describing how to properly use N95 respirators.
- FDA posting regular guidance documents and updates about effective PPE usage designed for different audiences.

Furthermore, HHS enhanced existing communication processes with Tribal entities to facilitate messaging from the federal government to Tribal-run health programs about implementing community practices to prevent the spread of COVID-19.97 Additionally, NIST released videos to the public that showed airflow and droplet movements in the air while wearing different kinds of masks compared to not wearing a mask. These videos served as a visual aid to bolster the CDC recommendation to wear masks in public to slow the spread of COVID-19.98

These communication efforts and guidance documents were designed to relay the importance of non-pharmaceutical interventions; however, the United States encountered significant impediments. Guidance on face masks and social distancing varied across jurisdictions and at different times during the pandemic, which led to varying levels of adherence and confusion among the public. This created long-term challenges towards widescale adoption of critical non-pharmaceutical interventions.

## Beyond the Homeland: Examples of U.S. Efforts to Promote Non-Pharmaceutical Interventions Abroad

As evidenced by the COVID-19 pandemic, infectious disease threats do not obey international borders and an infectious disease threat abroad can pose a serious health security threat to the United States. In response to this, the United States contributed to international efforts to promote and implement non-pharmaceutical interventions against COVID-19. For example, USAID collaborated with a local Nigerian telecommunications company and the Nigerian Center for Disease Control to send text messages to Nigerian citizens with information about proper hygiene practices and social distancing and to combat misinformation. These text messages were accompanied by a social media campaign. It was estimated that approximately one million Nigerians received the messages sent as part of this effort every day. CDC released and continues to update its Framework for Implementation of COVID-19 Community Mitigation Measures for Lower-Resource Countries. This framework includes the latest guidance on how resource-limited countries can best use mitigation strategies in community settings and in different types of population groups.

Opportunities exist to help prevent similar challenges from occurring in the future. Using clear and unified messaging across all levels of government to explain the benefits of non-pharmaceutical interventions can help the public better understand their importance and increase adherence. Federal and SLTT entities may also wish to coordinate more closely with nongovernmental organizations and local citizens that have a greater sphere of influence in their respective communities to promote positive behavioral changes. Furthermore, the United States can increase strategic communications designed to combat misinformation, disinformation, and malinformation about non-pharmaceutical interventions and tailor communication strategies to different subgroups of the population.

#### Biosafety and Biosecurity

While biotechnology advancements have resulted in scientific and medical breakthroughs, they also involve health security threats that must be considered. For example, synthetic biology has the potential to generate existing or novel harmful components, systems, or organisms from genetic sequencing data. The increased availability of synthetic biology tools means there is greater opportunity for these technologies to be misused for nefarious purposes. Additionally, the increase in the use of biotechnologies also leads to an increase in risk of laboratory accidents, underscoring the critical need for safe and secure sample collection, handling, storage, and disposal practices. The United States continues to be a global leader in biosafety and biosecurity.99 This status has

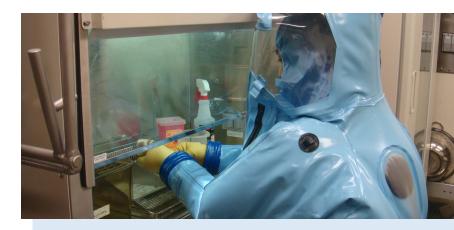


Figure 7: Trainee at the National Biosafety and Biocontainment Training Program

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#### Federal Biosafety and Biosecurity Highlights:

- DOD, EPA, HHS, the Department of Labor, and the Department of Transportation released <u>Guidance on</u> <u>Managing Solid Waste Contaminated with a Category A</u> <u>Infectious Agent.</u>
- CDC and NIH released the <u>Biosafety in Microbiological</u> and Biomedical Laboratories (BMBL) 6th edition.
- NIH released the revised <u>NIH Guidelines for Research</u>
   Involving Recombinant or Synthetic Nucleic Acid
   Molecules.
- CDC issued <u>interim guidance</u> for laboratory biosafety for research involving SARS-CoV-2.
- Federal entities continue to implement the <u>Dual</u>
   <u>Use Research of Concern</u> and <u>Potential Pandemic</u>
   Pathogen Care and Oversight policy frameworks.
- The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences, co-led by HHS and USDA, published <u>A Guide to Training and Information</u> Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences.
- Through efforts in support of the <u>United States</u> <u>Government Global Health Security Strategy</u> and the Global Health Security Agenda, federal departments and agencies strengthen partner countries' ability to have a whole-of-government national biosafety and biosecurity system in place.

been bolstered through ongoing work at the federal level to ensure appropriate biosafety and biosecurity practices.

The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences—co-led by ASPR and USDA's Animal and Plant Health Inspection Service (APHIS)—released an organizational culture (Self) Assessment Framework, which includes suggested guidance and a series of assessment questions that allow laboratories to evaluate the culture of responsibilities at their laboratories, identify potential weaknesses, and make improvements as needed. This working group also published a repository of biosafety and biosecurity training and educational resources available to laboratory workers. 100 Additionally, the HHS Biosafety and Biosecurity Coordinating Council is developing the Laboratory Biological Incident Reporting Survey, a reporting mechanism for biological incidents in HHS laboratories.

The United States continued to support ongoing biosafety and biosecurity efforts through international fora, such as the Global Health Security Agenda and the G7 Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, and domestically through efforts to monitor and oversee work with dangerous organisms. For example, the Federal Select Agent



Program, jointly operated by CDC and APHIS, restricts the possession, use, and transfer of the most dangerous pathogens and toxins.<sup>101</sup>

Furthermore, HHS is in the process of considering updates for the Screening Framework Guidance for Providers and Users of Synthetic Double Stranded DNA. A draft version of the proposed guidance was posted as a Federal Register Notice. 102 This proposed guidance, if finalized, would enable better tracking of synthetic nucleic acid material, and would continue to assist in limiting access to such material by potentially malicious actors.

Through the continued implementation of these frameworks and the release of updated guidance documents, the United States has taken an active role in building an organizational culture of responsibility among life science researchers. This culture of responsibility is critical to mitigating accidental biological releases and intentional misuse of biotechnologies. Maintaining a culture of responsibility, coupled with improving laboratory worker training and laboratory oversight, are key to ensuring proper biosafety conduct and identifying and reporting suspicious behaviors. It is paramount that the United States continues to update biosafety guidance documents, as appropriate, and engage in efforts to improve laboratory oversight to mitigate biosafety and biosecurity threats.



#### **Objective 3**

Leverage the capabilities of the private sector.

Objective three of the 2019-2022 NHSS focuses on ensuring strategic partnerships among all levels of government and the private sector are based on coordination, integration, and mutual aid. The United States must leverage an array of authorities, technical capabilities, and resources to enhance readiness, response, and recovery capabilities through collaboration with the private sector. The 2019-2022 NHSS set out to:

- Develop and sustain robust public-private partnerships for MCM development and production.
- Sustain and improve private sector healthcare surge capacity for large-scale incidents.
- Foster the creation of a resilient medical product supply chain that includes drugs, biological products, medical devices, PPE, and testing and ancillary supplies.

#### **PROGRESS AND KEY FINDINGS**

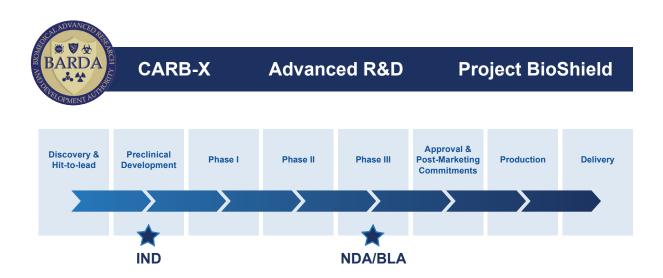
#### Public-Private Partnerships

Establishing and maintaining strong partnerships between the U.S. government and the private sector are integral to protecting the country's health security, especially for MCM development and production. Such collaborations have facilitated progress in combating COVID-19 and AMR. Close cooperation between pharmaceutical firms, NIH, and FDA through public-private partnerships allows for coordinated implementation of a unified research agenda, improves resource use, and accelerates progress from one stage of MCM development to another. Potential MCMs can move more rapidly from preclinical development to clinical trials to production and emergency use authorization while safety and efficacy standards are maintained. These collaborations enabled government and industry to work together based on a well-planned joint research agenda, allowing for evaluation of the safety and effectiveness of vaccines and treatments and their expedited authorization for emergency use. Analysis and refinement of such partnership arrangements can improve future response.

ASPR built partnerships with private healthcare entities to improve healthcare response capabilities. The HPP cooperative agreement provides funding to health department recipients in all 50 states, eight territories and freely associated states, three metropolitan areas (Los Angeles, Chicago, and New York City), and Washington, D.C. to prepare hospitals and other healthcare entities to save lives. HPP utilizes and builds health care coalitions, networks of individual public and private organizations in a defined geographic area that partner to prepare hospitals and other healthcare entities, to increase healthcare preparedness and response capabilities.

Such close federal-private sector cooperation made safe, effective vaccines available to the public in under a year, far less than the typical years-long vaccine development process. Public-private efforts such as FDA's Coronavirus Treatment Acceleration Program (CTAP) and NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) were crucial to the expedited development and approval of therapeutics for COVID-19. Through these and similar initiatives, NIH, FDA, and industry coordinated clinical trial design, identification and investigation of new treatments, trial implementation, and submission of trial data to FDA for authorization, greatly expanding treatments available to physicians and the public despite the continued challenges posed by new SARS-CoV-2 variants. 103,104

Figure 8: BARDA Support for AMR Development Pipeline<sup>105</sup>



AMR continues to be a significant health, economic, development and security threat globally. In 2021, CDC estimated that treating six antibiotic resistance threats contributes to more than \$4.6 billion in healthcare costs annually in the United States. Effectively addressing AMR requires collaboration with private sector and international partners. For example, these partnerships are critical for developing, bringing to market and scale, and effectively deploying alternative treatments and new diagnostics and therapeutics to detect and combat AMR in healthcare and community settings. BARDA's CARB-X accelerates the development of antibacterial MCMs through innovative partnerships with industry. Since its launch in 2016, the CARB-X portfolio has 62 active projects aimed at developing diagnostics, therapeutics, and preventatives.<sup>35, 36</sup>

Despite progress in advancing antibacterial MCMs, the World Health Organization reported that the antibiotic pipeline is not sufficient to combat the rising threat of AMR. <sup>106</sup> Additionally, the COVID-19 pandemic could hinder progress made on AMR, especially in healthcare settings. <sup>107</sup> Continued collaboration with the private sector and creating incentives for companies to manufacture antimicrobials will drive investment in research focused on new, innovative combinations of antibiotic therapies to protect the United States from AMR and other health security threats.

#### **Supply Chain**

To effectively prepare for and respond to public health emergencies, the public health and MCM supply chain must be reliable and resilient. The COVID-19 pandemic highlighted the stresses on domestic and global supply chains and emphasized the need for diverse and redundant sourcing. Throughout the pandemic, there have been shortages of PPE for healthcare workers and the public, diagnostic testing reagents, rapid testing kits, medical devices, and therapeutics. These supply chain shortcomings arose from several factors, including increased global demand, inadequate domestic manufacturing capacity, transportation and distribution challenges, and a rapidly depleting stockpile.

Executive Order 14001 on a Sustainable Public Health
Supply Chain directed immediate actions to secure supplies necessary for responding to the pandemic, so that those supplies are available and remain available at all levels of government and to the healthcare workforce. As part of the mission to create a resilient supply chain, the U.S. government published a National Strategy for a Resilient Public Health Supply Chain. This strategy focuses on making bold investments in the U.S. public health industrial base, improving the robustness of the Strategic National Stockpile, and maintaining end-to-end visibility throughout the supply chain. The strategy directly addresses lessons learned from COVID-19 and offers recommendations for building and

## International Private Sector Collaborations Contribute to Protecting National Health Security

Collaboration with the international private sector is critical to developing and promoting adoption of policies and best practices for infectious disease prevention and control, reducing the need for antimicrobials, and ensuring appropriate use of antimicrobials in public health, animal health, and animal production value chain settings. For example, USAID's Transformational Strategies for Farm Output Risk Mitigation (TRANSFORM) project will engage global market actors across the private sector to develop, test, and scale innovative solutions that address AMR and enhance global health security.

Increased access to antimicrobials around the world, including in low- and middle-income countries, with appropriate market shaping incentives, regulatory systems, surveillance, and stewardship will be critical to furthering sustainable antimicrobial pipelines and slowing down the development of resistance, safeguarding U.S. and global AMR investments while meeting critical healthcare needs.

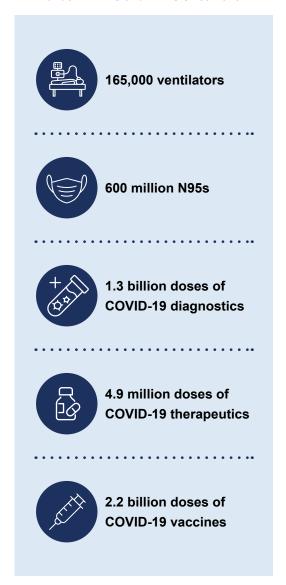
maintaining a resilient public health supply chain to improve overall national health security. In addition, <u>Executive Order 14017 on America's Supply Chains</u> addresses issues with the manufacturing process and location, single points of failure, critical goods supply, research and development, transportation of goods, and legislative, regulatory, and policy changes. Executive Order 14017 also mandated a <u>100-day</u> review of supply chain risks, including pharmaceuticals and active pharmaceutical ingredients.

Domestic manufacturing capabilities are key components of a resilient and robust public health supply chain and industrial base. Throughout the COVID-19 pandemic, reliance on foreign sources for raw materials and some finished goods resulted in critical deficiencies of PPE, therapeutics, vaccines, pharmaceuticals, and diagnostics. To mitigate these issues, the federal government authorized the use of the HRPAS or the DPAS to augment the development, production, and/or procurement of critical COVID-19 countermeasures such as vaccines, therapeutics, diagnostics, PPE, ventilators, and ancillary medical supplies. COVID-19 emergency supplemental appropriations provided at least \$11 billion for Defense Production Act purchases and other actions related to COVID-19 or other public health emergencies through September 2025.<sup>39</sup>

Executive Order 14005: Ensuring the Future Is Made in All of America by America's Workers is designed to expand domestic manufacturing. This Executive Order directs federal agencies to partner with the NIST-based Manufacturing Extension Partnership (MEP) to identify American companies to produce materials, goods, and products in the United States to meet federal procurement needs. The MEP National Network™ initiated several efforts to meet medical supply chain needs during the COVID-19 pandemic. A few examples include:

- Manufacturer's Edge (Colorado MEP) launched the Coronavirus Aid Relief and Economic Security (CARES) Act Outreach Program to connect with manufacturers around nine topics: production and operations, workforce, customer demand, supply chain, business continuity, research and development, outlook on industry, current pain points, and policies on or related to COVID-19 vaccinations.
- FloridaMakes (Florida MEP) launched Connex
  Florida, a supply chain database tool for the
  manufacturing industry in Florida to help Florida
  manufacturers better connect with each other, get
  discovered, and increase business opportunities.
- The Indiana MEP created a pandemic assistance portal used by 350 companies and a return-towork guide in conjunction with the New Jersey and Washington MEP Centers and sent guides to 130 companies.

Figure 9: MCMs and Medical Supplies Procured under HRPAS and DPAS since 2020



- The Missouri MEP created a COVID-19 Products and Services Directory.
- The South Carolina MEP developed the South Carolina Emergency Supply Collaborative portal.
   The portal joined forces with national marketplace PPE Exchange, an online marketplace of more than 200 regional and national PPE suppliers which connects hospitals, healthcare providers, and businesses with verified PPE suppliers so that buyers can search for items, compare prices, complete transactions, and schedule orders in one consolidated location.

As part of the expansion of domestic manufacturing, ASPR created the Office for Innovation and Industrial Base Expansion. This office coordinates a strategic, industrial-based expansion across ASPR, federal partners, academia, and the private sector to innovate solutions for public health emergency response and recovery. It released solicitations to find solutions for PPE manufacturing and made investments in novel drug manufacturing technologies. <sup>108</sup> Additionally, the Strategic National Stockpile has worked to replenish and expand the amount and types of MCMs included as a direct response to the COVID-19 pandemic to include more PPE and ventilators and added drugs and equipment commonly used to manage patients. <sup>109</sup> ASPR has also established the Supply Chain Control Tower, a platform allowing visibility into the public health supply chain. The Supply Chain Control Tower uses real-time data across PPE and pharmaceutical manufacturing partners to provide information for decision-making regarding Strategic National Stockpile supply deployment.

In 2020, DOD and HHS jointly released the Operation Warp Speed strategy for delivering COVID-19 vaccines across the nation. The strategy employed centralized distribution, partnerships with SLTT and commercial entities, and an online vaccine tracking system. Doses were initially distributed using a phased approach, which was adjusted as vaccine production ramped up. Doses were allocated pro-rata, with direct distribution also as an option. Vaccine doses and ancillary supplies required for administration were allocated to states for further distribution within their respective jurisdictions, as well as to select federal and commercial partners. The Operation Warp Speed distribution strategy is outlined in **Figure 10**.

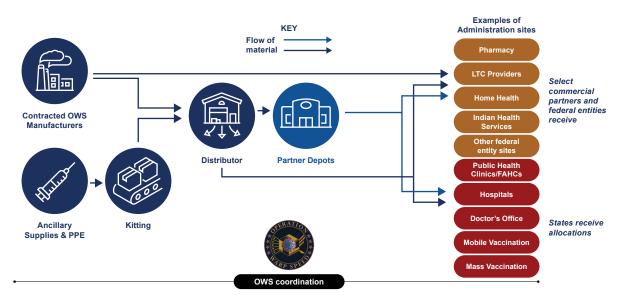


Figure 10: Overview of the Operation Warp Speed Distribution Strategy<sup>110</sup>

#### Cybersecurity and Health Technology

Cybersecurity risks continued to threaten health security. In the five months of 2021 alone, 82 ransomware incidents impacted the healthcare sector globally, with 59% of those affecting the U.S. health sector.<sup>111</sup> Cyber threats to the U.S. supply chain have also increased.<sup>112</sup>

DHS's Cybersecurity and Infrastructure Security Agency (CISA) and NIST, provided cyber guidance and education resources for both public and private healthcare organizations to facilitate improved information sharing and partnerships related to cybersecurity.

Additionally, CISA developed two playbooks: one for incident response and one for vulnerability response. These playbooks provide federal enterprise with a standard set of procedures to identify, coordinate, remediate, recover, and track successful mitigations from incidents and vulnerabilities affecting the Federal Civilian Executive Branch systems, data, and networks. The intent of these playbooks is to strengthen cybersecurity response practices and operational procedures for the federal government, as well as for the public and private sectors. The playbooks contain checklists for incident response, incident response preparation, and vulnerability response that can be adapted to any organization and track necessary activities to completion. The

Increasing telehealth services introduced new concerns for privacy and cybersecurity in telehealth remote patient monitoring (RPM) ecosystems. Patient data is transmitted between many entities in RPM ecosystems, including biometric devices, third-party telehealth platform providers, and clinical teams providing patient care. Interaction of devices and data transmission through multiple domains imposes security and privacy risks for both the patient and healthcare delivery organization. NIST's National Cybersecurity Center of Excellence (NCCoE) performed a risk assessment based on the NIST Risk Management Framework to analyze risk factors regarding an RPM ecosystem. The

#### Federal Government Cybersecurity Guidance and Resources:

- NIST published their <u>Secure Software</u>
   <u>Development Framework</u> containing
   recommendations and software
   development best practices for mitigating
   the risk of software vulnerabilities.
- NIST released an initial public draft of Implementing the Health Insurance
   Portability and Accountability Act
   (HIPAA) Security Rule: A Cybersecurity
   Resource Guide to help regulated entities manage risk to electronic protected health information and improve their organizational security posture.
- CISA and NIST released a joint publication titled <u>Defending Against Software Supply</u> <u>Chain Attacks</u>, providing recommendations on how software customers and vendors can use their frameworks to identify, assess, and mitigate software supply chain risks.
- CISA launched the <u>Stop Ransomware</u> <u>website</u>, which includes a readiness selfassessment tool and educational content to prevent and respond to ransomware incidents.
- NIST developed a spreadsheet of healthcare work roles with technical and cyber responsibilities aligned to the National Initiative for Cybersecurity Education Workforce Framework for Cybersecurity (NICE Framework) and repeatedly updated its collection of Security and Privacy Controls that organizations can use to tailor their own risk management approaches.

NCCoE project team, in collaboration with healthcare, technology, and telehealth partners, built an RPM ecosystem in a laboratory environment and explored methods to improve RPM cybersecurity. The project demonstrated a solution that organizations could implement to enhance the privacy and security of their respective telehealth RPM ecosystems.<sup>43</sup>

#### Healthcare and Public Health Critical Infrastructure

National health security is dependent upon robust healthcare and public health infrastructure that can adapt, prepare for, respond to, and recover from challenges. The public health and healthcare sector include goods and services, including hospital and ambulatory healthcare, public health, public health information, mental health, substance abuse treatment, environmental and occupational health, long-term care, telehealth, pharmaceuticals, mortuary services, and medical supplies. Healthcare and public health infrastructure are critical to managing ongoing and emerging issues that impact the health of an individual, region, or country, such as incidents relating to terrorism and infectious disease outbreaks and impacts from natural hazards.

CDC's Public Health Emergency Preparedness (PHEP) program supports SLTT jurisdictions in accelerating their progress across 15 public health emergency preparedness and response capabilities nationally.<sup>117</sup> Through the PHEP program, CDC provides the Cities Readiness Initiative (CRI) funding to enhance preparedness in the nation's largest population centers where nearly 60% of the population reside. This funding enables CRI jurisdictions to effectively prepare for and respond to large public health emergencies needing life-saving medicines and medical supplies.<sup>44</sup> PHEP also supports 31 career epidemiology field officers and 23 preparedness field assignees to directly support the development of emergency preparedness capabilities in state and local health departments.<sup>118</sup>

As an integral part of the National Response Framework, CDC's Laboratory Response Network (LRN) infrastructure has underpinned the U.S. response to various biothreat events and emerging infectious disease outbreaks over the past 20 years. The LRN model allows for both flexibility and consistency for high-confidence results to inform local, state, and national responses. The LRN also supports other federal programs such as BioWatch. Additionally, in 2020 CDC launched a Data Modernization Initiative (DMI) to modernize core data and surveillance infrastructure across the federal and state public health landscape. The Data Modernization Initiative is critical component of national effort to create modern, integrated, and real-time public health data and surveillance intended to protect Americans from any

health threat. 121

DHS and HHS entities also engaged in efforts to improve public health critical infrastructure. CISA offers a wide variety of infrastructure resources and training by sector. ASPR launched the Healthcare and Public Health Risk Identification and Site Criticality (RISC) Toolkit. This toolkit assisted hospitals with identifying and addressing hazards. An updated version, the RISC Toolkit 2.0, is scheduled for release in 2023.

In 2021, HHS released the HHS Maternal Child Health Emergency Planning Toolkit. This toolkit is a resource for healthcare, public health, and social services professionals to improve maternal and child health during emergency preparedness, response, recovery, and mitigation efforts.

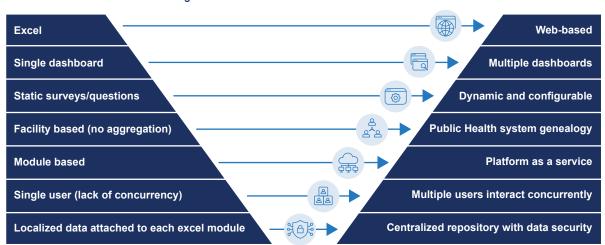


Figure 11: RISC Toolkit 1.0 vs. RISC Toolkit 2.045

Research and clinical trial capacity are also an important components of public health critical infrastructure. Having strong research infrastructure in place contributes to the development of vaccines, diagnostics, and therapeutics. Medical research capacity of the United States has been a vital asset for mitigating the effects of the pandemic. By establishing innovative public-private partnerships like Operation Warp Speed, ACTIV, and CTAP, the country was able to draw on decades of noncommercial research on mRNA vaccine platforms and significant preclinical investment on structure-based vaccine design to formulate SARS-CoV-2 vaccine candidates and get them into well-designed clinical trials relatively quickly. Progress on MCM development during a response can be slowed by lack of clinical trial capacity.<sup>124</sup>. Future preparedness could benefit from standing clinical trial networks to ensure planning

and implementation of well-designed, non-duplicative clinical trials. Such networks can provide high-quality research capacity for ongoing MCM development and should be organized so they can guickly pivot to national research needs in an emergency.

Vulnerabilities in public health and medical critical infrastructure weaken national health security. Underfunding of public health infrastructure leads to challenges in communications, disease surveillance, contact tracing, and vaccine delivery, as well as limitations in important, ongoing non-pandemic-related projects. Weaknesses in public health and healthcare critical infrastructure during the pandemic contributed to the inability to consistently perform contact tracing, reduced availability of PPE for healthcare workers in the initial stages of the pandemic, cancellation of elective procedures in hospitals, and delays in test results due to overwhelmed public health laboratories. While the United States has engagement in activities to fortify healthcare and public health critical infrastructure in recent years, continual investment in these efforts is critical to ensuring infrastructure is resilient and ready for future threats.

NIH's National Institute of Environmental Health Sciences' Worker Training Program created tools, resources, and provided training to inform and educate worker populations through its network of grantees and their partners to ensure workers were empowered to identify risk and advocate for their health and safety. Several worker populations who benefit from this program work in the critical infrastructure sector or other essential industries. Program grantees continue this work through community recovery centers that provide education and training on COVID-19, as well as other topics such as mental health resilience and opioids.



#### **PROMISING PRACTICES:**

Select National Health Security Highlights from HPP, PHEP, NDMS, BARDA, and Vaccine Tracking Activities

The United States Public Health Service Act requires the NHSS Evaluation of Progress to include updates regarding HPP, PHEP, NDMS, BARDA, and vaccine tracking activities.¹ This requirement was most recently reauthorized as part of the 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act.⁴6 These programs are critical components of U.S. health security. For example, they provide funding to SLTT entities to improve public health preparedness and response capabilities, provide technical assistance during public health emergencies, and drive MCM research and development activities. This section details specific examples about how HPP, PHEP, NDMS, BARDA and vaccine tracking activities have protected national health security between 2019 and 2022. HPP, NDMS, and BARDA are housed within ASPR, and PHEP is operated by CDC.

#### HHS FUNDING EXPANDS COVID-19 IMMUNIZATION INFORMATION SHARING<sup>125</sup>

In January 2021, HHS's Office of the National Coordinator for Health Information Technology awarded \$20 million through the CARES Act to increase data sharing between health information exchanges and immunization information systems. The investments built on the Strengthening the Technical Advancement and Readiness of Public Health Agencies via Health Information Exchange Program to improve data sharing related to COVID-19 vaccinations. This collaboration allowed for easier tracking of people who received the COVID-19 vaccine, identification of high-risk patients who had not yet been vaccinated, and a mechanism to measure vaccination outcomes.

## BARDA CONTRIBUTES TO THE DEVELOPMENT OF MCMS FOR COVID-19<sup>126</sup>

In response to the COVID-19 pandemic, BARDA partnered with private industry, NIH, FDA, and other federal partners to develop MCMs for SARS-CoV-2. BARDA supplied billions of dollars in funding to pharmaceutical companies for vaccine research, development, and manufacturing. These partnerships



proved critical in enhancing the speed at which COVID-19 vaccines were developed. By December 2020, EUAs were issued for two BARDA-supported vaccines produced by Pfizer-BioNTech and Moderna. A third partnership with Johnson & Johnson and Janssen Pharmaceuticals, Inc., led to a third EUA for a COVID-19 vaccine in February 2021. The Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) vaccines were licensed by the FDA in August 2021 and January 2022, respectively.

In addition to vaccine development, BARDA funding also contributed to the development of other MCMs for SARS-CoV-2. As of October 21, 2022, BARDA is actively supporting <u>57 diagnostics</u>, <u>8 therapeutics</u>, and <u>15 rapidly deployable technologies</u> to aid in the detection and treatment of COVID-19. Of these, 26 diagnostics, five therapeutics, and one rapidly deployable technology have active EUAs as of October 21, 2022 and one diagnostic has received FDA clearance as of that date.

## BARDA SUPPORTED DIAGNOSTICS FOR CBRN AGENTS AND INFECTIOUS DISEASE THREATS BEYOND COVID-1983

Even with BARDA's focus on developing diagnostics for COVID-19, the organization has continued to support the development of diagnostics for other CBRN and infectious disease threats. Between 2019 and 2022, BARDA collaborated with private sector partners to develop diagnostics to detect health security threats, including Zika, Ebola, anthrax, and influenza. Seven of the diagnostics received FDA approval, licensure, or clearance. A summary of these diagnostics is in **Table 1**.

Table 1: Non-COVID-19 BARDA Supported Diagnostics that Received FDA Approval, Clearance, or Licensure between 2019-2022

Product	Private Sector Partner	Threat	Date of FDA Approval, Clearance, or Licensure
Zika Antibody Response Detection - DPP® Zika IgM System	Chembio	Zika	June 2020
OraQuick Ebola Rapid Antigen Test	OraSure Technologies, Inc.	Ebolavirus	October 2019
Applied Biosystems™ <i>Bacillus antracis</i> Detection Kit	Applied Biosystems	Anthrax	October 2019
LIAISON XL Zika Capture IgM II and LIAISON XL Zika Capture IgM II Control Set	DiaSorin Inc.	Zika	October 2019
ADVIA Centaur® Zika Test	Siemens Healthcare Diagnostics, Inc.	Zika	July 2019
InBios International Manual Zika IgM Assay	InBios International, Inc.	Zika	May 2019
FluChip-8G Influenza A+B Assay	InDevR, Inc.	Influenza	April 2019

## BARDA SUPPORTED THERAPEUTICS AND MEDICAL DEVICES FOR CBRN AGENTS AND INFECTIOUS DISEASE THREATS BEYOND COVID-1983

BARDA continued to partner with private industry to develop therapeutics and medical devices to treat an array of health security threats unrelated to COVID-19, including smallpox, Ebola, influenza, and chemical agents. Eight BARDA-supported therapeutics and medical devices received FDA approval, licensure, or clearance between 2019 and 2022. These therapeutics and medical devices are outlined in **Table 2**.

Table 2: Non-COVID-19 BARDA-Supported Therapeutics and Medical Devices that Received FDA Approval, Clearance, or Licensure between 2019 and 2022

Product	Private Sector Partner	Threat	Date of FDA Approval, Clearance, or Licensure
TPOXX (tecovirimat) injection, for intravenous use	SIGA Technologies Inc.	Smallpox	May 2022
StrataGraft	Stratatech Corporation and Mallinckrodt Company	Thermal Burns	June 2021
TEMBEXA	Chimerix Inc.	Smallpox	June 2021
Lumify Ultrasound	Philips North America	Pulmonary injury	February 2021
Nplate (romiplostim)	Amgen Inc.	Radiological/Nuclear injury	January 2021
Ebanga (Ansuvimab/mAb 114)	Ridgeback Biotherapeutics, LP	Ebolavirus	December 2020
Inmazeb® (REGN-EB3)	Regeneron Pharmaceuticals	Ebolavirus	October 2020
Silverlon	Argentum Medical	Sulfur Mustard	July 2019
Trilogy Evo Universal (K181170) Ventilator	Philips	Influenza	July 2019

#### CDC COVID-19 VACCINE TRACKING<sup>127</sup>

CDC, in partnership with other federal partner agencies, vaccine providers, jurisdictions, state and local health departments, and tribal health facilities, has implemented an extensive domestic vaccine tracking data system for the COVID-19 vaccine. This system integrates new and existing data streams to provide critical information about the vaccine for decision-making and monitoring. This network collects data on vaccine allocation, distribution, administration, monitoring, and reporting. CDC and its partners also use several complementary vaccine safety systems to monitor for adverse events and ensure that the benefits continue to outweigh the risks for people who receive vaccines.

There are several data components that allow for management of the complete domestic tracking system. Vaccine Administration Management System tracks vaccines from the arrival at the clinic to the administration into a patient, providing near real-time data tracking in participating jurisdictions. The Immunization Information System consolidates patient vaccine records and at the population level can be used to help identify populations at risk for vaccine-preventable diseases. Immunization Gateway is a secure cloud-based service that allows exchange of Immunization Information System data among jurisdictions and multijurisdictional vaccine partners. V-safe provides personalized and confidential health

check-ins via text messages and web surveys so that people can quickly and easily share with CDC how they, or their children, feel after getting a COVID-19 vaccine. This information helps CDC monitor the safety of COVID-19 vaccines in near real time. VTrckS is CDC's vaccine order management system and is being used for all COVID-19 vaccine ordering. Collectively, these systems provide the CDC, SLTT, and public health and medical partners with critical vaccine tracking information. These systems collect, manage, and share COVID-19 vaccination data throughout the country. Currently, all states are using some form of COVID-19 vaccine tracking management system. 128

## REDUCING THE SPREAD OF COVID-19 DURING THE 2020 PRESIDENTIAL NOMINATING CONVENTIONS<sup>129</sup>

The 2020 Democratic National Convention (DNC) and the 2020 Republican National Convention (RNC) modified their traditional convention formats to include additional precautions to limit the spread of COVID-19. DNC organizers in Wisconsin and RNC organizers in North Carolina worked with HPP-supported healthcare coalitions, namely the Southeast Wisconsin Healthcare Emergency Readiness Coalition (HERC Region 7) and the Metrolina Healthcare Preparedness Coalition (MHPC), to design health safety protocols and ensure their state-level healthcare systems were prepared for the conventions.



HPP collaborated with HERC Region 7 and MHPC to support response planning, medical preparedness, and surveillance activities that helped safeguard DNC and RNC participants. Examples include leveraging existing systems for contact tracing, administrating health screenings and temperature checks, isolating confirmed cases, and conducting timely information sharing. These actions allowed HERC Region 7 and MHPC, with HPP support, to successfully limit the spread of COVID-19 at the DNC and RNC.

## HPP SUPPORTS COORDINATION AND RESOURCE DEPLOYMENT FOLLOWING A LIQUID OXYGEN SPILL<sup>130</sup>

In January 2019, a pipe leading to a liquid oxygen tank at Cedars-Sinai Marina del Rey Hospital ruptured. Cedars-Sinai Marina del Rey hospital is a member of the Cedars-Sinai health system, which is part of the HPP-funded Los Angeles County Disaster Resource Center program. As such, the hospital was able to request the program's assistance.

The Los Angeles County Disaster Resource Center consists of 13 hospitals, 66 umbrella hospitals, and healthcare coalition partners that work together to coordinate the stockpiling of supplies that can be deployed in the event of an emergency. In 2013, Cedars-Sinai used HPP funds to refurbish a VA surplus trailer into a deployable liquid oxygen trailer. The Los Angeles County Disaster Resource Center

was able to deploy this asset to Cedars-Sinai Marina del Rey within one day of the pipe rupturing. The oxygen trailer served as a back-up oxygen tank for the hospital while the primary tank underwent repairs, enabling Cedars-Sinai Marina del Rey to continue caring for patients that required oxygen rather than transferring them to another facility.

#### PHEP HELPS ATLANTA PREPARE FOR SUPER BOWL LIII<sup>131</sup>

PHEP regularly offers assistance to jurisdictions as they plan for potential emergencies at mass gathering events, which are termed Special Security Events. The Super Bowl is one such event, and in 2019 PHEP helped the city of Atlanta prepare for the anticipated one million visitors that would descend upon the city for Super Bowl LIII and its leadup events. In advance of the Super Bowl, a PHEP-funded CDC Epidemiology Field Officer tracked symptoms and monitored vendors to detect signs of potential foodborne outbreaks. The CDC Epidemiology Field Officer plays a critical coordinating role between federal, state, and local partners in the event of an emergency response.

Additionally, Fulton County used PHEP funds to develop and update its National Special Security Event plans. PHEP funds were also used by the county to hold trainings for large groups and conduct emergency preparedness exercises in the year leading up to Super Bowl LIII. Together, these efforts supported by PHEP funding contributed to the success of the event, which reported no major incidents.

## LOS ANGELES COUNTY USES HPP FUNDS TO EXPAND SURGE CAPACITY AND SECURE RESOURCES<sup>132</sup>

Like many other hospitals in the United States, those in Los Angeles County were regularly operating at near maximum capacity during the COVID-19 pandemic. As COVID-19 infections in the area continued to surge in late 2020, many hospitals were running low on resources and bed availability. Because of this, certain hospitals were close to implementing crisis standards of care. HPP funding was used to prepare the already strained Los Angeles County hospitals for the anticipated spike in COVID-19 cases during the winter of 2020-2021.

HPP funding allowed Los Angeles County to establish a disaster preparedness program and set up a supply warehouse. The warehouse was stocked with PPE, pharmaceuticals, surge tents to increase bed capacity, medical equipment, and other ancillary medical supplies that could be sent to hospitals upon request. In 2020, more than 6,000 resource requests were filled, which resulted in the dispensing of 50 million medical items and more than 100 surge tents to hospitals. These supplies proved critical in helping Los Angeles County hospitals weather the winter surge of COVID-19 and avoid the need to implement crisis standards of care.

#### NDMS DEPLOYED TO MEMPHIS, TENNESSEE, TO AID IN THE COVID-19 RESPONSE<sup>133</sup>

In September 2021, 15 NDMS healthcare professionals were deployed to Memphis, Tennessee's Baptist Memorial Hospital to assist the emergency department in responding to a surge of COVID-19 cases. NDMS personnel arrived to find ambulances lined up outside the emergency department, hospital rooms at maximum capacity, and patients waiting to be seen overflowing into the emergency room hallways. The extremely high volume of patients resulted in the hospital being place on critical advisory.

The NDMS team quickly coordinated with hospital staff and began to assist. NDMS personnel helped triage patients in ambulances and in the emergency waiting room, discharged patients, and subsequently prepared hospital rooms for incoming patients. Within hours of the NDMS team's arrival, the hospital was taken off critical advisory status. Even after the change in status, NDMS teams continued to provide care to those in need, restock supplies, and move patients from the emergency department to inpatient rooms when needed. By the end of the NDMS team's shift, only a single ambulance remained at the hospital's entrance.

## PHEP FUNDING PROVIDES EMERGENCY MEDICAL SERVICES (EMS) COMMUNICATIONS SUPPORT IN TENNESSEE<sup>134</sup>

In 2019, several county EMS agencies were acquired by the West Tennessee Healthcare/Medical Center EMS. The acquisition resulted in the newly acquired EMS agencies needing to update their communication systems. During this update, it was discovered that one of the EMS agencies was unable to dispatch to its southernmost area of operation.

A dental bus converted into a functional mobile dispatch center using PHEP funding was deployed to provide communications assistance. The mobile dispatch center took over all ambulance dispatching in McNairy County for approximately four hours. The mobile dispatch center was then moved to nearby Chester County to reestablish the county's EMS communication network and provide dispatch services for six hours. Without the PHEP-funded mobile communication center, these areas would have been cut off from critical EMS communications.

#### NDMS RESPONDS TO HURRICANE LAURA

On August 27, 2021, Hurricane Laura made landfall as a Category 4 storm in Louisiana. The healthcare system in Louisiana, like many parts of the United States, was already strained due to the COVID-19 pandemic. The landfall of a major hurricane only added to the existing pressures on the state's hospital systems.

NDMS deployed teams consisting of nurses, physicians, physician assistants, paramedics, and pharmacists to support three hospitals in the affected area. NDMS personnel collaborated with hospital staff and supported patient triage and treatment efforts for those injured during the storm and its aftermath.



Figure 13: Ambulances Outside
Baptist Memorial Hospital in Memphis,
Tennessee<sup>133</sup>



Figure 14: NDMS Responders Treat
Family for Carbon Monoxide Poisoning
Following Hurricane Laura

# Looking Ahead to the 2023-2026 NHSS: OPPORTUNITIES TO ADVANCE NATIONAL HEALTH SECURITY

The United States faced unique health security challenged from 2019 to 2022. COVID-19 pushed health security to the forefront of the minds of American leaders and the public. The COVID-19 pandemic spurred a massive shift of federal, SLTT, private sector, and societal resources towards protecting the health security of the United States. Lessons learned from the COVID-19 pandemic, and the significant investments made to combat it, have led to the United States being more prepared today for future health security threats than in pre-pandemic times. As the nation moves forward, it is imperative that the United States continues to build upon progress made and sustain its focus on national health security to be ready for the array of health security threats that may arise in the future.

Though many improvements were made between 2019 and 2022, opportunities exist for the United States to further expand its capabilities to prepare for, respond to, and recover from health security threats. These opportunities informed the goals and objectives of the next NHSS, which covers 2023 to 2026.

The COVID-19 pandemic highlighted opportunities for the United States to strengthen its healthcare and public health systems. The nation can focus on recruiting and retaining additional healthcare and public health professionals—including those in MCM research and development—and improving the healthcare and public health sector's physical infrastructure readiness. A well-staffed and flexible



healthcare and public health workforce, combined with more resilient health infrastructure, will better equip the United States to respond to health security threats, disasters, and simultaneous emergencies. The United States can also work towards ensuring its healthcare systems are protected against cybersecurity threats and able to address the complex needs of its communities to promote equitable access to care and tailored response and recovery actions during disasters or public health emergencies.

The years 2019 to 2022 also showed the United States can better its capabilities to protect the public from health security threats, including emerging, zoonotic, and other infectious diseases. Integrating surveillance across the human, animal, plant, and environmental sectors can result in more timely detection of diseases, quicker identification of spillover events, and protect the security of the food supply

chain. The United States can also enhance its public health surveillance systems to include health equity and socioeconomic demographic data, which can lead to better health outcomes for underserved communities. These actions can be augmented by implementation of more effective risk communication systems to promote coordinated and accurate public health messaging in plain language that is accessible underserved populations and those with limited English proficiency.

Maintaining a resilient public health industrial base and supply chain capable of rapidly developing MCMs will also benefit national health security going forward. This can be accomplished by expanding domestic manufacturing capacity, by diversifying supply sourcing, and through close coordination between the federal government and the private sector. As the United States expands domestic manufacturing and diversifies source production of essential raw materials, it will lessen U.S. dependence on foreign markets and ensure production of critical supplies and raw materials are not dependent on a single source. It will also be critical to ensure that the expansion of U.S.-based manufacturing capacity is sustainable through the manufacturing of products for the commercial markets and other means. Strengthening partnerships between federal entities and MCM suppliers, manufacturers, and distributors can mitigate shortages and supply chain vulnerabilities.

Continued MCM research and development activities can also better equip the United States to combat health security threats. Broadening MCM research and development activities helps the public health supply chain maintain adequate stockpiles of critical medications, medical devices, and ancillary health supplies for known threats. Additionally, improved MCM research and development processes, from concept to laboratory to patient can lead to the United States being better prepared to respond to novel or emerging threats. For example, continued research in MCM technologies that are easily adaptable and quickly scalable can enable a more rapid response to unknown threats. Maintaining the nation's biomedical research enterprises and strengthening clinical trial networks for coordinated rapid action when needed, in coordination with other partners, is also key.

The 2023-2026 NHSS aims to translate these opportunities for improvement into a strategic direction that can propel the United States toward better protecting the public from health security threats in the years to come.

# Appendix A: HPP FUNDING

Table 3: FY 2019 – FY 2022 HPP Funding<sup>135, 136, 137</sup>

Awardee	FY 2019	FY 2020	FY 2021	FY 2022*
Alabama	\$3,101,457	\$3,145,268	\$3,145,268	\$3,145,268
Alaska	\$1,097,949	\$1,111,466	\$1,111,466	\$1,111,466
American Samoa	\$276,077	\$279,211	\$279,211	\$279,211
Arizona	\$4,704,562	\$4,716,474	\$4,716,474	\$4,716,474
Arkansas	\$2,073,408	\$2,099,822	\$2,099,822	\$2,099,822
California	\$23,274,780	\$23,171,118	\$23,171,118	\$23,171,118
Chicago	\$2,742,281	\$2,818,423	\$2,818,423	\$2,818,423
Colorado	\$3,255,651	\$3,281,648	\$3,281,648	\$3,281,648
Connecticut	\$2,241,789	\$2,261,523	\$2,261,523	\$2,261,523
Delaware	\$1,069,426	\$1,086,723	\$1,086,723	\$1,086,723
District of Columbia	\$1,148,960	\$1,187,386	\$1,187,386	\$1,187,386
Florida	\$11,823,573	\$11,800,098	\$11,800,098	\$11,800,098
Georgia	\$7,984,714	\$7,950,996	\$7,950,996	\$7,950,996
Guam	\$344,674	\$356,511	\$356,511	\$356,511
Hawaii	\$1,272,454	\$1,276,715	\$1,276,715	\$1,276,715
Idaho	\$1,306,270	\$1,318,146	\$1,318,146	\$1,318,146
Illinois	\$8,808,313	\$8,353,473	\$8,353,473	\$8,353,473
Indiana	\$3,927,515	\$3,956,143	\$3,956,143	\$3,956,143
lowa	\$2,040,550	\$2,049,436	\$2,049,436	\$2,049,436
Kansas	\$2,002,917	\$2,009,918	\$2,009,918	\$2,009,918
Kentucky	\$2,851,105	\$2,803,092	\$2,803,092	\$2,803,092
Los Angeles County	\$9,155,013	\$9,142,488	\$9,142,488	\$9,142,488
Louisiana	\$2,990,820	\$2,934,248	\$2,934,248	\$2,934,248
Maine	\$1,107,031	\$1,122,201	\$1,122,201	\$1,122,201
Marshall Islands	\$269,480	\$268,164	\$268,164	\$268,164
Maryland	\$5,134,799	\$5,297,615	\$5,297,615	\$5,297,615
Massachusetts	\$4,069,878	\$4,090,461	\$4,090,461	\$4,090,461
Michigan	\$5,770,572	\$5,799,153	\$5,799,153	\$5,799,153
Micronesia	\$282,682	\$283,060	\$283,060	\$283,060
Minnesota	\$3,376,813	\$3,399,515	\$3,399,515	\$3,399,515
Mississippi	\$2,038,196	\$2,062,902	\$2,062,902	\$2,062,902
Missouri	\$3,636,821	\$3,626,688	\$3,626,688	\$3,626,688

Awardee	FY 2019	FY 2020	FY 2021	FY 2022*
Montana	\$1,090,377	\$1,099,880	\$1,099,880	\$1,099,880
N. Mariana Islands	\$276,615	\$278,796	\$278,796	\$278,796
Nebraska	\$1,398,788	\$1,401,496	\$1,401,496	\$1,401,496
Nevada	\$2,593,012	\$2,531,286	\$2,531,286	\$2,531,286
New Hampshire	\$1,098,617	\$1,106,453	\$1,106,453	\$1,106,453
New Jersey	\$5,369,840	\$5,370,096	\$5,370,096	\$5,370,096
New Mexico	\$1,590,617	\$1,581,141	\$1,581,141	\$1,581,141
New York	\$9,864,244	\$9,895,682	\$9,895,682	\$9,895,682
New York City	\$7,501,609	\$7,486,901	\$7,486,901	\$7,486,901
North Carolina	\$6,086,316	\$6,083,849	\$6,083,849	\$6,083,849
North Dakota	\$1,063,632	\$1,071,922	\$1,071,922	\$1,071,922
Ohio	\$7,072,358	\$7,059,431	\$7,059,431	\$7,059,431
Oklahoma	\$2,510,199	\$2,549,685	\$2,549,685	\$2,549,685
Oregon	\$2,588,708	\$2,614,621	\$2,614,621	\$2,614,621
Palau	\$256,518	\$255,889	\$255,889	\$255,889
Pennsylvania	\$7,728,428	\$7,702,626	\$7,702,626	\$7,702,626
Puerto Rico	\$2,596,212	\$2,590,019	\$2,590,019	\$2,590,019
Rhode Island	\$1,063,672	\$1,071,962	\$1,071,962	\$1,071,962
South Carolina	\$3,139,944	\$3,147,824	\$3,147,824	\$3,147,824
South Dakota	\$1,071,504	\$1,083,466	\$1,083,466	\$1,083,466
Tennessee	\$4,004,671	\$4,013,830	\$4,013,830	\$4,013,830
Texas	\$15,493,193	\$15,577,836	\$15,577,836	\$15,577,836
U.S. Virgin Islands	\$303,699	\$305,421	\$305,421	\$305,421
Utah	\$2,368,945	\$2,373,046	\$2,373,046	\$2,373,046
Vermont	\$1,066,451	\$1,067,602	\$1,067,602	\$1,067,602
Virginia	\$6,897,199	\$6,857,550	\$6,857,550	\$6,857,550
Washington	\$4,336,358	\$4,367,027	\$4,367,027	\$4,367,027
West Virginia	\$1,404,726	\$1,400,530	\$1,400,530	\$1,400,530
Wisconsin	\$3,416,869	\$3,417,594	\$3,417,594	\$3,417,594
Wyoming	\$1,066,149	\$1,076,454	\$1,076,454	\$1,076,454
Totals	\$231,500,000	\$231,500,000	\$231,500,000	\$231,500,000

<sup>\*</sup>FY 2022 HPP funding reflects planning numbers subject to change based on the availability of funding.

# Appendix B: PHEP FUNDING

Table 4: FY 2019 – FY 2022 PHEP Funding 138, 139, 140, 141

Awardee	FY 2019	FY 2020	FY 2021	FY 2022
Alabama	\$9,054,221	\$8,740,894	\$8,892,198	\$9,021,541
Alaska	\$5,447,600	\$5,169,900	\$5,210,000	\$5,760,000
American Samoa	\$411,385	\$412,042	\$422,440	\$413,424
Arizona	\$12,446,524	\$12,164,945	\$12,695,698	\$13,142,567
Arkansas	\$6,894,830	\$6,558,883	\$6,666,795	\$6,962,659
California	\$41,896,344	\$42,272,321	\$44,070,003	\$44,440,891
Chicago	\$9,715,194	\$9,651,560	\$10,070,627	\$10,207,392
Colorado	\$10,368,137	\$10,066,666	\$10,407,154	\$10,828,721
Connecticut	\$7,842,523	\$7,514,989	\$7,693,758	\$7,756,083
Delaware	\$5,075,000	\$5,312,726	\$5,383,535	\$5,405,020
District of Columbia	\$6,831,442	\$6,467,129	\$6,548,017	\$6,527,834
Florida	\$30,329,229	\$30,596,524	\$31,844,745	\$32,589,946
Georgia	\$16,429,205	\$16,188,726	\$16,818,599	\$17,715,933
Guam	\$532,702	\$534,657	\$550,942	\$543,123
Hawaii	\$5,075,000	\$5,627,369	\$5,315,643	\$5,642,210
Idaho	\$5,075,000	\$5,546,900	\$5,246,538	\$5,382,980
Illinois	\$16,296,979	\$16,052,302	\$16,541,884	\$16,906,455
Indiana	\$11,527,724	\$11,238,343	\$11,575,238	\$12,002,107
lowa	\$7,053,143	\$6,718,250	\$6,825,471	\$7,158,236
Kansas	\$6,600,607	\$7,009,071	\$6,778,745	\$6,818,460
Kentucky	\$8,293,772	\$8,348,507	\$8,510,043	\$8,553,495
Los Angeles County	\$20,235,667	\$19,648,468	\$20,733,030	\$20,923,151
Louisiana	\$8,672,294	\$9,102,809	\$8,934,209	\$8,919,448
Maine	\$5,075,000	\$5,542,500	\$5,210,000	\$5,510,000
Marshall Islands	\$408,616	\$409,243	\$426,964	\$418,761
Maryland	\$11,399,141	\$11,105,328	\$11,510,060	\$12,077,135
Massachusetts	\$12,943,677	\$13,031,996	\$13,421,314	\$13,800,043
Michigan	\$16,185,611	\$16,309,591	\$16,711,689	\$16,981,692
Micronesia	\$467,114	\$468,367	\$488,764	\$478,510
Minnesota	\$11,164,582	\$11,235,645	\$11,559,800	\$12,131,089
Mississippi	\$6,527,773	\$6,936,267	\$6,655,374	\$6,601,489
Missouri	\$10,987,397	\$10,691,802	\$11,007,602	\$11,383,901

Awardee	FY 2019	FY 2020	FY 2021	FY 2022
Montana	\$5,075,000	\$5,542,500	\$5,210,000	\$5,210,000
N. Mariana Islands	\$410,851	\$411,502	\$425,119	\$408,982
Nebraska	\$5,329,627	\$5,726,102	\$5,446,141	\$5,483,678
Nevada	\$7,258,599	\$6,924,768	\$7,157,460	\$7,297,816
New Hampshire	\$5,447,600	\$5,280,301	\$5,345,470	\$5,663,127
New Jersey	\$15,400,178	\$15,144,167	\$15,725,569	\$16,344,236
New Mexico	\$6,638,183	\$6,664,176	\$6,760,227	\$6,949,221
New York	\$18,544,755	\$18,683,356	\$19,480,531	\$19,763,713
New York City	\$18,790,865	\$18,608,800	\$19,398,987	\$20,055,935
North Carolina	\$15,356,128	\$15,108,972	\$15,545,983	\$15,894,002
North Dakota	\$5,075,000	\$5,169,900	\$5,210,000	\$5,210,000
Ohio	\$17,356,642	\$17,502,622	\$18,042,980	\$18,224,028
Oklahoma	\$7,693,590	\$7,742,012	\$7,910,584	\$7,950,479
Oregon	\$8,109,807	\$8,161,938	\$8,382,359	\$8,444,226
Palau	\$374,215	\$374,474	\$380,471	\$370,357
Pennsylvania	\$18,782,276	\$19,315,104	\$19,517,788	\$19,783,265
Puerto Rico	\$6,522,620	\$6,560,315	\$6,613,160	\$6,653,125
Rhode Island	\$5,447,600	\$5,271,773	\$5,336,988	\$5,669,497
South Carolina	\$9,917,925	\$9,979,562	\$10,217,636	\$10,404,117
South Dakota	\$5,075,000	\$5,542,500	\$5,210,000	\$5,210,000
Tennessee	\$11,198,104	\$11,654,608	\$11,636,659	\$12,135,779
Texas	\$39,141,025	\$39,129,703	\$40,952,164	\$42,270,242
U.S. Virgin Islands	\$465,667	\$466,904	\$478,140	\$466,932
Utah	\$7,157,125	\$6,823,464	\$7,004,062	\$7,461,137
Vermont	\$5,447,600	\$5,169,900	\$5,210,000	\$5,510,000
Virginia	\$14,857,347	\$14,966,098	\$15,481,874	\$15,885,898
Washington	\$12,756,443	\$12,478,656	\$12,955,078	\$13,507,141
West Virginia	\$5,556,448	\$5,196,440	\$5,255,093	\$5,229,883
Wisconsin	\$11,333,547	\$11,404,763	\$11,623,201	\$11,917,508
Wyoming	\$5,075,000	\$5,169,900	\$5,210,000	\$5,210,000
Totals	\$622,858,200	\$622,850,000	\$637,850,603*	\$653,588,620

<sup>\*</sup>PHEP FY 2021 total includes an additional \$1 million from the Cities Readiness Initiative supplemental funding award.

## Acronyms

Acronym	Definition
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
AMR	Antimicrobial Resistance
APHIS	Animal and Plant Health Inspection Service
ASPR*	Administration for Strategic Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CARB-X	Combatting Antibiotic Resistance Bacteria Accelerator
CARES Act	Coronavirus Aid Relief and Economic Security Act
CBRN	Chemical, Biological, Radiological, Nuclear
CDC	Centers for Disease Control and Prevention
CISA	Cybersecurity and Infrastructure Security Agency
COVID-19	Coronavirus Disease 2019
CRI	Cities Readiness Initiative
CTAP	Coronavirus Treatment Acceleration Program
DHS	Department of Homeland Security
DNC	Democratic National Convention
DOD	Department of Defense
DPAS	Defense Priority and Allocations System
EMS	Emergency Medical Services
EPA	Environmental Protection Agency
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FY	Fiscal Year
H-CORE	HHS Coordination Operations and Response Element
HERC	Healthcare Emergency Readiness Coalition
HHS	Department of Health and Human Services
HPP	Hospital Preparedness Program
HRPAS	Health Resources Priority and Allocations System
LRN	Laboratory Response Network
MEP	Manufacturing Extension Partnership
MCM	Medical Countermeasure
MHPC	Metrolina Healthcare Preparedness Coalition
MRC	Medical Reserve Corps
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Acronym	Definition
mRNA	Messenger RNA
N3C	National COVID Cohort Collaborative
NCCoE	National Cybersecurity Center of Excellence
NDMS	National Disaster Medical System
NHSS	National Health Security Strategy
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NS3	National SARS-CoV-2 Strain Surveillance Program
NSSP	National Syndromic Surveillance Program
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHEP	Public Health Emergency Preparedness Program
PPE	Personal Protective Equipment
PREP Act	Public Readiness and Emergency Preparedness Act
PULSE™	Patient Unified Lookup System for Emergencies
RADx	Rapid Acceleration of Diagnostics
RDHRS	Regional Disaster Health Response System
RESPTC	Regional Ebola and Other Special Pathogens Treatment Centers
RISC	Risk Identification and Site Criticality
RNC	Republican National Convention
RPM	Remote Patient Monitoring
SAVE	SARS-CoV-2 Assessment of Viral Evolution
SLTT	State, Local, Tribal, and Territorial
SPHERES	Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance
USAID	United States Agency for International Development
USDA	Department of Agriculture
VA	Department of Veterans Affairs

<sup>\*</sup>ASPR was known as the Office of the Assistant Secretary for Preparedness and Response until July 20, 2022. Use of the ASPR acronym in reference to activities prior to that date reflects the Office of the Assistant Secretary for Preparedness and Response, while activities from that date onward reflect the Administration for Strategic Preparedness and Response.

### References

- 1 42 U.S.C 300hh-1; Government Publishing Office; https://www.govinfo.gov/content/pkg/USCODE-2009-title42/pdf/USCODE-2009-title42-chap6A-subchapXXVI-partA-sec300hh-1.pdf.
- 2 2019-2022 National Health Security Strategy; Department of Health and Human Services; 2018; https://www.phe.gov/ Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf.
- 3 Pandemic Oversight; Pandemic Response Accountability Committee; 2022; https://www.pandemicoversight.gov.
- 4 Funding Overview: Six Laws that Funded Pandemic Relief Programs; Pandemic Response Accountability Committee; 2022; https://www.pandemicoversight.gov/data-interactive-tools/funding-overview.
- 5 STAR HIE Program; Department of Health and Human Services; 2021; https://www.healthit.gov/topic/star-hie-program.
- 6 The Medical Reserve Corps Volunteers Aid COVID-19 Vaccination Efforts in 46 States and U.S. Territories; Department of Health and Human Services; 2021; https://www.phe.gov/Preparedness/news/Pages/mrc-COVID19-vaccination-efforts-25mar2021.aspx.
- Medical Reserve Corps Updates and Reports; Department of Health and Human Services; 2021; https://aspr.hhs.gov/MRC/ Pages/MRC-Updates-and-Reports-Archive.aspx.
- 8 National Disaster Medical System and COVID-19 2020-2021; Department of Health and Human Services; 2021; https://www.phe.gov/Preparedness/responders/ndms/Pages/COVID-Response-Timeline.aspx.
- 9 Fact Sheet: Biden-Harris Administration to Invest \$7 Billion from American Rescue Plan to Hire and Train Public Health
  Workers in Response to COVID-19; The White House; 2021; https://www.whitehouse.gov/briefing-room/statementsreleases/2021/05/13/fact-sheet-biden-harris-administration-to-invest-7-billion-from-american-rescue-plan-to-hire-and-trainpublic-health-workers-in-response-to-covid-19/.
- 10 CMS Funding 1,000 New Residency Slots for Hospitals Serving Rural and Underserved Communities; Centers for Medicare and Medicaid Services; 2021; https://www.cms.gov/newsroom/press-releases/cms-funding-1000-new-residency-slots-hospitals-serving-rural-underserved-communities.
- 11 HHS Awards \$6 Million to Create Pediatric Disaster Care Centers of Excellence; Department of Health and Human Services; 2019; Center; https://emscimprovement.center/domains/preparedness/asprcoe.
- 12 Fast Facts: Operation Warp Speed; Government Accountability Office; 2021; https://www.gao.gov/products/gao-22-104453.
- HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues; Government Accountability Office; 2022; https://www.gao.gov/assets/gao-22-104453.pdf.
- Operation Warp Speed: Accelerated COVD-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges; Government Accountability Office; 2021; https://www.gao.gov/assets/gao-21-319.pdf.
- 15 COVID-19 Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine; Food and Drug Administration; 2022; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.
- 16 Comirnaty and Pfizer-BioNTech COVID-19 Vaccine; Food and Drug Administration; 2021; https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine.
- 17 <u>COVID-19 EUA Information</u>; Food and Drug Administration; 2022; https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas.
- 18 SPHERES; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/coronavirus/2019-ncov/variants/spheres. html.
- 19 CDC's Role in Tracking Variants; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/coronavirus/2019-ncov/variants/cdc-role-surveillance.html.
- 20 Rapid Acceleration of Diagnostics (RADx) Programs; National Institutes of Health; 2021; https://www.nih.gov/research-training/medical-research-initiatives/RADx/RADx-programs.
- 21 <u>COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions</u>; Government Accountability Office; 2020; https://www.gao.gov/assets/gao-20-701.pdf.
- 22 <u>EPA Researchers Test Effectiveness of Face Masks, Disinfection Methods Against COVID-19</u>; Environmental Protection Agency; 2021; https://www.epa.gov/sciencematters/epa-researchers-test-effectiveness-face-masks-disinfection-methods-against-covid-19.

- 23 Evaluating Disinfection Methods for Personal Protective Equipment Items Intended for Reuse; Environmental Protection Agency; 2021; https://www.epa.gov/covid19-research/evaluating-disinfection-methods-personal-protective-equipment-ppe-items-intended.
- 24 Sickbert-Bennet, Samet, Price, et al; Fitted Filtration Efficiency of Double Masking During the COVID-19 Pandemic; Journal of the American Medical Association; 2021; https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2778913.
- 25 Laboratory Modeling of SARS-CoV-2 Exposure Reduction Through Physically Distanced Seating in Aircraft Cabins Using Bacteriophage Aerosol November 2020; Centers for Disease Protection and Control; 2021; https://www.cdc.gov/mmwr/volumes/70/wr/mm7016e1.htm?s cid=mm7016e1 x#.
- 26 <u>Use and Care of Masks</u>; Centers for Disease Control and Prevention; 2022; https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.
- 27 Interim Infection Prevention and Control Recommendations for Healthcare Personnel during the COVID-19 Pandemic; Centers for Disease Control and Prevention; 2022; https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.
- 28 Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes; Centers for disease Control and Prevention; 2022; https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.
- 29 Managing Solid Waste Contaminated with a Category A Infectious Substance; Department of Transportation; 2019; https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/transporting-infectious-substances/6821/cat-waste-planning-guidance-final-2019-08.pdf.
- 30 Biosafety in Microbiological and Biomedical Laboratories 6th Edition; Centers for Disease Control and Prevention; 2020; https://www.cdc.gov/labs/pdf/SF 19 308133-A BMBL6 00-BOOK-WEB-final-3.pdf.
- 31 NIH guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules; National Institutes of Health; 2019; https://osp.od.nih.gov/wp-content/uploads/NIH Guidelines.pdf.
- 32 Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated for Coronavirus Disease 2019; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines. html
- 33 <u>Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Science (Self) Assessment Framework;</u> International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences; 2020: https://absa.org/wp-content/uploads/2020/02/Culture\_of\_Biosafety-Biosecurity\_Self-Assessment\_Framework.pdf.
- 34 Strengthening Health Security Across the Globe: Progress and Impact of U.S. Government Investments in the Global Health Security Agenda; The White House; 2020; https://www.whitehouse.gov/wp-content/uploads/2021/10/Global-Health-Security-Agenda-Annual-Report.pdf.
- 35 <u>CARB-X Annual Report 2020-2021</u>; Combating Antibiotic Resistant Bacteria; 2021; https://carb-x.org/wp-content/uploads/2021/10/CarbX\_AR\_20-21.pdf.
- 36 CARB-X is Funding Accelerate Diagnostics to Develop a Rapid Optical Diagnostic for Sepsis and Serious Antibiotic-resistant Bacterial Infections; CARB-X; 2021; https://carb-x.org/carb-x-news/carb-x-is-funding-accelerate-diagnostics-to-develop-a-rapid-optical-imaging-diagnostic-for-sepsis-and-serious-antibiotic-resistant-bacterial-infections.
- 37 Executive Order on America's Supply Chains; The White House; 2021; https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/executive-order-on-americas-supply-chains.
- 38 <u>Executive Order on a Sustainable Public Health Supply Chain;</u> The White House; 2021; https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-a-sustainable-public-health-supply-chain.
- 39 COVID-19: Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities; Government Accountability Office; 2021; https://www.gao.gov/assets/gao-22-105380.pdf.
- 40 What is the Defense Production Act?; Council on Foreign Relations; 2021; https://www.cfr.org/in-brief/what-defense-production-act.
- 41 <u>Biden Administration Announces Historic Manufacturing Collaboration Between Merk and Johnson & Johnson to Expand Production of COVID-19 Vaccines;</u> Department of Health and Human Services; 2021; https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-expand-production-covid-19-vaccines.html.
- Defending Against Software Supply Chain Attacks; Cybersecurity and Infrastructure Security Agency; 2021; https://www.cisa.gov/sites/default/files/publications/defending\_against\_software\_supply\_chain\_attacks\_508\_1.pdf.

- 43 <u>Securing Telehealth Remote Patient Monitoring Ecosystem</u>; National Institute of Standards and Technology; 2021; https://www.nccoe.nist.gov/healthcare/securing-telehealth-remote-patient-monitoring-ecosystem.
- 44 <u>Cities Readiness Initiative</u>; Centers for Disease Control and Prevention; 2020; https://www.cdc.gov/cpr/readiness/mcm/cri. html.
- 45 Coming in 2023: RISC Toolkit 2.0; Department of Health and Human Services; 2022; https://aspr.hhs.gov/cip/RISC-2.0/Pages/default.aspx
- 46 Pandemics and All Hazards Advancing Innovation Act; Government Publishing Office; 2019; https://www.congress.gov/116/bills/hr269/BILLS-116hr269pcs.pdf.
- 47 Ready or Not: Protecting the Public's Health from Disease, Disasters, and Bioterrorism 2021; Trust for America's Health; 2021; https://www.tfah.org/wp-content/uploads/2021/03/TFAH ReadyOrNot2021 Fnl.pdf.
- 48 The National Health Security Preparedness Index: 2021 Release; NHSPI; 2021; https://nhspi.org/wp-content/uploads/2021/06/NHSPI-2021-Key-Findings.pdf.
- 49 Record-Breaking Atlantic Hurricane Season Draws to an End; National Oceanic and Atmospheric Administration; 2021; https://www.noaa.gov/media-release/record-breaking-atlantic-hurricane-season-draws-to-end.
- 50 <u>National Syndromic Surveillance Program;</u> Centers for Disease Control and Prevention; 2022; https://www.cdc.gov/nssp/index.html.
- 51 Syndromic Data and Collaboration Enhance Substance Overdose Surveillance Nebraska Department of Health and Human Services; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/nssp/success-stories/NE-Substance-Abuse.html.
- 52 Georgia Uses Syndromic Surveillance to Identify Cryptosporidiosis Outbreak at Water Park; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/nssp/success-stories/GA-Cryptosporidiosis.html.
- 53 Syndromic Surveillance Provides Critical Clues on E-cigarette, or Vaping, Product Use-Associated Lung Injury; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/nssp/success-stories/SyS-in-action-lung-injury.html.
- 54 The National Syndromic Surveillance Program Infographic; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/nssp/images/nsspinfo/Final\_NSSP-Infographic.pdf.
- 55 Patient Unified Lookup Ssystem for Emergencies (PULSE); Department of Health and Human Services; 2021; https://www. healthit.gov/topic/health-it-health-care-settings/public-health/patient-unified-lookup-system-for-emergencies-pulse.
- 56 <u>PULSE Supports Health Care During Disasters</u>; Department of Health and Human Services; 2020; https://www.healthit.gov/buzz-blog/health-it/pulse-supports-health-care-during-disasters.
- 57 HHS Protect Public Data Hub; Department of Health and Human Services; 2022; https://protect-public.hhs.gov.
- 58 Federal Support to Combat COVID-19; Federal Emergency Management Agency; 2021; https://www.fema.gov/sites/default/files/documents/fema\_federal-support-combat-covid-19.pdf.
- 59 <u>ASPR Homepage: By the Numbers;</u> Department of Health and Human Services; 2022; https://aspr.hhs.gov/Pages/Home.aspx.
- More Active Troops to Help Take COVID-Related Pressure off Civilian Hospitals; Department of Defense; 2022; https://www.defense.gov/News/News-Stories/Article/2899822/more-active-troops-to-help-take-covid-related-pressure-off-civilian-hospitals.
- 61 <u>HPP Factsheet: April 2021</u>; Department of Health and Human Services; 2021; https://aspr.hhs.gov/HealthCareReadiness/HPP/Documents/HPP%20Fact%20Sheet%20April%202021.pdf.
- 62 DoD Awards \$1.74 Billion Agreement to Moderna, Inc. to Secure Over 65 Million Doses of COVID-19 Vaccine for Fall Vaccinations; Department of Defense; 2022; https://www.defense.gov/News/Releases/Release/Article/3109705/dod-awards-174-billion-agreement-to-moderna-inc-to-secure-over-65-million-doses.
- DoD Awards Contract Modifications to Purchase COVID-19 Antigen Over-the-Counter Test Kits in Support of POTUS's One
  Billion Free At-Home COVID-19 Tests; Department of Defense; 2022; https://www.defense.gov/News/Releases/Release/Article/2977992/dod-awards-contract-modifications-to-purchase-covid-19-antigen-over-the-counter.
- National Animal Health Laboratory Network 20th Anniversary Report; Department of Agriculture Animal and Plant Health Inspection Service; 2022; https://www.aphis.usda.gov/animal\_health/nahln/downloads/nahln-20th-anniv-report.pdf.
- 65 AHA 2022 Environmental Scan; American Hospital Association; 2021; https://www.aha.org/system/files/media/file/2021/11/2022-Environmental-Scan.pdf.

- ACL Investing \$150 Million to Expand the Public Health Workforce to Respond to the Needs of People with Disabilities and Older Adults; Administration for Community Living; 2021; https://acl.gov/news-and-events/announcements/acl-investing-150-million-expand-public-health-workforce-respond.
- 67 Fiscal Year 2022 Medicare Prospective Payment System and Long Term Care Hospital Rates Proposed Rule; Centers for Medicare and Medicaid Services; 2021; https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care.
- 68 Fiscal Year 2022 Medicare Hospital Inpatient Prospective Payment System Final Rule with Comment Period; Centers for Medicare and Medicaid Services; 2021; https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2022-medicare-hospital-inpatient-prospective-payment-system-ipps-final-rule-comment.
- 69 Public Health Emergency Q&As; Department of Health and Human Services; 2019; https://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx#faq9.
- 70 Compact Nursing States List; Nurse.org; 2021; https://nurse.org/articles/enhanced-compact-multi-state-license-eNLC.
- 71 Regional Disaster Health Response System Fact Sheet; Department of Health and Human Services; https://aspr.hhs.gov/RDHRS/Documents/RDHRS-Fact-Sheet-March2021-508.pdf.
- 72 National Special Pathogen System of Care; National Special Pathogen System; 2022; https://netec.org/nsps.
- 73 National Special Pathogens System Fact Sheet; Department of Health and Human Services; 2021; https://aspr.hhs.gov/ HealthCareReadiness/HealthCareReadinessNearYou/Documents/NSPS-FactSheet-April2021-508.pdf.
- 74 Safety of COVID-19 Vaccines; Centers for Disease Control and Prevention; 2022; https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=The%20Pfizer%2DBioNTech%2C%20Moderna%2C,COVID%2D19%20 vaccines%20are%20safe.
- 75 <u>Blood Purification Devices EUAs</u>; Food and Drug Administration; 2022; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/blood-purification-devices-euas.
- 76 Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs; Food and Drug Administration; 2022; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/continuous-renal-replacement-therapy-and-hemodialysis-devices-euas.
- 77 <u>Infusion Pumps EUAs;</u> Food and Drug Administration; 2022; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas.
- 78 Remote or Wearable Patient Monitoring Devices EUAs; Food and Drug Administration; 2022; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas.
- 79 Respiratory Assist Devices EUAs; Food and Drug Administration; 2022; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/respiratory-assist-devices-euas.
- 80 Other Medical Device EUAs; Food and Drug Administration; 2022; https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas.
- 81 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19; The Federal Register; 2021; https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx.
- 82 First FDA-Approved Vaccine for the Prevention of Ebola Virus Disease, Marking a Critical Milestone in Public Health Preparedness and Response; Food and Drug Administration; 2019; https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health#:~:text=The%20U.S.%20 Food%20and%20Drug,years%20of%20aqe%20and%20older.
- FDA Approval, Licensures, and Clearances for BARDA Supported Products; Department of Health and Human Services; 2022; https://www.medicalcountermeasures.gov/barda/fdaapprovals.
- 84 Mpox (MPXV) Synthetic DNA PCR Standards; National Institute of Standards and Technology; 2022; https://www.nist.gov/programs-projects/mpxv-monkeypox-synthetic-dna-pcr-standards.
- 85 Global VAX: A New "Initiative for Global Vaccine Access" to Accelerate U.S. Vaccine Delivery Assistance Around the World;
  United States Agency for International Development; 2022; https://www.usaid.gov/coronavirus/fact-sheets/global-vax.
- 86 APHIS' American Rescue Plan Surveillance Program: Strategic Framework; Department of Agriculture; 2022; https://www.aphis.usda.gov/publications/aphis\_general/arp-strategic-framework.pdf.

- 87 National Animal Health Laboratory Network; Department of Agriculture; 2022; https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services/nahln/nahln.
- 88 Abbasi J; How the US Failed to Prioritize SARS-CoV-2 Variant Surveillance; Journal of the American Medical Association; 2021; https://jamanetwork.com/journals/jama/fullarticle/2777988.
- 89 SARS-CoV-2 Assessment of Viral Evolution (SAVE) Program; National Institutes of Health; 2022; https://www.niaid.nih.gov/research/sars-cov-2-assessment-viral-evolution-program.
- 90 National COVID Cohort Collaborative; National Institutes of Health; 2022; https://ncats.nih.gov/n3c/about.
- 91 Rapid Acceleration of Diagnostics (RADx); National Institutes of Health; 2022; https://www.nih.gov/research-training/medical-research-initiatives/radx
- 92 Munnink et al.; The Next Phase of SARS-CoV-2 Surveillance: Real-Time Molecular Epidemiology; Nature Medicine; 2021; https://doi.org/10.1038/s41591-021-01472-w.
- 93 Face Coverings Made From Layered Cotton Fabric Likely to Slow the Spread of COVID-19 Better Than Synthetics; National Institute of Standards and Technology; 2022; https://www.nist.gov/news-events/news/2020/06/face-coverings-made-layered-cotton-fabric-likely-slow-spread-covid-19.
- 94 Masks Under the Microscope; National Institute of Standards and Technology; 2021; https://www.nist.gov/feature-stories/masks-under-microscope.
- 95 Poster DL, Miller CC, Martinello RA, Horn NR, Postek MT, Cowan TE, Obeng YS, Kasianowicz JJ; 2021; <u>Ultraviolet Radiation Technologies and Healthcare-Associated Infections: Standards and Metrology Needs</u>. J Res Natl Inst Stan 126:12601 https://doi.org/10.6028/jres.126.
- 96 Larason T, Grantham S, Zarobila C, Zong Y, Schuit M, Holland B, Wood S, Krause M, Miller CC. Traveling tunable laser projector for UV-blue disinfection dose determinations. Appl Opt. 2022 Jul 1;61(19):5559-5566. doi: 10.1364/AO.460317. PMID: 36255782.
- 97 Fact Sheet: How HHS is Supporting Indian Country in Response to COVID-19; Department of Health and Human Services; https://www.hhs.gov/sites/default/files/iea-covid-19-fact-sheet.pdf.
- 98 New Airflow Videos Show Why Masks with Exhalation Valves Do Not Slow the Spread of COVID-19; National Institute of Standards and Technology; 2020; https://www.nist.gov/news-events/news/2020/11/new-airflow-videos-show-why-masks-exhalation-valves-do-not-slow-spread.
- 99 2021 Global Health Security Index; Nuclear Threat Initiative; 2021; https://www.ghsindex.org/wp-content/uploads/2021/12/2021\_GHSindexFullReport\_Final.pdf.
- A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences; Caribbean Public Health Agency; 2021; https://carpha.org/Portals/0/Documents/Culture%20of%20Biosafety%20 and%20Biosecurity%20Guide%20to%20Training%20and%20Information 2021.pdf.
- 101 <u>Federal Select Agent Program</u>; Department of Health and Human Services and Department of Agriculture; 2021; https://www.selectagents.gov.
- 102 Screening Framework Guidance for Providers and Users of Synthetic Oligonucleotides; The Federal Register; 2022; https://www.federalregister.gov/documents/2022/04/29/2022-09210/screening-framework-guidance-for-providers-and-users-of-synthetic-oligonucleotides.
- 103 Coronavirus Treatment Acceleration Program (CTAP); Food and Drug Administration; 2022; https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap#intro
- Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV); National Institutes of Health; https://www.nih.gov/research-training/medical-research-initiatives/activ#:~:text=On%20April%2017%2C%20200%20the,most%20promising%20treatments%20and%20vaccines.
- 105 <u>Combating Antimicrobial Resistance</u>; Department of Health and Human Services; 2021; https://www.medicalcountermeasures.gov/stories/combating-amr.
- 106 2020 Antimicrobial Agents in Clinical and Preclinical Development: An Overview and Analysis; World Health Organization; 2020; https://www.who.int/publications/i/item/9789240021303.
- 107 <u>COVID-19 & Antibiotic Resistance</u>; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/drugresistance/covid19.html.

- 108 ASPR Program Office for Innovation and Industrial Base Expansion (IBx); Department of Health and Human Services; https://aspr.hhs.gov/Pages/About-Us/Program%20Offices/ASPR-Program-Office-for-Innovation-and-Industrial-Base-Expansion-(IBx). aspx.
- 109 Expanding and Enhancing SNS Capabilities; Department of Health and Human Services; 2021; https://www.phe.gov/about/sns/COVID/Pages/expanding-sns-capabilities.aspx.
- 110 From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine; Department of Health and Human Services; 2020; https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf.
- 111 Ransomware Trends 2021; Department of Health and Human Services; 2021; https://www.hhs.gov/sites/default/files/ransomware-trends-2021.pdf.
- 112 HPH Cyber Supply Chain Risk Management (C-SCRM); Department of Health and Human Services; 2021; https://www.hhs. gov/sites/default/files/hph-cyber-supply-chain-risk-management.pdf.
- 113 Executive Order on Improving the Nation's Cybersecurity; Cybersecurity and Infrastructure Security Agency; 2021; https://www.cisa.gov/executive-order-improving-nations-cybersecurity.
- 114 CISA Releases Incident and Vulnerability Response Playbooks to Strengthen Cybersecurity for Federal Civilian Agencies; Cybersecurity and Infrastructure Security Agency; 2022; https://www.cisa.gov/news/2021/11/16/cisa-releases-incident-and-vulnerability-response-playbooks-strengthen.
- 115 Securing Telehealth Remote Patient Monitoring Ecosystem; National Institute of Standards and Technology; 2021; https://www.nccoe.nist.gov/sites/default/files/legacy-files/rpm-nist-sp1800-30b-2nd-draft.pdf.
- Public Health and Healthcare Critical Infrastructure and Key Resources Sector-Specific Plan as Input to the National Infrastructure Protection Plan; Homeland Security Digital Library; 2007; https://www.hsdl.org/?abstract&did=683165.
- 117 Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/cpr/readiness/capabilities.htm.
- 118 CDC Career Epidemiology Field Officer Program: 2018 Annual Report; Centers for Disease Control and Prevention; 2018; https://www.cdc.gov/cpr/readiness/00\_docs/2018\_CEFO\_Report\_FINAL\_508.pdf.
- 119 The Laboratory Response Network; Centers for Disease Prevention and Control; 2019; https://emergency.cdc.gov/lrn/.
- 120 Detecting Bioterrorist Attacks; Department of Homeland Security; 2020; https://www.dhs.gov/biowatch-program.
- 121 What is the Data Modernization Initiative?; Centers for Disease Control and Prevention; 2022; https://www.cdc.gov/surveillance/projects/dmi-initiative/index.html#:~:text=CDC's%20Data%20Modernization%20Initiative%20(DMI,us%20 from%20any%20health%20threat.
- 122 <u>Critical Infrastructure Training;</u> Cybersecurity and Critical Infrastructure Security Agency; https://www.cisa.gov/critical-infrastructure-training.
- 123 <u>HPH Risk Identification and Site Criticality (RISC) Toolkit 1.0;</u> Department of Health and Human Services; 2018; https://www.phe.gov/Preparedness/planning/RISC/Pages/default.aspx.
- 124 Bugin, K. and Woodcock, J.; <u>Trends in COVID-19 Clinical Trials</u>; Nature; 2021; https://www.nature.com/articles/d41573-021-00037-3.
- 125 HHS Awards Funds to Expand Immunization Information Sharing Collaboration; Department of Health and Human Services; 2021; https://www.hhs.gov/about/news/2021/01/19/hhs-awards-funds-to-expand-immunization-sharing-collaboration.html.
- 126 COVID-19 Medical Countermeasure Portfolio; Department of Health and Human Services; 2022; https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx.
- 127 <u>COVID-19 Vaccine Data Systems</u>; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/vaccines/covid-19/reporting/index.html.
- 128 Supporting an Equitable Distribution of COVID-19 Vaccines; National Governors Association; 2020; https://www.nga.org/center/publications/supporting-equitable-distribution-covid-19-vaccines.
- 129 Hospital Preparedness Program Proved Critical in Reducing Spread of COVID-19 during Historic 2020 Presidential

  Nominating Conventions; Department of Health and Human Services; 2020; https://www.phe.gov/Preparedness/planning/hpp/events/Pages/hpp-2020-rnc-dnc.aspx.
- 130 <u>HPP Supports Coordination of Resource Deployment Following a Liquid Oxygen Spill;</u> Department of Health and Human Services; 2019; https://www.phe.gov/Preparedness/planning/hpp/events/Pages/liquid-oxygen-spill.aspx.

- 131 PHEP Helps Atlanta Prepare for Super Bowl LIII; Centers for Disease Control and Prevention; 2019; https://www.cdc.gov/cpr/readiness/phep/stories/sb2019.htm.
- 132 Los Angeles County Uses Hospital Preparedness Program Funds to Expand Surge Capacity and Secure Essential

  Resources; Department of Health and Human Services; 2020; https://www.phe.gov/Preparedness/planning/hpp/events/
  Pages/LAC-November2020.aspx.
- 133 NDMS Team Deploy to Support Healthcare Facilities and Save Lives in Communities Overwhelmed by COVID-19; Department of Health and Human Services; 2021; https://www.hhs.gov/blog/2021/10/07/ndms-teams-deploy-to-support-healthcare-facilities-save-lives-in-communities-overwhelmed-by-covid-19.html.
- 134 Public Health Emergency Preparedness Stories from the Field; Tennessee Department of Health; 2019; https://www.tn.gov/content/dam/tn/health/documents/cedep/ep/PHEP\_Impact\_Statements\_2019.pdf.
- 135 <u>HPP Fiscal Year 2019/Budget Period 1 Funding;</u> Department of Health and Human Services; 2019; https://aspr.hhs.gov/\_catalogs/masterpage/ASPR/Documents/Health%20Care%20Readiness%20Programs/HPP/Programs-Funding/2019-HPP-Funding-Table.pdf.
- 136 HPP Fiscal Year 2020/Budget Period 2 Funding; Department of Health and Human Services; 2020; https://aspr.hhs.gov/\_catalogs/masterpage/ASPR/Documents/Health%20Care%20Readiness%20Programs/HPP/Programs-Funding/2020-HPP-Funding-Table.pdf.
- 137 HPP Fiscal Year 2021/Budget Period 3 Funding; Department of Health and Human Services; 2021; https://aspr.hhs.gov/\_catalogs/masterpage/ASPR/Documents/Health%20Care%20Readiness%20Programs/HPP/Programs-Funding/2021-HPP-Funding-Table.pdf.
- 138 PHEP Budget Period 1 (Fiscal Year 2019) Funding; Centers for Disease Control and Prevention; 2019; https://www.cdc.gov/cpr/readiness/00\_docs/PHEP\_Budget\_Period\_1\_FY\_2019\_Funding\_Table\_August\_2\_2019.pdf.
- 139 PHEP Budget Period 2 (Fiscal Year 2020) Funding; Centers for Disease Control and Prevention; 2020; https://www.cdc.gov/cpr/readiness/00\_docs/CDC\_PHEP-FY-2020\_Budget-Period-2\_Funding-Table\_final.pdf.
- 140 Final PHEP Budget Period 3 (Fiscal Year 2021) Funding: September 2021 Update; Centers for Disease Control and Prevention; 2021; https://www.cdc.gov/cpr/readiness/00\_docs/PHEP\_BP3\_Funding\_Table\_September\_21\_2021.pdf.
- PHEP Budget Period 4 (Fiscal Year 2022) Funding; Centers for Disease Control and Prevention; 2022; https://www.cdc.gov/cpr/readiness/00\_docs/PHEP\_BP4\_Funding\_Table\_April\_2022\_508c\_1.pdf.

