



U.S. SENATE COMMITTEE ON

**HEALTH, EDUCATION,
LABOR & PENSIONS**

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Reforming and Strengthening ASPR: Ensuring Specialized Capabilities, Sufficient Capacity, and Specific Authorities to Meet 21st Century Public Health Threat

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POLICY BRIEF

Background: The 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) created the position of the Assistant Secretary for Preparedness and Response (ASPR). By statute, the ASPR is the principal advisor to the Secretary of the Department of Health and Human Services (HHS) on all matters related to federal public health and medical preparedness and response for public health emergencies.¹

Among ASPR's specific authorities, the ASPR is responsible for the credentialing, organizing, training, and equipping of HHS public health and medical personnel that can be utilized to surge medical capabilities during an emergency. This includes the National Disaster Medical System (NDMS), and operational authority to deploy NDMS personnel during a response, as well as the coordination of personnel assigned to the Medical Reserve Corps operated by state governments.^{2,3} ASPR also oversees the Hospital Preparedness Program (HPP), designed to bolster our medical surge capacity.⁴

Finally, the ASPR is responsible for our nation's medical countermeasure enterprise. PAHPA created the Biomedical Advanced Research and Development Authority (BARDA) under the ASPR to support, coordinate, and provide oversight of advanced development of vaccines and other medical countermeasures. Along with development, the ASPR oversees procurement and deployment of these life-saving products through Project BioShield and the Strategic National Stockpile (SNS).⁵

Vision for the Future

More than 600,000 Americans have died from COVID-19 during this pandemic. Future pandemics and other potential national security threats could exceed the number lost or made seriously ill from COVID-19. Much of the federal government's response system was implemented as conceived by Congress, including the rapid development of countermeasures by BARDA and the deployment by ASPR of NDMS assets.⁶ However, significant limitations existed that resulted in gaps in the nation's response that must be urgently addressed and

¹ Section 2811(b)(1) of the Public Health Service Act.

² NDMS Authorities. <https://www.phe.gov/Preparedness/responders/ndms/Pages/default.aspx>

³ MRC. <https://mrc.hhs.gov/pageViewFldr/About/MRCProgram>

⁴ HPP. <https://www.phe.gov/Preparedness/planning/hpp/Pages/default.aspx>

⁵ <https://www.phe.gov/about/Pages/highlights.aspx>

⁶ <https://www.phe.gov/Preparedness/responders/ndms/Pages/COVID-Response-Timeline.aspx>

corrected. In preparing for the next potential public health threat, we need to evaluate lessons *observed* and implement them to become lessons *learned*.

While we, as a nation, assess how to improve preparedness, we must evaluate the decisions that were made during all phases of the COVID-19 response: anticipatory planning, the early stages of the outbreak in the United States, ongoing response operations, long-term recovery, and subsequent reform. It is incumbent on all of us to determine how the United States preparedness and response framework for public health emergencies can be improved and strengthened, including for nationwide responses like we experienced during the COVID-19 pandemic. At a bare minimum, Congress must strengthen the coordination of preparedness and response activities across HHS, with ASPR at the center of HHS's response. The ASPR is charged with coordinating and leveraging the expertise within HHS, with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Office of the Assistant Secretary for Health, the Centers for Medicare and Medicaid Services (CMS) and the Health Resources Services Administration playing vital roles.

Congress must better align interagency coordination between HHS and the Federal Emergency Management Agency (FEMA) and the Department of Defense (DoD).

Reforms at ASPR, BARDA, and HHS are needed to ensure the organization is strong, agile, and remains focused on the important mission Congress designed: protecting Americans from public health threats. This mission demands ASPR have the ability to leverage cutting-edge innovation and logistics for the ever-changing threats confronting the nation in the 21st Century.

The Need for Accountable Leadership within HHS at ASPR

While the ASPR's role was too limited during the COVID-19 response, this was not the first time that an administration failed to follow the letter and spirit of the PAHPA law. During the 2014-2016 Ebola response, the Obama administration established a separate, White House-based structure to coordinate the response to this virus as well, calling into question who was in charge during this difficult time for our country and the world.^{7,8}

Over the course of the COVID-19 response, HHS and ASPR preparedness and response efforts were inadequate. Some of these failures can be attributed to a lack of specific authorities in statute, ineffective inter- and intra-agency coordination mechanisms, and inconsistent and insufficient federal appropriations for preparedness and response activities.⁹ Some of these inadequacies were anticipated and identified prior to the pandemic during the 2019 Crimson Contagion pandemic exercises.

⁷ HELP Committee Transcript, February 26, 2015. <https://www.govinfo.gov/content/pkg/CHRG-114shrg93617/pdf/CHRG-114shrg93617.pdf>

⁸ <https://obamawhitehouse.archives.gov/blog/2014/10/17/president-obama-names-ron-klain-coordinate-us-response-ebola>

⁹ Bipartisan Policy Center. Budgeting for Medical Countermeasures: An Ongoing Need for Preparedness.

<https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2019/03/BPC-Health-Budgeting-For-Medical-Countermeasures-An-Ongoing-Need-For-Preparedness.pdf>. Pg. 8

Statutory Authorities and Policies: Prior to the pandemic, the Crimson Contagion After Action Report noted that existing authorities and policies tasking HHS to lead the federal government’s response and ASPR’s role were insufficient and unclear.¹⁰ The differing roles of the HHS Secretary and ASPR during a pandemic were not specified or were unclear in statute. In the early days of the COVID-19 response, ASPR’s coordination role was ill-defined when the President transitioned authority of the response from the HHS Secretary to the Vice President, and after the national emergency declaration by the President on March 13, 2020, ASPR’s role was subsumed by FEMA.

Interagency Coordination with FEMA: While ASPR and FEMA have historically worked together during responses to natural disasters, coordination between the two agencies during other types of public health emergency responses were insufficient to support a nationwide response to a pandemic. One gap in the public health preparedness framework is the lack of strategic coordination with FEMA.¹¹ And, during the COVID-19 response, FEMA took a dominant role.

Prior to the pandemic, ASPR did not serve as a formal operational medicine subject matter expert to FEMA or fully and effectively integrate with FEMA’s national and regional offices and preparedness activities. ASPR’s limited regional presence and interaction with FEMA and state emergency management and public health authorities contributed to some initial missteps. For example, after FEMA took over as the lead federal agency coordinating the response, the state of Rhode Island requested personal protective equipment (PPE) from the federal government and was assured by FEMA that a truckload of PPE was en route to state health officials. However, once FEMA informed the governor that the truck had arrived, state health officials stated that the truck was empty, and no PPE had been delivered.¹²

Additionally, during the first wave of COVID-19 cases in New York City, state and local officials dealt with overflowing emergency departments in some parts of the city, despite available beds at other facilities and multiple field hospitals that the state and the federal government quickly stood up.¹³ At times, these facilities reportedly competed with each other and led to inefficient use of resources, which demonstrates a lack of coordination, both within the federal government and with state, local, and nongovernmental partners.¹⁴ In contrast, during the response to Hurricane Sandy, New York State implemented a process for coordinating bed capacity and transferring patients between facilities.¹⁵

Lack of Coherent Data System for Situational Awareness: The PAHPA statute calls for the use of a national network of systems to strategically leverage valuable public health data at the federal, state, and local levels.¹⁶ Neither FEMA, ASPR, CDC, nor HHS could provide a

¹⁰ “Crimson Contagion Functional Exercise After-Action Report,” Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, January 2020.

¹¹ <https://www.gao.gov/assets/gao-21-396t.pdf>

¹² <https://www.politico.com/news/magazine/2020/07/08/gina-raimondo-interview-rhode-island-governor-covid-353799>

¹³ <https://www.nytimes.com/2020/07/21/nyregion/coronavirus-hospital-usta-queens.html?action=click&module=Top%20Stories&pgtype=Homepage>

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Section 31D of the Public Health Service Act

coherent, comprehensive common operating picture with these systems across the federal state, local, tribal and territorial governments. Having a common operating picture enables officials at all levels of government to make decisions based on the same data, which streamlines the process of states requesting and receiving federal assets to support their medical and public health responses. The lack of this common operating picture impacted all aspects the medical and public health response. Not being able to visualize and better understand state, local, tribal and territorial requests and on-the-ground needs led to an inefficient and ineffective response.¹⁷

Strategic National Stockpile and Supply Chain Limitations: The shortages of PPE and other critical materials had major effects on the response. The on-hand SNS and commercial PPE inventory was inadequate to meet state requests, and ASPR lacked visibility of the supply chain to effectively allocate available SNS assets. The administration of the SNS has changed hands multiple times over the last two decades,¹⁸ its funding has limited its capabilities,¹⁹ and reforms to the SNS need to be considered in more detail.

Health Care System Surge Capacity and Resilience: In the early years of the HPP, the program received significant funding, reaching over \$500 million in 2003 and 2004. Since that time, annual appropriations have decreased by 50% as appropriators have shifted focus to other priorities and provided emergency supplemental funding to HPP.²⁰

Local, regional, and national health care systems were stressed, lacking adequate bed capacity, sufficient staffing, and limited medical supplies to manage the large influx of COVID-19 patients.²¹ States and localities requested federal medical assistance under Emergency Support Function 8²² that was often greater than the availability of federal medical assets. As noted by the Government Accountability Office in September 2019, in an evaluation of the public health and medical response to the 2017 hurricane season, ASPR “did not have a full understanding of the capabilities and limitations of its support agencies, including the Departments of Defense, Homeland Security, and Veterans Affairs.”²³ This limitation was also seen during the COVID-19 response and resulted in FEMA directing mission assignments that caused a mismatch between federal capabilities and state’s needs.²⁴ For example, the deployment of USNS Comfort, a hospital ship maintained by the DoD, to New York City did not necessarily address the city’s needs for surge COVID-19 care because the ship was not designed for managing highly infectious patients. As a result, the ship could only be used to care for patients hospitalized for

¹⁷ <https://www.gao.gov/assets/gao-20-635sp.pdf>

¹⁸ <https://www.help.senate.gov/imo/media/doc/Preparing%20for%20the%20Next%20Pandemic.pdf>

¹⁹ https://files.gao.gov/reports/GAO-21-387/index.html#d572e3a2334_1616498768501

²⁰ Compiled by the Congressional Research Service from HHS annual "Budget in Brief" and congressional budget justification documents, <http://hhs.gov/asfr/ob/docbudget/>.

²¹ https://files.gao.gov/reports/GAO-21-387/index.html#d572e3a2334_1616498768501

²² <https://www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf>

²³ US Government Accounting Office, DISASTER RESPONSE: HHS Should Address Deficiencies Highlighted by Recent Hurricanes in the U.S. Virgin Islands and Puerto Rico, September, 2019. <https://www.gao.gov/assets/gao-19-592.pdf>

²⁴ <https://www.fema.gov/news-release/20200328/photos-whole-america-covid-19-response-0>

reasons other than COVID-19. During its 3-week deployment to New York, the Comfort treated only 180 non-COVID-19 patients, less than half of its total capacity of 500 beds.^{25,26}

Along with these challenges, the National Emerging Special Pathogen Training and Education Center and associated National Special Pathogen System of Care, as well as the NDMS and its Disaster Medical Assistant Teams, were indispensable, but did not have the capacity or capabilities to meet increased state requests for medical support and assistance.

Limited Federal Funds: When the virus first emerged, the HHS Secretary was able to use existing authorities that allow the transfer of funds between accounts to make \$52 million available to ASPR for COVID-19 response to support the procurement of additional PPE and BARDA's initial investments in medical countermeasures. Sufficient funds to support the response would only become available when Congress passed the first COVID-19 emergency supplemental funding bill, providing \$3.1 billion on March 6, 2020 for the ASPR, and outlays for ASPR were approved by OMB and HHS weeks later.²⁷

The lessons that will be observed and learned from the COVID-19 pandemic will be ongoing, and addressing these shortfalls is an urgent matter. The risks of future emerging infectious disease outbreaks and pandemics remain high. In addition to emerging infectious diseases, the potential for other national catastrophic incidents has not diminished. Our health care and public health infrastructures remain at risk to cyberattacks. Our health care supply chain is vulnerable to disruption that could be seriously impacted by economic competition or military conflicts with adversarial nations. Significant weather events such as hurricanes, floods, and wildfires continue to occur each year. These 21st century public health security threats are growing and will evolve.

Congress must act to improve HHS' and ASPR's preparedness and response posture to save lives and protect Americans in the future. This effort must take stock of both the failures and successes of the COVID-19 response. Congress must learn from its mistakes of not prioritizing sustained, annual investments and close oversight of essential preparedness programs such as SNS and HPP. Long-term commitments to maintain the public-private partnerships for medical countermeasures, hospital preparedness, and supply chain resilience are necessary. The entire public health and medical preparedness and response architecture must be routinely practiced and tested.

RECOMMENDATIONS

Promoting Strong, Effective Leadership and Coordination

- HHS and ASPR need clear and effective leadership to promote better all-hazard preparedness and operational response coordination within HHS and across federal interagency efforts.

²⁵ Collman, A., How USNS Comfort went from a symbol of hope with the president's blessing, to heading back from NYC having treated fewer than 180 patients, Insider Magazine A Timeline of USNS Comfort's Short and Dramatic Stay in New York City (businessinsider.com)

²⁶ https://media.defense.gov/2020/May/18/2002302024/-1/-1/1/FAQ_USNSCOMFORT_V6.PDF

²⁷ <https://www.appropriations.senate.gov/imo/media/doc/Coronavirus%20Emergency%20Supplemental%20Summary.pdf>

The ASPR is responsible for ensuring an organized, coordinated, and effective response in support of the medical and public health needs of state, local, tribal and territorial authorities during pandemics, disasters, and other public health emergencies. In order to achieve this mission, the Secretary's and ASPR's authorities should be made clearer and more specific about the operational role of executing a coordinated response to any future public health emergency, and should be routinely exercised. Timely public health and medical situational awareness is essential to anticipating risks and needs that have to be met in a pandemic or a disaster.

Keeping with its existing Strategic Plan, ASPR should further integrate with FEMA at the national and regional levels to ensure close coordination during all phases of pre-incident preparedness: planning, training, and exercising. During public health emergency responses, ASPR should coordinate and effectively marshal all of HHS's and other federal medical and public health expertise for an effective response. Such coordination will enable FEMA to issue mission assignments in response to state requests to bring the right care to those in need.

Strengthening Public-Private Partnerships

- ASPR needs to expand, strengthen, and sustain public-private partnerships in the medical countermeasure, health care system and medical supply chain sectors.

During the COVID-19 pandemic, a “whole of government” response was necessary. The success of Operation Warp Speed (OWS) is the most prominent example of that kind of effort. Operation Warp Speed was built on a foundation created by BARDA, which leveraged partnerships between and among the federal government, the private sector, and academia. Through the Public Health Emergency Medical Countermeasures Enterprise, BARDA formed a partnership with DoD, the National Institutes of Health (NIH), CDC, and FDA. Leveraging and expanding this partnership was essential to organizing the federal government's efforts develop and deploy COVID-19 vaccines and other countermeasures to combat COVID-19.

BARDA's scientific and product development expertise and DoD's robust contracting and logistics capacities were significant factors in the success of OWS. BARDA's capabilities did not start from scratch, and were refined during each reauthorization of PAHPA. In the decade prior to the pandemic, BARDA developed and sustained effective partnerships among biotechnology and pharmaceutical companies that enabled accelerated development and deployment of COVID-19 diagnostics, therapeutics, and vaccines.

Similarly, the public-private partnerships that were developed through the National Emerging Special Pathogen Training and Education Center and Regional Disaster Health Response System programs were vital to expand and mobilize medical capacity and capabilities needed during the pandemic response. These public-private partnerships must be improved and sustained to address lessons learned during the pandemic.

Innovation, Capacity, and Capability Improvements

- ASPR should leverage innovation to expand public health and medical preparedness and response capacity and capabilities, including those of the medical countermeasures enterprise, health care system, and public health programs.

Necessity is the mother of invention. However, innovation cannot be limited to times of crisis. It must be integrated into preparedness efforts and during responses to future public health emergencies. Innovation is needed for faster and more efficient identification, development, and manufacture of medical countermeasures against emerging and pandemic disease threats, as well as other chemical, biological and radiological and nuclear agents.

Health care systems must expand their limited surge capacity, and there is a need to better coordinate and rapidly surge personnel and staffed medical beds to meet future contingencies. Capacity must also reflect specialized capabilities that may be needed in future public health emergencies, which will likely not always require the same capabilities that were quickly developed to respond to COVID-19, a respiratory illness.

CONCLUSION

The ASPR is designed to serve in a leadership position during public health emergencies, and must bring a daily urgency to the role – whether it is in the midst of a response, or during routine planning and exercises to be prepared for the next threat. The ASPR role requires constant vigilance to help determine the public health threats that we will face and to protect the American people.

The ASPR's job is to save lives.

The recommendations listed above are designed to build on the original, bipartisan intent of the ASPR role in the Pandemic and All-Hazards Preparedness Act. Reaffirming the ASPR's leadership, strengthening the ASPR's ability to leverage and partner with the private sector, and integrating innovative technologies throughout the preparedness framework will each help to improve the role and leave our country better prepared for the future.