



Fiscal Year 2019 Budget-in-Brief Public Health and Social Services Emergency Fund

The Office of the Assistant Secretary for Preparedness and Response (ASPR) was established by Congress a decade ago (in the Pandemic and All Hazards Preparedness Act of 2006) to create “unity of command” by consolidating substantial federal public health and medical preparedness and response functions under the ASPR (subject to the authority of the Secretary).

ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR is the national security mission manager for HHS. On behalf of the Secretary, ASPR leads the federal public health and medical, preparedness, response and recovery to disasters and public health emergencies, in accordance with the National Response Framework. ASPR coordinates the nation's medical and public health capabilities to help Americans during emergencies and disasters, whatever their cause.

ASPR works to enhance medical surge capacity when needed during disasters by organizing, training, equipping, and deploying federal public health and medical personnel and providing logistical support for federal responses to public health emergencies. ASPR improves readiness and preparedness at the state and local levels by administering grants to enhance the capacity and capability of the nation's healthcare infrastructure to respond to disasters and by carrying out drills and operational exercises. ASPR also oversees advanced research, development, procurement and stockpiling of medical countermeasures (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies) against biological, chemical, radiological and nuclear agents and pandemic or epidemic diseases.

The FY 2019 President's Budget Request for ASPR is \$2.2 billion, an increase of \$722 million above the FY 2018 Annualized Continuing Resolution level. This funding level reflects the transfer of the Strategic National Stockpile (SNS) from the Centers for Disease Control and Prevention to ASPR, supports emergency operations planning and response, and

maintains critical investments in medical countermeasures (MCMs). The request provides:

- \$1.27 billion for ASPR's Biomedical Advanced Research and Development Authority (BARDA) including:
- \$512 million to support the advanced development of the highest priority MCMs, which includes \$192 million to combat antimicrobial resistant bacteria (CARB), \$260 million to support Advanced Research and Development (ARD), and \$60 million for BARDA operations;
- \$245 million for diagnostic tools, vaccines, immunotherapeutics, and international preparedness for pandemic influenza (PI) and emerging infectious diseases, and
- \$510 million for Project BioShield (PBS) to support late-stage development and procurement of MCMs for national security threats.
- \$575 million for the SNS.
- \$254.5 million for the Hospital Preparedness Program (HPP) to support cooperative agreements with state, local, and territorial health departments to improve healthcare delivery surge capacity and enhance regional emergency preparedness and response coordination through healthcare coalitions.
- \$80.3 million for federal Preparedness and Emergency Operations, the National Disaster Medical System (NDMS), and the Civilian Volunteer Medical Reserve Corps (MRC).
- \$46 million for health security policy, strategic planning, and ASPR operations.

To accomplish its mission, ASPR has four priority pillars:

- 1) enhancing the MCM enterprise;
- 2) building a regional disaster health response system;
- 3) sustaining public health security capacity; and,
- 4) providing strong leadership.

Pillar #1 Enhancing the Medical Countermeasures Enterprise

ASPR's first priority pillar is developing, stockpiling, and using innovative vaccines, medicines, and supplies to protect Americans against 21st century threats.

Developing MCMs Against 21st Century Threats \$1.27

billion: The FY 2019 Budget for BARDA provides a \$145 million increase above the FY 2018 Annualized Continuing Resolution level. BARDA's mission is to develop and make available MCMs that address some of our most serious national threats including chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging/re-emerging infectious diseases. BARDA accomplishes their mission through a combination of programs including ARD, PBS, and PI.

During 2017, major milestones reached in MCM development included:

- The first BARDA supported antibacterial drug received approval from the Food and Drug Administration (FDA);
- The first BARDA supported smallpox treatment applied for FDA approval; and
- The first BARDA-led portfolio partnerships formed to fight pandemic influenza and emerging infectious diseases.

The BARDA portfolio includes 34 FDA approvals of 30 unique products addressing CBRN, PI, and Emerging Infectious Disease threats. Under PBS, 27 MCMs have been supported for late-stage development and procurement to address a wide range of threats, such as Ebola, anthrax, smallpox, botulism, viral hemorrhagic fever, as well as chemical, radiological and nuclear threats. Of the 27 products, 14 have been delivered to the SNS, and six have achieved FDA approval.

ARD \$511.7 million: The budget request for ARD is an increase of \$3.4 million above the FY 2018 Annualized Continuing Resolution level. These resources support the advanced development of high priority MCMs. ARD funding supports development of MCMs to address a wide range of primary and secondary effects of exposures to various threat agents and treatments for injuries caused by radiation, nuclear, thermal burns, viral hemorrhagic fever, and chemical agents.

Under BARDA's ARD program, funds are dedicated to the CARB-X program via novel public-private partnerships. CARB-X is a collaborative program that identifies, builds, and manages a portfolio of antibacterial MCMs, and promotes innovations in antibacterial drugs, vaccines, and diagnostics. As of late 2017, CARB-X had made awards to 22 different companies and is currently investing in ten non-traditional approaches to treating bacterial infections, nine new classes of antibiotics, and four next-generation antibiotics to overcome known resistance mechanisms.

PBS \$510 million: The budget request for PBS is an increase of \$3.4 million above the FY 2018 Annualized Continuing Resolution level. The Administration proposes advanced

appropriation and no-year funds. This would align with the original Special Reserve Funds that was established under PBS to serve as a market guarantee to entice developers to support the unique requirements for products that have little to no commercial market. The FY 2019 funding level will ensure continued development and procurement of Ebola vaccines and therapeutics, next-generation anthrax vaccines, procurements of antibacterial drugs, and chemical agent MCMs. In several ways, PBS also addresses the needs of special populations and those who are severely ill by, for example, supporting new intravenous formulations of currently stockpiled smallpox antiviral drugs. During FY 2019, BARDA anticipates that three additional PBS-supported products will be approved by the FDA.

PI \$245 million: The budget request for PI is \$138 million above the FY 2018 Annualized Continuing Resolution level. Because supplemental funds have been expended, the FY 2019 funds are needed to sustain critical domestic influenza vaccine manufacturing infrastructure, ensure that vaccines and therapeutics can be deployed in time for an effective pandemic response, and maintain pandemic readiness. The budget supports the advanced development of promising MCM candidates, including novel antiviral therapies that can address drug resistance. Public-private partnerships help to leverage the expertise, infrastructure, and manufacturing capacity needed. Such partnerships are being used in response to a strain of H7N9 avian influenza virus circulating in China.



SPOTLIGHT on H7N9: The current influenza season highlights the importance of continuing efforts to improve our national response capability. The FY 2019 Budget Request for PI addresses some of the most serious health threats faced by our nation, including the potential threat of an H7N9 pandemic. Avian influenza A (H7N9) is a subtype of influenza viruses. Most human infections with the H7N9 virus happen after exposure to infected poultry or a contaminated environment. H7N9 viruses are now circulating in some of the poultry found in China. Virus mutations enable limited transmission to people and those infected with the H7N9 virus often have severe respiratory illness (e.g., pneumonia). Since the H7N9 virus could possibly mutate and spread easily between people, monitoring for human infection and person-to-person spread is extremely important. BARDA is committed to improving our domestic capacity to respond to influenza strains with pandemic potential such as H7N9.

Pillar #2 Building a Regional Disaster Health Response System

ASPR's second priority pillar is improving healthcare readiness to respond to disasters through building a comprehensive, cohesive and capable tiered health response system.

Regional, State, and Local Preparedness \$331 million

(excluding SNS): ASPR leads the nation's public health and medical emergency response efforts. Through the Office of Emergency Management's HPP and NDMS programs, ASPR modernized the federal emergency management infrastructure and strengthened states', communities', and the healthcare system's disaster response and recovery posture.

ASPR plays a vital role in leveraging emergency management in ways that help HHS respond to, recover from, and mitigate the impacts of public health and medical emergencies. ASPR promotes resilient communities and prepares the healthcare system to be ready when disaster strikes, responding to events and incidents in ways that expedite recovery.

When ASPR responds to emergencies, the organization deploys both specialized personnel and medical caches that include lifesaving supplies and equipment.

SNS \$575 million: The SNS has been transferred to ASPR. SNS is the nation's largest repository of life saving MCMs and medical supplies. This repository is the only federal resource readily available for use in a public health emergency that is severe enough to cause state and local supplies to be depleted, or when unique medical supplies are required yet not commercially available. The transfer of the SNS to ASPR streamlines the MCM development and procurement enterprise while integrating the Stockpile with other preparedness and response capabilities. Shifting operational control of SNS to ASPR will improve the speed and effectiveness of emergency responses. The budget also supports continued training for responders nationwide to sustain the state and local capabilities needed to receive and dispense stockpiled MCMs.

Preparedness and Emergency Operations (PEO)

\$26.6 million: The FY 2019 request is \$2.1 million above the FY 2018 Annualized Continuing Resolution level. PEO funding plays a critical role in monitoring emerging public health threats, coordinating Department-wide response activities, and leading recovery efforts after an emergency has occurred. The funding supports ten divisions that work together to assist communities in building and maintaining resilience in the face of disasters. The divisions include funding for HHS management of all emergencies and events, both domestic and international through the Secretary's Operation Center (SOC). PEO funding will ensure that states and local entities can prepare for, plan for, respond to, and recover from public health emergencies and other disasters. FY 2019 PEO resources will be used to carry out a national-level exercise for a biological emergency involving HHS agencies and other

U.S. government departments. Through the simulation of a biological incident, agencies will be able to test-run and improve their response plans. The exercise will increase overall preparedness as the simulated response strengthens interagency coordination, identifies solutions for gaps in response plans, and validates successful incidence response mechanisms.

SPOTLIGHT on the 2017 Hurricane Season Response: As the lead agency for emergency response, ASPR coordinated HHS's preparedness and response efforts for the 2017 Hurricane season, including hurricanes Harvey, Irma, and Maria. The SOC served as the command center to coordinate HHS's efforts. The SOC coordinated the public health response and recovery planning efforts, ensuring the affected states and localities were supported to save lives during and after each hurricane. As of the end of 2017, ASPR supported the deployment of over 4,674 trained, professional personnel who provided medical care, mental health services, and support to 36,370 patients, evacuated 782 patients, and sent 944 tons of critical equipment and supplies to places in need.

NDMS \$49.8 million: NDMS funding for FY2019 is \$244,000 above the FY 2018 Annualized Continuing Resolution level. NDMS funds are used to augment the nation's medical and public health response capability. The request supports NDMS operations, logistics support, and regional emergency



coordination. NDMS is comprised of approximately 6,000 episodic intermittent federal employees divided into 74 teams. Responders are clinical, pharmaceutical, and emergency healthcare providers and staff with special, ongoing training. Teams are deployed during a natural or manmade disaster in order to provide critical medical services, protect and restore public health, and help communities recover faster. During deployments and coordination with local health personnel, NDMS teams carry out a variety of medical, public health, veterinary, and mortuary response activities; support patient movement and the modernization of equipment; and, provide definitive care and behavioral health support. NDMS funding also supports training of NDMS deployable personnel to ensure a knowledgeable and prepared workforce.

"We deployed our disaster medical assistance teams even before the storms hit landfall to ride out the storms and be ready to provide healthcare services immediately after the storms passed. We evacuated vulnerable dialysis patients before the storms hit so they would not be without care if the power went out and we worked closely with VA, FEMA, and DOD to provide healthcare services in remote areas."

Robert P. Kadlec, MD, MS
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

HPP \$254.5 million: The FY 2019 Budget Request is \$1.7 million above the FY 2018 Annualized Continuing Resolution level. HPP supports regional healthcare system readiness. This is accomplished through the development and sustainment of healthcare coalitions (HCCs). HCCs are comprised of diverse and often competitive healthcare organizations with differing priorities and objectives, such as hospitals and emergency medical services, within a geographic area. HCCs serve as multiagency coordination groups that integrate public health and medical service activities. HCC members are incentivized to collaborate so that each member is able to respond to emergencies and planned events, including through planning, training, and exercises; deployment of medical equipment and supplies; real-time information sharing; and communication and patient tracking systems. HCCs play a critical role in developing healthcare delivery system preparedness and response capabilities, including strategic and operational planning, information sharing, and resource management. During FY 2019, HPP will continue to fund 62 awardees: the health departments in all 50 states, eight U.S. territories and freely-associated states, and four localities. Funds are awarded based on risk and consideration of awardee performance.

Pillar #3 Sustaining Public Health Security Capacity

ASPR's third priority pillar is supporting public health agencies' ability to quickly detect, diagnose, monitor and respond to infectious diseases and other 21st century threats.

MRC \$3.9 million: MRC funding for FY 2019 decreased by \$2 million compared to the FY 2018 Annualized Continuing Resolution level. The MRC is a national network of over 190,000 local volunteers organized into approximately 900 community units across the country. MRC units strengthen communities by supporting local preparedness and response capabilities. ASPR also supports volunteer recruitment, training, and retention. During 2017, MRC completed 15,919 activities and 413 responses with more than 140,000 MRC participants contributing over 440,000 hours of volunteer service. MRC assistance in Puerto Rico includes near-daily community education and outreach in local municipalities across the island.

SPOTLIGHT on Texas: In response to Hurricane Harvey, the Brazoria County MRC in Texas operated five shelters, which provided a safe place for almost 1,000 residents for 41 days. After the shelters were closed, the MRC unit provided water sampling for 96 potentially contaminated water wells for an underserved community and continued to provide case management services for over 50 displaced families.

Pillar #4 Providing Strong Leadership

ASPR's fourth priority pillar is providing strong leadership and bringing the full weight of federal medical and public health response capabilities to support state and local authorities during emergencies and disasters.

Operations \$30.9 million: The FY 2019 Budget is an increase of \$151,000 above the FY 2018 Annualized Continuing Resolution level. ASPR Operations supports the stewardship of public resources; the development of a world class workforce; risk management and mitigation; communications; legislation; and, provides decisive leadership to ensure the nation's health security.

Office of Policy and Planning (OPP) \$14.8 million: For FY 2019, OPP funding is \$14.8 million, which is \$73,000 above the FY 2018 Annualized Continuing Resolution level. OPP supports the HHS Secretary and sets strategic goals and objectives to strengthen preparedness and response to disasters and other emergencies that impact the nation's health security. Specific priorities for FY 2019 include addressing policy issues affecting federal response operations as well as advancing healthcare system and community resilience, surge capacity, and behavioral health integration.

KEY ACTION: Reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA): PAHPA is due for reauthorization by Congress by September 30, 2018. This groundbreaking legislation first passed in 2006, established ASPR and BARDA, and transformed federal public health and medical preparedness and response activities.

The reauthorization of PAHPA would:

- 1) help ASPR achieve its mission of saving lives and protecting Americans,
- 2) demonstrate Congress' commitment to strengthening national preparedness and response for public health emergencies and disasters, and
- 3) accelerate the development and stockpiling of medical countermeasures for 21st century threats.

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