



## U.S. Department of Health and Human Services

### The Office of the Assistant Secretary for Preparedness and Response (ASPR)

# FISCAL YEAR 2017 BUDGET IN BRIEF

ASPR's budget request to Congress for fiscal year 2017 supports our mission and efforts that focus on promoting community preparedness and resiliency; strengthening the nation's health and response systems; building research and development partnerships with federal agencies, academic institutions, and private industry; and enhancing national health security.

**DEVELOPING MEDICAL COUNTERMEASURES AGAINST THREATS TO AMERICANS' HEALTH: \$632 MILLION:** ASPR continues to develop and make available medical countermeasures (MCMs) that address the public health and medical consequences of chemical, biological, radiological, and nuclear agents and incidents as well as pandemic influenza and other emerging infectious diseases. The Biomedical Advanced Research and Development authority (BARDA) supports activities such as clinical testing, the scaling-up of manufacturing for commercial production, regulatory review, and procurement and stockpiling of MCMs. In FY 2017, ASPR requests funding for:

- Investments in new projects for advanced research and development including clinical evaluation of next-generation anthrax vaccines; platform biodiagnostics devices to quantify the level of exposure to biological agents; existing antiviral drug and vaccine candidates against Ebola and Marburg viruses; new candidate products for addressing the five illnesses resulting from injuries from radiological or nuclear events, including thermal burns; and, new antidotes for treatment of chemical agents (for example, mustard gas exposure).
- Combating Antimicrobial Resistant Bacteria (CARB): The request maintains the significant investment proposed in the FY 2016 President's Budget. BARDA will continue utilizing innovative

public-private partnering mechanisms to form relationships with pharmaceutical and biotech companies developing antibacterial therapies. These partnerships will explore novel and improved antibiotics and non-traditional antimicrobial therapies. At this funding level, BARDA anticipates that at least one of these awards will be for a nontraditional antibacterial therapy (e.g. monoclonal antibody, microbiome modulation), in alignment with the CARB National Strategy.

- **Pandemic Influenza:** Significant progress has been made in domestic and international pandemic preparedness. In defining strategic priorities for pandemic influenza planning domestically and abroad, ASPR leadership has enhanced both seasonal and pandemic influenza capabilities. ASPR has also strengthened preparedness for other infectious disease outbreaks with pandemic or epidemic potential such, as MERS-COV, Ebola, and Zika. Efforts over the past decade to identify and resolve barriers that meet the need for MCMs used for pandemic influenza have created a capacity to develop MCMs for other emerging infectious diseases. The request supports pandemic influenza MCM programs as well as international preparedness, policy, and diplomacy programs. In FY 2017, ASPR requests funding to support:
  - Planning efforts to update the 2005 HHS Pandemic Influenza Plan.
  - The advanced development of vaccine candidates that are expected to yield more effective influenza vaccines, including potential universal influenza vaccines, as well as the storage, analytical and stability testing,

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and maintenance of existing H5N1, H7N9, and other influenza vaccines and adjuvants in the national pre-pandemic influenza vaccine.

- The advanced development of a new kind of treatment for influenza: broadly reactive immunotherapeutics, including monoclonal antibodies and immune modulators.
- Work with international partners through the North American Plan for Animal and Pandemic Influenza and the Global Health Security Initiative (GHSI), among others, to coordinate response plans for international assistance, including accessing and deploying resources internationally, such as laboratory and clinical samples, MCMs, and response personnel.
- Strengthen capacity building in partner countries to detect, prevent, and respond to outbreaks of infectious diseases with pandemic potential under the framework of the Global Health Security Agenda (GHSI) and the International Health Regulations (IHR).

**PROJECT BIOSHIELD: \$350 MILLION:** BARDA would make six procurements through Project BioShield: new antimicrobial drugs to address biothreat pathogens; a new acute radiation syndrome MCM; new biodiagnostic for anthrax; a new high-throughput biodosimetry diagnostic device; and, a new Ebola therapeutic and vaccine candidates.

**REGIONAL, STATE AND LOCAL PREPAREDNESS: \$340 MILLION:** ASPR provides critical operational leadership and support for all major public health and medical incidents on behalf of the federal government. ASPR is vital to fulfilling the U.S. Department of Health and Human Services' (HHS) responsibilities for public health emergencies. HHS is the coordinator and primary agency for Public Health and Medical Emergency Support Function 8 (ESF-8) of the National Response Framework and the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework and can serve as the Lead Federal Agency in coordinating the federal and medical response to public health emergencies. ASPR leads these functions within HHS and the federal government, and also holds the designation as the lead federal agency for these components in the Emergency Support Function Leadership Group as well as the Recovery Support Function Leadership Group. Through these functional designations, ASPR provides critical operational leadership and support

for all major public health and medical incidents on behalf of the federal government. These programs work together to assist communities in building and maintaining resilience in the face of disasters.

- **Incident Response and Emergency Operations: \$24.7 Million:** Funding would support critical coordination and development of operational plans and procedures that the Office of Emergency Management (OEM) undertakes as the lead for all HHS disaster response and recovery efforts across the federal government with interagency partners. Included in the total is \$5.0 Million to support National Special Security Events (NSSEs) and other public health emergencies that may not have funds provided under a Stafford Act declaration. These include known events such as the State of the Union address and the Presidential Inauguration, as well as new requirements, such as the 2015 Papal visit, or emerging public health incidents, like the 2014 Ebola outbreak.
- **National Disaster Medical System (NDMS): \$55.0 Million:** Funding would support NDMS operations and regional emergency coordination to prepare and respond to public health emergencies. Additionally, funding is used for medical response assets, including NDMS teams, supplies, and equipment. Lastly, the request strengthens federal response capabilities by investing in additional team trainings and incorporating new stakeholders into existing trainings. New appropriations language also requests the Equitable Coverage for Intermittent Employees of NDMS under the Public Safety Officers Benefit Act. This proposal would provide catastrophic disability and death benefits to NDMS intermittent federal employees when they are activated to respond to a public health emergency or location at risk of a public health emergency and during authorized training exercises.
  - Additional Funding for Essential Training: Since beginning its agreement, in FY 2013, with the Federal Emergency Management Agency's Center for Domestic Preparedness to train NDMS teams at their training center in Anniston, Alabama, 15 percent of NDMS teams have been trained. The FY 2017 funding level is projected to support 20 percent training to NDMS personnel annually.

- **Hospital Preparedness Program (HPP): \$254.6 Million:** The investment in HPP will improve preparedness, response, and recovery activities at hospitals and throughout the entire U.S. health care system. The ultimate mission of HPP is to save lives during emergencies that exceed the day-to-day capacities of the health and emergency response systems.
  - This is accomplished through health care system collaboration in the 486 regional health care coalitions (HCCs) established nationwide. HCCs across the U.S. include a diverse membership to ensure that no single hospital or other health care entity is overburdened during a disaster. As of June 30, 2015, there are 26,271 HCC members, including:
    - 83 percent of all hospitals,
    - 100 percent of state and 64 percent of local public health departments,
    - 42 percent of emergency management agencies, and
    - 26 percent of all emergency medical services (EMS) agencies.
  - HCCs incentivize diverse and often competitive health care organizations, including hospitals, with differing priorities and objectives to work together before and during emergencies to help each patient receive the right care at the right place at the right time.
  - With the FY 2017 request, HPP will advance an innovation agenda for the new project period that begins in July 2017 to incorporate lessons learned and best practices from the previous five-year period. These innovation activities include:
    - refining health care preparedness and response capabilities to focus specifically on hospitals and other health care entities;
    - improving HPP performance measurement to be objective and exercise-based;
    - optimizing HCCs to maximize their effectiveness and functionality;

- refocusing HPP funding on hospitals and other health care entities to ensure funds target medical preparedness; and
- engaging more frequently with health care stakeholders and experts to better inform program decisions.

- **Civilian Volunteer Medical Reserve Corps (MRC): \$6.0 Million:** Funding supports regional coordination efforts and technical assistance to MRC unit leaders to guide the development of MRC units. Funding also supports efforts to develop a system that tracks, monitors and assesses unit readiness, as well as standardizes “Mission Ready Packages” designed to help state and local partners assess available MRC resources.

**COLLABORATING WITH PARTNERS ON HEALTH SECURITY POLICY STRATEGY: \$14.9 MILLION:** ASPR’s integrated policy approach spans three functional policy components: 1) strategic planning and evaluation; 2) preparedness policy; and 3) response and recovery policy. In FY 2017, ASPR will:

- Engage with national stakeholders to drive implementation and evaluate the progress towards implementing the National Health Security Strategy 2015-2018 as required by the Pandemic and All Hazards Preparedness Reauthorization Act.
- Use strategic policy initiatives to encourage healthcare systems to be resilient, sustainable, and prepared.
- Oversee the implementation of health security actions under the Beyond the Border Initiative with Canada, and the trilateral and multi-sectorial North American Plan for Animal and Pandemic Influenza efforts, through which ASPR coordinates international preparedness efforts designed to address chemical, biological, radiological, and nuclear events, pandemic influenza, and infectious disease threats through GHSI, GHSA, International Health Regulations (IHR), and Biological Weapons Convention, among others.
- Work across ASPR offices, as well as with the National Institutes of Health, the Food and Drug Administration, Centers for Disease Control and Prevention, and state, local, tribal and territorial

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partners to define civilian MCM requirements that meet the nation's needs. ASPR assesses national preparedness against these needs through the preparedness assessment process, the 2017 Strategic National Stockpile Annual Review, and the Public Health Emergency Medical Countermeasures Multi-Year Budget.

- Ensure that preparedness, response and recovery efforts promote resilience and address behavioral health and the needs of at-risk individuals.
- Expand, intensify, and accelerate efforts to strengthen biosafety and biosecurity through implementation of concrete actions with partners designed to optimize biosafety and biosecurity policies and practices, as well as oversight.

#### **WORKING TOGETHER BEHIND THE SCENES:**

**\$30.9 MILLION:** ASPR is committed to exemplary stewardship of public resources, the development of a world class workforce, ongoing quality improvement in all aspects of programmatic and management operations, and decisive leadership that ensures the nation's health security. In FY 2017, ASPR will:

- Continue to strengthen initiatives that promote a leadership and mentoring culture through expansion of a career and leadership development program that helps assure that ASPR is capable of addressing evolving threats and emerging challenges to public health as well as implementing innovative solutions in the face of future disasters.
- Provide functional mission support to include requirements analysis, operations development, consultation and collaboration, and continued implementation of acquisition management innovations, long-term fiscal planning, and internal controls.

#### **COMBATING THE EMERGING THREAT OF THE ZIKA VIRUS FY 16 EMERGENCY SUPPLEMENTAL: \$188 MILLION:**

ASPR has a critical need to accelerate research, development, and manufacturing of vaccines, diagnostics, platform technologies, and virus inactivation methods to combat the current public health emergency posed by the Zika virus. The request will support:

- Vaccine Development and Manufacturing through the development of vaccine platform technologies that is rapidly amenable to different emerging infectious diseases. This includes ASPR's support of the manufacturing infrastructure in Butantan, Brazil for production of clinical investigational lots of a live, attenuated Zika vaccine candidate. Also included are expansion of large commercial scale manufacturing capacity for vaccine production; and the manufacturing of a killed whole-virus Zika vaccine candidate to be used in clinical trials.
- Rapid Diagnostics Development through the development of Zika ELISA laboratory multiplex assays; Zika multiplex lateral flow point-of-care immunoassays; and production and validation of Zika diagnostic reagent panels (virus and antibodies). The request also supports the development of one ELISA and one lateral flow serological assay as well as production of validated reagent panels.
- ASPR is supporting two approaches to ensure safety of the blood supply. The first is to work with commercial partners to assist in the development and support studies for the validation of blood screening assays. Having these assays available will allow blood centers to identify units of blood that should not be processed. The second approach is to support the development of pathogen reduction technologies. The technologies have the potential to inactivate known and yet to be identified bacterial and viral pathogens in blood products. This is also a longer term strategy to address future emerging and infectious diseases perhaps preventing the necessity for a validated blood screening assay to be developed for each identified pathogen.