



# Ebola Response Improvement Plan

January 2017 - Progress Report

U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Preparedness and Response



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## Progress Report

### Introduction:

In response to the 2014-2016 Ebola Epidemic, the Secretary of the U.S. Department of Health and Human Services (HHS) asked a contractor to convene an outside expert panel to review the HHS Ebola response and provide recommendations on improving the Department's preparedness and response efforts. The expert panel released its findings in a report titled, [Report of the Independent Panel on the U.S. Department of Health and Human Services \(HHS\) Ebola Response](#), in June 2016. Shortly thereafter, the Department released the [U.S. Department of Health and Human Services Ebola Response Improvement Plan \(ERIP\)](#), outlining how the expert panel's findings and recommendations from the aforementioned report would be addressed. HHS Operating and Staff Divisions (Op/StaffDiv) have invested effort and made progress on each of the distinct corrective actions as described below. Responsible Op/StaffDivs are in brackets at the end of each corrective action, with the designated lead marked with bold font. Each corrective action is followed by a description of the HHS response to date. In addition, lessons learned from the Ebola virus outbreak response implemented in the HHS response to the 2016 Zika virus outbreak are highlighted in the appropriate sections.

The Assistant Secretary for Preparedness and Response is pleased to provide this status report, outlining the progress toward addressing key recommendations made by the expert panel. In addition, the report provides a pathway for strengthening the planning and response to future outbreaks of Ebola virus and other emerging infectious diseases.

A table showing overall progress on corrective actions can be found in Appendix A.

### Key Categories, Corrective Actions, and Progress:

#### 1. Global Health Security and Coordination with International Partners

To improve coordination with international partners and to continue supporting the Global Health Security Agenda (GHSA), HHS will:

- 1.1 Support the World Health Organization (WHO) reform efforts that reorganize and improve its capabilities and operations for capacity building and emergency response. [**Office of Global Affairs (OGA)**, Centers for Disease Control and Prevention (CDC), Assistant Secretary for Preparedness and Response (ASPR), National Institutes of Health (NIH)]

**Actions:** The Department played a central role in leading WHO Member States to advance the organizational reforms, outlined in [WHO reform: High-level implementation plan and report – May 2013](#). The HHS Assistant Secretary for Global Affairs and Director-General of Health for South Africa co-chaired negotiations on a [resolution](#) adopted by the 2015 WHO Executive Board Special Session on Ebola. The

resolution focused on immediate Ebola response actions and policies to strengthen the WHO's response capabilities for future outbreaks.

The 2015 World Health Assembly (WHA) agreed to several emergency response reforms, including the formation of a new [WHO Health Emergencies Programme](#). The Programme has unique operational capabilities to complement its traditional roles for setting global standards and providing technical support. The Programme will also incorporate the "WHO Blueprint", which includes "research roadmaps for high priority, highly pathogenic pathogens with pandemic potential". HHS will continue to play a central role in collaborating with WHO leadership and Member States to develop and approve financing plans that aid the WHO to achieve the ambitious reform agenda that has collectively been set out.

As part of the reform and in an effort to fully implement the International Health Regulations (IHR, 2005), OGA and CDC are actively supporting the new Health Emergencies Programme in developing the necessary tools and processes to evaluate country-level preparedness on a regular basis, and to assist countries in developing and implementing plans to address critical health security gaps.

In addition, ASPR is supporting the WHO Health Emergencies Programme reforms on multiple levels. ASPR is working with the Pan American Health Organization (PAHO) to implement the WHO's [Emergency Medical Team \(EMT\) initiative](#) throughout the Americas Region. The initiative supports the work of the [WHO Emergency Operations Centres Network \(EOC-NET\)](#), to improve overall coordination of international public health emergency response through standardization and dissemination of best practices.

- 1.2 Support the GHSA, including assisting at least 31 countries to evaluate and strengthen their ability to implement the GHSA targets and other targets related to the IHR (2005), including their ability to prevent, detect, and respond to urgent public health threats. [CDC, OGA, ASPR, NIH]

**Actions:** The Joint External Evaluation (JEE) is a tool to evaluate countries' health security capacities, using targets derived from both the GHSA and the IHR. The international evaluation process is voluntary and collaborative, and designed to assist countries to identify the most urgent needs within their health security system. HHS supports the WHO in the coordination of the JEE process in the following ways:

- The CDC formed a JEE Support Team to facilitate the development of JEE assessments by international partners. The target is to complete 60 country assessments by end of FY2018 Q1. CDC facilitated nine of the 10 JEE assessments conducted in 2016.
- OGA provided management and administrative oversight and guidance in the development and implementation of the JEE process, in support of the CDC's technical/operational leadership, and in coordination with U.S. Government (USG) and multilateral partners.

- ASPR led 23 federal departments/agencies (D/A) through the USG JEE process in 2016 to evaluate U.S. health security capacities. This included leading the coordination of both a rigorous domestic self-assessment as well as a week-long consultation and review of U.S. capacities and facilities by foreign assessors. A comprehensive [Mission Report](#) was released in June 2016. ASPR will continue to lead the development and implementation of a U.S. strategic roadmap to address gaps and challenges identified by the evaluators.

OGA provides diplomatic support for implementation work in GHSA Phase 1 and Phase 2 countries. Implementation work includes supporting links between the USG and external partners, to facilitate coordination of work being done at the country level with ongoing USG implementation efforts.

OGA serves as the principal USG point of contact for members of the GHSA Steering Group (SG). In this role, OGA tracks overall progress on the Action Packages (AP) and works with AP leaders and the SG chair to promote the collaborative development and dissemination of tools, guidelines, and best practices to support GHSA and IHR implementation efforts. HHS actively serves on the following action packages:

- Laboratory Strengthening, as a lead, to build the capacity of laboratory systems nationally, regionally and globally for rapid and accurate detection, diagnosis and tracking of emerging public health threats. CDC, OGA and other D/As provide technical expertise and administrative support to the AP in order to move progress forward.
- Emergency Operations Centers (EOC), as a contributor, which aims to ensure every country has a public health EOC functioning according to minimum common standards. In FY2016 the CDC provided technical assistance and emergency management capacity building support in 28 GHSA countries.
- Medical Countermeasures (MCM) and Personnel Deployment, as a co-lead, which seeks to address the policy challenges associated with the cross-border deployment of public health and medical personnel.

- 1.3 Confirm the USG focal point within HHS with the responsibility for direct coordination and liaison with senior leadership at the WHO to help plan and implement joint emergency response efforts. [OGA, CDC, ASPR, NIH, FDA]

**Actions:** The Assistant Secretary for Global Affairs is the designated lead liaison with the WHO. While OGA serves as the overall HHS focal point, operationally, the CDC, ASPR, NIH, and the FDA may communicate with the WHO as required on specific operational, technical, and research issues (e.g., domestic and international emergency response planning, coordination, and execution). In September 2016, the Assistant Secretary for Global Affairs met with the Executive Director of the WHO Health Emergencies Programme, to discuss overall engagement with the USG.

ASPR continues to be the U.S. IHR National Focal Point, providing a 24/7/365 connection to the WHO's global alert and response system via the HHS Secretary's

Operations Center (SOC) and the action officers in the IHR Program. Post-Ebola, the U.S. IHR National Focal Point has implemented a number of new standard procedures to rapidly identify and disseminate relevant medical intelligence from the global network of national focal points representing other countries.

## 2. Incident Management and Operational Coordination

To improve incident management and operational coordination, HHS will:

- 2.1 Codify how infectious disease emergencies are managed under the National Response Framework (NRF) by completing the Biological Incident Annex (BIA) to the NRF and supporting efforts to finalize a Presidential Policy Directive (PPD) for designating and defining the role of a lead federal agency for complex, non-traditional responses. As part of this effort, clarify the types of infectious disease incidents that would require a coordinated national response, and identify the thresholds for triggering such coordination, particularly for a high-consequence event/threat. Until or unless a separate HHS emergency response fund is created, identify mechanisms to fund such a response, including through suggesting criteria for a Stafford Act declaration. [ASPR, CDC]

**Actions:** HHS collaborated with the Federal Emergency Management Agency (FEMA) and other interagency partners to finalize the BIA. The National Security Council (NSC) is finalizing the document. The NSC staff, in collaboration with HHS and other key agencies, has developed an international assistance and response checklist to guide decision-making in the event of a large-scale communicable disease emergency in countries with public health capacity gaps.

A separate HHS Emergency Response Fund has been proposed and was included in the President's FY2016 budget request. The proposed budget request has been highlighted as high priority of the current Administration for the incoming Administration to consider. During the Zika virus outbreak response, the Secretary used reprogramming authorities and Secretarial budget transfers to fund the response until Emergency Supplemental funds became available. In the absence of a separate response fund, those mechanisms remain available for initial support of large scale response to emerging infectious diseases.

- 2.2 Identify and maintain a cadre of senior career officials (SES or equivalent level) who have been involved in previous responses and can provide institutional memory and advice during public health emergency responses. [ASPR, CDC, NIH, FDA, Office of the Assistant Secretary for Health (OASH)]

**Actions:** HHS has drafted a list of senior career officials with a broad mix of backgrounds and experience who have responded to previous public health emergencies on behalf of the USG. This list will be updated by ASPR on an annual basis and maintained by the SOC, for potential use in future emergencies.

- 2.3 Coordinate through the NSC with the Department of State, and the U.S. Agency for International Development to develop a USG-wide framework for response to international public health emergencies. The framework should define a government-wide coordination structure for international response and the HHS role within this structure, and should also include provisions for managing a combined international and domestic event. [ASPR, OGA, CDC, NIH, FDA]

**Actions:** In December 2016, the NSC finalized the *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents*. The Playbook serves to assist White House leadership with coordinating a complex USG response to a high-consequence emerging disease threat anywhere in the world with the potential to cause an epidemic, pandemic, or other significant public health event. The goal of the Playbook is to assist White House leadership by providing a decision-making tool that identifies: (1) questions to ask; (2) agency counterparts to consult for answers to each; and (3) key decisions which may require deliberation through the PPD-1 process, including action by the President.

Additionally, ASPR has developed a complementary framework that outlines the USG interagency process to receive, adjudicate, and process international requests for public health and medical assistance during emerging infectious disease outbreaks. The framework would work in coordination with the mechanisms of the NSC Playbook. The concepts are based on the 2013 *United States Government Policy Framework for Responding to International Requests for Public Health and Medical Assistance during an Influenza Pandemic*. ASPR plans to provide a full, formal briefing to the NSC and interagency partners in early FY2017 Q2.

- 2.4 Explore mechanisms, such as memoranda of understandings, letters of intent, or concepts of operations between HHS and relevant USG D/As, to outline mutual assistance protocols to transport public health and medical assets, such as laboratory specimens, MCMs and personnel, in an international emergency. [ASPR, CDC, OASH, Office of the General Counsel (OGC), OGA, NIH, FDA]

**Actions:** The complementary framework described in the response to 2.3 outlines how the USG will process international requests for assistance. Additional policies developed by ASPR provide further principles and considerations detailing how HHS, in particular, responds to international requests for certain types of assets, including laboratory specimens and related research materials, MCM, personnel, and funding.

In addition, HHS provided critical input to the *United States Government International Chemical, Biological, Radiological, and Nuclear Response Protocol*. The protocol provides principles, guidance and considerations for a USG response to a catastrophic, international chemical, biological, radiological or nuclear incident. The protocol includes the HHS international assistance frameworks for the deployment of MCM and personnel.

HHS has collaborated with the Department of Defense (DoD) to leverage its *Interagency Transportation Support Framework Concept of Operations* to use DoD

airlift assets to move HHS personnel/teams for domestic events. This interagency framework also allows for the movement of personnel/teams from the Department of Energy, FEMA and the FBI to speed the deployment of interagency partners. For international use, agreements with DoD will have to be made on a case-by-case basis.

- 2.5 Review how Department-wide responses to *international* incidents are routinely organized and led. This includes detailing the roles and authorities of ASPR, CDC, NIH, OGA and other HHS components during different international response scenarios. [CDC, ASPR, OGA, Immediate Office of the Secretary (IOS), NIH, FDA]

**Actions:** HHS has actively contributed to several USG-wide efforts to improve response coordination during international public health and medical incidents. First, HHS has collaborated to finalize the BIA to the NRF. Second, HHS worked with the NSC and interagency partners to finalize a policy to enhance domestic incident response. Finally, as referenced in the response to 2.3, HHS provided critical input to the NSC Staff *Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents*.

In addition, HHS is developing an internal policy framework to coordinate the response to public health emergencies with a domestic/international interface. This framework describes the roles, responsibilities, and legal and funding authorities of relevant HHS stakeholders. The framework also describes the triggers and coordinating structure for initiating response to potential and actual public health emergencies with domestic-international implications. A draft of the framework will be submitted for review by subject matter experts in early FY2017 Q2, and HHS review in FY2017 Q3.

- 2.6 Review administrative authorities and address obstacles to clearly define whether the Commissioned Corps Ready Reserve can be deployed for short notice responses. [OASH, OGC]

**Actions:** Administrative authorities were reviewed and HHS determined the Commissioned Corps Ready Reserve (CCRR) cannot be deployed for short notice responses. Changes in the current legislative language authorizing the CCRR would need to be considered and modified.

- 2.7 Formalize a structure for obtaining confidential, external advice regarding the execution of a public health response in real time. External groups have often advised CDC, ASPR or other components during emergencies. These groups, which are independent and external, can help highlight perspectives and issues that may not be immediately apparent to those involved in the day-to-day response. A nimble, standing mechanism, including a working group of the National Preparedness and Response Science Board (NPRSB) and/or the Advisory Committee to the Director of CDC, to execute this function, should be considered. [ASPR, CDC, NIH, OGC]

**Actions:** ASPR and the CDC have federal advisory committee structures in place to seek external, expert advice on a range of public health issues. The NPRSB provides expert advice and guidance to the Secretary of HHS and the ASPR on scientific, technical, and other matters related to public health emergency preparedness and response. ASPR has the authority to convene a working group of the NPRSB to provide external advice through the NPRSB, and will/has incorporate the need to consider this body in future planning documents.

### 3. Public Health and Healthcare Response

To improve the public health and healthcare response, HHS will:

- 3.1 Pre-identify facilities that HHS can use for quarantine, isolation and treatment. In doing so, consider how many individuals may need to be simultaneously housed in such a facility, and whether the facilities need to be near hospitals with specific capabilities. [ASPR, CDC, NIH]

**Actions:** On October 30, 2016, ASPR awarded a contract for an infectious disease training center, currently located on the grounds of an existing Ebola regional treatment center. In the event of another Ebola virus outbreak or other severe emerging infectious disease, the treatment center could be immediately turned into a quarantine center for up to 20 individuals. The occupancy number was based on data from the 2014-2015 Ebola virus outbreak and represented the largest group of individuals returning from West Africa. Space requirements for the facility were established by the CDC, ASPR and GSA, also based on the maximum capacity cited above.

- 3.2 Review current evidence and codify evidence-based components of a comprehensive, multi-pronged approach for traveler screening for future Ebola or Ebola-like outbreaks, including: (1) actions to be taken on exit from affected countries for travelers to the U.S.; (2) actions to be taken for screening travelers entering the United States from countries experiencing an outbreak, including, if needed, describing the process of limiting the number of points of entry; (3) how such efforts, if undertaken, would be staffed; and (4) how travelers would be monitored for disease-appropriate periods of time, once they arrive in the U.S. [CDC, ASPR]

**Actions:** The CDC conceptualizes traveler screening for future public health emergencies in four phases: 1) exit from an affected country; 2) entry into the United States; 3) staffing; and 4) monitoring. The projected timeframe for completion of these documents is FY2017 Q3.

Additionally, the CDC and ASPR are working with DHS to develop a border health plan for passenger entry, which focuses on keeping infectious diseases from entering and spreading within the United States. A draft plan is expected to be delivered to the NSC in FY2017 Q2.

Additionally, ASPR is coordinating with the Department of Transportation (DOT) and Federal Aviation Administration (FAA) to refine the current national guidelines for public health protection at U.S. international points of entry (air, land, and sea) that are not directly staffed by federal public health officers. Those guidelines and a “national strategy” will be provided to airport operators and state/local public health officials to help them enhance local systems and conduct specific, public health emergency planning and exercises. Focusing on the challenges in the aviation sector first, ASPR, DOT, FAA and the CDC are in the process of developing a guideline document that is consistent with the International Civil Aviation Organization standards. A draft of the document will be available in FY2017 Q3.

- 3.3 Develop an evidence-based interagency Concept of Operations (CONOPS) for the management of waste related to Category A agents; review the appropriateness of the Ebola classification. [CDC, ASPR]

**Actions:** The *Interim-Planning Guidance for the Handling of Waste Contaminated with a Category A Infectious Substance* has been drafted. The guidance will assist hospital or healthcare facility personnel, public health officials, environmental officials, and federal, state, and local officials who have to handle, transport or dispose of waste from a person with a suspected or known exposure to a Category A infectious substance. A final draft was submitted for review in December 2016 to the NSC DRG. Comments were adjudicated and the revised document resubmitted to D/As for clearance. A final version of the document has been released to D/As.

- 3.4 Refine guidance for USG and facility-level Personal Protective Equipment (PPE) stockpiling.

- 3.4.1 Incorporate outcomes from the ongoing HHS study initiated by the National Institute for Occupational Safety and Health (NIOSH) and CDC on PPE use, burn rate, and stockpiling. [CDC, ASPR]

**Actions:** Since 2015, NIOSH has been collaborating with Vanderbilt University Medical Center and other federal and academic partners to develop a surveillance system. The system will monitor PPE supply, use, and distribution to anticipate potential PPE supply shortfalls and distribution needs in a systematic way. To date, six hospitals have been recruited and trained along with survey instruments being developed. An additional six hospitals are planned for recruitment in 2017. In August 2015, a 3-year contract was awarded to expand the current project to incorporate Ebola PPE and evaluate PPE monitoring across 15-20 hospitals. The CDC plans to explore sustainability funding after the present 3-year funding ends in 2018.

- 3.4.2 Fully coordinate and fund a science preparedness program within the Department to support response initiatives. [ASPR, NIH, CDC, FDA]

**Actions:** The Department has developed a science preparedness program as a collaborative effort to establish and sustain a scientific research framework. The framework is intended to enable emergency planners, responders and the

community to better prepare for, respond to, and recover from major public health emergencies and disasters. ASPR has hired a full-time manager to lead, further develop and mature the program. Under this program, the Science Preparedness Research Interagency Team (SPiRIT) provides a central forum, across HHS Op/StaffDivs, for the coordination and collaboration of preparedness, response and recovery activities. SPiRIT played an active role in the Federal Disaster Research Community information sharing during the 2014-2016 Ebola virus outbreak and more recently during the response to the Flint, Michigan water contamination crisis.

Additionally, ASPR, the CDC and NIH have jointly funded a *Standing Committee on Medical and Public Health Research During Large-scale Emergency Events* at the National Academies of Sciences, Engineering, and Medicine (National Academies). This group not only provides advice regarding long-term science preparedness activities but can convene rapid-cycle workshops to identify research priorities as public health emergencies unfold. For example, on February 16, 2016, the National Academies convened a rapid-cycle workshop, at the request of the ASPR, entitled [Research Priorities to Inform Public Health and Medical Practice for Domestic Zika Virus](#). This workshop convened domestic and international subject matter experts and other stakeholders to inform preparedness and response requirements for a potential Zika virus outbreak in the continental United States and associated territories; and to provide guidance regarding critical near-term and future research topics associated with the virus.

The National Academies also established the [Committee on Clinical Trials During the 2014-15 Ebola Outbreak](#) to explore and analyze scientific and ethical issues related to clinical trial design, conduct and reporting, based on the outbreak in West Africa. The Committee intends to issue a public report in early 2017. The Department will actively consider the report findings and incorporate novel approaches applied to prioritization of research needs into future emergency responses.

Finally, the NIH National Institute of Environmental Health Sciences (NIEHS) [Worker Training Program \(WTP\)](#) has been tracking and developing health and safety information on Ebola virus disease and other infectious diseases as it pertains to protecting workers involved in emergency response and cleanup activities performed in the United States. Additionally, the NIEHS WTP has been working in collaboration with the CDC and through funding of NIEHS awardees to provide health and safety training for a range of high risk occupations.

- 3.5 Develop mechanisms for involving private sector PPE manufacturers, and for other commodities in potential short supply, in the process of developing departmental recommendations to ensure that concepts put forward do not unnecessarily stress the supply chain. [ASPR, CDC]

**Actions:** In FY2016, ASPR supported a project to assess the healthcare supply chain, identify challenges, and propose further activities to coordinate supply chain preparedness and response. A summary of the findings, and an accompanying ASPR

blog post, will be released prior to January 30, 2017. ASPR has developed an operating model for coordination of supply chain activities across the federal government and with state, local, tribal and territorial governments, and private sector partners utilizing the existing Critical Infrastructure Partnership Advisory Council (CIPAC) structure. ASPR refined the operating model through a workshop with CIPAC partners, in September 2016, using Ebola PPE activities as an example. Standing up the structure of the coordination body will be a FY2017 priority for ASPR.

As an example of progress, during the initial stages of the Zika virus outbreak response, HHS coordinated with the private sector to better understand which products were critical to an effective response, the availability of those products, and challenges for manufacturing, distributing, or purchasing those products. The potential shortfalls of mosquito traps and repellents were discussed with manufacturers and distributors. While traps were already being produced at the maximum possible rate, HHS shared the list of states most likely to sustain local transmission of Zika virus. This allowed distributors to prioritize shipments to those areas as product became available. Manufacturers, marketers, and distributors of mosquito repellent also discussed potential shortfalls and voluntarily increased production. As a high demand for repellent was not realized during 2016, remaining stock is available for potential needs in 2017.

- 3.6 In collaboration with U.S. federal agencies, develop a mechanism to coordinate the purchase and distribution of PPE and/or MCMs by federal partners. [ASPR, CDC, FDA]

**Actions:** Early in the Zika virus outbreak of 2016, ASPR convened an interagency working group to promote a shared understanding of necessary products, product availability, and private sector shortfalls, related to insecticides, traps, and repellents. The working group, identified mechanisms for coordination of federal purchasing of large quantities of the identified products; ASPR is now developing a formalized mechanism for coordination of purchases with the CIPAC. A document outlining the mechanism will be delivered in FY2017 Q3. While this mechanism will be generic, it should be applicable to Ebola PPE.

ASPR has also instituted a decision making framework known as the Rapid Analysis for Informed Decisions (RapidAID), to identify, analyze, and provide options for MCM needs during a response when formal MCM requirements are not available. It has been used successfully to determine and document the quantities of Ebola vaccines recommended for procurement for naturally occurring scenarios and Zika toxicant threshold and objective product characteristics.

- 3.7 Determine whether additional strategies could be employed to ensure healthcare facilities participate in responding to future emerging public health threats. [ASPR, OASH, CDC, NIH]

**Actions:** ASPR has engaged the MITRE and RAND Corporations to conduct an analysis of the need for a more formalized system to ensure patients with highly

infectious diseases have the necessary access to care, in order to effectively treat their illness. The project will determine the strategies necessary to ensure sufficient geographic distribution of access to, and sustainability of healthcare facilities that provide care for patients with high consequence infectious diseases. Further, this project will also involve extensive stakeholder input to determine if the capabilities and capacities necessary during an emerging infectious disease outbreak can be built on the foundation of existing Ebola regional treatment centers, as well as the day-to-day infectious disease expertise that exists throughout the nation's healthcare system. A stakeholders meeting was held November 21-22, 2016, resulting in a preliminary analysis of capabilities and capacities of the healthcare system to support future infectious disease responses. A final report is pending.

- 3.8 Determine whether the Department should establish and maintain a cadre of response staff (both civilians and U.S. Public Health Service (USPHS) Commissioned Corps officers) that is trained and readily available to deploy internationally to provide clinical care. If so, define the size and scope of that cadre, language competencies required and the conditions for their deployment. [ASPR, OASH, CDC, NIH]

**Actions:** ASPR is leading an interagency effort to develop recommendations for HHS, and USG leadership on how, if determined, the United States will participate in the WHO's EMT Initiative (see 1.1, above). ASPR is conducting research and analysis toward this effort as the chair of the HHS International Policy Group for Personnel Sharing, established under the *Policy Framework for Responding to Requests for the International Deployment of Health and Human Services Public Health and Medical Personnel*. This policy framework outlines how the Department will receive, analyze, make decisions about and respond to international requests for HHS public health and medical personnel during international medical and/or public health emergencies that warrant coordination among HHS offices and agencies and/or other USG departments.

- 3.9 Document and codify all available surge mechanisms to augment staff (civilian and uniformed USG, non-USG, and international) for use across HHS Op/StaffDivs for large-scale event response support, to include how to efficiently access USPHS staff, establish interagency agreements with FEMA and others, pre-approve international agreements, hire professional organization staff, etc. Widely share the collected information with relevant Op/StaffDivs. [Office of the Assistant Secretary for Administration (ASA), ASPR, OASH, CDC, OGA, NIH]

**Actions:** ASPR has developed a process to identify and coordinate additional personnel to augment the Emergency Management Group (EMG) response to National Special Security Events and other incident responses. These individuals are recruited from a variety of areas, including the Incident Response Coordination Team, interagency partners, and HHS Op/StaffDivs, and fill key EMG roles (e.g., Operations, Logistics, Planning and Administration & Finance). Prioritization of personnel activation is first sought within ASPR, followed by small augmentation packages from USPHS. If the event is large enough, full activation of the USPHS by

the Secretary may be initiated. If the surge cannot be fulfilled through ASPR and USPHS recruitment, additional personnel requests can be initiated through FEMA for interagency support, such as what was utilized in support of the Zika virus outbreak response in Puerto Rico. The EMG CONOPS for surge personnel was completed in September 2016.

3.10. Determine and implement the most feasible approach to using USPHS Commissioned Corps officers to support prolonged HHS emergency responses. [OASH, OGC]

**Actions:** Preliminary discussions have taken place with additional information and background coming from recent deployments and planning in response to the Flint, Michigan water crisis and Zika virus outbreak. In response to the requirements of these deployments, the Commissioned Corps is:

- Updating its deployment, development and training processes to support a rapidly deployable force capable of sustained operations. OASH is working closely with the Chief Professional Officers, Agency Liaisons, and Commissioned Corps officers to enhance deployment training, ensure the maintenance of technical skills, maintain high levels of individual medical readiness, and provide pre and post deployment health assessments of the Corps.
- Reviewing after action reports from previous deployments and considering the creation of a dedicated cadre of officers to be ready for a prolonged HHS emergency response. This group of individuals would be at the ready for both domestic and international events.

3.11. Evaluate and simplify the processes to enact [Direct-Hire Authority](#) (DHA) as a potential mechanism for surging personnel during responses to urgent public health threats. [ASA, ASPR, NIH, OGC]

**Actions:** On February 26, 2016, the Office of Personnel Management issued DHA to HHS, for specific occupational series. This authority was issued based on critical hiring needs to address the outbreak and spread of the Zika virus. This DHA allowed the CDC to quickly and successfully hire over 200 personnel to assist in their response to the Zika virus outbreak.

3.12. Leverage the quarterly meetings sponsored by the National Healthcare Preparedness Programs (NHPP) with their state, local, and territorial public health awardees to outline an effective outreach plan to delineate the role of the government and public health agencies and organizations during an emerging infectious disease (EID) response. [ASPR, CDC]

**Actions:** Efforts have been initiated to improve coordination of governmental and non-governmental agencies and organizations during disasters, including response to emerging infectious diseases. The ASPR NHPP has recently published its new [2017-2022 Health Care Preparedness and Response Capabilities](#). The new Capability 4—Medical Surge, has specific objectives and activities that delineate the roles and responsibilities of healthcare organizations, health care coalitions, and government agencies during an infectious disease response.

## 4. Risk Communication

To strengthen risk communications, HHS will:

- 4.1 Develop/codify a Department-wide strategy for communicating risk information to the public during any domestic or international public health emergency, urgent health threat, or health-related incident that may be perceived to pose a significant risk to healthcare providers or the public. The framework should institutionalize the use of crisis and emergency risk communication principles. [**Office of the Assistant Secretary for Public Affairs (ASPA)**, CDC, ASPR]

**Actions:** The CDC has developed a draft, strategic document outlining the overarching principles of risk communication and its purpose and relevance to communicating in public health emergencies. The goal of the document is to codify the Department's commitment to integrating risk communication across all Op/StaffDivs into their work and reflect on lessons learned during past significant events. The document will not be prescriptive and tactical, but rather reference a vast array of existing practical resources (e.g., CDC's Crisis & Emergency Risk Communication program). The draft document has been submitted to ASPA, for review with the intent to have concurrence on the document, across the Op/StaffDivs, by early FY2017 Q2.

- 4.2 Identify and train a cadre of personnel from across HHS that have public health expertise and a thorough understanding of, and fluency in, health crisis and risk communications to serve as spokespersons during domestic or international public health and medical emergencies. This training can draw upon a body of work developed since the 9/11 terrorist attacks. [**ASPA**, CDC, ASPR]

**Actions:** The CDC Joint Information Center staff and ASPR are working to identify best practices from past events to develop a proposed core curriculum of existing training related to incident management and risk communication. The curriculum will be packaged and offered as an opportunity to develop a more consistent approach to deployment.

- 4.3 Develop a mechanism to augment steady state crisis and risk communication staff, as needed. [**ASPA**, CDC]

**Actions:** Once a proposed core curriculum package of existing training related to incident management and risk communication comes together and is finalized, next steps will focus on developing a more consistent and targeted approach to identify interested individuals and to maintain their credentials and level of experience.

## 5. Medical Countermeasures

To improve development of MCMs, HHS will:

5.1 Draft and implement an EID Countermeasure Response Plan. [ASPR/ BARDA, NIH, CDC, Food and Drug Administration (FDA)]

**Actions:** The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has continued to evaluate progress of MCMs for EIDs, leading to the eventual FDA licensure or approval of drugs and vaccines, both for domestic and international use. Actions include:

- The PHEMCE has continuously stressed the value and development of definitive requirements documents that outline the characteristics and overall level of need of vaccines, diagnostics, and therapeutics for EIDs. This is informed also by modeling against deliberate as well as naturally occurring disease.
- Assessment of potential MCM capabilities and candidates: An up-to-date assessment of existing MCMs and those in development will take place simultaneously with the ground assessment. ASPR will draw upon ASPR/BARDA and the PHEMCE Integrated Program Teams for this step.
- The PHEMCE Integrated Program Teams identify the challenges and goals for full life cycle management of the various products that are required during a public health emergency. Working with the various programs and with the Enterprise Executive Council, products are moved forward along with industry partners through the rigorous regulatory process to demonstrate safety and efficacy of the candidate products. Establishment of other incentives, such as PREP act coverage for products, or availability to use the products under Emergency Use Authorization (EUA) stimulate public-private partnership to achieve final product development and eventual stockpile, as further defined by the PHEMCE.
- ASPR/BARDA will evaluate the maturity level of candidate products that can potentially be fully developed to licensure/approval and establish contractual relations with industry to accelerate the manufacturing and advanced development of appropriate candidates.
- ASPR/BARDA will serve to establish mechanisms to evaluate and either support further development or cease development of products based on the achievement of specified intermediate goals that demonstrate successful progress being made toward licensure/approval.
- ASPR/BARDA will identify funding needed to secure the eventual final development in concert with the activities of the industrial partners.

5.1.1 Codify a process to rapidly determine the design and conduct of scientific studies while still allowing HHS agencies time and opportunity to offer ample input. [NIH, CDC, FDA, ASPR]

**Actions:** Once ASPR declares a research response is needed, the NIH and the NIH Director will have the responsibility to ensure the USG and HHS Departmental need for an efficient, clear, expedient research agenda is met efficiently during an emergency as follows:

- NIH will lead in providing the clinical, medical, and research expertise necessary for the initial assessment to ensure expeditious consideration of research needs in a specific infectious disease outbreak or other health emergency.
- NIH will ensure expeditious development and implementation of the research agenda according to the process steps outlined here.
- NIH will lead research efforts across the U.S. response and will ensure synergy with other USG and multilateral response efforts.
- Resolution of conflicts: The NIH Director will have the authority to resolve conflicts that may impede development and efficient execution of the USG and HHS Research Agenda.

5.1.2 FDA should continue to review its implementation of processes for authorizing, approving, or licensing new countermeasures when the risk benefit ratio is dramatically shifted (e.g., as it was for Ebola) and continue to work with countermeasure developers, other international regulators, and other relevant USG partners. [FDA, NIH/ National Institute of Allergy and Infectious Diseases (NIAID), CDC, ASPR]

**Actions:** The FDA is committed to using its authorities to the fullest extent possible to rapidly enable access to investigational medical products during public health emergencies (i.e., clinical trials under an IND/IDE, expanded access, or EUA), as well as leveraging appropriate export mechanisms to provide access in affected foreign countries. In any given circumstance, the FDA will bring to bear the most appropriate regulatory mechanism to afford access to a candidate MCMs commensurate with its risk/benefit profile.

The FDA has a seasoned public health response diagnostics team that has demonstrated its ability to work with our USG partners and international community to rapidly review and issue EUAs when appropriate during the very earliest stages of an emerging infectious disease. The pre-EUA processes and ongoing collaborations with the CDC and DoD enable the FDA to assess and make available diagnostics early on in an outbreak, and then work with commercial developers to expand capacity. For example, the FDA worked with USG partners and the international community to access and make samples available, assist diagnostic developers with templates and clear guidance about what data to submit, and rapidly review and issue EUAs during the Zika virus outbreak. As of December 22, 2016, the FDA has issued [14 EUAs](#) for diagnostic tests to respond to the Zika virus outbreak. In addition, the FDA created standardized Zika virus reference materials for nucleic acid-based in vitro diagnostics devices and is making it available as part of the pre-EUA process.

Further, the FDA has finalized and published the April 2016 draft guidance entitled [“Emergency Use Authorization of Medical Products and Related Authorities”](#).

In addition, the FDA is working to define the most efficient regulatory pathways and supporting the development of streamlined clinical trial approaches (including adaptive protocol designs) to assess the highest priority candidate products in

clinical trials during an emerging infectious disease outbreak. This approach, which is a departure from the traditional stepwise product development process, dramatically expedited the availability of Ebola MCMs during the Ebola epidemic. Currently, the FDA is working with USG partners, with NIH/NIAID lead, to continue to advance these process improvements to develop investigational vaccines for the Zika virus. In addition, the FDA is working with sponsors of the lead Ebola vaccine and antiviral candidates to provide regulatory advice on appropriate regulatory pathways for licensure/approval, as well as ensuring mechanisms for access should new Ebola outbreaks emerge.

- 5.2 Continue current efforts to solicit input—supported by research and data—from across the Department and the scientific community on clinical trial designs for EIDs. This may include development of manuscripts for peer-reviewed journals on the experiences of using randomized, placebo-controlled clinical protocols for vaccine candidates and adaptive common master protocols for therapeutic candidates, and the use of modeling to inform clinical trial design. [NIH, FDA, ASPR/BARDA]

**Actions:** NIH, ASPR, and the FDA are sponsoring a National Academies review of the ethics and scientific validity of clinical trials implemented during the Ebola virus outbreak response that will deliver recommendations about the design and implementation of such studies in future emerging infectious disease outbreaks. Outcomes of the National Academies study will be released in FY2017. Additionally, the NIH, in collaboration with other HHS agencies, will outline anticipated research needs in compliance with U.S. and international research ethics and regulations. The primary goal is rigorous, interpretable data to inform regulatory decision-making on the use of new MCMs and advance scientific and clinical understanding. During the second quarter of FY2017, NIH will develop procedures for determining and meeting emergency clinical research requirements. The requirements will include assessing clinical research needs at the outset of potential emergencies, identifying appropriate exemplar research protocols, and strategies for meeting ethical and regulatory standards.

## 6. Response Funding

To improve access to sufficient response funding, HHS will:

- 6.1 Continue to pursue Secretarial transfer authority to allow HHS to redirect existing funds in order to initiate and sustain response activities. [Office of the Assistant Secretary for Financial Resources (ASFR), ASPR]

**Actions:** In the 2015 and 2016 enacted appropriations, Congress authorized increasing the HHS Secretary's transfer authority into the Refugee and Entrant Assistant appropriation from three percent up to 10 percent. This appropriation provides funding for programmatic activities addressing issues of refugees, entrants, and unaccompanied children. The Department made the recommendation to the

DRG to expand this transfer authority to Public Health and Social Services Emergency Fund appropriation which will allow HHS to surge in advance of supplemental appropriations.

- 6.2 Investigate pursuing appropriations for a standing Public Health Emergency Response Fund to enable HHS to begin responding to a potential public health crisis before it becomes a full-blown public health emergency. [ASFR, ASPR, CDC, OGA, NIH, FDA]

**Actions:** The *FY 2016 President's Budget Request for HHS*, submitted to Congress, included a \$110 million Public Health Emergency Response Initiative Fund to be available to respond to an urgent or emergency need that could cause severe consequences and for which rapid action would help mitigate the threat. While the final FY2016 appropriation did not include this funding, contingency funds provided in the Ebola Emergency Supplemental Appropriation were re-programmed to support the early phases of the response to the Zika virus outbreak. This further demonstrated the need for a stable source of contingency funding.

- 6.3 Consider whether additional legal authorities are needed to allow state and local government grantees to use unspent federal grant funds received under an HHS grant program to establish a reserve fund that could pay for the expenses of responding to public health crises and emergencies, with authorization from HHS. [ASFR, CDC, ASPR]

**Actions:** The underlying concern addressed in the action item is centered upon getting funds quickly to state and local partners, during a public health crisis. Specific legal authority is needed to permit state and local grantees to utilize unspent federal grant funds for purposes other than those stated in the statutory authority for the grant, grant regulations, and grant terms and conditions. The Op/StaffDivs will work closely with OGC and legislative leads to determine the best path forward to address this issue.

## Conclusion:

The Department continues to improve on policies and procedures for preparing for and responding to disasters and other emergencies. New focus has been placed on preparing for public health emergencies where there is an interface between international and domestic responses, as seen with the Ebola virus outbreak and more recently following the Zika virus outbreak. HHS continues to strengthen communications and clarify lines of efforts across the Op/StaffDivs, to ensure quick, effective responses to these emergencies. HHS also continues to engage with federal, state, local and international partners, to strengthen the nation's preparedness, detection and communications capacities. ASPR will actively continue to monitor and coordinate actions across HHS to implement the improvement plan, including convening working groups, as necessary. The Department will publish an additional semi-annual report to show progress on activities toward meeting each of the action items outlined in the improvement plan.

## Acronyms:

ASA	Office of the Assistant Secretary for Administration
ASFR	Office of the Assistant Secretary for Financial Resources
ASPA	Office of the Assistant Secretary for Public Affairs
ASPR	Office of the Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority (ASPR)
BIA	Biological Incident Annex
CDC	Centers for Disease Control and Prevention
CONOPS	Concept of Operations
D/A	Departments and Agencies (USG)
DHS	Department of Homeland Security
DoD	Department of Defense
DRG	Domestic Resilience Group (EOP)
EMT	Emergency Medical Team
EOC	Emergency Operations Center
EOP	Executive Office of the President
EUA	Emergency Use Authorization
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency (DHS)
GHSA	Global Health Security Agenda
HHS	U.S. Department of Health and Human Services
IHR	International Health Regulations
IOS	Immediate Office of the Secretary
IRCT	Incident Response Coordination Team
JEE	Joint External Evaluation (WHO)
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NRF	National Response Framework
NSC	National Security Council (EOP)
OASH	Office of the Assistant Secretary for Health
OEM	Office of Emergency Management (ASPR)
OGA	Office of Global Affairs
OGC	Office of the General Counsel
Op/StaffDiv	Operating and Staff Divisions (HHS)
PPE	Personal Protective Equipment
USG	United States Government
USPHS	United States Public Health Service
WHA	World Health Assembly (WHO)
WHO	World Health Organization
WTP	Worker Training Program (NIH)

## APPENDIX A: Status of Corrective Actions (as of 1/13/2017)

Corrective Actions	Timeline
1.1 - Support WHO Reform	Complete
1.2 - GHSA Support	Complete
1.3 - Confirm Focal Point	Complete
2.1 - NRF/BIA & PPD Support	Complete
2.2 - SES Core Group	Complete
2.3 - USG - International Response	Complete
2.4 - USG -D/A Support to HHS	TBD
2.5 - HHS - International Response	Q3-FY17
2.6 - PHS CC Ready Reserve	Complete
2.7 - Advisory Committees	Complete
3.1 - Quarantine Sites	Q1-FY19 <sup>1</sup>
3.2 - Traveler Screening	Q3-FY17
3.3 - Waste Management	Complete
3.4.1 - NIOSH PPE Study	Q1-FY19
3.4.2 - Science Preparedness	Complete
3.5 - PPE Supply Chain	FY17
3.6 - PPE Purchase and Distribution	Q3-FY17
3.7 - Healthcare Facility EID Analysis	Q4-FY17
3.8 - HHS International Deployment	TBD
3.9 - HHS Staff Surge	Complete
3.10 - USPHS Prolonged Deployments	Q2-FY17
3.11 - Direct Hire Authority	Complete
3.12 - NHPP Partner Outreach	Complete
4.1 - Risk Communications Strategy	Q2-FY17
4.2 - PH Communications Staff Training	TBD
4.3 - Communications Staff Augmentation	TBD
5.1 - EID MCM Response Plan	TBD
5.1.1 - Scientific Study Design and Conduct	TBD
5.1.2 - Authorizing/Approving/Licensing MCMs	Complete
5.2 - Clinical Trials Design	Q2-FY17
6.1 - Moving Federal Funds	TBD
6.2 - PHE Response Fund	Congress
6.3 - Moving State and Local Funds	TBD

<sup>1</sup> Contract awarded in 2016. Timeline is for completion of facility.