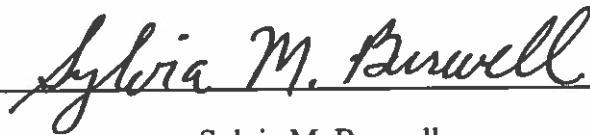

Department of Health and Human Services

Zika Supplemental Funding Spend Plan

October 26, 2016



Sylvia M. Burwell

Department of Health and Human Services
Zika Supplemental Funding Spend Plan

Table of Contents

INTRODUCTION 3

HHS OVERVIEW 4

CENTERS FOR DISEASE CONTROL AND PREVENTION 5

NATIONAL INSTITUTES OF HEALTH 6

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND 8

INTRODUCTION

The Zika Response and Preparedness Act, 2017 (H.R. 5325) provided \$933 million in emergency supplemental funding to the Department of Health and Human Services (HHS) for Zika preparedness and response activities. The Act allocated \$394 million to the Centers for Disease Control and Prevention (CDC), \$152 million for the National Institutes of Health, and \$387 million to the Public Health and Social Services Emergency Fund (PHSSEF). The Public Health and Social Services Emergency Fund appropriation was directed to support preparedness and response activities within the Assistant Secretary for Preparedness and Response (ASPR), the Health Research and Service Administration (HRSA), for oversight activities, and the Centers for Medicare and Medicaid Services (CMS).

The reporting requirements within Section 103 of the Zika Response and Preparedness Act, 2017 (H.R. 5325) states:

Reporting Requirements. – Not later than 30 days after enactment of this Act, the Secretary of Health and Human Services shall provide a detailed spend plan of anticipated uses of funds made available in this title, including estimated personnel and administrative costs, to the Committees on Appropriations: *Provided*, That such plans shall be updated and submitted to the Committees on Appropriations every 60 days until September 30, 2017.

The following spend plan details the planned uses of the supplemental funds appropriated to HHS. With these resources, HHS will further enhance domestic preparedness and response; contain and mitigate the spread of Zika in the United States; accelerate the development, testing, and use of vaccines, therapeutics, and diagnostics, and make critical investments in public health capacity to ensure State, local, and Federal efforts are able to prepare, prevent, and respond to the Zika virus and related health conditions. The USG strategy may evolve over time to respond to the changing factors of the Zika virus.

HHS OVERVIEW

To respond to the growing global presence of the Zika virus, the United States has supported a government-wide response to combat the virus and limit the negative health outcomes which can result. The HHS-wide effort was launched encompassing CDC, NIH, ASPR, HRSA, the Office of Global Affairs, and the Food and Drug Administration (FDA). HHS has and continues to work with partners across the Federal government, states, and the private sector. Activities include aiding in the coordination of the international and domestic response with federal and international partners, establishing emergency operations infrastructure, deploying public health experts for surveillance, training of local health care workers, and managing and staffing response efforts in Puerto Rico. In addition, HHS is advancing the development, testing, and availability of potential vaccines, diagnostics, and therapeutics. Supplemental funding appropriated to HHS will support activities across the Department to enhance ongoing efforts and continue a comprehensive and coordinated response to contain and end the Zika epidemic.

HHS Supplemental Zika Funding Spend Plan

(dollars in millions)

Budget Activity	HHS Zika Supplemental Funding
<u>Centers for Disease Control and Prevention</u>	394.0
<i>Immediate Zika Response</i>	350.0
<i>PHEP Reimbursement</i>	44.0
<u>National Institutes of Health</u>	152.0
<i>National Institute of Allergy and Infectious Diseases</i>	152.0
<u>Public Health and Social Services Emergency Fund</u>	387.0
<i>Biomedical Advanced Research and Development Authority</i>	245.0
<i>Office of Inspector General and Comptroller General Oversight Activities</i>	1.0
<i>Health Resources and Service Administration</i>	66.0
<i>Special Projects of Regional and National Significance</i>	20.0
<i>Health Centers</i>	40.0
<i>National Health Service Corps</i>	6.0
<i>Centers for Medicaid and Medicare Services</i>	75.0
<i>U.S. Territories with Highest Zika Transmission</i>	60.0
Total, HHS Zika Supplemental Funding	933.0

CENTERS FOR DISEASE CONTROL AND PREVENTION

FY 2017 Zika Response and Preparedness Funding

(Dollars in millions)

Activity	Amount
Cross-cutting Activities and Program Support	350.0
<i>Immediate Zika Response</i>	350.0
Public Health Preparedness and Response	44.0
<i>Public Health Emergency Preparedness Cooperative Agreement</i>	44.0
Total, CDC Zika Funding	394.0

Zika has been an unprecedented and complex response. CDC has been operating its Emergency Operations Center at the highest level since February 2016, and approximately 1,900 CDC staff members have provided support for the Zika virus response. CDC has unparalleled experience responding to emerging infectious disease threats. CDC's focus on Zika is consistent with the core principles of public health:

- PREVENT or mitigate avoidable outbreaks and lessen the spread of disease.
- DETECT epidemics and new disease threats quickly
- RESPOND effectively to public health emergencies, protecting lives abroad and in the U.S.

CDC's key priority in responding to this epidemic is to reduce the risk of Zika virus infection to pregnant women and their partners. CDC is acting based on what we know and, at the same time, continuing to undertake research to better prevent adverse health outcomes in the future. CDC is working intensively with Puerto Rico and other areas with local transmission of the virus to provide information to women who are or who may become pregnant and their partners, and to reduce the threat of Zika. There is no way to predict when or where health threats will emerge, but we will continue to see new infectious disease threats such as Zika. CDC's focus is protecting the health, safety, and security of Americans; learning more about Zika and fighting it is a top priority.

HHS is closely coordinating across the Department to ensure that activities funded through the Zika Response and Preparedness Act are complementary across programs, investments to date, considering evolving factors of the Zika Virus, and support the highest priority response activities to protect public health.

ACTIVITY DETAIL

Immediate Zika Response: A total of \$350 million is provided to support CDC's Zika response activities. CDC will fund the following core public health activities.

Public Health Emergency Preparedness and CDC Response Activities

- Funding will support ongoing CDC response efforts:
 - Provide funds directly to key states/territories to bolster emergency management activities, risk communications, and community resilience efforts to rapidly identify and investigate a possible outbreak of Zika virus in communities; coordinate a comprehensive response across all levels of government and non-

governmental partners (including the healthcare sector); and identify and connect families affected by Zika to community services. Funding can also be used to purchase preparedness resources like repellent, screens, and supplies for Zika Prevention Kits.

- Provide technical assistance to state, local, tribal and territorial health departments for emergency preparedness and response, including investigating outbreaks; bolster emergency management activities, and risk communications and community resilience efforts; and, coordinate a comprehensive response across all levels of government and non-governmental partners.
- Operate CDC's Emergency Operations Center, which serves as the command center for coordinating staffing, operations, resources and activities across multiple units within the agency, ensuring a 24/7 approach to this complex response.
- Support CDC rapid response teams, which will be deployed quickly to areas experiencing transmission as necessary.

Public Health Outreach and Control

- CDC will continue communication and outreach efforts, broadening the reach of key Zika messages.

Vector Surveillance and Control

- Funding will expand critical CDC and partner vector surveillance and control efforts:
 - Fund CDC's vector-borne disease regional centers of excellence
 - Provide direct funding and technical assistance to more than 60 State and local jurisdictions to improve mosquito vector control, including but not limited to surveillance, assessments of local insecticide resistance, and capacity building.
 - Continue to provide support to the vector control unit in Puerto Rico.
 - Continue technical assistance to build the capacity to address the problem of emerging and exotic vector-borne diseases in the U.S.

Laboratory Capacity and Equipment

- CDC will support more than 60 State, local and territorial health departments to improve surveillance and laboratory diagnostic capacity:
 - Provide funding and technical assistance for laboratory capacity and epidemiology.
 - Launch more research and innovation to better understand changes in virulence and other Zika virus characteristics and to improve diagnostic technology.

Surveillance, Epidemiology, and Public Health Investigations

- CDC will expand its support of surveillance, epidemiology and public health investigations, both domestic and international, working with states and other partners:
 - Provide funding and technical assistance to states, local and territorial health departments with the Zika Pregnancy Registry, which collects information about pregnancy and infant outcomes following laboratory evidence of Zika virus infection during pregnancy.
 - Provide funding and technical assistance to states and cities for birth defects surveillance programs that enhance, and maintain rapid population-based

monitoring of microcephaly and other adverse outcomes possibly linked to Zika virus infection during pregnancy.

- Provide funding and technical assistance for other state-based data collection systems, including the Behavioral Risk Factor Surveillance System and the Pregnancy Risk Assessment Monitoring System.
- Provide funding and technical assistance for the Zika Active Pregnancy Surveillance System/Sistema de Vigilancia Activa de Zika en Embarazos. The surveillance system will be used to evaluate the association between Zika virus infection during pregnancy and adverse outcomes during pregnancy, birth, and early childhood up to three years old.
- Continue to evaluate pathogen reduction techniques for blood supplies.
- Expand the number of health studies to improve understanding of adverse outcomes (e.g. Guillain-Barré Syndrome, birth defects) related to Zika virus infection and better define modes of transmission and period of risk, both domestic and abroad.

These resources will also support the Emergency Operations Center operations, including, but not limited to, staffing, travel, equipment, and supplies. In addition, CDC will use funds to continue critical staffing for the laboratories and provide oversight for the state and university-based programs such as the Centers of Excellence.

Public Health Emergency Preparedness: A total of \$44 million is provided to restore the reductions in the fiscal year 2016 Public Health Emergency Preparedness cooperative agreement.

- \$44 million to support the Public Health Emergency Preparedness cooperative agreement through 62 awards to upgrade the ability of jurisdictions to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events.

NATIONAL INSTITUTES OF HEALTH
FY 2017 Zika Response and Preparedness Funding
(Dollars in millions)

Activity	Amount
National Institute of Allergy and Infectious Diseases	152.000
<i>Vaccine Development</i>	<i>129.00</i>
<i>Zika in Infants and Pregnancy</i>	<i>7.000</i>
<i>Diagnostics, Therapeutics, Vector Control and Other Interventions</i>	<i>16.000</i>
Total, NIH Zika Funding	152.000

NIAID’s response to the Zika virus epidemic will support the development, preclinical testing and clinical evaluation of at least five vaccine candidates; fund the development of diagnostics, therapeutics and vector control strategies; sustain the Zika in Infants and Pregnancy (ZIP) study begun in FY 2016; and support basic discovery research critical to better understand Zika and its complications and inform the development of new interventions. NIAID will support these research activities through its intramural research labs and vaccine development facilities in Bethesda and Frederick, MD and Hamilton, MT; and through grant and contract awards made to public and private institutions and for-profit enterprises. This structure allows NIAID to support development of strategies at all stages in the product development pathway including the discovery of new or repurposed countermeasures that could be available for clinical evaluation. This investment also will allow NIAID to sustain a research infrastructure that continues to be ready to respond to future emerging and re-emerging vector-borne disease outbreaks.

HHS is closely coordinating across the Department to ensure that activities funded through the Zika Response and Preparedness Act are complementary across programs, investments to date, considering evolving factors of the Zika Virus, and support the highest priority response activities to protect public health. In addition, NIAID is also closely coordinating its research activities with DoD partners to ensure that activities funded through the Zika Response and Preparedness Act are complementary across agency programs. These FY 2017 supplemental funds will enable NIAID to continue progress made with the repurposed resources and NIAID’s based appropriation. Our response plan has taken into account many variables including the evolving nature of the Zika virus outbreak and will support the highest priority response activities to protect public health.

ACTIVITY DETAIL

Vaccine Development: A total of \$129 million is provided to support vaccine development and clinical trials. NIAID will continue to support the critical development of vaccines including the discovery and development of new and existing candidates, manufacturing activities, preclinical testing, the establishment of clinical trials sites in endemic regions, and the conduct of clinical trials to evaluate the safety, immunogenicity, and efficacy of vaccine candidates.

Currently, NIAID is advancing five lead candidates and will continue to support the discovery and development of additional potential vaccine platforms and candidates, such as virus-like particle and other virus vectored vaccines.

The funding for vaccine candidates include:

- **DNA Based** - support a Phase II clinical trial of a DNA-based vaccine candidate developed by NIAID's Vaccine Research Center.
- **Whole-Particle Inactivated** - support preclinical and clinical evaluation of a Whole Particle Inactivated vaccine developed in collaboration with WRAIR/BARDA.
- **Live-Attenuated Zika Chimera** - support product development including preclinical and Phase I/II clinical trials of a Live-Attenuated Zika Chimera vaccine developed in NIAID's Intramural laboratories in collaboration with the Butantan Institute, Brazil.
- **Self-Amplifying mRNA** - develop, manufacture and conduct preclinical studies and Phase I clinical trials of a Self-Amplifying mRNA-based vaccine candidate developed by NIAID's Vaccine Research Center in collaboration with Glaxo Smith Kline.
- **Vesicular Stomatitis virus** -support further development, manufacture of pilot lots, preclinical and Phase I testing of a recombinant Vesicular Stomatitis virus vectored vaccine currently under development through a collaboration with Harvard University.
- **Virus-Like Particle and Monoclonal Antibody** - support the discovery manufacture, and preclinical and clinical evaluation of additional candidates such as virus-like particle and monoclonal antibody based vaccines.

Zika in Infants and Pregnancy (ZIP): A total \$7 million will support the continuation of the ZIP study in the U.S. and abroad, which will provide important new data to help guide the medical and public health response to Zika. The study aims to improve our understanding of the health effects of Zika virus infection in pregnant women and infants by following 10,000 pregnant women for the duration of their pregnancies and their infants at several intervals for at least one year after birth. Funding in FY 2017 will support continued enrollment in ZIP, support clinical sites and clinicians conducting the research and continue following the infants through their first year to provide critical answers regarding the range and risk of congenital abnormalities caused by the virus.

Diagnostics, Therapeutics, Vector Control and Other Interventions: A total of \$16 million will support the discovery, development, and evaluation of diagnostics, therapeutics, vector control and other countermeasures. NIAID will primarily support extramural researchers through grant and contract mechanisms.

NIAID will support research to develop rapid, specific and low cost Zika virus diagnostic tests. These tests will have increased sensitivity to more accurately distinguish Zika virus infection from other related viruses such as dengue. Funds will support the development and validation of molecular and serological diagnostics.

NIAID and its NIH partners are supporting several approaches to therapeutics including screening of FDA-approved and investigational antiviral drugs for potential use in treatment or prophylaxis, as well as evaluation in animal models of potential therapeutics such as BCX4430 and monoclonal antibodies (mAb) against Zika.

NIAID will also continue to develop animal models that can be used to test new diagnostic tools as well as therapeutic candidates.

NIH has included travel and conference costs in its estimates for vaccine, diagnostic, therapeutic, vector control, ZIP study and discovery research.

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

FY 2017 Zika Response and Preparedness Funding

(Dollars in millions)

Activity	Amount
Assistant Secretary for Preparedness and Response/1	246.000
Health Resources and Services Administration	66.000
<i>Special Projects of Regional and National Significance</i>	<i>20.000</i>
<i>Health Centers</i>	<i>40.000</i>
<i>National Health Service Corps</i>	<i>6.000</i>
Centers for Medicare and Medicaid Services	75.000
<i>U.S. Territories with Highest Zika Transmission</i>	<i>60.000</i>
Total, PHSSEF Zika Funding	387.000

1/Of this total, \$1 million will be allocated to support oversight activities.

This plan reflects the allocation and planned uses of resources for the Public Health and Social Services Emergency Fund appropriation. Within the total of \$387 million, funding will support the advanced development of promising Zika vaccine candidates, point of care diagnostic tests, and pathogen reduction systems initiated in FY 2016. In addition, funding will support the delivery of primary health care services for pregnant women and children affected by the Zika virus, loan repayment awards to individuals providing primary care services in Puerto Rico and other territories, and reimbursements for health care related to the Zika virus.

HHS is closely coordinating across the Department to ensure that activities funded through the Zika Response and Preparedness Act are complementary across programs, investments to date, considering evolving factors of the Zika Virus, and support the highest priority response activities to protect public health.

ACTIVITY DETAIL

Assistant Secretary for Preparedness and Response:

In FY 2016, in response to the rapid spread of Zika virus and the documentation of its ability to cause microcephaly and other birth defects as well as Guillain-Barré Syndrome (GBS), BARDA initiated the development of Zika vaccine candidates, laboratory and point-of-care diagnostics, and blood screening tests as well as pathogen reduction technologies that help protect the blood supply. Of the amount appropriated, a total of \$245 million will support activities within ASPR's Biomedical Advanced Research and Development Authority (BARDA). The supplemental funding will support further development of Zika vaccine candidates, diagnostics, and pathogen reduction technologies initiated in FY 2016 to advance projects toward FDA licensure or approval. No supplemental funding will support administrative or personnel costs.

Vaccine Development:

- Advanced development of promising Zika virus vaccines for Phase I and II clinical trials and manufacturing process development and optimization, production scale-up, analytical development, and additional non-clinical studies to support later-stage studies toward

FDA licensure. A total of five vaccine projects were initiated in FY 2016 – three (3) contracts, one (1) task order and one (1) cooperative agreement. Two vaccine candidates were previously supported during early development by U.S. government efforts, one through a research collaboration between the National Institute of Allergy and Infectious Diseases, Walter Reed Army Institute of Research and BARDA, and another by the Defense Advanced Research Projects Agency. These and three other vaccine candidates will comprise BARDA’s advanced development portfolio of Zika vaccines.

Diagnostic Development:

- Advanced development of point-of-care Zika diagnostics tests to expand the usability and utility of the diagnostics and to support test optimization, clinical trials, and validation toward FDA approval. A total of four diagnostic development projects were initiated in FY 2016 – two (2) contracts for the development of laboratory Zika diagnostic tests and two (2) contracts for the development of point-of-care Zika diagnostics tests. BARDA will support the advanced development of point-of-care diagnostic tests which would dramatically decrease wait time for test results.

Pathogen Reduction Systems:

- Advanced development of pathogen reduction technologies, including a Phase I clinical trial to evaluate safety and efficacy of pathogen reduced blood products in special populations requiring frequent blood transfusions or at risk of complications from blood transfusion, and a Phase II trial to support FDA premarket approval. Two projects were initiated in FY 2016 to inactivate Zika virus in donated blood to secure the blood supply.

No supplemental funding will support administrative or personnel costs.

Health Resources and Services Administration:

Health Centers: \$40 million to support the delivery of primary health care services in Puerto Rico and other territories.

- Supplemental grant awards to support existing health centers in Puerto Rico and other territories in their efforts to expand the delivery of health care services, including the prevention of Zika and prevention and treatment of Zika-related illness. HRSA plans to fully fund awards that will be carried out over a multi-year project period.
- Support supplemental grant awards to existing Health Center Program cooperative agreements in their efforts to provide training and technical assistance for Zika-related health center expansion activities.

Special Projects of Regional and National Significance: \$20 million to support public health departments and other entities in Puerto Rico and other territories to ensure access to recommended services for pregnant women, infants, and children infected by the Zika virus in the prenatal, perinatal, and neonatal period.

- HRSA will award cooperative agreements to support pregnant women and children born to women that test positive for Zika, through activities such as: early identification through developmental screening, regular assessments and monitoring, telemedicine, care

coordination, enabling services, family engagement and family-to-family support; purchasing of diagnostic equipment and health information technology; and the training of healthcare providers, care coordinators, and other healthcare and public health professionals to ensure delivery of comprehensive, interdisciplinary health and social services for this population.

- HRSA will also provide technical assistance to Puerto Rico and other territories by supporting existing entities providing services in those jurisdictions.

National Health Service Corps: \$6 million to make loan repayment awards to individuals providing primary care services in Puerto Rico and other territories.

- HRSA will work with the existing National Health Service Corps sites in Puerto Rico and the sites in other territories to support loan repayment to additional providers. HRSA will also explore new sites to support needed providers in Puerto Rico and the other territories.

No supplemental funding will support administrative or personnel costs.

Centers for Medicare and Medicaid Services:

A total of \$75 million shall be available for necessary expenses for support to States, territories, tribes, or tribal organizations with active or local transmission cases of the Zika virus, as confirmed by the Centers for Disease Control and Prevention, of which not less than \$60 million shall be for territories with the highest rates of Zika transmission. Applicants must submit a proposed budget and narrative which would be negotiated prior to final award. Funds will support:

- Cooperative agreements to reimburse the costs of health care for health conditions related to the Zika virus (other than costs that are covered or compensated by an individual's private health coverage). Reimbursable services include: preventive services; case management; long-term services and supports; and other health care services.
- Technical assistance during the funding opportunity development, award, and implementation phases; working with internal and external partners including ASPR, CDC, and HRSA; providing subject matter expertise related to health care services, delivery systems, and cooperative agreement administration; and conducting monitoring activities.