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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2431-N]

Zika Health Care Services Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the November 9, 2016 publication of a funding opportunity providing up to \$66.1 million available to support prevention activities and treatment services for health conditions related to the Zika virus. The funding opportunity solicited single source emergency applications for a cooperative agreement aimed at supporting prevention activities and treatment services for women (including pregnant women), children, and men adversely or potentially impacted by the Zika virus. Entities eligible to apply for this funding opportunity are states, territories, tribes or tribal organizations, with active or local transmission of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC). As of October 12, 2016, the CDC designated American Samoa, Puerto Rico, the U.S. Virgin Islands, and Florida as areas with laboratory-confirmed active or local Zika virus transmission. As such, this emergency funding opportunity is currently available to the territorial and state health departments in these areas.

DATES: The project period of performance for the Cooperative Agreement will be 36 months from the date of award.

FOR FURTHER INFORMATION CONTACT: Elizabeth Garbarczyk, 410-786-0426.

SUPPLEMENTARY INFORMATION:

I. Background

The Zika Response and Preparedness Act (P.L. 114-223) provides \$387,000,000 in funding to prevent, prepare for, and respond to the Zika virus. Of the funds appropriated by P.L.

114-223, Congress designated \$75 million to support 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 (CDC), to reimburse the costs of health care for health conditions related to the Zika virus not covered by private insurance. No less than \$60 million of this funding is for territories with the highest rates of Zika transmission.

II. Provisions of the Notice

In accordance with the Zika Response and Preparedness Act (P.L. 114-223), entities eligible to apply for this funding opportunity include states, territories, tribes or tribal organizations with active or local transmission of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC). As of October 12, 2016, the CDC reports that American Samoa, Puerto Rico, the U.S. Virgin Islands, and Florida are the only areas with laboratory-confirmed active or local transmission of the Zika virus, and therefore, these are the only territories and state eligible to receive funding as authorized under the legislation. Funding available under the "Zika Health Care Services Program" may be used to address the following four critical components of a comprehensive response to Zika. Applicant needs may vary and some applicants may not have unmet needs across each of the four areas. If approved by CMS, recipients may use grant funds for additional health care services for health conditions related to the Zika virus that are not listed in the following section.

1. Increase Access to Contraceptive Services for Women and Men

Contraceptive services for women and men can reduce the risk of unintended pregnancy, as well as sexual transmission of Zika. Preventing unintended pregnancy in areas affected by the Zika virus outbreak among people who may have been exposed is a primary strategy to reduce the number of pregnancies affected by Zika virus. To increase access to all FDA-approved contraceptive methods, a territory or state must use grant funds to provide client-centered contraceptive counseling to educate women (including women who are pregnant and post-

partum) and men on effective contraception methods, increase contraceptive supplies in provider offices, increase family planning delivery sites, train providers on the full range of contraceptive methods and their use, including insertion and removal of long-acting reversible contraception (LARC), and to remove a patient's financial barriers to use of effective contraception through methods such as cost sharing assistance for contraceptive services.

2. Reduce Barriers to Diagnostic Testing, Screening, and Counseling for Pregnant Women and Newborns

Uninsured or underinsured pregnant women may not seek testing and medical follow-up if Zika testing does not begin at the initial point of prenatal care or if it presents financial hardship. Testing should be performed as a part of routine prenatal care. However, additional unscheduled prenatal visits may be necessary to complete the testing protocol (for example, reflex testing) and to provide pre-and post-test counseling on the interpretation of results. Funds designated for diagnostic testing, screening, and counseling will be used to ensure access to diagnostic services to test for Zika infection wherever a pregnant woman initially presents for care. This will increase the identification of pregnant women infected with Zika, who require increased monitoring and prenatal care services, and will lead to early diagnosis of infants with special medical needs.

3. Increase Access to Appropriate Specialized Healthcare Services for Pregnant Women, Children born to Mothers with Maternal Zika Virus Infection, and their Families

Complex clinical and psychosocial needs associated with maternal Zika virus infection require access to comprehensive and appropriate specialized healthcare, and a coordinated suite of services that serves mother, child, and their families. Increased access to prenatal care is critical to plan for post-natal care, particularly access to ultrasounds which can detect abnormalities in fetal development. In addition, high-risk pregnancies and pregnancy loss, can be stressful for both the pregnant woman and her family and require psychosocial support.

Moreover, the infants themselves require enhanced follow-up, regardless of whether microcephaly or other conditions are diagnosed prenatally or at birth. CDC has published clinical guidance for care of pregnant women with evidence of Zika infection and care of infants born to mothers who had Zika infection.

4. Improve Provider Capacity and Capability

We recognize that award recipients will have varying levels of infrastructure, provider capacity and capability, and other funding sources devoted to addressing Zika. Sufficient provider capacity and capability is critical to ensure successful implementation of an effective Zika prevention initiative in increasing access to contraceptives; reducing barriers to diagnostic testing, screening and counseling; and increasing access to appropriate specialized healthcare services.

This funding opportunity has been structured to ensure an effective Zika response that addresses the four critical components of a comprehensive response to Zika as quickly as possible. Accordingly, the single source emergency funding opportunity is solely available to the territorial and state health departments in American Samoa, Puerto Rico, the U.S. Virgin Islands, and Florida, based on their ability to quickly and efficiently expand their existing Zika response efforts and to further determine the most effective use and dissemination of funds in their respective jurisdictions. The health departments in American Samoa, Puerto Rico, U.S. Virgin Islands, and Florida are uniquely positioned to meet the goals of the emergency cooperative agreement based on their capacity, partnerships, resources, prior experience, and ability to begin implementing the project immediately. Immediate implementation is critical to successfully addressing this rapidly spreading public health threat.

The budget and project period under the specific funding opportunity will be 36 months. The total amount of federal funds available in the first round is up to \$66,100,000 as follows:

- American Samoa Government Department of Health: \$1,100,000

- Puerto Rico Health Department: \$60,600,000
- U.S. Virgin Islands Department of Health: \$2,100,000
- Florida Department of Health: \$2,300,000

A majority of the first round funds are being allocated to Puerto Rico based on the magnitude of infections and likely rates of infants born to mothers with maternal Zika infection. We expect to issue a second round of funds through an additional funding opportunity announcement in 2017. The initial funding opportunity seeks to issue funds to currently support areas of greatest need, while maintaining additional funds to prevent, detect, and respond to future Zika outbreaks.

III. Collection of Information Requirements

This notice establishes funding opportunities for health departments in areas with laboratory-confirmed active or local Zika virus transmission. Since we estimate fewer than ten respondents (American Samoa, Puerto Rico, the U.S. Virgin Islands, and Florida), any information collection requirements and burden are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

CMS-2341-N

Dated: November 30, 2016.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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