**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-16AFR]**

**[Docket No. CDC-2016-0040]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on an information collection request proposal entitled "Continuing International and Domestic Information Collections from the 2016 Zika Virus Emergency

Response." These collections will allow CDC to continue its ongoing response to the Zika virus outbreak.

**DATES:** Written comments must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0040 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether

the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

Continuing International and Domestic Information Collections

from the 2016 Zika Virus Emergency Response – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed Zika virus infections in Brazil. Since then, CDC has been responding to increased reports of Zika and has assisted in investigations with PAHO and the Brazil Ministry of Health. The first regional travel notices for Zika in South America and Mexico were posted in December 2015. In December 2015, the Commonwealth of Puerto Rico, a United States territory, reported its first confirmed locally transmitted Zika virus case. Cases of local transmission have recently been confirmed in two other US territories, the United States Virgin Islands and American Samoa. As of April 6, 2016, US territories had reported 351 locally acquired Zika cases and 3 travel-associated Zika cases to CDC. Of the 354 cases reported, 37 were in pregnant women. Zika has not been spread by mosquitoes in the continental United States. However, lab tests have confirmed Zika virus in travelers returning to the United States. These travelers have gotten the virus from mosquito bites and a few non-travelers got Zika through sex. With the recent outbreaks in the Americas, the number of Zika

cases among travelers visiting or returning to the United States is increasing. CDC monitors and reports to the public cases of Zika, which will help improve our understanding of how and where Zika is spreading.

Zika virus is spread to people primarily through the bite of an infected *Aedes* species mosquito (*A. aegypti* and *A. albopictus*). Mosquitoes that spread Zika virus are aggressive daytime biters, but they can also bite at night. A pregnant woman can pass Zika virus to her fetus during pregnancy. CDC is studying how Zika affects pregnancies. Zika is linked to microcephaly, a severe birth defect that is a sign of incomplete brain development. Microcephaly is a condition where a baby's head is much smaller than expected. During pregnancy, a baby's head grows because the baby's brain grows. Microcephaly can occur because a baby's brain has not developed properly during pregnancy or has stopped growing after birth.

In February and March 2016, CDC used OMB emergency clearance procedures to initiate and expedite multiple urgently needed information collections in American Samoa, Puerto Rico, Brazil, and domestically within state, tribal, local, and territorial (STLT) jurisdictions. These procedures have allowed the agency to target and refine public health interventions to arrest ongoing spread of infection.

With this notice, the CDC is announcing its intention to

seek OMB clearances to continue four Zika-related information collections beyond their current emergency expiration dates. These four projects will be submitted to OMB as standalone ICRs:

1. A call center in CDC's Emergency Operations Center (EOC) to respond to inquiries on clinical care of persons potentially of interest for Zika virus infection [OMB Control No. 0920-1101, expiration date 8/31/16]. Respondents to this information collection include the general public, clinicians, and employees at STLT health departments. The purpose of this information collection is to document and track clinical inquiries made to the CDC EOC call center and to systematically collect standardized clinical/demographic/epidemiological information about suspected cases. The emergency clearance for this information collection dealt specifically with Zika-related clinical inquiries. However, the new ICR will cover this project for any EOC activation. Regardless of the disease or hazard being responded to, the EOC operates this call center to answer and respond to clinical inquiries. This information collection is a necessary part of operating this call center and responding to emergency situations.
2. A study, in Puerto Rico, on the persistence of Zika virus in bodily fluids [OMB Control No. 0920-1106, expiration date 9/30/16]. Since getting OMB approval in March 2016, CDC has

investigated the persistence of Zika virus in different body fluids (shedding) and its relation to immune response to provide a basis for development of non-blood-based diagnostic tools, and target and refine public health interventions to arrest ongoing spread of infection. CDC has begun a prospective cohort study of symptomatic individuals with reverse transcription-polymerase chain reaction (RT-PCR) positive Zika virus infection and a cross-sectional study of their household contacts. Information collection is expected to conclude within one year. Results and analyses will be used to update relevant counseling messages and recommendations from the CDC. Participants for the shedding study are patients with laboratory-confirmed Zika virus infection and their household contacts.

3. A study, carried out in the United States, on the persistence of Zika virus in the semen and urine of men with laboratory-confirmed Zika virus infection [OMB Control No. 0920-1109, expiration date 9/30/2016]. Since getting emergency OMB approval in March, 2016, specimens have been tested for Zika RNA by reverse transcriptase polymerase chain reaction assay (RT-PCR) at CDC; those testing positive may be further evaluated by virus isolation techniques. Zika virus disease is a nationally notifiable condition, and participants are recruited through contact with CDC personnel. Urine and semen

specimens are self-collected using home collection kits, a short questionnaire is self-administered, and participants receive a token of appreciation. Results of testing will be provided to participants at the conclusion of testing. The results of this study are expected to have immediate implications for public health recommendations and disease prevention. The results of this study will be of great relevance to provide evidence-based information to circumvent Zika virus transmission. They will inform the development of recommendations used in the current epidemic setting, as well as in future Zika virus situations. Results and analysis will be used to update and refine relevant counseling messages and recommendations.

4. Registry of pregnant women with laboratory-confirmed Zika virus infections in the U.S. [OMB Control No. 0920-1101, expiration date 8/31/16]. As part of the public health response to the Zika virus disease outbreak, CDC has been collecting information from clinicians in the U.S. about pregnant women they treat who are diagnosed with Zika virus infection. CDC also plans to collect information from clinicians about their patients' infants in order to better understand the clinical consequences of Zika virus infection in pregnancy and its impact on newborn infants. Information gathered directs public health messages provided by CDC on

reducing the risk of adverse outcomes for pregnant women and their infants.

These information collections will align with their legislative authority, Section 301 of the Public Health Service Act (42 U.S.C. 241).

There are no costs to the respondents other than their time. The total annualized burden requested is 1,146 hours. This number represents the number of burden hours yet to be imposed. It does not include the burden hours sustained during the initial six-month emergency clearance period.

Estimated Annualized Burden Hours

1 — Clinical Inquiries Database

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Total Burden (in hrs.) |
|---|---|---|---|---|---|
| Local health departments | Clinical inquiries database | 420 | 1 | 15/60 | 105 |
| Clinicians and other providers | Clinical inquiries database | 800 | 1 | 15/60 | 200 |
| Total | | | | | 305 |

2 — Persistence of Zika virus in bodily fluids study, Puerto Rico

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in | Total Burden (in hrs.) |
|---|---|---|---|---|---|

| | | | | hrs.) | |
|---|---|---|---|---|---|
| Public health personnel | Questionnaire (Symptomatics) | 200 | 8 | 10/60 | 267 |
| | Questionnaire (Cross-Sectional household contacts) | 600 | 1 | 10/60 | 100 |
| General public | Eligibility Form | 1,000 | 1 | 2/60 | 33 |
| Total | | | | | 400 |

3 — Persistence of Zika virus in bodily fluids study, United States

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Total Burden (in hrs.) |
|---|---|---|---|---|---|
| General public | Introductory survey | 175 | 1 | 2/60 | 6 |
| | Follow-Up survey | 175 | 12 | 1/60 | 35 |
| Total | | | | | 41 |

4 — Pregnancy Registry

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Total Burden (in hrs.) |
|---|---|---|---|---|---|
| State and Local Health Departments | Maternal Health History Form | 100 | 5 | 30/60 | 250 |
| | Specimen Collection Form | 100 | 1 | 15/60 | 25 |
| Clinicians and other providers | Assessment at Delivery Form | 100 | 1 | 30/60 | 50 |
| | Infant | 100 | 1 | 30/60 | 50 |

| | | | | | |
|---|---|---|---|---|---|
| | Health Follow-Up Form | | | | |
| Total | | | | | 400 |

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