



BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18TH; Docket No. CDC-2018-0027]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico". Data collected will be used to assess implementation of a patient-centered prevention program and associated outcomes.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0027 by any of the following methods:

- Federal eRulemaking Portal: Regulations.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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments 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 Leroy A. Richardson, 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Assessment of a Preventive Service Program in the Context of a Zika Virus Outbreak in Puerto Rico - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Puerto Rico has reported the highest number of Zika virus infections in the United States, including infections in pregnant women. Zika virus infection during pregnancy has been identified as a cause of microcephaly and other severe brain abnormalities, and has been linked to other problems such as miscarriage, stillbirth, defects of the eye, hearing deficits, limb abnormalities, and impaired growth. One strategy to prevent these devastating outcomes is to prevent unintended pregnancy among women at risk of Zika virus infection. To this end, an initiative was launched in April 2016 to train physicians at clinics across Puerto Rico to provide patient-centered services to women who chose to delay or avoid pregnancy during the Zika virus outbreak.

As part of the public health response to the Zika virus outbreak, CDC seeks to assess approaches to mitigating the

effects of Zika virus infection and determine which approaches have utility. Previous assessment of the prevention program indicated high satisfaction of Z-CAN patients with program services. The specific objectives of this data collection are to assess: (1) prevention strategy adherence among Z-CAN patients at approximately 18 months after receipt of program services; and (2) prevention strategy adherence, patient satisfaction, and unmet need for services among Z-CAN patients at approximately 30 months after receipt of program services. The practical utility of the collected information is to assess services delivered to women in Puerto Rico, monitor outcomes of interest, and determine potential for replication/adaptation in other jurisdictions similarly affected by the Zika virus or during other emergency responses.

For the information collection project, CDC plans to conduct online surveys with 1,600 patients approximately 18 and 30 months after receiving program services.

Participation in all data collection activities will be completely voluntary. CDC intends to request a two-year OMB approval to collect information. Total Annualized Burden Hours are estimated to be 259, and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Average Burden	Total Burden
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			per Respondent	per Response (in hours)	(in hours)
Patients aged 18 years or older	Online surveys (18- month follow- up)	960	1	7/60	112
Patients aged 18 years or older who completed 18-month survey	Online surveys (30- month follow- up)	660	1	10/60	110
Patients aged 18 years or older who did not complete 18-month survey	Online surveys (30- month follow- up)	220	1	10/60	37
Total					259

Leroy A. Richardson,

Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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