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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-FY-xxxx]

[Docket No. CDC-201x-xxxx]

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 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 Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN). The goal of this effort is to monitor and evaluate the implementation of the Z-CAN

program which was designed to increase access to reversible contraceptive methods among reproductive-aged women in Puerto Rico who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes, and assess patterns of contraceptive use and pregnancy rates after participating in Z-CAN.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-201x-xxxx 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. 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: 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

Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN) – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Puerto Rico continues to report 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. These adverse pregnancy outcomes along with ongoing Zika virus transmission in Puerto Rico intensify the need to reduce high rates of unintended pregnancy by removing barriers and increasing contraception access for women who choose to delay or avoid pregnancy as a primary strategy to reduce Zika-related adverse pregnancy and birth outcomes.

The proportion of all pregnancies that are unintended in Puerto Rico is higher than in the U.S. overall (65% vs. 45%). In April 2016, CDC estimated that approximately 138,000 women in Puerto Rico may be at risk of unintended pregnancy and not using

one of the highly effective or moderately effective methods of reversible contraception. To date, access to contraception in Puerto Rico has been limited by reduced availability of the full range of reversible contraceptive methods, high out-of-pocket costs for patients, insurance reimbursement that does not cover the full cost of devices and services, logistical barriers that limit same-day provision, lack of patient education on the range of reversible contraception methods available and their effectiveness, and a shortage of physicians trained to insert and remove long-acting reversible contraception (LARCs, i.e., intrauterine devices [IUDs] and implants). Several projects in settings without active Zika virus transmission have demonstrated the importance of removing barriers to access to the full-range of reversible contraceptive methods, including LARCs, on increasing use of the most effective reversible methods and on reducing unintended pregnancies.

In response to the Zika virus outbreak in Puerto Rico, the CDC Foundation, with technical assistance from the CDC, and in collaboration with the Puerto Rico Department of Health (PR DOH), Puerto Rico Obstetrics and Gynecology (PROGyn) and other partners, launched the Zika Contraception Access Network (Z-CAN) in April 2016. Z-CAN is a program designed to develop a network of physicians at clinics across Puerto Rico trained to provide patient-centered contraceptive counseling and same-day access to

the full range of Food and Drug Administration (FDA)-approved, reversible contraceptive methods at no cost to women who choose to delay or avoid pregnancy during the Zika virus outbreak.

As part of the public health response to the Zika virus disease outbreak, CDC seeks to monitor and evaluate the implementation of the Z-CAN program and assess patterns of contraceptive use and pregnancy rates after participating in Z-CAN. The specific objectives are to evaluate (1) perceived facilitators and barriers to accessing reversible contraception in Puerto Rico among both Z-CAN and non-Z-CAN patients aged 18 years or older and able to conceive to improve the Z-CAN program; (2) Z-CAN physician and clinic staff perceptions of potential areas for Z-CAN program improvement and sustainability that could better enhance patient access to contraception; and (3) contraceptive use patterns, contraceptive continuation rates, and pregnancy rates among Z-CAN patients at 6 and 12 months after receipt of Z-CAN services. The practical utility of the information to be collected as part of this ICR is to improve program implementation and services delivered to women in Puerto Rico, understand changes in outcomes of interest over a longer period of time, and determine the Z-CAN program’s appropriateness/potential for replication/adaptation in other jurisdictions that may be similarly affected by the Zika virus.

For the information collection, CDC plans to conduct a mixed-method study to evaluate the Z-CAN program including: (1) focus groups with approximately 240 women aged 18 years or older and able to conceive (120 who are enrolled in Z-CAN and 120 who are not); (2) semi-structured, individual interviews with 25 Z-CAN physicians and 25 clinic staff; and (3) online surveys with all Z-CAN physicians (n=163) approximately six months after beginning to provide Z-CAN services, one randomly selected Z-CAN staff member from each clinic that provides Z-CAN services (n=150) approximately six months after beginning to provide Z-CAN services, and 3,200 Z-CAN patients aged 18 years or older six and 12 months after enrollment in the program.

Participation in all data collection activities will be completely voluntary. OMB approval is requested for three years.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hrs.)
Women aged 18 years or older and able to conceive	Focus group screener form	300	1	5/60	25
Women aged 18 years or older and able to conceive	Focus group guide	240	1	1.5	360
Z-CAN physicians	Semi-structured,	25	1	1	25

	individual interview guide				
Z-CAN staff	Semi-structured, individual interview guide	25	1	1	25
Z-CAN physicians	Online survey for physicians	163	1	15/60	41
Z-CAN staff	Online survey for staff	150	1	15/60	38
Z-CAN patients aged 18 years of older	Online survey for Z-CAN patients (6-month)	800	1	10/60	136
Z-CAN patients aged 18 years of older	Online survey for Z-CAN patients (12-month)	534	1	10/60	91
				Total	741

Dated:

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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