



January 23, 2017

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, "Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN)" be processed in accordance with section 1320.13, Emergency Processing. I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to CDC's mission to protect America from health, safety, and security threats.

The goal of this information collection is to evaluate Z-CAN, a program aimed at preventing adverse pregnancy outcomes and birth defects in infants and children due to Zika infection in Puerto Rico by providing contraceptive services to prevent unintended pregnancy for women who wish to avoid or delay pregnancy. Z-CAN is a program designed to address access barriers and is being implemented by the CDC Foundation in collaboration with the Puerto Rico Department of Health, Puerto Rico Obstetrics and Gynecology, and other local partners, with technical assistance from the CDC. A recent publication has shown that an effective program for reducing barriers to contraception could prevent over 3,000 unwanted pregnancies each year that might otherwise be affected by Zika and reduce Zika virus-related costs by \$65.2 million.¹ The information obtained through this request will be used for continuous quality improvement to guide and maximize the effectiveness of the ongoing implementation of the program in Puerto Rico and to assess whether it can be adapted for other areas with widespread mosquito transmission of the Zika virus. Because this program is unique in rapidly removing barriers to contraceptive access in the context of Zika, the proposed information to be collected is not available by any other means; evaluation of this data therefore represents a unique opportunity to gain insight into contraceptive barriers in Puerto Rico and the feasibility of such a program for other areas with widespread mosquito transmission of the Zika virus.

The service program to be evaluated began in July 2016, trainings with providers were completed in September 2016, patient enrollment accelerated in October 2016, and the program is currently expected to end July 2017. It was recently decided that it is likely that quality improvement would be possible and assessment of the program's potential for adaptation in other settings would be valuable. To ensure timely data collection, the evaluation should begin at the earliest possible date for program improvement. Patient evaluations, scheduled for 6- and 12-months from enrollment in the Z-CAN program must begin by April 2017 to capture the majority of participants.

Findings will be assessed on a rolling basis and information gained will be put to immediate use to affect program improvements. A delayed start would potentially mean this critical information is gathered too late to improve the Puerto Rico program, and too late to determine its suitability for adaptation in other

¹ Li et al. Cost-effectiveness of Increasing Access to Contraception during the Zika Virus Outbreak, Puerto Rico, 2016. *Emerg Infect Dis.* 2017 Jan; 23(1): 74-82..



areas with widespread mosquito transmission of the Zika virus during the current outbreak. Therefore, CDC requests a 90-day emergency clearance to launch the information collection. A 60-day notice will be published in the Federal Register to make the public aware of this proposed information collection. Because this is a request for an emergency clearance, CDC requests OMB review without waiting for the 60-day comment period to expire. As more than three months are needed to complete this information collection, CDC will pursue a formal ICR as soon as emergency approval is granted. For this formal, non-emergency ICR, a new 60-day notice will be published in the Federal Register inviting public comment, followed by a 30-day notice and ICR application for three years of OMB clearance.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business January 25.

Respectfully,

A handwritten signature in blue ink that reads "Ursula E. Bauer". The signature is written in a cursive style.

Ursula E. Bauer, PhD, MPH
Director, National Center for Chronic Disease Prevention and
Health Promotion