



March 22, 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, "Emergency Zika Package: Zika Postpartum Emergency Response Survey and Telephone Follow-up, Puerto Rico" 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 the CDC's mission to protect America from health, safety and security threats.

Since the beginning of the Zika virus outbreak in the Western Hemisphere, Puerto Rico has reported the highest number of Zika virus cases in the United States, and 3,076 cases have been confirmed in pregnant women as of February 15, 2017.¹ Because the most common mosquito vector of Zika virus, *Aedes aegypti*, is present throughout Puerto Rico, Zika virus transmission is ongoing. The island has been designated at the highest level of risk according to a 3-tiered Zika virus infection risk scale developed by the Centers for Disease Control and Prevention's (CDC) Emergency Operations Center (EOC). During August-December of 2016, the Puerto Rico Department of Health successfully collected information from 2,364 women immediately following birth in hospitals in Puerto Rico to determine their knowledge and access to prevention strategies and services during pregnancy (Emergency OMB approval, control # 0920-1127). The information obtained has been critical for informing clinical guidance, developing communication messages, and providing resources for pregnant women.

In January 2017, The Health Resources and Services Administration (HRSA) provided funding to various agencies in the Puerto Rico Department of Health to address the issues of screening, access, and coordination of care for women, children and families. However, there is currently no population-based information about health care for young infants born to women in Puerto Rico who were pregnant in the first year of the Zika outbreak to inform the use of this funding: although clinical data are available, they are limited to those who seek and receive services. Data is urgently needed to fill this critical gap so that the Puerto Rico Department of Health, CDC, HRSA and other federal agencies involved in the Zika Emergency Response can better understand adherence to prevention strategies and assess the availability, accessibility and utilization of postpartum and newborn services – especially for women and infants who may have been affected by Zika. Subsequent to the funding provided by HRSA, in January 2017, the Puerto Rico Department of Health was funded by CDC to collect population based data to inform these efforts. The goal of this information collection, planned to begin in April 2017, is to gather scientifically valid and current information from previously surveyed mothers by re-contacting them by phone to assess: 1) their access to and utilization of health care services for themselves and their infants within the first months following delivery; 2) their use of prevention

¹<http://www.salud.gov.pr/Estadisticas-Registros-y-Publicaciones/Informes%20Arbovirales/Reporte%20ArboV%20semana%205-2017.pdf>

²https://www.cdc.gov/mmwr/volumes/65/wr/mm6533e2.htm?s_cid=mm6533e2_w

measures to avoid Zika infection after delivery and use of postpartum contraception to prevent unintended pregnancies that may be affected by Zika.

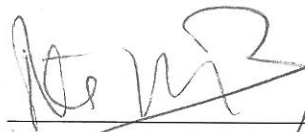
CDC also plans to collect data from a second cohort of women in the immediate postpartum period in August 2017, to assess the effectiveness of emergency response efforts from the first season and to determine where additional efforts and resources are needed for Zika outbreaks in subsequent seasons. Data from this second cohort will be collected on: 1) their behaviors and experiences related to Zika virus during pregnancy and knowledge of prevention strategies; 2) the role of father's concerns about Zika related birth defects and contribution to prevention efforts. This second cohort of women will also be followed up by phone to assess their postpartum experiences and access to healthcare for themselves and their infants.

CDC cannot reasonably comply with the normal clearance process and timeline for re-contacting the first cohort of women surveyed during August-December 2016 to assess the care received by their infants and their early postpartum experiences. CDC recommendations emphasize the immediate need for services among affected infants, many of which are supposed to be delivered during the first 2 months of life.² However, because funding was only identified in January, the goal is to re-contact the original participants in April-June 2017 when their infants are still young (6-10 months) and in need of ongoing services recommended during the first year. This will allow CDC to assess the receipt of early services with minimal recall bias. Any further delays in implementation will make it more difficult to rapidly respond to gaps in provision of early services for vulnerable infants in a timely manner.

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 March 30, 2017.

Respectfully,



Ursula E. Bauer, PhD, MPH
Director, National Center for Chronic Disease
Prevention and Health Promotion (NCCDPHP),
Centers for Disease Control and Prevention (CDC)