

**March 14, 2019**

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, “Verona Integron-Encoded Metallo- β -Lactamase (VIM)-Producing Carbapenem-Resistant *Pseudomonas aeruginosa* Infections Associated with Invasive Medical Procedures in Tijuana, Mexico” 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 support for healthcare facilities and health departments responding to outbreaks of multidrug-resistant organisms. Based on information from state health departments and the Antibiotic Resistance Laboratory Network (AR Lab Network), CDC has made the determination that individuals who received bariatric surgery at Facility 1 in Tijuana, Mexico since August 1, 2018 are at risk for acquiring a rare, highly resistant form of *Pseudomonas aeruginosa* that has potential to spread in U.S hospitals. Beginning in September 2018, CDC began investigating reports of this type of *Pseudomonas aeruginosa* from multiple states. An initial public health investigation identified 17 confirmed and 6 suspect cases from ten U.S. states and determined recent surgery in Tijuana, Baja California, Mexico at Facility 1 as a common risk factor among infected individuals. Mexican authorities conducted an onsite infection control assessment on December 4, 2018 and identified poor infection control practices at Facility 1. A travel notice was posted on the CDC website on January 9, 2019 informing U.S. residents of the potential risks associated with invasive procedures at Facility 1; however, U.S. residents continued to undergo surgery at Facility 1. Overall, 741 US residents from 43 states, the District of Columbia and Puerto Rico had surgery at Facility 1 from August 1, 2018 through March 1, 2019. As the outbreak strain of *P. aeruginosa* is rarely tested for in clinical laboratories, it is likely that other infections have occurred but have not been reported. We are requesting approval of a public health investigation to collect data on individuals who had surgery at Facility 1 in order to investigate the risk of infection and prevent spread in U.S. healthcare facilities.

CDC cannot reasonably comply with the normal clearance because our initial investigation suggests that it is critical that collection of patient data from multiple states begin rapidly in order to identify individuals with infections and prevent transmission of this highly resistant organism within U.S. healthcare facilities.

Because the collection of patient data is projected to begin on March 15, 2019, accelerated OMB review is requested. Therefore, CDC requests a 90 day emergency clearance to launch collection of patient data.



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

Respectfully,

Rima Khabbaz, MD
Director, National Center for Emerging and Zoonotic
Infectious Diseases (NCEZID), Centers for Disease Control
and Prevention (CDC)