



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

January 22, 2016

Stephanie Mok
CDC Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C.

Subject: Request for Emergency Clearance

Pursuant to the Office of Management and Budget (OMB) procedures established at 4 CFR 1320, *Controlling Paperwork Burdens on the Public*, I request that the following collection of information on cases of cardiac arrest during hemodialysis be processed in accordance with section 1320.13 Emergency Processing.

Seven patients in Connecticut have experienced sudden and unexpected cardiovascular collapse leading to cardiac arrest during routine outpatient hemodialysis since December 18, 2015. Three of the affected patients had evidence suggesting an anaphylactic reaction; all three of these patients died. Five of these events occurred in a single clinic and the remaining two events were in two nearby dialysis clinics owned by the same company.

CDC is currently conducting an epi-aid to support the Connecticut Department of Public Health (CT DPH) with their investigation of these events. Because these events could be linked to a healthcare product (e.g., medical device or pharmaceutical) with widespread distribution, broad case-finding efforts are needed.

I have determined that this information must be collected prior to the expiration of time period established under Part 1320, and that this information is essential to the CDC's ability to identify a cause of these events and prevent additional events from occurring.

CDC cannot reasonably comply with the normal clearance procedures due to the public harm that is reasonably likely to result if routine processing of this request is required, specifically cardiac arrests and death in patients exposed to a contaminated healthcare product. Therefore CDC requests a 180-day emergency clearance to conduct national case-finding and data collection for similar patient events.

Please provide an approval/disapproval determination of this request to collect information under and emergency clearance by close of business January 26, 2016.

Rebecca Miller, Associate Director of Policy, Office of the Director,
National Center for Emerging and Zoonotic Infectious Diseases, CDC