Template for 60-Day FRN

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-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 efforts 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 Undetermined cause of cardiac

arrest during hemodialysis — Connecticut 2015-2016 to perform expanded case-finding in order to determine the baseline frequency of cardiac arrest during dialysis following a cluster of occurrences.

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: Regulation.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 CONTACT: 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

Undetermined cause of cardiac arrest during hemodialysis—

Connecticut 2015-2016 – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Dialysis patients have higher mortality rates than the general population. According to the United States Renal Data System, sudden cardiac death is one of the leading causes of death among dialysis patients. However, sudden cardiac deaths and cardiac arrests that occur during dialysis treatment and are witnessed by dialysis clinic staff are not common. Published data reported a rate of 7 episodes per 1,000 patients-years for witnessed sudden cardiac arrest among dialysis patients.

In December 2015 and January 2016, the Connecticut Department of Public Health (CT DOH) received reports of six patients who experienced sudden and unexpected cardiovascular collapse and/or cardiac arrest during routine outpatient hemodialysis; three of the six expired. Four of these events occurred in one clinic: two on 12/18/2015, one on 12/19/2015 and one on 1/12/2016. The remaining two events occurred at two separate clinics: one on 12/18/2015 and one on 12/30/2015. These events occurred 30 to 135 minutes after the initiation of the dialysis treatment and not immediately following administration

of a medication. Three of the affected patients had findings suggestive of possible anaphylactic reaction (airway edema noted clinically and/or during autopsy and elevated serum tryptase level). Preliminary investigation has not implicated a common medication or healthcare device used by affected patients.

Given the severity and urgency of the problem and potential for additional cases, The Connecticut Department of Public Health requested assistance from CDC to investigate the issue.
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.

This information is essential to the CDC's ability to identify a cause of these events and prevent additional events from occurring.

Nationwide case finding will be implemented (through Epi-X or professional list serve). The target audience of the case finding will include, but not be limited to, state and local health departments, medical examiners, dialysis providers, and nephrologists. They will be asked to report any potential cases

to CDC. Information on each case will be collected using a data collection form. Depending on the nature of each case, CDC may reach out to relevant healthcare facilities or healthcare staff for additional information and any prevention measures. The data collected from the investigation will be used to identify potential risk factors leading to sudden cardiac arrest among dialysis patients in order to prevent further adverse events.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Patients	Questionnaire for patients who suffered from cardiac arrest but survived	4	1	30/60	2
	Questionnaire for other patients	40	1	30/60	20
Healthcare staff	Questionnaire for staff at the clinic	60	1	30/60	30
	Case finding for data collection	10	1	30/60	5
Total					57

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