4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-1092]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Sudden Death in the Young (SDY) Case Registry" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on November 6, 2018 to obtain comments from the public and affected agencies. CDC received no comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Sudden Death in the Young Registry – Reinstatement with Change - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Sudden Death in the Young (SDY) is defined as a sudden and unexpected death in an infant, child, or young adults (up to age 20), which is not explained by homicide, suicide, overdose, or the result of an external cause that was the only and obvious reason for the fatal injury, or terminal illnesses. Injury deaths where there may have been an initiating natural cause (e.g., drowning or death of the driver in a motor vehicle accident, which may have been triggered by an underlying cardiac or neurological condition) are also included in the definition.

SDY deaths are not systematically monitored and estimates of the annual incidence of SDY vary due to differences in definitions, inconsistencies in classifying cause, variable age and study populations, and differing case ascertainment methodologies. Because standardized information has not been collected on the incidence, causes, and risk factors, developing evidence-based prevention measures has been challenging.

To address these gaps, CDC, in collaboration with the National Heart, Lung, and Blood Institute and the National Institute of Neurological Disorders and Stroke at the National Institutes of Health implemented the SDY Case Registry in 2015 (OMB #0920-1092, Expiration 12/31/2018). Standardized data collected through the SDY Case Registry has been used by the NIH and CDC awardees to generate estimates of the incidence of SDY; to elucidate risk factors; and to develop evidence-based prevention strategies for SDY. The SDY Registry also creates infrastructure for future research about previously unknown or unrecognized risk factors for, and causes of, these deaths.

This information collection request is to reinstate OMB approval for the SDY Registry. By continuing the prior work of the SDY Registry, the information collected under this request will allow CDC to provide technical assistance to awardees so they can improve their jurisdiction's information on SDY. This includes two additions to their routine Child Death Review (CDR) program: 1) entering SDY information from existing data sources (e.g., medical records, autopsy reports) used during CDR review into the established web-based NCFRP Case Reporting System; and 2) convening clinicians with three different types of expertise (pediatric cardiology; pediatric neurology or epileptology; and forensic pathology) to conduct advanced clinical reviews of a subset of SDY cases to allow for a more thorough review of

information compiled and to generate additional data about the classification of the death. The intended result will be data that can establish incidence and guide program and policy decisions at the state/jurisdiction and local levels.

CDC estimates that the participating states/jurisdictions will collect data on approximately 739 SDY cases per year. For participating states/jurisdictions, burden is estimated for reporting required case information. Based on historical program information, it is estimated that approximately half (370) of the 739 estimated SDY cases each year will undergo an advanced clinical review and classification of cause by a team of three medical experts.

This reinstatement request differs from the previously approved information collection in reducing the number of burden hours. While CDC is not proposing changes to any of the data collection tools, the SDY module, or the advanced review process, CDC has, with experience, been able to: 1) obtain better estimates of the actual numbers of respondents anticipated on average per jurisdiction; 2) obtain more accurate estimates of the amount of time needed to completed the SDY modules; 3) better determine the number of cases that will need to continue to advance review and the types of medical experts that are needed. Because of these changes, despite the increase in participating jurisdiction, the net estimated burden is

lower. OMB approval is requested for three years. The total estimated annual burden is 521 hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
State Health Personnel	SDY Module I	14	53	10/60
Medical Experts	Advanced Review	42	26	15/60
State Health Personnel	SDY Module N	14	53	10/60

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