



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-1108; Docket No. CDC-2020-0119]

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 effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the existing information collection project titled Paul Coverdell National Acute Stroke Program (PCNASP) reporting system, which was established to improve quality of care for acute stroke patients from onset of signs and symptoms through hospital care and rehabilitation and recovery.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0119 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments 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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; 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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

Proposed Project

Paul Coverdell National Acute Stroke Program (PCNASP) (OMB Control No. 0920-1108, Exp. 09/30/2022) - Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Stroke is the fifth leading cause of death in the United States and results in approximately 145,000 deaths per year. Additionally, approximately 800,000 stroke events are reported each year, including approximately 250,000 recurrent strokes. However, many strokes are preventable, or patient outcomes post-stroke can be improved through coordinated care that begins at stroke onset and is delivered in a timely manner.

Stroke outcomes depend upon the rapid recognition of signs and symptoms of stroke, prompt transport to a treatment facility, and early rehabilitation. Improving outcomes requires a coordinated systems approach involving pre-hospital care, emergency department and hospital care, post-stroke rehabilitation, prevention of complications, and ongoing secondary prevention. Each care setting has unique opportunities for improving the quality of care provided and access to available professional and clinical care at the local level within a coordinated state-based system of care. In addition, there remains a need to identify disparities in stroke care and implement stroke interventions, such as community education and quality improvement activities, focused on priority populations.

Through the Paul Coverdell National Acute Stroke Program (PCNASP), CDC has been continuously worked to measure and improve acute stroke care using well-known quality improvement strategies coupled with frequent evaluation of results. There remains a national need to understand best practices of stroke systems of care, which includes prevention and awareness, use of EMS, in-hospital care, and rehabilitation and recovery. PCNASP awardees work statewide with participating hospitals, Emergency Medical Services (EMS) agencies, and other healthcare partners (e.g., community clinical partners) to improve quality of care for stroke patients. These efforts include implementing strategies to close the gap on stroke disparities, identifying effective stroke treatment centers, building capacity and infrastructure to ensure that stroke patients are routed to effective treatment centers in a timely manner, and improving transitions of care from the hospital to the next care setting.

During initial cooperative agreement cycles, PCNASP awardees focused on improving in-hospital quality of care (QoC) with technical assistance provided by CDC. Through lessons learned during this process and other supporting evidence in the field, it has become evident that it is also important to examine pre- and post-hospital transitions of care to link the entire continuum of stroke care when improving QoC for stroke patients.

The PCNASP's current five-year cooperative agreement started on July 1, 2015 and includes nine state health

department awardees and their selected partners (hospitals, EMS agencies, other healthcare facilities). This current funding period reflects additional emphasis on pre-hospital quality of care as well as the post-hospital transition of care setting from hospital to home or other healthcare facility. With technical assistance provided by CDC, awardees have worked on identifying and using data systems to systematically collect and report data on all three phases of the stroke care continuum and on hospital capacity.

PCNASP currently has OMB approval for the collection of pre-hospital (EMS), in-hospital, and post-hospital patient care data, as well as hospital inventory data (OMB Control No. 0920-1108, Exp. 09/30/2022). CDC plans to request a revision of this currently approved collection, with an extension of three years, reflecting a new Notice of Funding Opportunity (NOFO). The new PCNASP cooperative agreements will be expanded to include 13 awardees, which will be awarded on or about July 1, 2021.

In-hospital patient care data will continue to align with standards set by The Joint Commission (TJC) and the American Heart Association's Get With The Guidelines (GWTG) program. Estimated burden for the collection of in-hospital data will increase by a net increase of eight hours due to added program awardees under the new cooperative agreement. The average burden per response remains 30 minutes for awardees, for a total of 26 hours annually.

Data collection methods for pre-hospital care will continue to be collected similar to the two current methods, depending on awardees' access to data sources. These two methods are existing data systems currently available to awardees, including the AHA's GWTG and the National Emergency Medical Services Information System (NEMSIS). CDC has worked to reduce the overall number of required data elements and identified areas of alignment with AHA's GWTG. Total average burden will decrease due to the reduction in data elements under the new NOFO. Depending on the awardees' access to data sources (GWTG or NEMSIS), the average burden per response will vary from 30 minutes to one hour. Thus, the burden for pre-hospital data is estimated to decrease from 60 to 46 burden hours annually.

Under scope of the new NOFO, patient level quality of care post-hospital data will not be collected. Post-stroke transitions of care, rehabilitation, follow-up, etc. will be assessed in alignment with existing CDC cooperative agreements. This is an effort to better align resources, funding, and community efforts already working to connect stroke patients with post-acute clinical care. As a result, burden for this collection and transmission will not be included in the overall estimation of average burden.

Primary data collection of hospital inventory data will continue to be collected to understand the capacity and infrastructure of the hospitals that admit and treat stroke patients. Each hospital will report inventory information to its

PCNASP awardee annually. The average burden per response remains 30 minutes for hospitals. In addition, each PCNASP awardee prepares an annual aggregate hospital inventory file for transmission to CDC. The average burden of reporting hospital inventory information for each PCNASP awardee remains 8 hours per response. Based on current data and expected number of awardees under new NOFO, we are estimating the number of hospital partners per awardee to be 50 hospitals. Due to this increase in awardees, the estimated number of hospital respondents is anticipated to increasing from 378 to 650. Thus, there is a net increase of 136 hours for hospitals to collect and transmit this data. The total burden for hospital inventory data is increasing from 189 to 325 hours annually.

These requested changes will result in a net increase in total average burden from 361 to 501 hours. All patient, hospital, and EMS provider data that is submitted to CDC by PCNASP awardees will be de-identified and occur through secure data systems. Proposed data elements and quality indicators may be updated over time to include new or revised items based on evolving recommendations and standards in the field to improve the quality of stroke care.

OMB approval is requested for three years. Participation is voluntary and 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)	Total Burden (in hours)
PCNASP Awardee	Hospital inventory	13	1	8	104
	In-hospital care data	13	4	30/60	26
	Pre-hospital care data	3	4	30/60	6
		10	4	1	40
PCNASP Hospital Partners	Hospital Inventory	650	1	30/60	325
Total					501

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[FR Doc. 2020-26632 Filed: 12/2/2020 8:45 am; Publication Date: 12/3/2020]