**Information Collection Request**

**Reinstatement**

**Paul Coverdell National Acute Stroke Program**

**(PCNASP) Reporting System**

**OMB No. 0920-1108**

**Supporting Statement Part A: Justification**

**Program Official/Contact**

Sallyann Coleman King, MD, MSc

Medical Officer

Division for Heart Disease and Stroke Prevention

National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control and Prevention

Atlanta, GA 30341

Telephone: (770) 488-5892

Fax: (770) 488-8334

Email: FJQ9@cdc.gov

April 23, 2019

**Table of Contents**

1. Justification
2. Circumstances Making the Collection of Information Necessary
3. Purpose and Use of the Information Collection
4. Use of Improved Information Technology and Burden Reduction
5. Efforts to Identify Duplication and Use of Similar Information
6. Impact on Small Businesses or Other Small Entities
7. Consequences of Collection the Information Less Frequently
8. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
9. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
10. Explanation of Any Payments or Gifts to Respondents
11. Protection of the Privacy and Confidentiality of Information Provided to Respondents
12. Institutional Review Board (IRB) and Justification for Sensitive Questions
13. Estimates of Annualized Burden Hours and Costs
14. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
15. Annualized Cost to the Government
16. Explanation for Program Changes or Adjustments
17. Plans for Tabulation and Publication and Project Time Schedule
18. Reason(s) Display of OMB Expiration Date is Inappropriate
19. Exceptions to Certification for Paperwork Reduction Act Submissions

**List of Attachments**

1: 2015-2020 PCNASP Awardees

2: Section 317 of the Public Health Service Act [42 U.S.C. 247b(k)(2)]

3a: Crosswalk between program aims and short/intermediate/long term outcomes

3b: Crosswalk between short/intermediate/long term outcomes, performance measures, and data sources

4a: Pre-hospital care data elements

4b: In-hospital care data elements

4c: Post-hospital quality of care data elements

5a: Template of hospital inventory data elements for hospitals

5b: Template of hospital inventory data elements for awardees

6: 60-day Federal Register Notice (FRN)

7: IRB approval letter

8: Screenshot of Secure Access Management Services (SAMS) web portal

9: Information collection and transmission flow diagram

10a: Crosswalk of pre-hospital care data element changes

10b: Crosswalk of in-hospital care data element changes

10c: Crosswalk of post-hospital care data element changes

10d: Crosswalk of hospital inventory data element changes

11: Example table shells of performance measure summary reports

12: Data burden excerpt from PCNASP Reference Guide

**Goal of the Study**

CDC’s Paul Coverdell National Acute Stroke Program (PCNASP) seeks to improve quality of care for acute stroke patients by through systematic approaches to quality improvement activities. PCNASP works with nine state health departments (awardees) to focus on improving quality of care throughout the stroke continuum of care. The goal of this information collection is to allow CDC an additional 3 years of OMB approval to continue collecting information needed for PCNASP.

**Intended Use of the Resulting Data**

Data reporting will allow for continuous program monitoring, identification of successes and challenges for awardees, and assessment of the overall effectiveness and influence of PCNASP. Specifically, resulting data will be used to improve the quality of care for acute stroke patients, improve recovery, improve adherence to post-stroke guidelines, and reduce complications, readmissions, and early mortality for acute stroke patients. Lessons learned from the awardees will also help inform stroke care in settings across and outside of PCNASP.

**Methods to be Used to Collect**

Data from awardees’ partner hospitals, EMS agencies, and other healthcare facilities (e.g., stroke rehabilitation facilities) will be electronically transmitted to the PCNASP awardees (state departments of health). When possible, existing data collection systems are utilized to avoid unnecessary duplication of data collection. The awardees will then transmit de-identified files to CDC.

**The Subpopulation to be Studied**

PCNASP‑funded awardees will report all cases of acute hemorrhagic stroke (subarachnoid hemorrhage and intracerebral hemorrhage), acute ischemic stroke, acute ill-defined stroke, and transient ischemic attack (TIA) among patients age 18 and over from participating hospitals.

**How Data will be Analyzed**

CDC will perform annual data validation of select and highly important data elements, as well as quarterly data quality review and performance monitoring.

**Overview**

The Centers for Disease Control and Prevention’s (CDC’s) Paul Coverdell National Acute Stroke Program (PCNASP) currently collects information from nine state health departments (awardees) to administer its state-based quality improvement program (OMB No. 0920-1108; expiration 03/31/2019). Under the previous OMB approval, PCNASP collected data from awardees, who work with their partners to conduct organized quality improvement activities for acute stroke patients from stroke onset when the victim contacts the emergency medical service (EMS) through after they discharged from the hospital. Awardees’ partners can include hospitals, emergency medical service (EMS) agencies, and other healthcare providers (e.g., stroke rehabilitation facilities). The data collection spanned the entire continuum of stroke care, including pre-hospital quality data, in-hospital quality data, and post-hospital quality data. In addition, PCNASP was approved to collect hospital inventory data, which includes information on hospital demographics (e.g., number of hospital beds) and their capacity to treat stroke patients.

This reinstatement request details the proposed continued data collection for PCNASP, and describes changes to the pre-hospital, in-hospital, post-hospital, and hospital inventory data collection instruments, which result in an overall net decrease in burden. These changes reflect modifications to adapt to new scientific research in the stroke field, and align with changes to the electronic data collection systems that are commonly used by partners to submit data to awardees. The changes are needed to keep PCNASP current with scientific guidelines and research, while keeping the overall burden of data collection to a minimum. Thus, CDC seeks to reinstate OMB approval for data collected by PCNASP for three years, with revisions.

**A. Justification**

**A.1 Circumstances Making the Collection of Information Necessary**

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), CDC, is submitting a reinstatement request for OMB approval for an additional three years to collect information from awardees funded through PCNASP. The approval period reinitiates data submission following the time-limited lapse in approval for PCNASP. Awardees are state departments of health that will work with selected partners to improve systems of acute stroke care in their respective jurisdictions (**Attachment 1**). PCNASP is authorized under Section 317 of the Public Health Service Act (PHSA), 42 U.S.C. 247b(k)(2) as amended (**Attachment 2**).

Stroke is largely preventable, yet nearly 800,000 strokes and transient ischemic attacks (TIAs) occur each year, leading to ~145,000 deaths annually. To address this public health burden, CDC has initiated and progressively expanded PCNASP from 2001 to the present to conduct organized quality improvement activities for acute stroke patients from stroke onset through hospital discharge. There is 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. During previous funding cycles, initial PCNASP efforts focused on improving in-hospital stroke care, with awardees additionally individually piloting pre-hospital and post-hospital information collection methods.

During the 2015-2020 funding cycle, all PCNASP awardees are working with selected partners in their jurisdictions to collect information for the following three phases of stroke care: pre-hospital, in-hospital, and post-hospital care. Since acute stroke patient outcomes are influenced by rapid initiation of appropriate care in the pre-hospital setting, followed by effective communication and coordination during transitions to in-hospital and post-hospital care, a systems approach that addresses the entire continuum of care is needed to improve outcomes for patients. PCNASP uses quality improvement and systems analysis techniques to add value to information routinely collected for patient care.

Awardees work directly with their partners to place evidence-based quality improvement activities in the context of their states’ capabilities, health care structure, and needs. Examples of activities include awardees directly targeting stroke quality improvement activities in rural areas and awardees working with local EMS systems to launch pilot programs for linking pre-hospital and in-hospital data. Specific activities that are implemented may be influenced by the current capacity of hospitals in stroke care; thus, this information collection request includes the collection of hospital inventory data that is important to more fully understanding settings involved and improving the quality of stroke care within states.

Pre-hospital data focuses on improving pre-hospital care for acute stroke by working with EMS agencies to develop pre-hospital data collection systems. Linking this pre-hospital and in-hospital data will enable EMS and emergency department hospital staff to collaboratively identify opportunities to improve early acute stroke care transitions. This is particularly important to ensure that patients who are eligible to receive time-sensitive therapies, such as intravenous tPA (tissue plasminogen activator) (alteplase), receive appropriate care within a timely manner. The post-hospital transition of care (TOC) data helps identify opportunities to improve the transition from hospital to the next care setting or home, patient education, access to community resources post-discharge, re-integration with primary care providers, and prevention of early complications after hospital discharge. Although this PCNASP information collection is across three different areas of care, it is significant and vital that PCNASP uses an integrated approach to stroke care by developing state-based stroke systems of care that link patient data across the system to examine care for the entire care continuum. To supplement patient data collected across the continuum, hospital inventory data helps to understand hospitals’ capacity for delivering stroke care. This data is not routinely collected outside of PCNASP.

**A.2 Purpose and Use of the Information Collection**

PCNASP has five program aims that are listed in Attachment 3a. Progress is assessed based on a variety of information sources that include both process performance measures and patient-level quality of care performance measures. **Attachment 3a** provides an overview of program aims and their relationship to short-, intermediate-, and long-term measures. **Attachment 3b** provides a detailed summary of information sources for these measures. Information that is collected is used to assess whether short-term and intermediate-term project activities are leading to intended long-term outcomes, as well as the reach and impact of the program; these are critical to enabling CDC to work with awardees to ensure appropriate dissemination of program impact and lessons learned. Process performance measures include information such as the number of partnerships between awardees and stroke-related entities, recruitment of hospital and EMS agencies, interventions implemented as a result of data reports, and quality improvement efforts. Process-related measures are principally addressed by awardees through annual reports of activities that are not part of this information collection request. However, some process-related measures will be derived from quality of care data described in the current information collection request.

Under the previous OMB package, PCNASP had approval to collect pre-hospital, in-hospital care, and post-hospital care data elements, as well as hospital inventory data. PCNASP has used the collected data to track performance measures for in-hospital quality of care, such as receipt of time-sensitive therapies at a national and state-level through quarterly reports. Hospital inventory data has been used to understand processes of care by the capacity level of various hospitals (e.g., availability of a dedicated stroke unit for patients at a comprehensive stroke facility). These data also provided PCNASP the ability to track changes in stroke-focused quality improvement activities over time. Additionally, PCNASP has worked closely with awardees to collect pre-hospital data and understand where gaps, challenges, and priorities in data collection lie. PCNASP has also worked with awardees to modify and strengthen the sources of pre-hospital information collection that can now be obtained from EMS agencies or hospitals. The choice of method varies according to the states’ capacity to access this type of data. For post-hospital data collection, PCNASP has worked with awardees and their partners to pilot this information collection, better understand the time intervals and settings from which this data can be obtained, and refine the process of this type of data collection. Furthermore, PCNASP has worked with partners such as the American Heart Association (AHA) to integrate post-hospital data elements into existing data collection systems to reduce the burden of this information collection. This data collection has been crucial to measuring the current state of stroke care, progress-to-date, gaps in care, and priority areas that need attention. PCNASP is requesting an additional three years of data collection to continue work with awardees and their partners on improving quality of care and linking data across the system to improve stroke outcomes.

Specifically, pre-hospital quality of care data (**Attachment 4a**) will continue to support analysis and performance on metrics measuring adherence to guidelines for early management of potential stroke patients, identify gaps in pre-hospital patient care, and drive improvement in care as needed. In-hospital quality of care data (**Attachment 4b**) will be used to support identification of opportunities for improvement in acute care. Post-hospital transition of care information will identify opportunities to improve the prevention of complications, readmissions, and recurrent stroke as well as improve recovery, access to community services, and reintegration with primary care providers. Together, information obtained from pre-hospital, in-hospital, and post-hospital data elements will reflect the full continuum of care for stroke patients and provide opportunities to assess quality and establish opportunities for improvement across this continuum. Thus, the collection of this information is a critical component to track the progress and completion of meeting essential program aims and outcomes. Additionally, the collection of this patient-level quality of care information is vital to assessing some of the process performance measures that help determine success of the program and inform lessons learned.

CDC also requests OMB approval to continue to collect information through a hospital inventory survey (**Attachments 5a and 5b**). Many of the hospital inventory data elements are not routinely collected by hospitals, and are thus are important for program monitoring and included in the information collection request. These data are specific to the capabilities of hospitals to provide stroke treatments, and this detailed information is not available from other national datasets. Data captured in the hospital inventory survey, such as facility size and capacity, will continue to be used in data analyses to stratify patient-level quality improvement performance measures.

**A.3 Use of Improved Information Technology and Burden Reduction**

All data that will be submitted to CDC for PCNASP will be electronically reported and skip logic/patterns are built into data collection systems when possible. Burden will be reduced by allowing use of an existing data platform that is available through the AHA (called “Get With The Guidelines”). This system automatically transmits data from hospitals to the awardee.

**A.4 Efforts to Identify Duplication and Use of Similar Information**

In-hospital quality data and quality indicators are based on standards and recommendations set forth by national partner organizations, such as The Joint Commission and the AHA, to reflect evidence-based stroke care strategies. PCNASP quality indicators will continue to align closely with these recommendations. PCNASP pre-hospital data elements are currently collected by EMS providers via the National Emergency Medical Services Information System (NEMSIS) and an AHA data collection platform. Additionally, awardees may use existing state-based programs and/or methods that currently collect pre-hospital data elements that will overlap with those collected by PCNASP. Post-hospital care data can also be collected using a new platform available through the AHA. Methods to use existing data collection systems for PCNASP are discussed with awardees to avoid data duplication and pre-existing state-based programs and/or methods can be continued if the awardee believes this is beneficial. PCNASP works with the AHA to harmonize efforts when appropriate, such as data elements, element names, and performance measures.

The hospital inventory data is unique to PCNASP and is not available through alternative programs or databases. This information is important to understand if and how certain elements of stroke capacity influence quality of care and outcomes. To our knowledge, similar information about hospital stroke capacity and quality improvement initiatives are not captured by partner organizations.

Occasionally, PCNASP data elements may need to be updated to maintain alignment with research findings, guidelines, or recommendations from partner organizations. CDC anticipates that technical adjustments will be consistent with currently defined PCNASP objectives, burden estimates, and information collection methods. CDC will submit change requests to obtain OMB approval of updates to the data elements. If substantive changes are needed, CDC will submit a revision.

**A.5 Impact on Small Businesses or Other Small Entities**

This data collection will not involve small businesses.

**A.6 Consequences of Collecting the Information Less Frequently**

Awardees will transmit pre-hospital, in-hospital, and post-hospital data to CDC quarterly and hospital inventory data annually. Improvements in quality of care will be measured by adherence to established guidelines for care and quality metrics. This requires consistent review of the data with careful monitoring so that quality improvement can take place efficiently and effectively. Thus, the ability of CDC to monitor and improve quality of care would be compromised if data were collected less frequently.

**A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

**A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

PCNASP is in close and continuous consultation with the AHA, a non-profit organization that currently collects data on the quality of stroke care using an electronic data platform that awardees and their partners often use to collect in-hospital data. During the past three years, PCNASP has continued to work with AHA to harmonize in-hospital data elements to avoid data duplication and minimize burden. Furthermore, PCNASP has worked with AHA to leverage their data platform to also include pre-hospital and post-hospital data elements that are collected by PCNASP. This gives awardees the opportunity to use AHA’s platform to collect this data more easily.

Consultations occur through monthly conference calls between AHA and CDC, as well as email (when needed). These consultations have occurred throughout the current cooperative agreement, which began in July 2015. The primary point of contact for these consultations is:

Christine Rutan

National Director Quality and Health IT

American Heart Association

christine.rutan@heart.org

914-475-0955

A 60-day Notice was published in the *Federal Register* on February 7, 2019, Vol. 84, No.26, pp.2510-12 (see **Attachment 6**). No public comments were received.

**A.9 Explanation of Any Payments or Gifts to Respondents**

PCNASP will not provide any payments or gifts to individuals.

**A.10 Protection of the Privacy and Confidentiality of Information Provided by Respondents**

CDC’s Privacy Office has reviewed this submission and determined that the Privacy Act does not apply (Privacy Narrative). The CDC’s Paul Coverdell National Acute Stroke Program (PCNASP) seeks to improve quality of care for acute stroke patients through systematic approaches to quality improvement activities. The PCNASP data collection continues to be conducted primarily for continuous quality improvement of patient care, evaluation, and assessment of pre-hospital, in-hospital, and post-discharge care.

It was also previously determined that the Privacy Act does not apply for PCNASP and that PCNASP does not collect information in identifiable form (IIF) (OMB 0920-1108; expiration 03/31/2019). PCNASP will continue to not collect information IIF or personal identifying information (PII). All patient, hospital, and emergency medical service (EMS) agency identifiers will continue to be de-identified in the data collected by PCNASP. While PCNASP does collect some date and time-based data elements (e.g., date and time of EMS arrival at the hospital), without direct identifiers it is not possible to use this data in combination with other data elements (e.g., age in years) to identify the patient.

PCNASP does not maintain an Information Technology (IT) system used for the data collection. It also does not require that state awardees or their partners use a specific IT system. Data is transmitted from state awardees to CDC through the Secure Access Management Servers (SAMS). De-identified data is maintained by CDC in secure, password-protected servers, which only select program staff have access to (statistician, data analyst).

 **A.11 Institutional Review Board (IRB) and Justification for Sensitive Questions**

The primary intent of this cooperative agreement and information collection is quality improvement. However, PCNASP data do provide opportunities for research as a secondary use. CDC has IRB approval for secondary research uses of the information collection (**Attachment 7**).

PCNASP, along with national partner organizations, collects patient data about race and ethnicity (**Attachment 4b**). The collection of this information for acute stroke patients is important to assessing disparities in access to care across the care continuum as well as quality of care. The American Heart Association/American Stroke Association released a scientific statement in 2011 that stated the importance of understanding features of the health care system that affect existing racial-ethnic disparities in stroke care. Thus, the recognition of these disparities are an essential component of improving the quality of stroke care. PCNASP does not have any other potentially sensitive questions incorporated into the program.

**A.12 Estimates of Annualized Burden Hours and Costs**

OMB approval is requested for three years.

There are four categories of information collection: pre-hospital (**Attachment 4a**), in-hospital (**Attachment 4b**), post-hospital (**Attachment 4c**), and hospital inventory (**Attachments 5a and 5b**). Pre-hospital, in-hospital, and post-hospital quality of care data will be transmitted by awardees to CDC on a quarterly schedule. Hospital inventory data will be collected and transmitted annually. Awardees use their selected data systems to electronically receive or extract data from their partners.

The burden of primary data collection of in-hospital data is not assessed for hospitals, because it is routine but strengthened through PCNASP. Additionally, the burden of data transmission from hospitals to their respective awardee is not assessed because it is an electronic and automated process. The average burden per response is 30 minutes for awardees to compile and transmit in-hospital data to CDC quarterly. Thus, the total average burden for the collection and transmission of in-hospital data is 18 hours annually (Table A.12.a).

Pre-hospital data will be collected by awardees from their partners by two possible methods, depending on their state’s access to data sources: from hospitals (two awardees) or from data systems used by EMS agencies (seven awardees). For the two awardees that will collect pre-hospital data from hospital partners, data will be electronically received by the awardee and then compiled and transmitted on a quarterly basis to CDC for an average burden per response of 30 minutes. The seven awardees that extract pre-hospital data from EMS agencies will have an average burden per response of 2 hours, which accounts for the time needed to extract the data and then compile and transmit it to CDC. Thus, the total average burden for the collection and transmission of pre-hospital data will be 60 hours annually (Table A.12.a).

Post-hospital data will be collected by awardees from their partners by two possible methods: from hospitals (seven awardees) or from other partners (e.g., rehabilitation facilities) (two awardees). Both methods will use automatic data transfer from the partners to the awardees, so burden is not assessed for this data transmission. For the seven awardees that collect data from hospitals, the average burden per response will be 30 minutes to transmit the data to CDC. The two awardees that collect post-hospital data from other partners will have an average burden per response of 1 hour, because additional time is needed to compile this data from different non-hospital sources and submit it to CDC. Thus, the total average burden for the collection and transmission of post-hospital data will be 22 hours annually (Table A.12.a).

All pre-hospital, in-hospital, and post-hospital data files that are sent to the CDC will be in the form of a SAS (Statistical Analysis System) data set. The transmission will occur through the Secure Access Management Services (SAMS) web portal (**Attachment 8**). SAMS is operating under an approved security plan.

Finally, burden is assessed for the total number of estimated hospital partners (n=378, mean=42 per awardee) to collect and transmit hospital inventory data annually to their awardee. This average burden per response is 30 minutes. Additionally, burden is assessed for each PCNASP awardee to annually compile the hospital inventory information for its jurisdiction and transmit its aggregate file to CDC. This average burden per response is 8 hours. Awardees then transmit a de-identified file to CDC (**Attachment 5b**). The total average burden for the collection and transmission of hospital inventory data will be 261 hours annually (Table A.12.a). Data will be submitted as an Excel file through the SAMS web portal. **Attachment 9** has a diagram of the collection and transmission process.

Thus, the total estimated annualized burden to respondents is 361 hours, as summarized in Table A.12.a.

**Table A.12.a. 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 | 9 | 1 | 8 | 72 |
| In-hospital care data | 9 | 4 | 30/60 | 18 |
| Pre-hospital care data | 2 | 4 | 30/60 | 4 |
| 7 | 4 | 2 | 56 |
| Post-hospital transition of care data | 7 | 4 | 30/60 | 14 |
| 2 | 4 | 1 | 8 |
| PCNASP Hospital Partners | Hospital inventory | 378 | 1 | 30/60 | 189 |
| Total |  | 361 |

The total estimated annualized cost to respondents will be $12,987 (Table A.12.b). This estimate is based on data from the United States Department of Labor’s Bureau of Labor Statistics (BLS). The estimate of costs to awardees’ partners is $6,683, and is based on an average hourly wage of $35.36 for staff (Registered Nurses; BLS occupation code 29-1141) to collect and transmit hospital inventory data to their awardee. Additionally, the estimate of costs to awardees is $6,304, and is based on an average hourly wage of $36.65 for awardee staff (epidemiologists; BLS occupation code 19-1041) to compile pre-hospital, in-hospital, post-hospital, and hospital inventory data received from hospitals and transmit the information to CDC. Costs to awardees are paid under terms of the cooperative agreement.

**Table A.12.b. Estimated Annualized Burden Costs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Mean Hourly Wage (dollars)** | **Total Burden (in hours)** | **Total Annualized Cost to Respondents** |
| PCNASP Awardee | Pre-hospital care data | $36.65 | 60 | $2,199 |
| In-hospital care data | $36.65 | 18 | $660 |
| Post-hospital care data | $36.65 | 22 | $806 |
| Hospital inventory data | $36.65 | 72 | $2,639 |
| PCNASP Hospital Partners | Hospital inventory data | $35.36 | 189 | $6,683 |
| Total |  | $12,987 |

**A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

The computer hardware and software needed for an electronic data submission of information to awardees and CDC are readily available to hospitals and awardees since they collect and distribute these data for state and other purposes. Hence, no additional capital or maintenance costs are anticipated.

**A.14 Annualized Cost to the Government**

The data collection will be funded under cooperative agreements to each of the states and Funding Opportunity Announcement No. CDC-RFA-DP15-1514 (Paul Coverdell National Acute Stroke Prevention). The annualized cost of the cooperative agreement is $6.74 million. The total estimated annualized cost to the federal government includes CDC personnel costs for a statistician/data manager and data analyst. This estimated annualized cost is $44,308.25 for a GS-12 data statistician at 50% FTE, $6,226.13 for a GS-14 at 5% FTE, and $31,130.63 for a GS-14 at 25% FTE. Thus the total annualized cost is $6,821,665.01.

**A.15 Explanation for Program Changes or Adjustments**

The total annual burden for this data collection is expected to decrease from 382 to 361 (Table A.15.a). **Attachment 9** describes the change in burden.

There are no changes in the burden for the collection and transmission of in-hospital data elements. The total burden per respondent remains at 18 hours.

Previously, PCNASP accounted for the burden of partners (hospitals) transmitting pre-hospital data to their awardees. PCNASP has worked closely with the AHA over the past 3 years to add and harmonize PCNASP pre-hospital data elements with the AHA’s existing electronic data platform. This now allows data to be automatically transmitted from hospitals to awardees, so the burden of this data transmission for hospitals is no longer accounted for (Table A.15.a; net decrease 78 hours). PCNASP also previously accounted for the burden of awardees transmitting pre-hospital data to CDC. This burden is still accounted for, but the average hours are being adjusted. For the two awardees who are able to use the AHA’s platform, the average burden per response remains 30 minutes. For the remaining seven awardees, additional burden is added for them to extract data from EMS agencies. This average burden per response is two hours. Thus, there is a net increase in burden of 42 hours for awardees. For awardees and partners combined, the total burden for pre-hospital data is decreasing from 96 hours to 60 hours (total net decrease 36 hours).

Similar to pre-hospital quality data, PCNASP previously accounted for the burden of partners (hospitals) transmitting post-hospital data to their partners. PCNASP has worked closely with AHA to add post-hospital data elements to AHA’s existing electronic data platform, and these data are now automatically transmitted from hospitals to awardees. The system used to collect this post-hospital data is available to non-PCNASP hospitals. The burden of this data transmission for hospitals is no longer accounted for (Table A.15.a; net decrease 20 hours). PCNASP also previously accounted for the burden of awardees transmitting post-hospital data to CDC. This burden is still accounted for, but the average hours are being adjusted. For the seven awardees who are choosing to use AHA’s platform, the average burden per response remains 30 minutes. For the remaining two awardees, additional burden is added for them to collect and compile data from other healthcare facilities or partners, which includes stroke rehabilitation facilities and community paramedics. This average burden per response is 1 hour. Thus, there is a net increase in burden of 4 hours for awardees. For awardees and partners combined, the total burden for post-hospital data is decreasing from 38 hours to 22 hours (total net decrease 16 hours).

For hospital inventory data, PCNASP previously accounted for 315 hospitals to collect and transmit the data annually to their respective awardees. The average burden per response for hospitals was 30 minutes (15 minutes collection + 15 minutes transmission), and is not expected to change. However, due to increased hospital partner participation in PCNASP, the estimated number of hospital respondents is increasing from 315 to 378. Thus, there is a net increase of 31 hours for hospitals to collect and transmit this data. PCNASP also accounted for awardees to compile and transmit hospital inventory data to CDC. This burden is not changing. Thus, for awardees and partners combined, the total burden for hospital inventory data is increasing from 230 to 261 hours (total net increase 31 hours).

Although there is a net increase in burden on PCNASP awardees due to methodology that is chosen to collect and transmit pre-hospital and post-hospital data, there is a net decrease in the burden on PCNASP partners because of available automatic data transmission methods. As shown in Table A.15.a, the result of these changes is a total net decrease in average burden from 382 to 361 hours.

Although PCNASP does not account for the burden of pre-hospital, in-hospital, or post-hospital data collection by hospitals or other partners, we are requesting modifications to the data dictionaries to ensure continued alignment with existing data collection systems (AHA GWTG, NEMSIS) (**Attachments 9a, 9b, 9c**). Additionally, we are requesting modifications to the hospital inventory survey to understand advances in stroke care capabilities, adapt to new scientific advances, and clarify questions based on awardees’ requests (**Attachment 9d**).

**Table A.15.a. Net Change in Average Burden Hours**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Current approval (OMB No. 0920-1108)** | **Proposed changes** | **Net Change (hours)** |
| **Description of burden** | **Total Burden Hours** | **Description or reason for change** | **Total Burden Hours** |
| PCNASP Awardees | Hospital inventory data | Data compiling and transmission | 72 | None | 72 | 0 |
| In-hospital care data | Transmission | 18 | None | 18 | 0 |
| Pre-hospital care data | Transmission | 18 | Data extraction and transmission | 60 | +42 |
| Post-hospital care data | Transmission | 18 | Data compiling and transmission | 22 | +4 |
| PCNASP Partners | Hospital inventory | Collection and transmission | 158 | Collection and transmission. Additional hospital partners | 189 | +31 |
| Pre-hospital data | Data transmission | 78 | Transmission automatic | 0 | -78 |
| Post-hospital data | Data transmission | 20 | Transmission automatic | 0 | -20 |
| **Total** |  |  | **382** |  | **361** | **-21** |

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

PCNASP’s OMB approval expired on 3/31/2019. CDC is requesting a reinstatement to continue collecting data for three years, which will cover the remaining time in the current cooperative agreement (July 1, 2015-June 30, 2020). Additional time is needed beyond the end of the cooperative agreement to finalize and ensure completeness of data collection through the end of the cooperative agreement.

Pre-hospital, in-hospital, and post-hospital transition of care data will be transmitted to CDC quarterly. Awardees work with their partners to assure that data is transmitted to them in a timely manner to meet CDC deadlines. This information will be submitted from awardees to CDC within two weeks of the quarter ending; PCNASP staff will then clean the data and provide feedback necessary to ensure that the data is of high quality. Within three months of the quarter ending, CDC will provide a data cleaning report back to awardees. There is a six month lag between the awardees’ quarterly data submission and CDC’s performance measure summary reports (see **Attachment 11** for example table shells) to allow for data to be aggregated across an appropriate amount of time. Additional delays may occur if there are technical issues with AHA’s data platform. In these cases, PCNASP works with AHA and awardees to identify the cause of the issue and minimize the additional time needed to collect the data. Performance measures will be assessed over time to detect trends in improvement in quality of stroke care within states; additionally, data across all awardee states will be aggregated to current national-level estimates.

For example, quarter 1 2018 data (January 1, 2018-March 31, 2018) will be submitted by awardees within two weeks of quarter 1 2018 ending. A data cleaning report for this quarter will be provided by CDC to the awardees by the end of quarter 2 2018 (June 30, 2018), and the performance measure summary report will be provided by the end of quarter 3 2018 (September 30, 2018).

Hospital inventory data will be submitted annually by awardees. Publications occur on an ad-hoc basis and are supported by a newly-created PCNASP Science Team.

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB expiration date and burden statement are displayed on data dictionaries provided to respondents (**Attachments 4a, 4b, 4c, 5a, 5b**) as well as the PCNASP Resource Guide, which is provided to all awardees (**Attachment 12**). Awardees use the Secure Access Management Services (SAMS) web portal to securely upload data to the CDC. The SAMS portal is used by other data collection programs within the CDC, so the display of the burden statement is not possible and would become confusing to other users.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

**References**

Cruz-Flores S, Rabinstein A, Biller J, Elkind MSV, Griffith P, Gorelick PB, Howard G, Leira EC, Morgenstern LB, Ovbiagele B, Peterson E, Rosamond W, Trimble B, Valderrama AL; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Epidemiology and Prevention, and Council on Quality of Care and Outcomes Research. Racial-ethnic disparities in stroke care: the American experience: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2011;42:2091–2116.

Jauch EC, Saver JL, Adams HP Jr, Bruno A, Connors JJ, Demaerschalk BM, Khatri P, McMullan PW Jr, Qureshi AI, Rosenfield K, Scott PA, Summers DR, Wang DZ, Wintermark M, Yonas H; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Peripheral Vascular Disease, and Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2013;44:870–947.

George M, Tong X, Yoon P. Use of a registry to improve acute stroke care--seven states, 2005-2009. MMWR Morb Mortal Wkly Rep. 2011 Feb 25;60(7):206-10.

George MD, Tong X, McGruder, et al., Paul Coverdell National Acute Stroke Registry Surveillance --- Four States, 2005-2007. MMWR 2009;58(SS07);1-23.

Goldstein LB, Bushnell CD, Adams RJ, Appel LJ, Braun LT, Chaturvedi S, Creager MA, Culebras A, Eckel RH, Hart RG, Hinchey JA, Howard VJ, Jauch EC, Levine SR, Meschia JF, Moore WS, Nixon JV, Pearson TA; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council on Epidemiology and Prevention, Council for High Blood Pressure Research, Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. Guidelines for the primary prevention of stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2011;42:517–584.

Higashida R, Alberts MJ, Alexander DN, Crocco TJ, Demaerschalk BM, Derdeyn CP, Goldstein LB, Jauch EC, Mayer SA, Meltzer NM, Peterson ED, Rosenwasser RH, Saver JL, Schwamm L, Summers D, Wechsler L, Wood JP; on behalf of the American Heart Association Advocacy Coordinating Committee. Interactions within stroke systems of care: a policy statement from the American Heart Association/American Stroke Association. *Stroke.* 2013;44:2961–2984.

Mozzafarian D, Benjamin EJ, Go AS, et al. on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics – 2015 Update: a report from the American Heart Association. Circulation. 2015;131:e29-e322.

Oostema JA, Nasiri M, Chassee T, Reeves MJ. The quality of prehospital ischemic stroke care: compliance with guidelines and impact on in-hospital stroke response. *J Cerebrovas Dis*. 2014;23(10):2273-2279.

Ovbiagele B, Goldstein LB, Higashida RT, Howard VJ, Johnston SC, Khavjou OA, Lackland DT, Lichtman JH, Mohl S, Sacco RL, Saver JL, Trogdon JG; on behalf of the American Heart Association Advocacy Coordinating Committee and Stroke Council. Forecasting the future of stroke in the United States: a policy statement from the American Heart Association and American Stroke Association. *Stroke*. 2013;44:2361–2375

Patel MD, Rose KM, O'Brien EC, Rosamond WD. Prehospital notification by emergency medical services reduces delays in stroke evaluation: findings from the North Carolina stroke care collaborative. Stroke; a journal of cerebral circulation. 2011 Aug;42(8):2263-8.

Sacco RL, Kasner SE, Broderick JP, Caplan LR, Connors JJ, Culebras A, Elkind MSV, George MG, Hamdan AD, Higashida RT, Hoh BL, Janis LS, Kase CS, Kleindorfer DO, Lee J-M, Moseley ME, Peterson ED, Turan TN, Valderrama AL, Vinters HV; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Council on Cardiovascular Radiology and Intervention, Council on Cardiovascular and Stroke Nursing, Council on Epidemiology and Prevention, Council on Peripheral Vascular Disease, and Council on Nutrition, Physical Activity and Metabolism. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2013;44:2064-2089

Schwamm LH, Pancioli A, Acker JE, Goldstein LB, Zorowitz RD, Shephard TJ, Moyer P, Gorman M, Johnston C, Duncan PW, Gorelick P, Frank J, Stranne SK, Smith R, Federspiel W, Horton KB, Magnis E, Adams RJ. Recommendations for the Establishment of Stroke Systems of Care: Recommendations from the American Stroke Association’s Task Force on the Development of Stroke Systems. Stroke. 2005;36:690-703.