**Paul Coverdell National Acute Stroke Program**

Extension: 0920-1108 Exp: 09/30/2024

**Supporting Statement A**

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**[ATTACHMENTS](#_REFERENCES_(Tool_Tip:" \o "Tool Tip: You may copy and paste your list of Attachments from SSA or fill in below))**

1. Public Health Service Act [42 U.S.C. 247b(k)(2)]

2. PCNASP NOFO 2024-Logic Model

3. Crosswalk of strategies and measures

4a. Coverdell Data Manual Edition 2

5a. Hospital inventory survey data elements for hospitals

5b. Hospital inventory data elements for awardees

6. 60-day Notice in Federal Register.

7. IRB Approval

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

**JUSTIFICATION SUMMARY**

**Goal of the project:** 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. PCNASP recipients will focus on state-wide assessment and improvement in stroke care while also implementing strategies to close the gap on stroke disparities. The goal of this information collection request is a ***no change extension*** for the continuity of the program***.***

**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 stroke care guidelines, and reduce complications, readmissions, and early mortality for acute stroke patients.

**Methods to be used to collect:** Data from awardees include hospitals and EMS agencies. De-identified files will be electronically transmitted to CDC. When possible, existing data collection systems are utilized to avoid unnecessary duplication of data collection.

**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 (re-abstraction) of select and highly important data elements, as well as data quality review and performance monitoring, 3 times a year.

1. **JUSTIFICATION**

## *A1. Circumstances Making the Collection of Information Necessary*

*Overview*

The Centers for Disease Control and Prevention’s (CDC’s) Paul Coverdell National Acute Stroke Program (PCNASP) requests a three-year approval for extension of existing OMB (OMB No. 0920-1108; expiration 09/30/2024). PCNASP is authorized under Section 317 of the Public Health Service Act (PHSA), 42 U.S.C. 247b(k)(2) as amended (**Attachment 1**).

Under the current OMB approval PCNASP collects information from thirteen state health departments (awardees) to administer its state-based quality improvement program. PCNASP collects 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). Current data collection spans the entire continuum of stroke care from pre-hospital quality data to in-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 extension request presents the proposed continued data collection for PCNASP for three years with no changes to the data collection.

*Background*

Stroke is largely preventable, yet nearly 800,000 strokes and transient ischemic attacks (TIAs) occur each year, leading to approximately 145,000 deaths annually [[1](#_ENREF_1)].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 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. 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 from pre-hospital care to in-hospital care, a systems approach is needed to improve outcomes for patients [[2](#_ENREF_2)]. PCNASP uses quality improvement and systems analysis techniques to add value to information routinely collected for patient care [3, 4].

A comprehensive evaluation of the PCNASP program called “CDC Coverdell Program from 2015-2020” found that fostering partnerships between hospitals and EMS agencies improved the sharing of information and helped them gain a better understanding of their role in improving their state’s stroke systems of care [5]. Facilitating the linking and sharing of data across the stroke system of care helped to identify areas for improvement during transitions of care which helped lead to improved timeliness and quality of stroke care.Additionally, the work of PCNASP awardees has also highlighted the critical need to improve stroke quality of care and outcomes, among priority populations. Sociodemographic differences in meeting stroke program performance measures and outcomes have been consistently identified [6, 7]. Findings from PCNASP studies reveal the continued need to identify disparities and implement stroke interventions, such as community education and quality improvement activities, focused on priority populations [8].

Awardees will focus on implementation of comprehensive stroke systems for individuals, both at highest risk for stroke events and for stroke patients, across the continuum of care. This will be achieved via enhancing and improving the quality of stroke care across the continuum of care in states with high burden populations. High burden populations are those that state-level data indicate are disproportionately impacted by stroke outcomes, including stroke hospitalizations and stroke mortality, and have disproportionately high prevalence for those at highest risk for stroke events, including individuals with high blood pressure and/or high blood cholesterol, which may be a result of socioeconomic factors, such as living in underfunded urban and rural communities, being uninsured/underinsured, having limited access to routine medical care, or other related factors. Awardees will use data-driven methods to analyze and use data in order to identify areas for quality improvement activities, along with evidence-based strategies to measure, track, and improve access to and quality of care for those individuals at highest risk for stroke events and for stroke patients, and work to improve transitions of care within EMS and hospital settings. Therefore, this information collection request includes the collection of pre-hospital data, in-hospital data, and hospital inventory survey data.

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. Patient level post-hospital data collection has not been part of the Coverdell Program since 2022.

This information collection request continues the collection of hospital inventory data that was implemented to better understand settings involved and improve the quality of stroke care within states.Awardees worked directly with their partners to place evidence-based quality improvement activities in the context of their states’ capabilities, health care structure, and specific needs, while also supplementing patient data collected across the stroke continuum.

***A2. Purpose and Use of the Information Collection***

PCNASP has three main program strategy categories as demonstrated in the logic model in **Attachment 2**. 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 3** provides an overview of these strategies and program measures. Information that is collected is connected to these strategies to advance the key objectives of the Coverdell program and assess whether short-term and intermediate-term project activities are working towards intended long-term outcomes. These are cross-walked with process performance measures include information such as the number of partnerships between awardees and stroke-related entities, monitoring of stroke care disparities, assessment of workforce development efforts to improve clinical knowledge, and protocols and interventions implemented as a result of 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 information collection request.

Under the currently approved OMB package, PCNASP has approval to collect pre-hospital and in-hospital care 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 tri-yearly 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.

*Requested Information Collection*

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 and in-hospital quality of care data will be used to support identification of opportunities for improvement in acute care (**Attachment 4**). Together, information obtained from pre-hospital and in-hospital data elements will reflect the critical components of the continuum of care for stroke patients and provide opportunities to assess quality and establish opportunities for improvement across this continuum. This information collection is vital for tracking the progress towards aims and outcomes. Additionally, the collection of this patient-level quality of care information helps assess process performance measures, informing program success and 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 part of routine data collection by hospitals, and thus are important for program monitoring. 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.

## *A3. 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 instruments and systems when possible. While awardees have the option to utilize data systems of their choosing to collect required data elements, awardees often use an existing data platform that is available through the American Heart Association (known as “Get With The Guidelines” or GWTG). This system is currently widely used by thousands of hospitals and automatically transmits data from participating hospitals to the awardee, thereby reducing the burden. Furthermore, to ensure data reporting burden is minimized, CDC will also provide remote technical assistance to awardees upon request.

## *A4. 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 American Heart Association (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 (GWTG). 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. 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, and in the assessment and evaluation of program strategies [9]. 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 any such technical adjustments will be consistent with currently defined PCNASP objectives, burden estimates, and information collection methods. CDC will submit change requests for non-substantive changes to obtain OMB approval of updates to the data elements. If substantive changes are needed, CDC will submit a revision.

## *A5. Impact on Small Businesses or Other Small Entities*

This data collection will not involve small businesses.

## *A6. Consequences of Collecting the Information Less Frequently*

Awardees will transmit pre-hospital and in-hospital data to CDC quarterly and hospital inventory data annually. Improvements in quality of stroke 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.

## *A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5*

This request fully complies with the regulation 5 CFR 1320.5.

## *A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency*

Part A: PUBLIC NOTICE

A 60-day Notice was published in the *Federal Register* on June 4, 2024 in Vol 89, 108, Page 47958. **(Attachment 6).** There were no comments to the published 60-day notice.

Part B: CONSULTATION

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 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 regular conference calls between AHA and CDC, as well as email (when needed).

**Table 1.** External Consultations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name**  | **Title**  | **Affiliation**  | **Phone**  | **Email**  | **Role** |
| *OUTSIDE CONSULTANTS*  |  |
| Jason Walchok | National Director – Data Solutions and Health IT | American Heart Association | 941-270-6460  | jason.walchok@heart.org | Consultant |

***A9. Explanation of Any Payment or Gift to Respondents***

PCNASP will not provide any payments or gifts to individuals.

## *A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent*

PCNASP activities do not involve the collection of individually identifiable information. The PCNASP data collection will continue to be conducted primarily for continuous quality improvement of patient care, evaluation, and assessment of short-term patient health outcomes and transition of care from hospital to home. CDC will continue to ***not*** collect direct patient identifiers or hospital identifiers. 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). SAMS is operating under an approved security plan. De-identified data is maintained by CDC in secure servers, which only select program staff have access to.

##

## *A11. Institutional Review Board (IRB) and Justification for Sensitive Questions*

The primary intent of the 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 as noted in the Coverdell Data Elements Manual Edition 2 **(Attachment 4).** The collection of this information for acute stroke patients is central to the aims of this cooperative agreement as it is important to assess disparities in access and quality of care across the stroke continuum [10]. 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 [11]. Thus, the recognition of these disparities is an essential component of improving the quality of stroke care. PCNASP does not have any other potentially sensitive questions incorporated into the program.

## *A12. Estimates of Annualized Burden Hours and Costs*

OMB approval is requested for three years.

There are three categories of information collection: pre-hospital and in-hospital (**Attachment 4**), and hospital inventory (**Attachments 5a and 5b**). Pre-hospital and in-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 26 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 or from data systems used by EMS agencies. For the 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. Currently, the number of awardees utilizing this method is 3 awardees. The awardees that extract pre-hospital data from EMS agencies will have an average burden per response of 1 hour, which accounts for the time needed to extract the data and then compile and transmit it to CDC. The number of awardees utilizing this method is 10 awardees. Thus, the total average burden for the collection and transmission of pre-hospital data will be 46 hours annually (Table A.12.a).

All pre-hospital and in-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 CDC’s 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=650 hospitals; estimating 50 hospitals per awardee) to collect and transmit hospital inventory data annually to their awardee. This average burden per response is 30 minutes. Based on current data the number of hospital partners per awardees is 50 hospitals (estimated total number is 650). 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. The total average burden for the collection and transmission of hospital inventory data will be 104 hours annually (Table A.12.a).

Thus, the total estimated annualized burden to respondents is 501 hours and remains unchanged. It is summarized in Table A.12.a.

**Table A12.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 | 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 |

The total estimated annualized cost to respondents will be $18,727.64 (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 $12,103.00 and is based on an average hourly wage of $37.24 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 $6,624.64, and is based on an average hourly wage of $37.64 for awardee staff (epidemiologists; BLS occupation code 19-1041) to compile pre-hospital, in-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 to Respondents**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Total Annual Burden Hours** | **Average Hourly Wage (dollars)** | **Total Respondent Labor Cost**  |
| PCNASP Awardee | Pre-hospital care data | 46 | $37.64 | $1,731.44 |
| In-hospital care data | 26 | $37.64 | $978.64 |
| Hospital inventory data | 104 | $37.64 | $3,914.56 |
| PCNASP Hospital Partners | Hospital inventory data | 325 | $37.64 | $12,3.00 |
| Total |  | $18,727.64 |

## *A13. Estimates of Other Total Annual Cost Burden to Respondents and 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.

## *A14.* *Annualized Cost to the Federal Government*

The total estimated annualized cost to the federal government includes the costs of a data collection contract and the cost of government personnel time for project oversight. The cost of the data collection contract with the current contractor is estimated to be $350,000 per year. This also includes CDC personnel costs for a health scientist and an ORISE fellow. This estimated annualized cost is $27,042 for a GS-13 Health Scientist at 20% FTE and ORISE fellow at 15% for $9,047. Thus, the annualized cost for personnel and data contract total is $386,089.

**Table A14-A.** Estimated Annualized Federal Government CostDistribution

|  |  |
| --- | --- |
|  | **Annualized Cost** |
| **CDC - GS 13 Technical Monitor at 20% FTE** | **$27,042** |
| **CDC – ORISE FELLOW (GS-9) at 15%**  | **$9,047** |
| **or** |  |
| **Data Contractor Total** | **$297,875**  |
| Data Collection | 78,875 |
| Data Analysis | 59,000 |
| Data Reporting | 126,000 |
| Data Training | 34,000 |
| **Total** | **$333,964** |

**Table A14-B.** Estimated Annualized Federal Government Operational and Maintenance Costs

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Equipment | Printing | Postage | Software Purchases | Licensing Costs | Other | Total |
| $0 | $0 | $0 | $0 | $6,000 | $0 | $6,000 |

**Table A14-C.** Total Cost to the Federal Government

|  |  |  |
| --- | --- | --- |
| Operational and Maintenance Costs | Estimated Annualized Federal Government Cost | Total Cost (O&M Costs + Labor Cost) |
| $6,000 | $333,964 | $339,964 |

## *A15. Explanation for Program Changes or Adjustments*

This is an extension request of a currently approved collection.There are no Program Changes or Adjustments. Annual burden for this data collection is 501 hours and it remains unchanged.

## *A16. Plans for Tabulation and Publication and Project Time Schedule*

CDC is requesting approval to continue collecting data for 3 years, which will cover the time between October 1, 2024 to September 30, 2027. A new cooperative agreement is anticipated to begin on October 1, 2024.

Pre-hospital and in-hospital transition of care data is 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 2 weeks of the quarter ending. CDC provides grantees with reports based on this data (attachment).

## *A17. Reason(s) Display of OMB Expiration Date is Inappropriate*

The display of the OMB expiration date is appropriate. The OMB expiration date and burden statement will continue to be displayed on Coverdell Data Manual Edition 2 (**Attachment 4**) provided to respondents. 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.

## *A18. Exceptions to Certification for Paperwork Reduction Act Submission*

There are no exceptions requested.

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