Paul Coverdell National Acute Stroke Program

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Supporting Statement B

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TABLE OF CONTENTS

ATTACHMENTS

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

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The Paul Coverdell National Acute Stroke Program (PCNASP) is funded to support the 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 through organized quality improvement activities. Awardees are expected to ensure all efforts are designed to close the gap in stroke care for high burden populations and improve state-level stroke care across the continuum of care , 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 from onset of stroke symptoms through rehabilitation and recovery. Awardees will work directly with their selected partners, which includes, but is not limited to, local/regional Emergency Medical Services (EMS) systems and hospitals, state/regional EMS Directors, hospitals, integrated healthcare systems, and community clinical services.

The target populations for data collection include acute stroke patients (intracerebral hemorrhage or ischemic stroke), potential acute stroke patients, and patients presenting with a transient ischemic attack (TIA). The inclusion criteria can be defined as all individuals diagnosed with an acute stroke (ischemic stroke or intracerebral hemorrhage) or transient ischemic attack (TIA) presenting to acute care hospitals or emergency departments, and all individuals presenting to EMS with a potential acute stroke or TIA. CDC encourages but does not require the inclusion of patients presenting with stroke in pregnancy (including peripartum stroke). CDC encourages the inclusion of patients with acute stroke or TIA that are in emergency department (ED) boarding. CDC strongly encourages the inclusion of patients presenting with subarachnoid hemorrhage.

Table B.1.a Respondent and Associated Partners for the Collection and Transmission of Information

Information	Respondent and Associated Partners (N)
Pre-hospital and In-hospital Patient level data	Awardees (13) in coordination with hospital and EMS partners
Hospital inventory data	Hospitals (650)
	Awardees (13)

**Note: burden is not assessed for the hospital's collection or transmission of in-hospital data. Burden is also not assessed for the collection or transmission of pre-hospital data when already existing data systems are used. Please reference section A.12 in Supporting Statement A for further details about this.*

PCNASP currently receives data from 13 awardees under the current cooperative agreement (CDC-RFA-DP21-2102). Neither hospital nor direct patient identifiers are included in the data sent to CDC.

B2. Procedures for the Collection of Information

Quality of care information collection includes data from 2 phases of the continuum of stroke care: pre-hospital and in-hospital (**Attachment 4)**. The pre-hospital and in-hospital care data elements are defined with national partner organizations to align data standards and collection methods when possible. Awardees choose their own data sources/systems to collect the data. The data system chosen by awardees depends on the availability of the data and their access to it. For example, pre-hospital care data can be collected by awardees from their partner hospitals or in partnership with their state office of EMS. Awardees send compiled data to CDC through secure access management services (SAMS) web portal quarterly (**Attachment 7**). Information is transmitted as a SAS (Statistical Analysis System) data set. All the information is de-identified.

Additionally, hospital inventory data will be collected by hospitals on an annual basis (**Attachment 5a**) and transmitted to the hospitals' awardee either electronically or on a paper form. The awardee then compiles all hospital responses into a single Excel file to submit to CDC annually (**Attachment 5b**). Without PCNASP, this data is not systematically or routinely collected by hospitals and sent to their respective awardee. The hospital inventory data can be linked to in-hospital data through a unique de-identified hospital ID common to both sources. CDC will aggregate data from all awardees. The data will reside in a secured file location on CDC servers, which is only accessible by the PCNASP staff.

B3. Methods to Maximize Response Rates and Deal with No Response

All PCNASP awardees are expected to report data in a timely manner. CDC requires data submission as a stipulation of the Notice of Funding Opportunity and the cooperative agreement notice of grant award. Awardees that have difficulty with data submission will be provided technical assistance by PCNASP data program personnel. On occasion, due to extenuating circumstances, extensions may be provided to give the awardees additional time to submit their data. The schedule for data reporting will remain consistent.

The use of existing Coverdell Data Manual Edition 2 (**Attachments 4)** and Hospital Inventory Data Dictionary **(5a, 5b**) and data abstraction guidelines facilitates for awardees to comply with the request. In addition, CDC's PCNASP team will provide a detailed assessment of data quality to all awardees after each data submission.

B4. Tests of Procedures or Methods to be Undertaken

The data uploading systems developed and maintained by CDC have been tested by PCNASP staff. SAMS is used by awardees for a variety of purposes and is a familiar process to them.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CDC staff from the PCNASP program were consulted about the substantive, methodological, and statistical aspects of the study.

CDC investigators will collaborate with the awardees and their partners on ideas for analyses, development of analytic plans, and interpretation of the data. The following is a list of PCNASP staff at CDC who work on the oversight, development, methodology, and statistical design of data that is collected.

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