**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request**

**Information Collection Request Title: Sickle Cell Disease Treatment Demonstration Regional Collaborative Program, OMB No. 0906-xxxx – New**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

**ADDRESSES:** Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Sickle Cell Disease Treatment Demonstration Regional Collaborative Program

OMB No. 0906- xxxx – New

*Abstract:* The Sickle Cell Disease Treatment Demonstration Regional Collaborative Program (SCDTDRCP) was reauthorized and amended in 2018 by the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act (Pub. L. 115-327), 42 U.S.C. 300b-5. The purpose of the proposed data collection is to monitor the progress of the SCDTDRCP in improving health outcomes in individuals living with sickle cell disease.

The goals of the program are to improve health outcomes in individuals with sickle cell disease; reduce morbidity and mortality caused by sickle cell disease; reduce the number of individuals with sickle cell receiving care only in emergency departments; and improve the quality of coordinated and comprehensive services to individuals with sickle cell and their families.

The program funds five grantees to establish regional networks to provide leadership and support for regional and statewide activities in sickle cell disease. The grantees develop and establish systemic mechanisms to improve the treatment of sickle cell disease, by: 1) increasing the number of providers treating individuals with sickle cell disease using the National Heart, Lung and Blood Institute (NHLBI) Evidence-Based Management of Sickle Cell Disease Expert Panel Report; 2) using tele-mentoring, telemedicine and other provider support strategies to increase the number of providers administering evidence-based sickle cell care; and 3) developing and

implementing strategies to improve access to quality care with emphasis on individual and family engagement/partnership, adolescent transitions to adult life, and care in a medical home. The SCDTDRCP is designed to improve access to services for individuals with sickle cell disease, improve and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait. Per the statutory requirement, the data collected will be used to evaluate the program and will be published in a report to Congress.

*Need and Proposed Use of the Information:* The purpose of the proposed data collection is to monitor the progress of the SCDTDRCP in improving care and health outcomes for individuals living with sickle cell disease/trait and monitor grantee progress in meeting the goals of the program. Each regional grantee will conduct one quality improvement initiative for hydroxyurea utilization among individuals with sickle cell disease. Grantees must conduct an additional quality improvement initiative on one of these topics: 1) pneumococcal vaccinations, 2) Transcranial Doppler Ultrasound (TCD) screening, or 3) transition planning. Grantees are encouraged to conduct additional clinical outcome quality improvement (QI) initiatives according to their ability. The regional grantees will also survey providers annually to assess provider comfort with treating individuals with sickle cell disease, awareness of the guidelines and involvement in Project ECHO (Extension of Community Health Outcomes) and other program activities. Pursuant to 42 U.S.C. § 300b-5(b)(3)(B), the Sickle Cell Disease Treatment Demonstration Regional Collaborative Program's National Coordinating Center (NCC) will work with the grantees to gather data and prepare a Report to Congress at the conclusion of the program. Additional information regarding the data collection activities is below:

**Provider Survey**

Regional grantees will administer the Provider Survey annually to providers within their region. The Provider Survey is a 13 item questionnaire that collects information on the provider type, their utilization of telementoring, and aggregate de-identified patient-level data. The number of states participating within a region may range from 5 to 17 states. Data from the Provider Survey will be aggregated by the regional grantee and submitted to the NCC.

**Quality Improvement**

As part of the requirement for funding under the grant, each regional grantee is required to conduct at least two quality improvement initiatives within their region. All grantees are required to conduct a quality improvement initiative on increasing the use of hydroxyurea. Grantees must conduct an additional quality improvement initiative on one of these topics: 1) pneumococcal vaccinations, 2) TCD screening, or 3) transition planning. Each regional grantee will collect QI data from participating providers and medical centers within their region and aggregate the data for submission to the NCC. Specific quality improvement data will be extracted from patients' charts quarterly, either manually or via electronic health records (EHR). This will require an initial set-up time in year 1 to develop data collection and reporting protocols for manual or electronic collection for the quality improvement project(s) that each regional grantee decides to measure. This initial set-up time has been included in the burden estimates listed in the chart.

*Likely Respondents:* Providers who treat individuals with sickle cell disease will complete the Provider Survey. The five regional grantees will aggregate these data and submit to the NCC. The grantees will also aggregate data from medical record extraction for the quality

improvement initiatives.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the tables below:

**Provider Survey and QI Measures**

Total Annual Burden Estimate Hours

| Form Name | Number of Respondents | Number of Responses per Respondent per Year | Total Responses per Year | Average Burden per Response (hrs/yr) | Total Burden Hours per Year |
|---|---|---|---|---|---|
| SCDTDP Provider Survey, participant responses | 70 | 1 | 70 | 1 | 70 |
| SCDTDP QI Measures* | 50 | 4 | 200 | 22 | 4,400 |
| Total | 120 | | 270 | | 4,470 |

*Note: Total burden hours per year shown represents the maximum number of estimated hours. Actual hours may be lower since many teams will not be assessing all four QI initiatives.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of

the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

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