Billing Code 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; 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 of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection

Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

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 by the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2018 (Pub. L. 115-327), which added section 1106 of the Public Health Service Act, 42 U.S.C. 300b-5. The purpose of the proposed Quality Improvement (QI) and Performance Measures (N) data collection is to evaluate the effectiveness of the SCDTDRCP and how the program can improve the coordination of service delivery for individuals with sickle cell disease (SCD), train health professionals to increase access to quality care and collaborate with various stakeholders to optimize health outcomes for individuals with SCD. The goals of the SCDTDRCP are to improve health outcomes in individuals with SCD; reduce morbidity and mortality caused by SCD; reduce the number of individuals with SCD receiving care only in emergency departments; and improve the quality of coordinated and comprehensive services to individuals with SCD and their families. The program funds five grantees to establish regional networks to provide leadership and support for regional and statewide activities in SCD. The grantees develop and establish systemic mechanisms to improve the treatment of SCD, by: (1) increasing the number of providers treating individuals with SCD using the National Heart, Lung and Blood Institute Evidence-Based Management of SCD 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. Per the statutory requirement, the data collected will be used to evaluate the program and will be published in a report to Congress.

A 60-day notice published in the **Federal Register** on January 23, 2020, vol. 85, No. 15; pp. 3935-37. There were no public comments.

Need and Proposed Use of the Information: The purpose of the proposed QI and PM data collection is to evaluate the effectiveness of the SCDTDRCP and how the program can improve the coordination of service delivery for individuals with sickle cell disease, train health professionals to increase access to quality care and collaborate with various stakeholders to optimize health outcomes for individuals with sickle cell disease. Pursuant to 42 U.S.C. 300b-5(b)(3)(B), the National Coordinating Center (NCC) will work with the grantees to gather data and prepare a Report to Congress at the conclusion of the program.

Quality Improvement

All five SCDTDRCP grantees are required to conduct QI initiatives to improve quality of SCD treatment and access to care. Each grantee also works with and supports local sites (i.e., university, medical center, etc.) that provide SCD care within their region to implement QI initiatives. All the grantees and local sites are required to implement initiatives to increase the hydroxyurea use and conduct one or more additional QI initiatives on the following topics: pneumococcal vaccinations, Transcranial Doppler screening, and transition planning. The grantees and local sites will collect data on a quarterly basis on applicable measures depending on which QI initiatives they are undertaking. The data will be extracted from patients' charts either via chart reviews or electronic health records. The local sites will send their data to the

grantees using an excel spreadsheet or by entering data into a database form of their choice developed by the grantee. The grantees will aggregate their own data and the data received from the local sites and submit the aggregate data to the NCC.

Performance Measures

In order to understand SCD care provided and the reach of the SCDTDRCP activities across regions, seven PM have been established (e.g. number of SCD patients seen by a provider in the past year). The five SCDTDRCP grantees will send a survey once a year to providers they work with within their region who provide care to SCD patients to collect PM data. Once the providers complete the survey, the grantees will aggregate the individual responses and submit the PM data to the NCC.

Likely Respondents: For QI data, the five SCDTDRCP grantees and local sites that provide SCD care that the grantees work with. For PM data, the five SCDTDRCP grantees and providers the grantees work with within their region who provide care to SCD patients.

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:

Total Estimated Annualized Burden - 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
SCDTDRCP Quality Improvement Measures*	55	4	220	13	2,860
SCDTDRCP Performance Measures	305	1	305	1	305
Total	360		525		3,165

*Note: Total burden hours per year shown represents the maximum number of estimated hours. Actual hours may be lower since many of the respondents may not be collecting data all QI initiatives.

Maria G. Button,

Director, Executive Secretariat.

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