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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Sickle Cell Disease Treatment Demonstration Program – Quality Improvement Data Collection for the Hemoglobinopathy Learning Collaborative (OMB No. 0915-xxxx) – [NEW]

Background: In response to the growing need for resources devoted to sickle cell disease and other hemoglobinopathies, the United States Congress, under Section 712 of the American Jobs Creation Act of 2004 (P.L. 108-357), authorized a demonstration program for the prevention and treatment of sickle cell disease (SCD) to be administered through the Bureau of Primary Health

Care and the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services. The program is known as the *Sickle Cell Disease Treatment Demonstration Program* (SCDTDP). The SCDTDP 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.

In 2006, the MCHB Genetic Services Branch (GSB) awarded funding to a National Coordinating Center (NCC). The NCC was established to: (1) collect, coordinate, monitor, and report on best practices and findings regarding the activities of the demonstration program; (2) identify a model protocol for eligible entities with respect to the prevention and treatment of Sickle Cell Disease; (3) identify educational materials regarding the prevention and treatment of Sickle Cell Disease; and, (4) prepare a final report on the efficacy of the demonstration program based on evaluation and quality improvement (QI) findings.

To achieve the goals/objectives of the NCC, the National Initiative for Children's Healthcare Quality (NICHQ) and partners are facilitating the Hemoglobinopathy Learning Collaborative (HLC). The HLC includes grantee teams funded from the SCDTDP and the Sickle Cell Disease for Newborn Screening Program (SCDNBSP). The HLC uses a process known as the Model for Improvement, which is a widely used approach to QI in health care settings. The Model for Improvement utilizes a structured process that asks grantee teams, who hereafter will be referred to as improvement teams, to build on small tests of change in their health care setting, while

providing monthly reporting on measurements. The proposed QI Data Collection and reporting system is an integral component of this model.

Purpose: The purpose of this QI Data Collection strategy is to implement a system to monitor the progress of MCHB-funded activities in improving care and health outcomes for individuals living with sickle cell disease/trait and meeting the goals of the SCDTDP. Each improvement team will be asked to report on a core set of measures related to quality improvement for hemoglobinopathies. Through an evidence-based process, a bank of QI measures has been developed to assess health care utilization of the SCD population as well as several aspects of the system of care.

The QI Data Collection strategy will provide an effective and efficient mechanism to do the following: (1) assess the services provided by grantees under the SCDTDP and monitor and drive improvement on quality measures; (2) collect, coordinate, and distribute data, best practices, and findings from network sites; (3) refine a common model protocol regarding the prevention and treatment of sickle cell disease; (4) examine/address barriers that individuals and families living with sickle cell disease face when accessing quality health care and health education; (5) evaluate the grantees' performance in meeting the objectives of the SCDTDP; and, (6) provide HRSA/Congress information on the overall progress of the program.

The proposed data collection and entry forms are as follows: (1) Participant Profile Form, (2) Acute Care Visit Form, and (3) Ambulatory Care Visit Form.

Respondents: Grantees funded by HRSA under the SCDTDP will be the respondents for this data collection activity. Each month, SCDTDP teams will complete up to three data collection and entry forms for 20 patients with SCD or sickle cell trait who were seen in their network that month. The Participant Profile form will collect demographic and basic health information. The Acute Care Visit and Ambulatory Care Visit forms will assess care in acute and ambulatory care settings, respectively.

All information will be collected via medical chart review. Data will be entered directly into a secure web-based data collection tool, Research Electronic Data Capture (REDCap). The data entered into REDCap will be analyzed via a custom measurement generator that will calculate and export the QI measures for viewing by improvement teams, the NCC, and HRSA.

The annual estimate of burden is as follows:

Instrument	Number of Respondents	Responses per Respondent *	Total Responses	Hours per Response	Total Burden Hours
Participant Profile Form	9	12	108	5.0	540
Acute Care Visit Form	9	12	108	10.0	1080
Ambulatory Care Visit Form	9	12	108	10.0	1080
Total	27		324		2700

* This burden table has been revised from the one published in the 60-day notice to reflect the accurate count of responses per respondent. The number 12 reflects the number of times a respondent will be approached for data collection annually, not the total number of data collection forms completed as was previously reported.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to

OIRA_submission@omb.eop.gov or by fax to (202) 395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: October 25, 2012

Bahar Niakan

Director, Division of Policy and Information Coordination

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