U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Maternal and Child Health Bureau
Division of Services for Children with Special Health Care Needs
Genetic Services Branch

Sickle Cell Disease Newborn Screening Follow-Up Program

Announcement Type: New, Competing Continuation
Funding Opportunity Number: HRSA-17-079

Catalog of Federal Domestic Assistance (CFDA) No. 93.110

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2017

Application Due Date: November 10, 2016

Ensure SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to one month to complete.

Issuance Date: September 9, 2016

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Authority: Social Security Act, § 501(a) (2) (42 U.S.C. 701(a) (2))

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Division of Services for Children with Special Health Needs/Genetic Services Branch (DSCSHN/GSB) is accepting applications for fiscal year (FY) 2017 for the Sickle Cell Disease Newborn Screening Follow-Up Program (SCDNBSFP). The purpose of the SCDNBSFP is to provide support for a Sickle Cell Newborn Screening Technical Assistance Center (TAC) that will work with community-based organizations (CBOs) to improve the care of individuals identified with sickle cell disease and sickle cell trait through universal newborn screening, by supporting efforts of CBOs on sickle cell disease education, and by coordinating services.

Funding Opportunity Title:	Sickle Cell Disease Newborn Screening Follow-Up Program
Funding Opportunity Number:	HRSA-17-079
Due Date for Applications:	November 10, 2016
Anticipated Total Annual Available Funding:	$2,904,400
Estimated Number and Type of Award(s):	Up to one (1) cooperative agreement
Estimated Award Amount:	Up to $2,904,400 per year
Cost Sharing/Match Required:	No
Project Period:	June 1, 2017 through May 31, 2021 (four (4) Years)
Eligible Applicants:	Per 42 CFR § 51a.3 (a), any public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 450b) is eligible to apply. Faith-based and community-based organizations are eligible to apply. [See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide,* available online at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this FOA to do otherwise. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

A pre-submission technical assistance webinar for all prospective applicants will be held:

Day/Date: Thursday, October 6, 2016
Time: 3:00 pm EST –5 pm EST
Dial-in: 888-385-9734
Passcode: 9522161
Web link: https://hrsa.connectsolutions.com/scdnbsfp/

Table of Contents

I. Program Funding Opportunity Description

1. Purpose[1]

This announcement solicits applications for the Sickle Cell Disease Newborn Screening Follow-Up Program (SCDNBSFP) to provide support for a Sickle Cell Newborn Screening Technical Assistance Center (TAC) that will improve the care and reduce rates of loss to follow-up of individuals identified with sickle cell disease (SCD) and sickle cell trait through universal newborn screening by supporting efforts of community-based organizations (CBOs) on sickle cell disease education and service coordination. This program will enhance sickle cell CBOs' ability to ensure that individuals diagnosed with sickle cell disease through newborn screening receive appropriate follow-up services including counseling, education, access to a medical home, and other support services. The primary population focus should be families of individuals identified with sickle cell disease and trait through newborn screening.

Program Goal:

The goal of this program is to ensure that individuals diagnosed with sickle cell disease through newborn screening receive appropriate follow-up services including counseling, education, access to a medical home, and other support services by supporting CBOs focused on SCD.

Program Objectives:

The award recipient will report annually on the following program objectives:

- By May 2021, train at least 150 CHWs in sickle cell disease to work in CBOs and other health care locations in at least 15 states.
- By May 2021, increase by 30 percent, the numbers of partnerships [Levels of Partnership: 1) Informal; 2) Collaborative; 3) Formal] among CBOs and hospitals, health systems, state/local public health departments, primary care providers, Federally Qualified Health Centers (FQHCs) family organizations, etc.
- By May 2021, at least 15,000 individuals with sickle cell disease are served by CBOs and receive care in a patient-centered medical home.
- By 2018, establish a baseline and ongoing evaluation measurement for each of the activities in this program objective section.

[1] For the purposes of this FOA, please note the following:

- Community Health Worker (CHW) – an individual who successfully completes a CHW training program and additional training in sickle cell disease. CHWs will have competency to provide education and referrals to connect individuals to appropriate care and social services.
- Sickle cell disease is inclusive of sickle cell genotypes including Hb SS, Hb S-Beta Thal. (0/+), and Hb SC
- Follow-up services include counseling, education, access to a patient and family-center medical home, transition, and other community support services.
- Activities should support individuals with sickle cell disease (as clarified in the previous bullet point) and individuals with sickle cell trait.

Program Requirements

The award recipient will be expected to perform the following activities:

1) Establish a national infrastructure that will implement the goals, objectives, requirements of the program.
2) Serve as the lead organization in a national effort to improve education and referrals for coordination of services for individuals with sickle cell disease identified through newborn screening and through the life-course.
3) Develop and implement a plan to identify and support (via subawards) CBOs in at least 15 states. Demonstrate the ability to initiate selection process to identify subawardees for this award through a competitive process, including developing criteria for the selection process. Location of subawardees should reflect the regional approach discussed in the Background section of this FOA. (See the Program Specific Instruction – Work Plan for more detail). Subaward agreements should be in place within six (6) months of award. Subawardees must demonstrate readiness to implement the activities outlined within this FOA. After the award is made, the awardee must take into consideration the location of the HRSA-funded Sickle Cell Disease Treatment Demonstration Program (SCDTDP) Regional Collaboratives awardees when selecting CBOs as subawardees. The selection process will be reviewed by MCHB.
4) Allocate and distribute at least 70 percent of the total award funding to the CBOs in at least 15 states for implementation of the program goals and requirements. The funds allocated to CBOs should cover travel costs to annual meetings and Quality Improvement (QI) trainings.
5) Provide guidance, expertise and technical assistance to CBOs including, but not limited to, the following:
    - conducting outreach to individuals and families;
    - developing partnerships with providers, hospitals and other care centers to facilitate referrals to patient and family-centered medical homes;
    - supporting the sharing of resources, data, and information on sickle cell education and referrals between CBOs; and
    - promoting individuals and families as partners in care.
6) Develop, disseminate and implement standards for the core competencies for sickle cell CHWs. In addition:
    - Train at least 150 CHWs to assist families with access to programs and services, health education, family-centered medial homes, and transition planning;
    - Assist CBOs with development of strategies to hire and sustain CHWs as an ongoing part of the sickle cell outreach portfolio. This should include working with CBOs to identify alternative and sustainable funding sources for CHWs and assisting CBOs with partnership development with state and local care and services entities.

7) Develop, lead, and support quality improvement (QI) projects. Support will consist of training CBOs in QI methodology, working with CBOs to participate in and implement QI projects, and using data to inform change. A centralized process to collect data from CBOs on a quarterly basis should be developed. QI projects should focus on the system of care for individuals with sickle cell disease and include:
    - newborn screening follow-up education and trait counseling for families;
    - participation in patient and family-centered medical home; and
    - transition[2] (e.g., from pediatric care to adult care, education to employment, and job readiness).
8) Develop and implement best practices for use by CBOs and CHWs to provide education and referrals to care by creating workgroups and learning communities that include participation from CBOs, CHWs and other experts. Topics for best practices may include:
    - Communication/Dissemination;
    - Connecting to a Patient Centered Medical Home;
    - Family Engagement; and
    - Sustainability.
9) Establish and maintain a publicly available online resource repository of evidence-based materials, articles and educational materials, and technical assistance materials for CBOs, patients, families, and the sickle cell community at large. The online repository should include at minimum the following:
    - Existing evidence-based materials, tools, resources, and technology for use by the CBOs (e.g., Got Transition materials, CDC Fact Sheets, CDC Living Well with Sickle Cell Disease Self-Management Toolkit, web-based decision aids, mobile apps, web-based educational tools, and online communities); and
    - Standards for CBOs and CHWs, best practices, white papers, and peer-review articles.
10) Form partnerships with various stakeholders including federal and non-federal organizations to address emerging issues related to sickle cell disease and sickle cell trait. Among these:
    - Work with the HRSA-funded Sickle Cell Disease Treatment Demonstration Project National Coordinating Center to align efforts between the two

[2] Health care transition is the process of changing from a pediatric to an adult model of health care. The goal of transition is to optimize health and assist youth in reaching their full potential. Achieving this goal requires an organized transition process to support youth in acquiring independent health care skills, preparing for an adult model of care, and transferring to new providers without disruption in care. Got Transition aims to improve transition from pediatric to adult health care through the use of new and innovative strategies for health professionals and youth and families. Accessed at: http://www.gottransition.org/

programs and to assist funded CBOs with developing working partnerships with HRSA-17-078[3] SCDTDP recipients to inform CBOs on clinical services available for patients and families identified through newborn screening.

- Selection of subawardees that should reflect a regional approach which considers the regions funded by the HRSA-17-078 SCDTDP.

11) Work with CBOs to establish common definitions, minimum dataset for shared measurement, data collection, program improvement and evaluation for data to conduct the Quality Improvement initiatives. Data should be collected by the CBOs at least quarterly and should be provided to the National Coordinating Center at least twice a year. You are expected to demonstration that you can develop and implement the data system within one year of award.
12) Support an annual in-person meeting of funded CBOs that includes at least two staff members per CBO.
13) Create a sustainability plan for the program, inclusive of sustainability strategies for your organization as the TAC continuing the provision of technical assistance to CBOs and for CBOs to continue education and support services for the sickle cell community and for the continuation of the use of CHWs after federal funding ends.

Community-Based Organizations (CBOs) supported through this initiative will be expected to implement the following activities:

1. Build partnerships with hospitals and health systems to facilitate referrals and access to family-centered medical homes;
2. Build partnerships with family organizations to support family leadership trainings, including partnerships with MCHB funded programs such as the Family-to-Family Health Information Centers;
3. When possible, build partnerships with state government agencies, such as the State Newborn Screening Program, to help facilitate and sustain activities;
4. Hire and sustain CHWs to assist individuals and families with sickle cell disease with access to programs and services; health education, patient and family-centered medical home, and transition; and
5. Provide access to programs for patients and families in three areas:
    a. Education of families of newly diagnosed individuals with sickle cell disease and sickle cell trait identified through universal newborn screening programs;
    b. Support for patients and families when engaging the education system and social support systems; and
    c. Transition to adulthood in respect to health care, work and social supports.
6. When possible, work with the HRSA-17-078 SCDTDP recipients to develop and disseminate educational information.

[3] HRSA-17-078 will be released this fiscal year, but is not yet available.

2. Background

This program is authorized by § 501(a) (2) of the Social Security Act as amended (42 U.S.C. 701(a) (2)).

Sickle Cell Disease

Sickle cell disease is an inherited red blood cell condition. In affected individuals, the abnormal red blood cells break easily and clog blood vessels to block blood flow to organs and tissues. This results in anemia, periodic pain episodes (at times severe), and ultimately can damage tissues and vital organs and lead to increased infections and early death. In the United States, sickle cell disease occurs most commonly among people of African ancestry (one in 400 African American births), but cases also occur in individuals of Mediterranean, Middle Eastern, and Indian background. It is estimated that more than two million individuals living in the United States are carriers or heterozygotes for sickle cell disease and over 100,000 have the disorder. Annually, approximately 1,000 newborns are identified with sickle cell disease through state newborn screening programs.

Early diagnosis of sickle cell disease is critical so that children who have the disorder can receive proper interventions. Newborn screening for sickle cell disease followed by health education, enrollment in comprehensive care, initiation of penicillin prophylaxis and anti-pneumococcal vaccination within the first two months of life can prevent death from severe infections. MCHB has long recognized the significance of early identification and treatment of sickle cell disease. In the mid-1960s, MCHB programs developed and disseminated sickle cell disease educational materials nationally. Following passage of the National Sickle Cell Anemia Control Act in 1972, MCHB, with initial funding from the National Institutes of Health (NIH), provided support for community-based sickle cell clinics to conduct testing, counseling, and education. In the mid-1980s, MCHB supported the development and implementation of state newborn screening programs for sickle cell disease. Currently, newborn screening for sickle cell disease occurs in every state. State newborn screening programs send abnormal results for sickle cell disease including for sickle cell trait to the pediatrician of record, who refers the family to a pediatric hematologist for immediate short-term follow-up treatment.

Sickle cell CBOs provide vital support services for families and persons with sickle cell disease outside of the health care or hospital setting. CBOs provide education on sickle cell disease, assist with navigating the health care system, and provide referrals to patient centered medical home, educational materials, transition and other community services. They provide services according to their individual missions and in the absence of national standards and best practices.

Definitions:
A **sickle cell CBO** is a community-based organization whose primary purpose is serving individuals with sickle cell disease and their families. A successful sickle cell CBO (1) provides health education and health promotion using evidence-based information for sickle cell and related issues; (2) develops partnerships with family organizations to ensure that families are empowered as partners in their care;

(3) assists families with obtaining educational and social support services; (4) assists with transition services; and (5) engages in activities that help ensure patients have access to services, including a medical home.

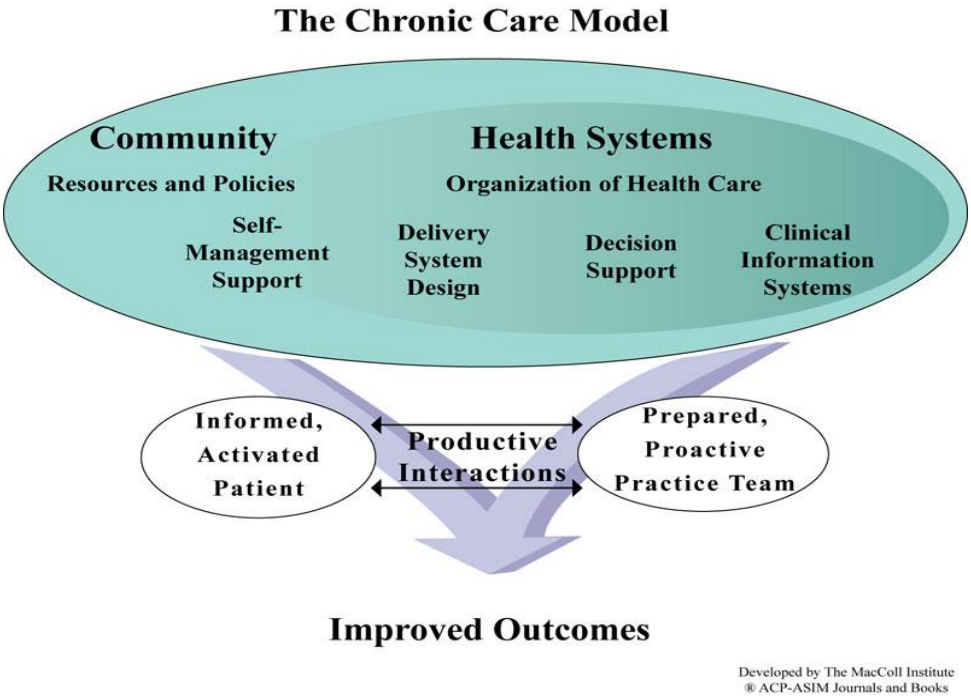
A **community health worker** is a lay health worker who is a trusted member of the community they serve and in many cases belongs to the community served. This enables CHWs to serve as a link between health and social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery. CHWs also build individual and community capacity by increasing knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy. For the purposes of this program, a sickle cell CHW is an individual who has successfully completed a CHW training program and has completed additional training in sickle cell disease.[4]

Sickle Cell Disease Treatment Demonstration Regional Collaboratives Program
If awarded this funding opportunity, you will be required to work closely with the HRSA-17-078 Sickle Cell Disease Treatment Demonstration Program (SCDTDP). The program aims 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 focus of the SCDTDP is to increase the number of providers treating sickle cell disease, while the focus of the SCDNBSFP is to provide education and referrals to individuals with sickle cell and trait identified through newborn screening and their families. In 2014, MCHB reorganized the SCDTDP and the SCDNBSFP into a regionalized approach that would allow the programs to serve more individuals with sickle cell disease.
You must work with CBOs to expand the use of CHWs as resources to improve patient awareness of sickle cell care, care coordination in a medical home and enhance the effective use of education and social support services. CBOs must be selected through a subaward selection process that reflects the regions funded by HRSA-17-078 SCDTDP. MCHB will provide guidance.

Chronic Care Model

As demonstrated by the Chronic Care Model in Exhibit 1, improved outcomes are achieved when informed patients actively establish productive relationships with knowledgeable providers in proactive clinical practice teams in a supportive health care system. By using the Chronic Care Model, SCDTDP recipients will be able to increase the number of knowledgeable providers treating patients with sickle cell and the SCDNBSFP through CBOs will provide the tools to patients and families so that they are empowered to be active partners in their care.

[4] American Public Health Association, 2008, https://www.apha.org/apha-communities/member-sections/community-health-workers.



Maternal and Child Health Bureau

MCHB is a component of HRSA within the U.S. Department of Health and Human Services (HHS). Since its inception, maternal and child health (MCH) services awards have provided a foundation for ensuring the health of our nation's mothers and children. The mission of MCHB is to provide national leadership in partnership with key stakeholders, to reduce disparities, assure availability of quality care, and strengthen the nation's MCH/public health infrastructure in order to improve the physical and mental health, safety and well-being of the MCH population.

The Division of Services for Children with Special Health Needs (DSCSHN)

With the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239 amended Title V of the Social Security Act to extend the authority and responsibility of MCHB to address the core elements of community-based systems of services for Children and Youth with Special Health Care Needs (CYSHCN) and their families. With this amendment, state Title V programs under the MCH Services Block Grant program were given the responsibility to provide and promote family-centered, community-based, coordinated care for CYSHCN and facilitate the development of community-based systems of services for such children and their families. CYSHCN are defined as "those children and youth who have or are at increased risk for chronic physical, developmental, behavioral or emotional conditions and who also require health and related services of a type or amount beyond that required by children generally."[5] According to the National Survey of Children with Special Health Care Needs (2009/2010), 15.1 percent of children under 18 years of age in the United States, or approximately 11.2 million children, are estimated to have special health care needs.

[5] Carman et al. (2013)

Overall, 23 percent of U.S. households with children have at least one child with special health care needs.

Through grant initiatives, DSCSHN works to achieve the following six critical systems outcomes:

1) Family/professional partnership at all levels of decision making.
2) Access to coordinated ongoing comprehensive care within a medical home.
3) Access to adequate private and/or public insurance and financing to pay for needed services.
4) Early and continuous screening for special health needs.
5) Organization of community services for easy use.
6) Youth transition to adult health care, work, and independence.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New, Competing Continuation

Funding will be provided in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

As a cooperative agreement, **HRSA Program involvement will include**:

- Participation, as appropriate, in meetings conducted during the period of the cooperative agreement;
- Ongoing review and approval of activities and procedures to be established and implemented for accomplishing the scope of work;
- Review of project information prior to dissemination;
- Review of information on project activities;
- Participation in disseminating project information;
- Working with the recipient to ensure that they are compliant and not duplicating the work of other MCHB-funded projects;
- Provision of information resources;
- Performing review and approval of substantive provisions of proposed subawards or contracts to ensure that such proposed subaward agreements are appropriate to program goals;
- Ensuring that HRSA and recipient are involved in collaboration or joint participation of efforts to obtain desired outcomes; and
- Agency monitoring to permit specified kinds of direction or redirection of the work, particularly because of interrelationships with other projects.

The cooperative agreement recipient's responsibilities will include:

- Adhering to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds (see Acknowledgement of Federal Funding in Section 2.2 of HRSA's *SF-424 Application Guide)*;
- Conducting all tasks as they relate to the goals, objectives and requirements listed under "Purpose;"
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the scope of work;
- Ongoing communication and collaboration with HRSA's MCHB, i.e., the MCHB Project Officer;
- Providing the MCHB Project Officer opportunities to review project information prior to dissemination;
- Working with the MCHB Project Officer to review information on project activities;
- Establishing contacts that may be relevant to the project's mission such as with federal and state agencies, Regional Genetics and Newborn Screening Collaboratives, the Newborn Screening Clearinghouse, the Newborn Screening Data Repository and Technical Assistance Center, Family Organizations such as the Family2Family Health Information Centers and the American Society of Hematology (ASH);
- Meeting deadlines for information and reports as required by the cooperative agreement;
- Working with the HRSA-17-078 Sickle Cell Disease Treatment Demonstration Program (SCDTDP) recipients and the Sickle Cell Disease National Coordinating Center (NCC),, and providing relevant information for the SCD Report to Congress; and,
- Arranging for and funding the reasonable logistical costs for at minimum one annual in-person meeting for all CBOs and staff.

2. Summary of Funding

Approximately $2,904,400 is expected to be available annually to fund one (1) recipient. You may apply for a ceiling amount of up to $2,904,400 per year. The actual amount available will not be determined until enactment of the final FY 2017 federal budget. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is June 1, 2017 through May 31, 2021 (four (4) years). Funding beyond the first year is dependent on the availability of appropriated funds for "SCDNBSFP" in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with this award are subject to the Uniform Guidance 2 CFR part 200 as codified by HHS at 45 CFR part 75, which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

The TAC must distribute at least 70 percent of the funds in the form of subaward agreements to at least 15 CBOs. Funding to the CBOs should also cover travel expenses.

III. Eligibility Information

1. Eligible Applicants

Per 42 CFR § 51a.3 (a), any public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 450b) is eligible to apply. Faith-based and community-based organizations are eligible to apply.

Foreign entities are not eligible for HRSA awards, unless the authorizing legislation specifically authorizes awards to foreign entities or the award is for research. This exception does not extend to research training awards or construction of research facilities.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this announcement.

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply for this FOA electronically through Grants.gov. You must download the SF-424 application package associated with this FOA following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the FOA to do otherwise.

See Section 8.5 of the *SF-424 Application Guide* for the Application Completeness Checklist.

Application Page Limit
The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments including biographical sketches (biosketches), and letters of commitment and support required in HRSA's *SF-424 Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit (Reminder: biographical sketches **do** count in the page limit). Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Where the prospective recipient is unable to attest to any of the statements in this certification, such prospective recipient shall attach an explanation to this proposal.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on this and other certifications.

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), please include the following:

i. *Project Abstract*
See Section 4.1.ix of HRSA's *SF-424 Application Guide*.

ii. *Project Narrative*
This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Use the following section headers for the Narrative:

- *INTRODUCTION -- Corresponds to Section V's Review Criterion 1 (Need)*
  Briefly describe the purpose of the proposed project. You should briefly discuss your appropriate expertise and understanding of the issues related to this program.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion 1 (Need)*
  Outline the needs of the sickle cell community. You must describe and document the population of newborns and children with sickle cell disease and sickle cell trait identified through newborn screening and the unmet health needs regarding community-based follow-up services available across the lifespan. In addition, describe the present roles of the CBOs in improving care for persons with sickle cell disease. Disparities based on race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions should be considered. You should also consider people with disabilities; non-English speaking populations; lesbian, gay, bisexual, and transgender populations; people with limited health literacy; or populations that may otherwise be overlooked when identifying the target population. Include socio-cultural determinants of health and health disparities impacting the population or communities served and unmet. You should also describe the extent to which patients have access to coordinated, integrated care in the context of a medical home model. Demographic data should be used and cited whenever possible to support the information provided. Please discuss any relevant barriers in the service area that the project hopes to overcome. This section should help reviewers understand the community and/or organization that will be served by the proposed project.

- *METHODOLOGY -- Corresponds to Section V's Review Criteria 2 (Response) and 4 (Impact)*
  Propose methods that will be used to address the stated needs and meet each of the previously described program requirements and expectations in this FOA. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families and communities of culturally, linguistically, socio-economically and geographically diverse backgrounds if applicable. If applicable, include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences.

Be sure to describe:

- Activities used to achieve each project goal, requirement, and objective.
- Methods for establishing a Technical Assistance Center to provide the following:
    - national expertise and technical assistance to CBOs on outreach to individuals and families, developing partnerships with hospitals and other care centers to facilitate referrals and access to patient and family-centered medical homes;
    - training to CHWs to assist individuals and families with access to programs and services, health education, family-centered medical homes, and transition planning;
    - sharing of resources, data, and information; and
    - promotion of individuals and families as partners in care.
- Methods for development of a formal procedure for conducting a process to establish subawards with CBOs within at least 15 states. Subaward agreements should be in place within six months of award. After an award is made, MCHB will review the proposed method for identifying subawards. The awardee will need to consider the location of subarwardees and how they correspond to the HRSA-17-078 SCDTDP regions during the selection process.
- Plans for using available information to establish national standards that explain the minimum roles and competencies for sickle cell CBOs and CHWs providing follow-up services for infants identified through newborn screening and their families.
- Plans to conduct national quality improvement (QI) activities for CBOs. Plans and methods to support CBO awardees to participate on national QI projects, focused on the system of community based supports for sickle cell patients and their families over the course of the project period, which should include: 1) improving education on sickle cell disease and trait and follow-up services for individuals who have been diagnosed with sickle cell disease and sickle cell trait through universal newborn screening programs, 2) increasing access to patient/family-centered medical home, and 3) improving transition activities (e.g., from pediatric care to adult care, education to employment, etc.).
- Plans to organize national working groups and learning communities with participating CBO leaders and key stakeholders that focus on topics such as: Quality Improvement; Communication & Dissemination; Patient Centered Medical Home; Family Engagement, and Sustainability.
- Plans to develop and maintain an online Resource Repository of evidence-based materials, articles and educational materials for CBOs, families, sickle cell community at large, and the public at large.
    - Methods to conduct an environmental scan of existing evidence-based materials, tools, resources and technology for use by the CBOs (e.g., Got Transition, CDC Fact Sheets, CDC Living Well with Sickle Cell Disease Self-Management Toolkit, web-based decision aids, mobile apps; web-based educational tools and online communities)

    - Plans to develop and disseminate evidence-based materials, standards, best practices, white papers, peer-review articles to the broader sickle cell community through and online repository.
    - Plans and methods to collaborate with HRSA-17-078 SCDTDP recipients develop educational materials based on the NHLBI sickle cell disease clinical care guidelines.
- Development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families and communities of culturally, linguistically, socio-economically and geographically diverse backgrounds if applicable. If applicable, include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences.
- Plans to support and fund an in-person annual meeting for all CBOs and staff.
- Plans and methods to assist CBOs in working with various stakeholders including HRSA-17-078 SCDTDP recipients to develop/disseminate educational information.

You must also propose a plan for project sustainability after the period of federal funding ends. Recipients are expected to sustain key elements of their projects, e.g., strategies or services and interventions, which have been effective in improving practices and those that have led to improved outcomes for the target population.

- *WORK PLAN -- Corresponds to Section V's Review Criteria 2 (Response)* Describe the activities or steps that will be used to achieve each of the activities proposed during the entire project period in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application and, further, the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversity of the populations and communities served.

  In your work plan you will be required to submit a detailed process for selecting subawardees as part of your application. This should include your criteria for selecting subawardees and any criteria you use to provide funding to the subawardees. Consistent with 45 CFR Part 75, describe a competitive process for making subawards within six months of the start date of this award.

  You must submit a logic model for designing and managing the project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this announcement, the logic model should summarize the connections between the:
  - Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable);
  - Assumptions (e.g., beliefs about how the program will work and is supporting resources. Assumptions should be based on research, best practices, and

experience.);
- Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources);
- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products or deliverables of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion2 (Response)*
  Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that will be used to resolve such challenges.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria 3 (Evaluative Measures), 4 (Impact), 5 (Resources/Capabilities), and*
  You must describe the plan for the program performance evaluation that will contribute to continuous QI. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities.
  - Explain how the goals will be measured.
  - Describe how the measures discussed previously in the FOA will be captured to demonstrate the impact of the SCDNBSFP
  - Propose intervals for these measurements throughout the term of the program
  - Explain how the data will be collected and used to inform program development and service delivery for the proposed project during the project period. Describe the methods that will be used to with the CBOs to establish common definitions and minimum dataset for shared measurement, data collection, program improvement and evaluation

  The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the project.
  You must describe the systems and processes that will support the organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g. assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze and track data to measure process and impact/outcomes, with different cultural groups (e.g., race, ethnicity, language) and explain how the data will be used to inform program development and service delivery. You must describe any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed.

In regards to the online resource repository, describe the technology capacity in place to develop, implement, and host an interactive and evidence-based designed data repository for easy utility.

Within the evaluation plan, you will be expected to provide data on how you are achieving the goals and objectives of the program and provide information on the following within the non-competing continuation report:

- Number and type of technical services provided to the Sickle Cell CBOs, CHWs, and staff.
- Number of CBO staff trained (See Program Objective 1)
- Number of QI activities
- Number of individuals engaged in NCC work groups/committees
- Number of individuals receiving care in a patient-centered medical home (see Program Objective 3)
- National QI project data
- CBOs should report:
    - Number of people served
    - Types of services provided
    - Number of partnerships

Note that data should be collected by the CBOs at least quarterly and should be provided to the TAC at least twice a year.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 2 (Response), 3 (Evaluative Measures), 5 (Resources/Capabilities), and 6 (Support Requested)*

  Provide information on the organization's current mission and structure, scope of current activities, and an organizational chart, and describe how these all contribute to the ability of the organization to conduct the program requirements and meet program expectations. Provide information on the program's resources and capabilities to support provision of culturally and linguistically competent and health literate services. Describe how the unique needs of target populations of the communities served are routinely assessed and improved.

  Provide a description of the organizational structure, the decision-making process and approaches that will be employed to work cooperatively with the CBOs and other partners and stakeholders. You should include an effective communication plan that ensures regular meetings amongst the TAC staff and the CBO Leadership. Describe responsibilities for collecting and analyzing data and how the results will be used. Provide a description of the organization's expertise on QI, including expertise on training QI methodology to CBOs and leading CBOs in QI activities.

NARRATIVE GUIDANCE

In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

Narrative Section	**Review Criteria**
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response and (4) Impact
Work Plan	(2) Response
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures (4) Impact (5) Resources/Capabilities
Organizational Information	(2) Response (3) Evaluative Measures (5) Resources/Capabilities (6) Support Requested
Budget and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. *Budget*

See Section 4.1.iv of HRSA's *SF-424 Application Guide*. Please note: the directions offered in the *SF-424 Application Guide* may differ from those offered by Grants.gov. Please follow the instructions included in the *Application Guide* and, *if applicable*, the additional budget instructions provided below.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a -HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

The Consolidated Appropriations Act, 2016, Division H, § 202, (P.L. 114-113) states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." Please see Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2017, as required by law.

iv. *Budget Narrative*

See Section 4.1.v. of HRSA's *SF-424 Application Guide*. In addition, the Sickle Cell Disease Newborn Screening Follow-Up Program requires the following:

The applicant should devote adequate resources to the CBOs, providing technical assistance to CBOs and conducting QI projects and this should be reflected in the budget. You are required to provide at least 70 percent of the total funds of the program to the CBOs through subaward agreements and this should be reflected in the Budget Narrative. Your organization is required to implement the subawards within six months of the start date.

v. *Program-Specific Forms*

1) Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects

HRSA has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant/cooperative agreement programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation. Performance measures for other MCHB-funded grant/cooperative agreement programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

1) Performance Measures for the National Hemophilia Program Coordinating Center

To inform successful applicants of their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found in Section "VI. Award Administration Information" of this FOA.

NOTE: The performance measures and data collection information is for your PLANNING USE ONLY. These forms are not to be included as part of this application.

vi. *Attachments*

Please provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Each attachment must be clearly labeled**.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative. Include the required logic model in this attachment.

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's *SF-424 Application Guide)*

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff.

Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the contractors and any deliverable. Letters of agreement must be dated.

Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project.

Attachment 6: Tables, Charts, etc.

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts, etc.).

Attachment 7: Summary Progress Report

ACCOMPLISHMENT SUMMARY (FOR COMPETING CONTINUATIONS ONLY)

A well-planned accomplishment summary can be of great value by providing a record of accomplishments. It is an important source of material for HRSA in preparing annual reports, planning programs, and communicating program specific accomplishments. The accomplishments of competing continuation applicants are carefully considered during the review process; therefore, you are

advised to include previously stated goals and objectives in the application and emphasize the progress made in attaining these goals and objectives. Because the Accomplishment Summary is considered when applications are reviewed and scored, **competing continuation applicants who do not include an Accomplishment Summary may not receive as high a score as applicants who do.** The Accomplishment Summary will be evaluated as part of Review Criterion *5: RESOURCES/CAPABILITIES*.

The accomplishment summary should be a brief presentation of the accomplishments, in relation to the objectives of the program during the current project period. The report should include:

(1) The period covered (dates).

(2) Specific Objectives - Briefly summarize the specific objectives of the project as actually funded.

(3) Results - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachments 8-15: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during an active federal award or an application or plan under consideration by an agency (unless you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d))**.**

HRSA may not make an award to an you until you have complied with all applicable DUNS and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that you are not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that it is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

For further details, see Section 3.1 of HRSA's *SF-424 Application Guide*.

Applicants that fail to allow ample time to complete registration with SAM or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date
The due date for applications under this FOA is *November 10, 2016 at 11:59 P.M. Eastern Time*.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The Sickle Cell Disease Newborn Screening Follow-Up Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a project period of up to four (4) years, at no more than $2,904,400 per year. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for the following purposes:

Foreign travel: Any foreign travel (using federal award dollars or program income) must be submitted to HRSA for approval through the Electronic Hand Book (EHB) under Prior Approval – Other.

The General Provisions in Division H of the Consolidated Appropriations Act, 2016 (P.L. 114-113) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in FY 2017, as required by law.

You are required to have the necessary policies, procedures and financial controls in place to ensure that the organization complies with the all federal funding requirements and prohibitions such as lobbying, gun control, abortion, etc. The effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which applications will be judged. Critical indicators have been developed for each review criterion to assist in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

These criteria are the basis upon which the reviewers will evaluate the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The Sickle Cell Disease Newborn Screening and Follow-Up Program has six (6) review criteria:

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Needs Assessment
The extent to which the application demonstrates the problem and associated contributing factors to the problem.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's Methodology, Work Plan and Resolution of Challenges
The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.
The extent to which the applicant describe an effective collaborative approach to:

- Establish a national infrastructure to support the work of the CBOs and to provide the following (4 Points):
    - national expertise and technical assistance to community-based organizations on outreach to individuals and developing partnerships with hospitals and other care centers to facilitate referrals and access to family-centered medical homes;
    - training to at least 150 CHWs to assist families with access to programs and services, health education, family-centered medical homes, and transition planning;
    - sharing of resources, data, and information; and
    - promotion of individuals and families as partners in care.
- Establish a formal procedure for conducting a subaward process to establish subawards with CBOs within at least 15 states and in place within six months of the start date. (3 Points)
- Use available information to establish national standards and describe the minimum roles and competencies for sickle cell CBOs and CHWs providing follow-up services for infants identified through newborn screening and their families. (3 Points)
- Develop plans and methods for coordinating and supporting national quality improvement (QI) projects to support CBO awardees to participate on national QI projects, focused on the system of community based supports for sickle cell patients and their families over the course of the project period, which should include: 1) improving education on follow-up services for individuals who have been diagnosed with sickle cell disease and sickle cell trait through universal newborn screening programs, 2) increasing access to patient centered medical home, and 3) improving transition activities (e.g., from pediatric care to adult care, education to employment, etc.). (3 Points)
- Develop plans to organize national working groups and learning communities with participating CBO leaders and key stakeholders that focus on topics such as: Quality Improvement; Communication & Dissemination; Patient/Family-Centered Medical Home; Family Engagement, and Sustainability. (3 Points)

- Develop and maintain an online resource repository of evidence-based materials, articles and educational materials for CBOs, families, sickle cell community at large, and the public at large. (3 Points)
    - Methods to conduct an environmental scan of existing evidence-based materials, tools, resources and technology for use by the CBOs (e.g., Got Transition, CDC Fact Sheets, CDC Living Well with Sickle Cell Disease Self-Management Toolkit, web-based decision aids, mobile apps; web-based educational tools and online communities)
    - Plans to develop and disseminate evidence-based materials, standards, best practices, white papers, peer-review articles to the broader sickle cell community through and online repository.
- Develop effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve individuals, families and communities of culturally, linguistically, socio-economically and geographically diverse backgrounds if applicable. If applicable, include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences. (3 Points)
- A sustainability plan for CBOs that sustains key elements of the project that improve practices and lead to improved outcomes for the target population. (3 Points)
- Partner with key stakeholders including federal and non-federal organizations to address emerging issues related to sickle cell disease and sickle cell trait. (3 Points)
- Develop plans and methods to assist CBOs in working with various stakeholders including HRSA-17-078 SCDTDP recipients to develop/disseminate educational information. (4 Points)
- Plans to support and fund an in-person annual meeting for all CBOs and staff. (3 Points)

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project. In addition, the extent to which the applicant:

- Provides an evaluation plan that monitors ongoing processes and the progress towards the goals and objectives of the award. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities. (4 points)
- Describes how the Program Objective data will be collected, analyzed, and tracked. (4 points)
- Provides methodology of how the quality improvement activities would be implemented and progress towards achieving QI project goals will be monitored and evaluated. (4 points)

- Describes the technology capacity in place to develop, implement, and host an interactive and evidence-based designed data repository for easy utility. (8 points)

Criterion 4: IMPACT (15 points) – Corresponds to Section IV's Methodology,

- The feasibility and effectiveness of plans for dissemination of project results, and scalability to a national effort. (5 Points)
- The extent to which project results may be national in scope and the degree to which the project activities are replicable, (5 Points)

The sustainability of the program beyond the federal funding. (5 Points)

Criterion 5: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity, and Organizational Information

- The extent to which project personnel are qualified by training and/or experience with sickle cell disease services and activities, technical assistance, quality improvement, capacity and infrastructure in place to implement and carry out the project. (5 points)
- The capabilities of the organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project. For this FOA, the applicant should demonstrate current capabilities of working with CBOs in multiple states and demonstrate their ability to lead a national program. For competing continuations, past performance will also be considered.(10 points)

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's Budget and Budget Narrative and Organizational Information

The reasonableness of the proposed budget for each year of the project period in relation to the objectives, the complexity of the research activities, and the anticipated results.

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

2. Review and Selection Process

The objective review provides advice to the individuals responsible for making award decisions. The highest ranked applications receive priority consideration for award within available funding. In addition to the ranking based on merit criteria, HRSA approving officials also may apply other factors in award selection, (e.g., geographical distribution), if specified below in this FOA. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

3. Assessment of Risk and Other Pre-Award Activities

The Health Resources and Services Administration may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

Applications receiving a favorable objective review that HRSA is considering for funding are also reviewed for other considerations. These may include, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. You may be asked to submit additional programmatic or grants information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that an award will be made. Following review of all applicable information, the HRSA approving official, in consultation with awarding agency program and grants staff, will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). Your organization may review and comment on any information about itself that a federal awarding agency previously entered. HRSA will consider any comments by your organization, in addition to other information in FAPIIS in making a judgment about your organizations integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by your organization as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

A determination that your organization is not qualified for a federal award will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of June 1, 2017.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of June 1, 2017. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2 of HRSA's *SF-424 Application Guide.*

Human Subjects Protection:
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, recipients must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

3. Reporting

On June 10, 2016, the Office of Management and Budget approved MCHB to collect new performance measures from recipients as part of its Discretionary Grant Information System (DGIS). The new performance measures reflects MCHB's strategic and priority areas including financial and demographic information, health domain and program-specific measures, and program-specific measures that highlight the unique characteristics of discretionary grant/cooperative agreement projects that are not already captured. Collectively, these data communicate the MCHB "story" to a broad range of stakeholders on the role of the Bureau in addressing the needs of maternal and child health populations. These performance data will also serve several purposes, including recipient monitoring, performance reporting, MCHB program planning, and the ability to demonstrate alignment between MCHB discretionary programs and the MCH Title V Block Grant program.

These new performance measures will allow a more accurate and detailed picture of the full scope of activities supported by MCHB-administered grant/cooperative agreement programs, while reducing the overall number of performance measures from what was previously used. The MCHB Project Officer will assign a subset of measures relevant to the program for which the recipient will report. In addition to reporting on the new performance measures, recipients will continue to provide financial and program data.

The new reporting package can be reviewed at: http://mchb.hrsa.gov/sites/default/files/mchb/Data/Discretionary_Grant_Information_System_Performance_Measure_Update.pdf.

New and continuing awards issued on or after October 1, 2016, will be required to report on the new measures. For successful competing continuation awards, recipients will report on their previous year activities (defined as those completed before October 1, 2016) using the forms and measures in DGIS as assigned in the previous FOA.

The successful applicant under this FOA must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

1) **Progress Report(s)**. The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.

2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.

3) **Performance Reports.** HRSA has modified its reporting requirements for SPRANS projects, CISS projects, and other grant/cooperative agreement programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation.

a) Performance Measures and Program Data
After the NoA is released, the Project Officer will inform grantees of the administrative forms and performances measures they must report.

b) Performance Reporting Timeline
Successful applicants receiving HRSA funds will be required, within 120 days of the Notice of Award (NoA), to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program-specific data forms that are required for this award. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other grant/cooperative agreement summary data as well as providing objectives for the performance measures.

c) Project Period End Performance Reporting
Successful applicants receiving HRSA funding will be required, within 90 days from the end of the project period, to electronically complete the program-specific data forms that appear for this program. The requirement includes providing expenditure data for the final year of the project period, the project

abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

4) **Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

VII. Agency Contacts

You may obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Djuana Gibson
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Room 10N
Rockville, MD 20857
Telephone: (301) 443-3243
Fax: (301) 443-6686
E-mail: dgibson@hrsa.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Edward Donnell Ivy, MD, MPH
Director of Hemoglobinopathies Programs
Genetic Services Branch
Division of Services for Children with Special Health Needs
Attn: Sickle Cell Newborn Screening Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18W
Rockville, MD 20857
Telephone: (301) 443-9775
Fax: (301) 480-1312
E-mail: eivy@hrsa.gov

You may need assistance when working online to submit application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
E-mail: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Telephone: (877) 464-4772
TTY: (877) 897-9910
Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Logic Models:

Additional information on developing logic models can be found at the following website: http://www.cdc.gov/eval/resources/.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. Information on how to distinguish between a logic model and work plan can be found at the following website: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance:

MCHB will host a pre-submission technical assistance conference call for all prospective applicants on Thursday, October 6, 2016. Call details are as follows:

Time: October 6 at 3:00pm Eastern Standard Time
Dial-in: 888-385-9734 ;Passcode: 9522161
Web link: https://hrsa.connectsolutions.com/scdnbsfp/

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's *SF-424 Application Guide*.