U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



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

Sickle Cell Disease Treatment Demonstration Program

Funding Opportunity Number: HRSA-21-032
Funding Opportunity Type(s): New, Competing Continuation
Assistance Listings (CFDA) Number: 93.365

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: May 3, 2021

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

Registration in all systems, including SAM.gov and Grants.gov,

may take up to 1 month to complete.

Issuance Date: February 23, 2021

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Authority: 42 USC § 300b-5(b) (§1106(b) of the Public Health Service Act)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2021 for the Sickle Cell Disease Treatment Demonstration Program (TDP). The purpose of the TDP is to increase access to quality, coordinated, comprehensive care for individuals with sickle cell disease by: 1) increasing the number of clinicians or health professionals knowledgeable about the care of SCD, 2) improving the quality of care provided to individuals with sickle cell disease, and 3) improving care coordination with other providers.

Funding Opportunity Title:	Sickle Cell Disease Treatment	
	Demonstration Program	
Funding Opportunity Number:	HRSA-21-032	
Due Date for Applications:	May 3, 2021	
Anticipated Total Annual Available FY 21 Funding:	\$5,000,000	
Estimated Number and Type of Award(s):	Up to five cooperative agreement(s)	
Estimated Award Amount:	Per year: Northeast - \$1,150,000 Southeast - \$1,150,000 Midwest - \$900,000 Heartland and Southwest - \$900,000 Pacific - \$900,000	
	Subject to the availability of appropriated funds.	
Cost Sharing/Match Required:	No	
Period of Performance:	September 1, 2021 through August 31, 2026 (5 years)	
Eligible Applicants:	A federally qualified health center, a nonprofit hospital or clinic, or a university health center that provides primary health care, that has a collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity with experience in working with individuals who have sickle cell disease; and has at least 5 years of experience in working with individuals who have sickle cell disease. See Section III.1 of this notice of funding	
	opportunity (NOFO) 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 NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Friday, March 19, 2021

Time: 2 p.m. - 3 p.m. ET

Call-In Number: 1-866-505-4412 Participant Code: 88987753

Weblink: https://hrsa.connectsolutions.com/hrsa21032/

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Sickle Cell Disease Treatment Demonstration Program (TDP). The purpose of the TDP is to increase access for individuals with sickle cell disease (SCD) to quality, coordinated, comprehensive care by: 1) increasing the number of clinicians or health professionals knowledgeable about the care of SCD, 2) improving the quality of care provided to individuals with SCD, and 3) improving care coordination with other providers.

Program Goals

HRSA funds a portfolio of three coordinated programs to improve outcomes of individuals with SCD and their families: the Sickle Cell Disease Newborn Screening Follow-up Program (HRSA-21-036), the Sickle Cell Disease Treatment Demonstration Program (HRSA-21-032), and the Hemoglobinopathies National Coordinating Center (funded by a contract). Together the programs strengthen the sickle cell disease system of care and support by: 1) educating patients, families and clinicians to improve knowledge and capacities; 2) linking individuals and families to evidence-based care; and 3) fostering partnerships between clinicians, community organizations and other stakeholders to improve the ability to deliver coordinated, comprehensive care across the lifespan.

The goal of the TDP is to improve outcomes of individuals with SCD and their families by developing and supporting a regional SCD infrastructure that includes components necessary for providing comprehensive services to individuals with SCD and their families. The successful recipient must collaborate with clinics/practices in at least seven (7) states within a single region in order to: develop and support comprehensive SCD care teams¹; implementation of telehealth technologies for health care delivery, education and health information services²; increased access to evidence-based care and the latest treatment options; and increased collaboration and care coordination within each region. One award will be made to a recipient providing such development and support in each of the five regions listed below, which have been programmatically designated as HRSA Sickle Cell Disease Regions.

- Northeast: Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont, District of Columbia, Delaware, Maryland, New York, New Jersey, Pennsylvania, Virginia, West Virginia, Virgin Islands and Puerto Rico
- 2. Southeast: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee

¹ Kanter J, Smith WR, Desai PC, et al. Building access to care in a dult sickle cell disease: defining models of care, essential components, and economic aspects. Blood Adv. 2020;4(16):3804-3813.

² Telehealth is defined as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications. https://www.hrsa.gov/rural-health/telehealth

- 3. Midwest: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, North Dakota, and South Dakota
- 4. Heartland and Southwest: Iowa, Missouri, Arkansas, Louisiana, Nebraska, Kansas, Oklahoma, and Texas
- 5. Pacific: New Mexico, Montana, Utah, Wyoming, Colorado, Alaska, Arizona, California, Hawaii, Idaho, Nevada, Oregon, and Washington

Per year, the recipient providing support to each region specified below will receive the following specified amounts:

Region	Award Amount	
Northeast	\$1,150,000	
Southeast	\$1,150,000	
Midwest	\$900,000	
Heartland and Southwest	\$900,000	
Pacific	\$900,000	

In addition, recipients of the TDP will work with the recipients of the Sickle Cell Disease Newborn Screening Follow-up Program (HRSA-21-036) and the Hemoglobinopathies National Coordinating Center to create synergies of efforts, reduce duplication and develop a Report to Congress.

Program Objectives

Each awardee will report annually on the following Program Objectives:

- By August 2022, establish a partnership (e.g., Memorandum of Understanding (MOU) or shared work plan) with the recipients of the Sickle Cell Disease Newborn Screening Follow-up Program (HRSA-21-036) within your region to develop an action plan to make services accessible to all individuals and families living with SCD within the region. Examples of activities that might be addressed by the plan include collaborating on:
 - Linking families to specialty SCD care;
 - Using telehealth to link individuals and families with education and support Identifying community-based services in the state and region;
 - Providing education, support, or disseminating resources through multiple vehicles: and/or
 - Linking to the state newborn screening program and/or the state Maternal and Child Health Services Block Grant Program.
- By August 2024, update the action plan described above.
- By August 2023, partner with organizations within at least seven states in your region to develop and implement a Sickle Cell Disease Regional/Organizational Action Plan to increase access to evidence-based care and treatments for individuals with sickle cell disease.³
- By August 2026, increase by 25 percent from baseline, the total number of providers⁴ in your region that are delivering evidence-based sickle cell disease care to patients as part of comprehensive care teams.

³ Recipients are expected to submit action plans in Year 2 and update the action plans in Year 4 of the project.

⁴ Providers may include hematologists, primary care physicians, advanced practice providers, social workers, nurse practitioners, behavioral health specialists and others.

- By August 2026, increase by 30 percent from baseline, the total number of individuals in your region receiving disease modifying therapies.
- By August 2026, increase by 25 percent from baseline, the number of patients receiving SCD care through telemedicine in your region.

Baseline data will be collected by March 2022. The regions will be expected to provide data annually (overall and by state) on how they are achieving the goals and objectives of the program.

2. Background

This program is authorized 42 USC 300b-5(b) (Public Health Service Act, Section 1106(b)). as added by the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention and Treatment Act of 2018 (P.L. 115-327). Sickle cell disease (SCD) is the most common inherited blood disorder in the United States (U.S.), affecting an estimated 100,000 individuals. This lifelong condition disproportionately affects Black (1 of every 365 births) and Hispanic Americans (1 of every 16,300 births with cases also occurring in individuals of Mediterranean, Middle Eastern and Asian descent. SCD causes the body to produce abnormal red blood cells that break forming a sickle shape impeding blood flow and causing anemia, severe pain, organ damage and other complications including reduced life expectancy. Early entry into evidence-based care improves health outcomes.

Over the past 40 years, life expectancy for individuals with SCD has increased significantly due to advances in evidence-based care⁶, including the availability of three U.S. Food and Drug Administration approved medications including hydroxyurea, crizanlizumab-tmca, and voxelotor. While newborn screening for SCD occurs in every state, there are still barriers to accessing comprehensive, high-quality care throughout the lifespan.⁷ Many individuals with SCD experience poor health outcomes resulting from barriers to accessing evidence-based care, new medications and therapies, education, care coordination, and other supports. Many individuals and families live far from SCD specialists and disproportionately access care through the emergency department. ⁸ During transition from the pediatric to adult health care system young adults frequently, experience an increase in adverse health events including premature death.⁹ In addition, discrimination and social determinants ¹⁰ of health negatively affect the health of individuals with SCD.⁸

⁵ Data and Statistics on Sickle Cell Disease. (2019). Centers for Disease Control and Prevention, Atlanta, GA.

⁶ https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease

⁷ Minkovitz CS, Grason H, Ruderman M, Casella JF. Newborn Screening Programs and Sickle Cell Disease: A Public Health Services and Systems Approach. Am J Prev Med. 2016;51(1 Suppl 1):S39-S47.

⁸ Mathur VA et al. Multiple levels of suffering: Discrimination in health-care settings is associated with enhanced laboratory pain sensitivity in sickle cell disease. Clin J Pain; 2016; 32:1076–1085.

⁹ Lanzkron S, Sawicki GS, Hassell KL, Konstan MW, Liem RI, McColley SA. Transition to adulthood and adult health care for patients with sickle cell disease or cystic fibrosis: Current practices and research priorities. J Clin Transl Sci. 2018;2(5):334-342.

¹⁰ What are social determinants of health? (2020). Centers for Disease Control and Prevention, Atlanta, GA.

Due to these challenges, there remains a critical need for comprehensive care for individuals with SCD. Comprehensive care must include a multidisciplinary, teambased approach that includes timely access to services. Models of care for SCD can vary from having dedicated, trained hematologists providing services (usually in an urban area) to extending the reach of hematologists via telehealth where care can be provided by a trained primary care provider. In September 2020, the National Academies of Sciences, Engineering, and Medicine released a report that included a blueprint and strategies to improve care for individuals with SCD. The report described the importance of collecting data to measure burden of disease, outcomes and needs of individuals with SCD; the need for organized systems of care to meet both clinical and social needs of individuals with SCD; and increase the number of qualified clinicians providing SCD care. 12

HRSA has funded the TDP since 2005 under section 712(c) of the American Jobs Creation Act of 2004, P.L.108-357, which authorized the TDP to improve the prevention and treatment of sickle cell disease, including by patient and provider education and coordinating service delivery for individuals with sickle cell disease. In this cycle, the TDP will build on previous funding cycles and advances in the field and support Healthy People 2030 SCD objective BDBS-2030-02 ¹³ by focusing on: building and supporting comprehensive sickle cell care teams; implementing telemedicine to reach individuals with sickle cell in rural areas; conducting Project ECHO ¹⁴ sessions to educate and train providers; increasing collaboration with the Sickle Cell Disease Newborn Screening and Follow-up program (HRSA-21-036) to strengthen patient and family engagement and increase educational opportunities for providers; and collaborating with the Hemoglobinopathies National Coordinating Center (HNCC) on data collection, developing a Report to Congress, and conducting quality improvement activities.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New and Competing Continuation.

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where HRSA anticipates substantial involvement with the recipient during performance of the contemplated project.

HRSA program involvement will include:

 Participating and collaborating in the planning, implementation, and evaluation of program activities under this cooperative agreement.

¹¹ Kanter J, Smith WR, Desai PC, et al. Building access to care in adult sickle cell disease: defining models of care, essential components, and economic aspects. Blood Adv. 2020;4(16):3804-3813.

¹² Addressing Sickle Cell Disease – A Strategic Plan and Blueprint for Action. The National Academies of Sciences, Engineering, and Medicine. (2020). https://www.nationalacademies.org/our-work/addressing-sickle-cell-disease-a-strategic-plan-and-blueprint-for-action#sectionPublications

¹³ https://www.healthypeople.gov/sites/default/files/ObjectivesPublicComment508.pdf

¹⁴ Project ECHO stands for Extension for Community Healthcare Outcomes and uses telehealth technology to train providers using practice-based learning. See https://hsc.unm.edu/echo/ for more information.

- Assessing and evaluating to determine program needs to meet the scope of work described in the NOFO on an ongoing basis.
- Reviewing information on project activities, reports, and any other product prior to dissemination as well as providing review of and advisory input for publications, audiovisuals, and other materials produced under the auspices of this cooperative agreement.
- Participating in the planning and scheduling of meetings and attending Project ECHO sessions (when appropriate) conducted during the period of the cooperative agreement.
- Participating in regular meetings and/or communications with the recipient to assess progress (at minimum monthly check-ins).
- Assisting the recipient in identifying and facilitating linkages with federal interagency and state contacts as necessary for the successful completion of tasks and activities identified in the approved scope of work.
- Participating in the design, direction, and evaluation of innovative activities.
- Facilitating efforts in the logistics related to the provision of technical support and training/education when needed.

The cooperative agreement recipient's responsibilities will include:

- Adhering to the process of planning, implementing, and evaluating program activities as outlined in this NOFO.
- Establishing monthly check-ins with HRSA Program staff, with increased frequency of meetings as needed.
- Responding in a timely and appropriate manner to requests by the HRSA project officer to collaborate on short-term, long-term and ongoing projects.
- Assuring sufficient staff to manage the expectations of this NOFO.
- Seeking HRSA project officer input prior to selecting and hiring new key project staff.
- Working closely with the HRSA project officer when developing, planning, and implementing new activities.
- Consulting with the HRSA project officer when scheduling any meetings that pertain to the scope of work and at which the HRSA project officer's attendance would be appropriate (as determined by the project officer).
- Providing the HRSA project officer with adequate time and opportunity to review, provide advisory input, and approve at the program level, any publications, audiovisuals, and other materials produced under the auspices of this cooperative agreement (such review should start as part of concept development and include review of drafts and final products).
- Providing the HRSA project officer with an electronic copy of, or electronic access to, each product developed under the auspices of this project.
- Ensuring that all products developed or produced, either partially or in full, under the auspices of this cooperative agreement are fully accessible and available for free to members of the public.
- Acknowledgement that the federal government, including HRSA/MCHB, has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use any products derived from activities conducted under this cooperative agreement.
- Collaborating and communicating with the HRSA Program staff and other key stakeholders.

- Participating in all HNCC led activities and workgroups.
- Supporting all related activities outlined in this NOFO.

2. Summary of Funding

HRSA estimates approximately \$5,000,000 to be available annually to fund five (5) recipients. You may apply for a ceiling amount predetermined for each region and the total cost includes both direct and indirect, facilities and administrative costs per year. Use the table below to determine the amount of funding you are allowed to apply for in your region:

Region	Award Amount	
Northeast	\$1,150,000	
Southeast	\$1,150,000	
Midwest	\$900,000	
Heartland and Southwest	\$900,000	
Pacific	\$900,000	

The period of performance is September 1, 2021 through August 31, 2026 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the Sickle Cell Disease Treatment Demonstration Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include a Federally-qualified health center, a nonprofit hospital or clinic, or a university health center that provides primary health care, that has a collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity with experience in working with individuals who have sickle cell disease; and demonstrates to the HRSA Administrator that either the federally-qualified health center, the nonprofit hospital or clinic, the university health center, the organization or entity described in clause (i) 42 USC § 300b-5, or experts as described in paragraph (2)(C) of 42 USC § 300b-5, has at least five (5) years of experience in working with individuals who have sickle cell disease. Federally-qualified health center is defined in section 1905(I)(2)(B) of the Social Security Act (42 U.S.C. 1396d(I)(2)(B)).

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

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 electronically. HRSA encourages you to apply through <u>Grants.gov</u> using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.

2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> 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 <u>SF-424 Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the Application Guide for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files included in the page limit may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit.

Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-032, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit. Any application exceeding the page limit of 80 will not be read, evaluated or considered for funding.

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).
- 3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 9: Other Relevant Documents*.

See Section 4.1 viii of HRSA's <u>SF-424 Application Guide</u> for additional information on all certifications.

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of the Department of Health and Human Services (HHS) with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness (ASPR) website via

http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), ensure details related to the following activities are included:

Infrastructure and Capacity Building

• Develop and support regional and state SCD network infrastructure.

- Develop and implement Regional/State/Organizational Action Plans and update at least once every 2 years.
- Collaborate with organizations in at least seven (7) states within the region to address SCD treatment and services.
- Establish partnerships and/or contracts as appropriate with academic institutions, health systems, public health entities, etc., to coordinate access to services.
- Establish SCD care teams within the region in order to provide comprehensive services to individuals with SCD.
- Engage individuals and families living with SCD in all aspects of the project including planning, implementation and monitoring.
- Implement telehealth to provide evidence-based care to individuals with SCD especially those who live in rural areas.

Collaboration and Partnerships

- Collaborate with recipients of the Sickle Cell Disease Newborn Screening Follow-up Program (HRSA-21-036) to develop, implement, and update an action plan to make community based services accessible to all individuals and families living with SCD within the state.
 - Establish Memoranda of Understanding/Memoranda of Agreement with recipients funded by the Sickle Cell Disease Newborn Screening Follow-up program (HRSA-21-036).
 - Collaborate and coordinate with HRSA-21-036 funding recipients on patient service referrals, and patient, health professional, and community education.
- Participate in HNCC activities including:
 - Serving on the National SCD Steering Committee (Steering Committee) and Regional Workgroups to develop and implement strategies that improve access to evidence-based SCD care nationally and within participating states/regions. Steering Committee/Workgroup activities will address priorities identified in the TDP Action Plans and other emerging needs at the national, regional, and state levels.
 - Participating in the HNCC-led quality improvement activities to identify best and promising practices and innovative strategies on topics including:
 - Current therapies and treatments, including hydroxyurea
 - Transcranial Doppler
 - Vaccinations
 - Transition from pediatric to adult care
 - Prevention of SCD complications
 - Behavioral health
 - Providing comprehensive, wrap-around services
 - Collaborating with the HNCC to evaluate program activities, including collecting regional data, aggregated data on objectives and performance measures, and submitting all data to the HNCC.
 - o Partnering with the HNCC to develop a Report to Congress, Model Protocol and Compendium of Resources.
 - o Attending annual grantee meetings hosted by the HNCC.

Education

- Collaborate with the American Society for Hematology, Pediatric Emergency Care Applied Research Network, and Patient-Centered Outcomes Research Institute in order to align quality improvement activities.
- Establish and support Project ECHO sessions to educate and train providers on evidence-based care and the latest disease-modifying therapies.
- Develop and widely disseminate provider educational tools and materials describing evidence-based guidelines in coordination with the HNCC.
- Develop educational resources (e.g., tools, toolkits, webinars, fact sheets, issues briefs, and other publications) for providers that make up a SCD care team to increase their ability to provide comprehensive services.
- Establish communication strategies to share information, successes, and barriers throughout the region.
- Convene an annual regional meeting of CBOs, partners, stakeholders, and SCD experts within the region.

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, consistent with forms and attachments, and well-organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please 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.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion 1 Need Outline the needs of individuals living with SCD in your region. Describe and document the target communities and/or populations and its unmet health needs. Provide an estimate of the SCD prevalence in your region. Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers in the service area that the project hopes to overcome. This section will help reviewers understand the communities/populations that you will serve with the proposed project.
- METHODOLOGY -- Corresponds to Section V's Review Criterion 2 Response
 Propose methods that you will use to address the stated needs and meet each of
 the previously described program requirements and expectations in this NOFO
 under Purpose and Program-Specific Instructions. 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. If applicable, include a plan
 to disseminate reports, products, and/or project outputs so key target audiences
 receive the project information.

Describe a plan to support a regional infrastructure of comprehensive SCD services. Provide an overview of how you will collaborate with organizations in at least seven (7) states within the region to address SCD treatment and services. Describe how you will establish partnerships and/or contracts as appropriate with academic institutions, health systems, public health entities, etc. to coordinate access to services and comprehensive care teams.

Describe how you will collaborate with recipients of the Sickle Cell Disease Newborn Screening Follow-up program (HRSA-21-036) and develop and implement a plan to make CBOs services accessible to all individuals and families living with SCD within the state.

In addition, describe a plan that trains providers in order to create a SCD care team that provides comprehensive services. Describe how health care providers such as hematologists, primary care providers, advanced practice providers, and other service providers will be recruited to participate in comprehensive SCD care teams.

Include a description of any innovative methods that you will use to address the stated needs.

Propose a plan for project sustainability after the period of federal funding ends. HRSA expects recipients 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 and 4 Impact

Work Plan

Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance 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 developing the application.

Logic Models

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 notice, the logic model should summarize the connections between the:

- Goals of the project (e.g., reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.);
- Inputs (e.g., organizational profile, collaborative partners, key personnel,

- 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 of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

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. You can find additional information on developing logic models at the following website:

https://www.acf.hhs.gov/archive/ana/training-technical-assistance/ana/resource/ana/resource/logic-model-template.

RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion
 Response

Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges. Specifically address how you will overcome barriers in identifying individuals with SCD living in rural areas and providing comprehensive services.

EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion 3 <u>Evaluative Measures</u> and 5 <u>Resources/Capabilities</u> Describe the plan for the program performance evaluation that will contribute to continuous quality improvement. 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 personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

Describe the systems and processes that will support your 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, and explain how the data will be used to inform program development and service delivery. Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

Within the proposed evaluation plan keep in mind that the following should also be tracked and reported in the annual progress report during the period of performance:

• Number of patients seen by TDP providers and receiving evidence-based

care including:

- o Current therapies and treatments including Hydroxyurea
- Transcranial Doppler
- Vaccinations
- Transition from pediatric to adult care
- Total number of patients seen within a SCD care team
- Number of Project ECHO sessions held by the region
- Number of providers participating in Project ECHO sessions held by region
- Percent of youth ages 12-26 that have a transition plan with a participating provider using nationally recognized best practices.
- Number of both formal and informal partnerships developed with entities including CBOs, primary care providers, and Federally Qualified Health Centers.
- Number of states within the region with a state action plan.
- Number of SCD patients seen through telemedicine.

In addition, recipients will be responsible to work with the HNCC and the recipients of the Sickle Cell Disease Newborn Screening Follow-up Program (HRSA-21-036) and address the following performance measures:

- By 2026, infants with a confirmed diagnosis of SCD from newborn screening will have been seen by a knowledgeable SCD provider by two months of age.
- By 2026, infants who are identified with possible SCD from newborn screening will have a primary care medical home by two months of age.
- ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 5 Resources/Capabilities

Succinctly describe your organization's current mission, structure, and scope of current activities, and how these elements all contribute to the organization's ability to implement the program requirements and meet program expectations. Include an organizational chart. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings. Describe how you will routinely assess and improve the unique needs of target populations of the communities served.

iii. Budget

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u> and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and, by carefully following the approved plan, may avoid audit issues during the implementation phase.

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

In addition, the Sickle Cell Disease Treatment Demonstration program requires the following:

At least 40 percent of the total awarded funding must be allocated to support the partner organizations within at least seven states.

The Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 202 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." See Section 4.1.iv Budget – Salary Limitation of HRSA's <u>SF-424 Application Guide</u> for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. Budget Narrative

See Section 4.1.v. of HRSA's <u>SF-424 Application Guide</u>.

In addition, the Sickle Cell Disease Treatment Demonstration program requires the following:

At least 40 percent of the total awarded funding must be allocated to support the partner organizations within at least seven states.

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. Attachments

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. **Clearly label each attachment**.

Attachment 1: Work Plan and Logic Plan

Attach the work plan for the project that includes all information detailed in <u>Section IV.2.ii. Project Narrative</u>. Also include the required logic model in this attachment. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

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. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

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 not yet hired, include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement, Memoranda of Understanding, 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 or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are signed and 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).

Attachment 7: For Multi-Year Budgets--5th Year Budget

After using columns (1) through (4) of the SF-424A Section B for a 5-year period of performance, you will need to submit the budget for the 5th year as an attachment. Use the SF-424A Section B, which does not count in the page limit:

however, any related budget narrative does count. See Section 4.1.iv of HRSA's SF-424 Application Guide.

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 Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. In April 2022, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following pages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed 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 the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

*Currently, the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- 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 <u>SF-424 Application Guide</u>.

<u>SAM.GOV</u> ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you 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 NOFO is *May 3, 2021 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 Application Guide</u> for additional information.

5. Intergovernmental Review

The Sickle Cell Disease Treatment Demonstration 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 period of performance of up to 5 years, at no more than the funding limits set for each region per year (inclusive of direct **and** indirect costs). 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.

The General Provisions in Division H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) 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 the following fiscal years, as required by.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all

other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

Be aware of the requirements for HRSA recipients and subrecipients at 2 CFR § 200.216 regarding prohibition on certain telecommunications and video surveillance services or equipment. For details, see the HRSA Grants Policy Bulletin Number: 2021-01E.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

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

Review criteria are used to review and rank applications. The Sickle Cell Disease Treatment Demonstration Program has six (6) review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's <u>Introduction</u> and <u>Needs</u>
Assessment

The clarity with which the applicant describes the problem and associated contributing factors and supports the problem/need statement with data/statistics, references, and expert views.

This includes the extent to which the application:

- Documents the SCD population within the region and existing SCD medical care, support services and other resources.
- Documents the needs of the SCD population and barriers to accessing evidencebased SCD care, high quality support services and other resources.
- Discusses relevant barriers and gaps in SCD support services and linkages to evidence-based SCD care that this project aims to address.

Criterion 2: RESPONSE (40 points) – Corresponds to Section IV's <u>Methodology</u>, <u>Work</u> <u>Plan</u>, and <u>Resolution of Challenges</u>

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.

Methodology (20 Points)

The strength, completeness, and feasibility of the applicant's approach to addressing the purpose, objectives, program requirements and expectations in this NOFO and under Purpose and Program-Specific Instructions including:

- Supporting a regional infrastructure of SCD services; collaborating with
 organizations in at least seven (7) states within the region to address SCD treatment
 and services; establishing partnerships and/or contracts as appropriate with
 academic institutions, health systems, public health entities, etc. to coordinate
 access to services particularly with underserved populations in rural areas.
- Collaborating with recipients of the Sickle Cell Disease Newborn Screening Followup program (HRSA-21-036); developing and implementing a plan to make CBOs services accessible to all individuals and families living with SCD within the state.
- Recruiting and training providers in order to create a SCD care team that provides comprehensive services.
- Using innovative methods to address the stated needs.
- Developing a plan for project sustainability after the period of federal funding ends.
- Sustaining 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 and Logic Model (10 points)

- The coherence between and completeness of activities or steps that will be used to achieve each of the corresponding objectives proposed in the methodology section.
- The extent to which the application identifies meaningful support and collaboration with key stakeholders in planning, designing, and implementing activities.
- The clarity and completeness of the logic model, demonstrating a clear relationship among resources, activities, outputs, target population, short-term outcomes, and long-term outcomes.

Resolution of Challenges (10 points)

• The thoroughness with which the application discusses potential challenges and the feasibility of proposed approaches to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity

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, 2) to what extent these can be attributed

to the project, and 3) the capability of the applicant to collect and report on Program Objectives and data specified under the Evaluation and Technical Support Capacity section.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Work Plan
The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include: the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

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 to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Budget and Budget Narrative

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives 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 process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for award. See Section 5.3 of HRSA's <u>SF-424 Application Guide</u> for more details.

3. Assessment of Risk

HRSA 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).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional

programmatic or administrative 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 HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, 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.

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

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 CFR § 75.212).

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2021. See Section 5.4 of HRSA's <u>SF-424 Application Guide</u> for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 Application Guide.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Requirements of Subawards

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability for more details.

Data Rights

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

Human Subjects Protection

Federal regulations (<u>45 CFR part 46</u>) 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 you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 Application Guide</u> and the following reporting and review activities:

1) DGIS Performance Reports. Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report annually, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants4.hrsa.gov/DGISReview/FormAssignmentList/U1e.html. The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	September 1, 2021 – August 31, 2026 (administrative data and performance measure projections, as applicable)	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	September 1, 2021 – August 31, 2022 September 1, 2022 – August 31, 2023 September 1, 2023 – August 31, 2024 September 1, 2024 – August 31, 2025	Beginning of each budget period (Years 2–5, as applicable)	120 days from the available date
c) Project Period End Performance Report	September 1, 2025 – August 31,2026	Period of performance end date	90 days from the available date

The full OMB-approved reporting package is accessible at https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (OMB Number: 0915-0298 | Expiration Date: 06/30/2022).

- 2) **Progress Report(s)**. The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year). Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.
- Integrity and Performance Reporting. The NOA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR part 75</u> Appendix XII.

Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at <u>2 CFR § 200.340 - Termination</u> apply to all federal awards effective August 13, 2020.

VII. Agency Contacts

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

David Colwander
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857

Telephone: (301) 443-7858 Email: <u>DColwander@hrsa.gov</u>

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Alisha S. Keehn, MPA
Branch Chief, Genetic Services Branch
Attn: Sickle Cell Disease Treatment Demonstration Program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 945-4817

Email: akeehn@hrsa.gov

You may need assistance when working online to submit your 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, 7 days a week, excluding key staff holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: 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 the EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 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

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Friday, March 19, 2021

Time: 2 p.m. – 3 p.m. ET

Call-In Number: 1-866-505-4412 Participant Code: 88987753

Weblink: https://hrsa.connectsolutions.com/hrsa21032/

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

Tips for Writing a Strong Application

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