

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

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

Thalassemia Program

Funding Opportunity Number: HRSA-21-035
Funding Opportunity Type(s): Competing Continuation, New
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: December 21, 2020

*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: September 21, 2020

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 Thalassemia Program. The goal of this program is to improve access to evidence-informed care for individuals with thalassemia. HRSA will support three awards for Thalassemia Regional Program (**Project 1**) recipients to establish regional infrastructures to increase the number of providers treating or co-managing individuals with thalassemia in their communities. The program will also support one award for the Thalassemia National Coordinating Program (**Project 2**) recipient to coordinate telementoring and educational initiatives across the regions and to improve knowledge of thalassemia and evidence-informed treatment recommendations among individuals with thalassemia and their families. You may only apply for either Project 1 or Project 2.

Funding Opportunity Title:	Thalassemia Program
Funding Opportunity Number:	HRSA-21-035
Due Date for Applications:	December 21, 2020
Anticipated Total Annual Available FY 2021 Funding:	<u>Total Annual Funding: \$600,000</u> Project 1: Thalassemia Regional Program: \$525,000 Project 2: Thalassemia National Coordinating Program: \$75,000
Estimated Number and Type of Award(s):	<u>Total Number: Four (4)</u> Project 1: Three (3) cooperative agreements Project 2: One (1) cooperative agreement
Estimated Award Amount:	Project 1: Up to \$175,000 per year Project 2: Up to \$75,000 per year Subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	June 1, 2021 through May 31, 2026 (5 years)

Eligible Applicants:	<p>Any domestic 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. See 42 CFR § 51a.3(a). Domestic faith-based and community-based organizations are eligible to apply.</p> <p>See Section III.1 of this notice of funding opportunity (NOFO) for complete eligibility information.</p>
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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: Thursday, November 12, 2020

Time: 2–3 p.m. ET

Call-In Number: 1-866-880-0834

Participant Code: 23996302

Weblink: <https://hrsa.connectsolutions.com/21035>

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 FY 2021 Thalassemia Program. This program is comprised of two projects – Project 1 is the Thalassemia Regional Program and Project 2 is the Thalassemia National Coordinating Program. The purpose of Project 1 is to have three recipients support a regional infrastructure to increase the number of providers treating or co-managing individuals with thalassemia in their communities. The purpose of Project 2 is to coordinate telementoring and educational initiatives across the regions and to improve knowledge of thalassemia and evidence-informed treatment recommendations among patients and families.

Program Goal:

The goal of the Thalassemia Program is to improve access to evidence-informed care for individuals living with thalassemia and their families. The program will do this by funding the **two** projects detailed below. You may only apply for Project 1 **or** Project 2 but not both projects.

Project 1: Thalassemia Regional Program

Up to three recipients will be funded for Project 1. HRSA will fund one application per region, and recipients will support activities in at least two states, including Washington DC or Puerto Rico, within the region in addition to the recipient's state. The three HRSA Thalassemia regions are:

- Western Region: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.
- Central Region: Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Texas, and Wisconsin.
- Eastern Region: Alabama, Connecticut, Delaware, Florida, Georgia, Kentucky, Maine, Maryland, Massachusetts, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, Washington DC, and West Virginia.

Each recipient is responsible for identifying and establishing a network of hematologists and other providers in a minimum of three states in the region. The goal is to extend the reach of the limited number of experts through telementoring, telemedicine, and other strategies in collaboration with the Thalassemia National Coordinating Program (see below). In collaboration with the Thalassemia National Coordinating Program, recipients will provide ongoing education on evidence-informed diagnostic/treatment guidelines and best practices for disease management¹ to hematologists and health care providers who see individuals with thalassemia. Recipients will also collaborate with the

¹ Vichinsky E, Levine E et al. *Standards of Care Guidelines for Thalassemia*. Oakland, California: Children's Hospital & Research Center Oakland.

Thalassemia National Coordinating Program to inform patients and families on evidence-informed treatment recommendations.

Project 2: Thalassemia National Coordinating Program

One recipient will be funded for Project 2 to support activities that improve the quality of care available to individuals living with thalassemia. This includes helping regions coordinate regional telementoring activities, and recruit hematologists and other health care providers to manage or co-manage individuals with thalassemia to reduce duplication. The Thalassemia National Coordinating Program will provide education and information to individuals and families on evidence-informed treatment. Project 2 will enhance coordination across the regions and increase the program's ability to respond to emerging needs in the field and among recipients.

Program Objectives:

Project 1: Each regional recipient will:

- By May 2026, serve a minimum of 420 individuals with thalassemia.
- By May 2026, increase by 25 percent from baseline the number of individuals with transfusion dependent thalassemia served.
- By May 2026, increase by 20 percent from baseline the number of health care providers receiving education or training on evidence-based/evidence-informed guidelines for thalassemia treatment.
- By May 2026, increase by 25 percent from baseline the number of health care providers who report the utilization of evidence-informed guidelines to treat individuals with thalassemia.

Project 2:

- By May 2026, increase by 20 percent from baseline the number of individuals with thalassemia or their families that access information on thalassemia and links to services and resources.
- By May 2026, in collaboration with the regional recipients, increase by 20 percent from baseline the number of health care providers receiving education or training on evidence-based/evidence-informed guidelines for thalassemia treatment.

If you are a competing continuation applicant for Project 1, use baseline data for the last year of the current (i.e., immediately preceding) project to establish the new benchmark for the objectives listed above. If you are a new applicant, you will collect and provide baseline data to HRSA to establish the benchmark for the objectives listed above by the end of year 1 of the award.

Program Priorities:

- 1) Support a regional infrastructure for the thalassemia health care delivery system (Project 1).
- 2) Engage patients and families^{2,3} and provide resources on evidence-informed

² [Guide to Patient and Family Engagement in Hospital Quality and Safety](#). (2017). Agency for Healthcare Research and Quality, Rockville, MD.

³ Marbell, P. (2017). Engaging Families in Improving the Healthcare System for Children with Special Healthcare Needs. Lucile Packard Foundation for Children's Health.

treatment options for individuals with thalassemia, families, and other stakeholders (Project 1 *and* Project 2).

- 3) Educate providers on various treatment options and standards of care⁴ using telementoring tools (Project 1 *and* Project 2).⁵

2. Background

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

Thalassemia, which primarily affects individuals of Asian, Mediterranean, and Middle Eastern decent, is a group of inherited blood disorders that inhibits the body's ability to produce sufficient hemoglobin.⁶ Individuals with the most severe forms of thalassemia require frequent blood transfusions and ongoing monitoring and management of complications such as heart failure and liver disease. Complications and lack of proper management could lead to organ failure and early death. Although there are no national estimates on the prevalence of Thalassemia, California has identified that 1 in 10,000 infants born in the state are diagnosed with some form of alpha-thalassemia.⁷ Due to immigration, prevalence of thalassemia may be higher.⁸

Many thalassemia patients and their families face barriers accessing high quality treatment. Primary care providers treat thalassemia infrequently and may not have a regular referral connection for when patients are identified as having thalassemia. The majority of thalassemia experts are located in a limited number of academic medical centers. This results in incomplete and inconsistent management of the disease.⁴

HRSA has funded the Thalassemia Program since 2015 to improve access to evidence-informed care for patients, including those who are transfusion dependent and considered to have the most severe forms of the disease. This funding opportunity will build upon the activities undertaken during the previous funding cycle but will promote a more even distribution of access to expert thalassemia care by funding one recipient in each defined region and thereby extending the reach of a limited number of experts. Additionally, the Thalassemia National Coordinating Program will create efficiencies and reduce duplication across regional activities as well as be able to respond to national, emerging issues.

⁴Vichinsky E, Levine E et al. Standards of Care Guidelines for Thalassemia. Oakland, California: Children's Hospital & Research Center Oakland.

⁵ Office of the Assistant Secretary for Planning and Evaluation (ASPE). A Report to Congress on the Current State of Technology-Enabled Collaborative Learning and Capacity Building Models. Retrieved 7/28/2020 from <https://aspe.hhs.gov/pdf-report/report-congress-current-state-technology-enabled-collaborative-learning-and-capacity-building-models>

⁶ What is Thalassemia? CDC. Retrieved 10/22/2019 from <https://www.cdc.gov/ncbddd/thalassemia/facts.html>

⁷ Hoppe CC. (2013). Prenatal and Newborn Screening for Hemoglobinopathies. Int J Lab Hematol; 35:297–305.

⁸ Sayani F, Kwiatkowski J. (2015). Increasing Prevalence of Thalassemia in America: Implications for Primary Care. Annals of Medicine 47:7, 592-604.

II. Award Information

1. Type of Application and Award

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

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.

The involvement and responsibilities below apply to both **Project 1 and Project 2**, unless otherwise noted.

HRSA program involvement will include:

- Participating in meetings conducted during the period of the cooperative agreement;
- Collaborating with recipients in developing activities and procedures to be established and implemented for accomplishing the goals and objectives of the project;
- Reviewing information on project activities, reports, and products prior to dissemination;
- Participating in dissemination of project information;
- Providing assistance in establishing and facilitating effective collaborative relationships with federal and state agencies, and especially HRSA MCHB award projects; and
- Providing technical assistance and support to recipients to ensure they are compliant with NOFO requirements and do not duplicate the work of other HRSA-funded projects.

The cooperative agreement recipient's responsibilities will include:

- Conducting all tasks as they relate to the goals and activities of the Thalassemia Program listed in the "[Purpose](#)" section (under I. Program Funding Opportunity Description) and in the "Methodology" section (under IV. Application and Submission Information, 2. Content and Form of Application, ii. Program Narrative) of this notice of funding opportunity (NOFO);
- **Project 1:** Establishing a steering committee comprised of hematologists, health care providers, patients/families, and other key stakeholders.
- Collaborate with all recipients participating in Project 1 and Project 2;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the program's goals, objectives, and activities;
- Providing ongoing, timely communication and collaboration with the federal project officer;
- Working with the federal project officer to review information on program activities, reports, and products prior to dissemination;
- Establishing contacts that may be relevant to the project's mission;
- Facilitating partnerships with federal and non-federal entities and other HRSA-funded programs relevant to the program activities; and

- Meeting deadlines for information requests and reports as required by HRSA.

2. Summary of Funding

HRSA estimates approximately \$600,000 to be available annually. The actual amount available will not be determined until enactment of the final FY 2021 federal appropriation.

Project 1: Thalassemia Regional Program has approximately \$525,000 to fund three (3) recipients. For this project, you may apply for a ceiling amount of up to \$175,000 total cost (includes both direct and indirect, facilities and administrative costs) per year.

Project 2: Thalassemia National Coordinating Program has approximately \$75,000 to fund one (1) recipient. For this project, you may apply for a ceiling amount of up to \$75,000 total cost (includes both direct and indirect, facilities and administrative costs) per year.

This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. The period of performance is June 1, 2021 through May 31, 2026 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the Thalassemia 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 domestic public or private entities, including Indian tribes or tribal organizations (as those terms are defined at 25 U.S.C. § 450b). See 42 CFR § 51a.3(a). Domestic faith-based and community-based organizations are eligible to apply.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

You must clearly state which project you are applying for in the application. You may not apply for funding as a recipient under both **Project 1 and Project 2**. If you apply for funding under both projects, your applications will be considered non-responsive and will not be considered for funding under this NOFO. In addition, HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

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 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 [Grants.gov](#) using the SF-424 workspace application package associated with this 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 [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 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 **60 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-21-035, 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.**

Applications must be complete, within the 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

- 1) 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 8: Other Relevant Documents*.

See Section 4.1 viii of HRSA's [SF-424 Application Guide](#) for additional information on all 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), include the following:

i. Project Abstract

Clearly state which project you are applying for. 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](#)
State which project you are applying for. Briefly describe the purpose of the proposed project, the methods to be used, and the projected outcomes.
- **NEEDS ASSESSMENT** -- Corresponds to Section V's Review Criterion [\(1\) Need](#)
Outline the needs of the community. Describe and document the target population and its unmet health needs. Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers experienced by

individuals with thalassemia, families, and providers who care for patients with thalassemia. This section will help reviewers understand the community and/or organization that you will serve with the proposed project. Be sure to describe the following:

Project 1:

- The prevalence of thalassemia within the [region](#), target population, unmet health needs, and barriers to receiving education or training on evidence-based/evidence-informed guidelines for thalassemia treatment.
- How individuals with thalassemia in the region access hematology care and treatment. Specifically describe access to university hospitals and medical centers with hematologists and other specialty clinicians that treat thalassemia and primary care providers within the region.
- The status of available thalassemia treatment options, level of clinician experience throughout the region and access to facilities (e.g., MRI T2* testing, etc.) that support implementation of expert recommended and evidence-informed thalassemia care.
- The three states (your state plus two other states) that you will be directly working with and a justification for the selection of states.

Project 2:

- The prevalence of thalassemia across the United States, unmet health needs, and barriers to receiving education or training on evidence-based/evidence-informed guidelines for thalassemia treatment.
- How individuals with thalassemia across the United States access hematology care.
- The status of available thalassemia treatment options, level of clinician experience and access to facilities that support implementation of expert recommended and evidence-informed thalassemia care.
- The need for patient education and information on thalassemia treatment options.

▪ **METHODOLOGY** -- Corresponds to Section V's Review Criteria [\(2\) Response and \(4\) Impact](#)

Propose methods that you will use to address the stated needs and address the goal, purpose, and objectives in this NOFO. 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.

Include a description of a plan and/or innovative methods that you will use to address the following:

Project 1:

- Establish a regional network comprised of hematologists and other health care providers in a minimum of three states within the [HRSA Thalassemia Region](#) (the state in which you are located plus two other states) to address

access to services for individuals with Thalassemia. MOUs/MOAs must be included from the partnering organizations in at least two other states within the HRSA Thalassemia Region.

- Establish a steering committee comprised of hematologists, health care providers, patients/families, and other key stakeholders. The steering committee can identify critical issues for patients and barriers to accessing quality care within the [region](#) (e.g., transition, lack of subspecialists willing to treat individuals with thalassemia). The steering committee should develop strategies for educating individuals, families, hematologists, and other providers. Describe how the steering committee will support the implementation of the program's goals, purpose, objectives, and activities. Provide information on the members' expertise on the steering committee.
- Engage individuals and families living with thalassemia in all aspects of the project including planning, implementation, and evaluation.
- Implement telementoring and other methods of training and communication to educate less experienced hematologists and other health care providers on evidence-informed thalassemia treatment guidelines.
- Create a diversity and inclusion plan to ensure health equity for individuals with thalassemia.

Project 2:

- Provide technical assistance and support activities conducted by Project 1 recipients that focus on telementoring.
- Collate and widely disseminate educational resources (e.g., through listservs, newsletters, podcasts, brochures, and training sessions) to educate individuals living with thalassemia and their families.

Both Projects (Project 1 and Project 2):

- Collaborate with all of the recipients of the Thalassemia Program to align national and regional efforts to educate hematologists and other health care providers, individuals, and families.
- Collate and disseminate thalassemia-specific resources on medical home and transition for hematologists and other health care providers participating within the regional networks.
- Collate and widely disseminate information and resources to key stakeholders such as community health workers (CHWs), social workers and nurses on thalassemia and evidence-informed care guidelines.
- 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 Criterion [\(2\)](#) Response**
For Project 1 and Project 2, submit a work plan in *Attachment 1* that describes 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

For Project 1 *and* Project 2, submit a logic model in *Attachment 1* 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/sites/default/files/fysb/prep-logic-model-ts.pdf>.

▪ ***RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion (2) Response***

For Project 1 *and* Project 2: 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.

▪ ***EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria (3) Evaluative Measures and (5) Resources/Capabilities***

For Project 1 *and* Project 2: 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, the following should also be tracked and reported in the annual progress report during the period of performance.

Project 1 and Project 2:

- Number of individuals living with thalassemia participating in a steering committee.
- Number of transfusion dependent and non-transfusion dependent thalassemia patients treated by hematologists within the region.
- Number and type of educational products and strategies developed and disseminated to individuals, families, hematologists, and health care providers by the regional network.
- Number of hematologists and clinical sites in the regional network.
- Number of telementoring sessions, topics discussed, and number of unique participants at each session.
- Number of hematologists and other health care providers receiving education or training on evidence-based/evidence-informed guidelines to treat patients within the regional network.
- Number of patients and families in the regional network with increased knowledge of evidence-informed treatment guidelines.
- Number of providers in the regional network with increased knowledge of evidence-informed treatment guidelines.

▪ **ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion [\(5\) Resources/Capabilities](#)**

For Project 1 and Project 2: 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 as *Attachment 5*. 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. Be sure to describe current partnerships with thalassemia community-based organizations and patient groups. Include any mechanisms that allow your organization to receive feedback from these groups.

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 [SF-424 Application Guide](#) 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.

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 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 [SF-424 Application Guide](#) 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 [SF-424 Application Guide](#).

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.	
<u>Narrative Section</u>	<u>Review Criteria</u>
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 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

Attach the work plan for the project that includes all information detailed in [Section IV.2.ii. Project Narrative](#). 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. MOUs/MOAs must be included from organizations in at least two other states (or Washington DC or Puerto Rico).

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. Beginning in December 2020, 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: [Planned UEI Updates in Grant Application Forms](#) and [General Service Administration’s UEI Update](#) page.

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 [SF-424 Application Guide](#).

[SAM.GOV](#) ALERT: For your SAM.gov registration, you must submit a [notarized letter](#) 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](https://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 December 21, 2020, *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 [SF-424 Application Guide](#) for additional information.

5. Intergovernmental Review

The Thalassemia 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

Project 1: You may request funding for a period of performance of up to 5 years, at no more than \$175,000 per year (inclusive of direct **and** indirect costs).

Project 2: You may request funding for a period of performance of up to 5 years, at no more than \$75,000 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 A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) 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 law.

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

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.

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 Thalassemia Program has six review criteria. See the review criteria outlined below with specific detail and scoring points.

The review criteria below apply to both **Project 1 and Project 2**, unless otherwise noted.

Criterion 1: NEED (10 points) – Corresponds to Section IV's [Introduction](#) and [Needs Assessment](#)

- The clarity and thoroughness with which the application describes the problem and associated contributing factors.
- The extent to which the applicant demonstrates the needs of individuals with thalassemia, families, hematologists, other providers.
- The quality of the description and documentation of the states identified to participate in the project, target population and its unmet needs.
- The strength and effectiveness of the application in utilizing demographic data to support the statement of problems and needs.
- The extent to which the application identifies and discusses relevant barriers that the project hopes to overcome.

Criterion 2: RESPONSE (30 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 challenges are described and how they will be resolved. In addition, the strength, completeness, and feasibility of the applicant's approach to:

Project 1:

- Establishing a [regional network](#) comprised of hematologists and other health care providers in a minimum of three states within the [HRSA Thalassemia Region](#) to address access to services for individuals with Thalassemia.
- Establishing a steering committee comprised of hematologists, health care providers, patients/families and other key stakeholders and how the steering committee will support the implementation of the program's goals, purpose, objectives, and activities.
- Engaging individuals and families living with thalassemia in all aspects of the project including planning, implementation, and evaluation.
- Implementing telementoring and other methods of training and communication to educate networks of less experienced hematologists and other health care providers on evidence-informed thalassemia treatment guidelines.
- Disseminating thalassemia-specific resources on medical home and transition for hematologists and other health care providers participating within the regional networks.
- Creating a diversity and inclusion plan to ensure health equity for individuals with thalassemia.

Project 2:

- Collaborating with all of the recipients of the Thalassemia Program to align national efforts to educate hematologists and other health care providers, individuals, and families.
- Providing technical assistance and support activities conducted by the other Thalassemia Program recipients that focus on telementoring.
- Disseminating educational resources (e.g., through listservs, newsletters, podcasts, brochures, and training sessions) to educate individuals living with thalassemia, families, and other key stakeholders such as CHWs, social workers, and nurses on thalassemia and evidence-informed care guidelines.
- Disseminating thalassemia-specific resources on medical home and transition for hematologists and other health care providers participating within the regional networks.

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

The strength and effectiveness of the methods 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. Describes an effective and achievable data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explains how data will be used to inform program development and service delivery.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's [Methodology](#)

The extent to which the proposed project has a public health impact and 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 feasibility of fulfilling the needs and requirements of the proposed project given the organization's capabilities and the quality and availability of facilities and personnel.

Criterion 6: SUPPORT REQUESTED (15 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 [SF-424 Application Guide](#) for more details.

Special Considerations

In making final award decisions, HRSA will take into consideration the geographic distribution of applicants, per 45 CFR part 75, Appendix 1 (E)(2).

PLEASE NOTE: In order to achieve the distribution of awards as stated above, HRSA may need to fund out of rank order.

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.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of June 1, 2021. See Section 5.4 of HRSA's [SF-424 Application Guide](#) for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's [SF-424 Application Guide](#).

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 ([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 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 [SF-424 Application Guide](#) and the following reporting and review activities:

The reporting activities below apply to both **Project 1 and Project 2**, unless otherwise noted.

- 1) **DGIS Performance Reports.** Available through the 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/U1A.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	June 1, 2021 – May 31, 2026 <i>(administrative data and performance measure projections, as applicable)</i>	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	June 1, 2021 – May 31, 2022 June 1, 2022 – May 31, 2023 June 1, 2023 – May 31, 2024 June 1, 2024 – May 31, 2025	Beginning of each budget period (Years 2–5, as applicable)	120 days from the available date
c) Project Period End Performance Report	June 1, 2025 – May 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.

The reporting below applies to **Project 1** recipients only.

- 3) **Integrity and Performance Reporting**. The NOA 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 request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

LaToya Ferguson
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-1440
Email: lferguson@hrsa.gov

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

Hakim Fobia
Project Officer
Attn: Thalassemia Program
Genetic Services Branch
Division of Services for Children with Special Health Needs
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 945-9842
Email: hfobia@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 federal 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 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: Thursday, November 12, 2020

Time: 2–3 p.m. ET

Call-In Number: 1-866-880-0834

Participant Code: 23996302

Weblink: <https://hrsa.connectsolutions.com/21035>

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](#).