

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



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

Thalassemia Program

Funding Opportunity Number: HRSA-18-079
Funding Opportunity Type(s): New, Competing Continuation
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: January 8, 2018

*Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to 1 month to complete.*

Issuance Date: November 3, 2017

Julia Kibunja
Project Officer, Division of Services for Children with Special Health Needs
Telephone: (301) 443-1330
Fax: (301) 534-0878
Email: jkibunja@hrsa.gov

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau is accepting applications for fiscal year (FY) 2018 for the Thalassemia Program. The purpose of this program is to improve quality of care delivered to individuals with clinically significant thalassemia, especially those who are transfusion-dependent. Awardees will establish collaborative regional networks to (1) promote the use of expert recommended and evidence-informed care, and (2) improve capacity of primary and subspecialty care clinicians to manage thalassemia, particularly in remote and/or medically underserved communities.

Funding Opportunity Title:	Thalassemia Program
Funding Opportunity Number:	HRSA-18-079
Due Date for Applications:	January 8, 2018
Anticipated Total Annual Available FY18 Funding:	\$600,000
Estimated Number and Type of Award(s):	3 cooperative agreements
Estimated Award Amount:	Up to \$200,000 per year
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	June 1, 2018 through May 31, 2021 (3 years)
Eligible Applicants:	As cited in 42 CFR Part 51 a.3(a), any public or private entity, including an Indian tribe or tribal organization (as those terms are defined in 25 U.S.C. 450b), is eligible to apply for this federal funding opportunity See Section III-1 of this notice of funding opportunity (NOFO), formerly known as the funding opportunity announcement (FOA), for complete eligibility information.

Application Guide

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

Technical Assistance

The following technical assistance webinar has been scheduled:

Webinar

Day and Date: Thursday, November 16, 2017

Time: 2 p.m. – 3 p.m. ET

Call-In Number: 1-866-905-1359

Participant Code: 8898714

Weblink: <https://hrsa.connectsolutions.com/preapp18079/>

To access the archived webinar recording, please visit the HRSA MCHB Funding Opportunities Webpage: <https://mchb.hrsa.gov/fundingopportunities/Default.aspx>

Table of Contents

I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION.....	1
1. PURPOSE	1
2. BACKGROUND	3
II. AWARD INFORMATION	5
1. TYPE OF APPLICATION AND AWARD	5
2. SUMMARY OF FUNDING	6
III. ELIGIBILITY INFORMATION	6
1. ELIGIBLE APPLICANTS	6
2. COST SHARING/MATCHING	6
3. OTHER	7
IV. APPLICATION AND SUBMISSION INFORMATION	7
1. ADDRESS TO REQUEST APPLICATION PACKAGE	7
2. CONTENT AND FORM OF APPLICATION SUBMISSION	7
i. <i>Project Abstract</i>	8
ii. <i>Project Narrative</i>	8
iii. <i>Budget</i>	14
iv. <i>Budget Narrative</i>	15
v. <i>Program-Specific Forms</i>	15
vi. <i>Attachments</i>	15
3. DUN AND BRADSTREET DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER AND SYSTEM FOR AWARD MANAGEMENT	16
4. SUBMISSION DATES AND TIMES	17
5. INTERGOVERNMENTAL REVIEW	17
6. FUNDING RESTRICTIONS	17
V. APPLICATION REVIEW INFORMATION.....	18
1. REVIEW CRITERIA	18
2. REVIEW AND SELECTION PROCESS	22
3. ASSESSMENT OF RISK AND OTHER PRE-AWARD ACTIVITIES	22
4. ANTICIPATED ANNOUNCEMENT AND AWARD DATES	23
VI. AWARD ADMINISTRATION INFORMATION	23
1. AWARD NOTICES	23
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS	23
3. REPORTING	24
VII. AGENCY CONTACTS.....	26
VIII. OTHER INFORMATION	27
IX. TIPS FOR WRITING A STRONG APPLICATION	28

I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the Thalassemia Program.

The purpose of this program is to improve quality of care delivered to individuals with clinically significant thalassemia, especially those who are transfusion-dependent. Awardees will establish collaborative regional networks that use collective impact¹ strategies and telehealth to (1) promote the use of expert recommended and evidence-informed care, and (2) improve capacity of primary and subspecialty care clinicians to manage thalassemia, particularly in remote and/or medically underserved communities.

Program Goals:

The goals of the Thalassemia Program are to improve the health and well-being for individuals with clinically significant thalassemia, especially those who are transfusion-dependent by increasing access to high quality thalassemia care in medically underserved communities.

Program Objectives:

Within the first year, each awardee must establish baseline measures for the following program objectives:

- By 2021, increase by 25 percent from baseline the number of clinicians in the regional network utilizing evidence-informed and expert recommendations to treat transfusion dependent thalassemia in the following areas:
 - Maintaining pre-transfusion hemoglobin levels within recommended ranges
 - Screening for iron overload
 - Using chelation therapy regimen for iron overload
- By 2021, increase by 25 percent from baseline the number of thalassemia patients/families in the regional network states reporting knowledge of expert recommended and evidence-informed treatment recommendations.
- By 2021, increase by 10 percent from baseline the number of unique patients served by the regional network.

Program Requirements:

Each awardee will conduct the following activities:

- 1) Establish a steering committee made up of stakeholders to provide support and assistance to the recipient on implementing project goals and activities. The steering committee should also:
 - Consist of key regional and national stakeholders, including patients and families; representatives of medically underserved populations; local

¹ Bonzon E, Callahan T. (2012 Nov/Dec). Systems-Level Impact: Using the Collective Impact Framework for Public Health Systems Building. Retrieved from: <http://www.amchp.org/AboutAMCHP/Newsletters/Pulse/Archive/2012/NovDec2012/Pages/Feature5.aspx>

and/or national patient advocacy and support organizations; thalassemia treatment centers; and, community-based primary and specialty care clinicians.

- Identify critical issues for thalassemia patients and barriers to accessing quality care in the region.
- Participate in developing a strategic plan to expand access to expert recommended and evidence-informed thalassemia care.
- Develop strategies to disseminate information on expert recommended and evidence-informed care to populations of underserved thalassemia patients.
- Identify clinicians who are eligible to join the regional network.

2) Establish a regional network and infrastructure that will:

- Identify and establish Memoranda of Agreement (MOAs) with partners in three contiguous states (federal awardee state plus two other states). state partners should be able to do the following:
 - Establish partnerships with primary and subspecialty clinicians, including hematologists and pediatric and adult clinicians.
 - Establish partnerships with clinicians who have varying ranges of expertise treating individuals with thalassemia.
- Build upon existing regional and/or national partnerships or networks.
- Develop a strategic plan using collective impact strategies to:
 - Implement activities that align resources within the region to improve patients' access to quality thalassemia care.
 - Identify, outreach and link underserved populations and populations with a high prevalence of thalassemia such as Asian immigrants, Asian Americans, African immigrants, and African Americans to high quality thalassemia care within each state.

3) Develop and implement telementoring activities and protocols that include:

- A diverse panel of thalassemia experts to train less experienced clinicians within the region on the implementation of recommended and evidence-informed treatment recommendations.
- Training clinicians within the region on strategies for delivering culturally and linguistically competent care to populations of underserved thalassemia patients.

4) Establish communication strategies to share information, successes and barriers within the network and among regions outside of telementoring sessions. The strategy should:

- Utilize Health Insurance Portability and Accountability Act (HIPAA) compliant channels of communication to foster collaboration and information sharing within and across regional networks. This could include activities such as participation in a listserv or regularly scheduled group calls.

- Identify common challenges, solve problems, and distribute resources and information to target populations including underserved thalassemia patients.
- 5) Facilitate patient and family engagement. This should include:
- Obtaining their input on strategies to disseminate information on treatment recommendations, clinical trials, and other resources to the thalassemia community.
 - Obtaining patient and family feedback to identify areas for improvement to enhance care and patient support.
 - Obtaining patient and family input to identify gaps in knowledge of expert recommended and evidence-informed care in the thalassemia community.
- 6) Develop a data collection and evaluation plan that assess the impact of the Thalassemia Program within the region.

2. Background

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

Thalassemia is a group of inherited (genetic) disorders that impair the body's ability to produce healthy blood cells. The two major forms of the disease are alpha and beta thalassemia with each manifesting a wide range of symptoms and health outcomes. For example, some types of alpha thalassemia are fatal in utero while others cause mild to severe anemia and can result in the need for blood transfusions. Beta thalassemia minima and intermedia causes severe anemia with many individuals becoming transfusion dependent as they age.

Beta thalassemia major is a debilitating condition that requires frequent transfusions to sustain life and if untreated leads to death in early childhood. Without proper monitoring and management for complications related to frequent transfusions, iron overload occurs, and by adolescence, results in organ failure and death. According to unpublished data, over 2,000 people in the United States have transfusion dependent thalassemia. Historically this disease has primarily affected Americans of Mediterranean descent; however, changing patterns in immigration, birth rates and adoption have resulted in the highest rates emerging among communities of Asian and African immigrants as well as populations of Asian Americans and African Americans.^{2,3}

Until recently, most children with thalassemia major died before 6 years of age.⁴ Expert-and evidence-informed treatment recommendations have increased life expectancy and provided guidance on life saving techniques for managing transfusion therapy. These recommendations stipulate optimal ranges for pre-transfusion hemoglobin levels; improved protocols for chelation therapy; and methods for accurate detection of organ damage resulting from iron overload. However, treating thalassemia

² Cooley's Anemia Foundation (<http://www.thalassemia.org>)(unpublished)

³ Vichinsky E. et al. *Pediatrics*. Dec 2005;116(6):818-825

⁴ Binaco Silvestroni I. Un problema medico-sociale: ieri e oggi. 1st. Ital. di Medicina Sociale Ed; Roma 1998. Le talassemie

is complex and specialty care providers with a comprehensive understanding of these recommendations are typically located in a limited number of urban academic medical centers. In medically underserved communities, patients often do not have access to the recommended methods of treatment that reduce the potential for medical complications and death. The majority of individuals with thalassemia are seen by clinicians who lack expertise treating thalassemia or who have limited knowledge of expert guidance.⁵

Transitioning pediatric patients to adult care is a growing need in the thalassemia patient population. In most states, very few adult hematological practices have the specialized skills -necessary to treat individuals with thalassemia. Adult patients frequently remain at pediatric practices well into middle age and if they transition, seek care from clinicians specializing in malignant blood disorders. When adult patients continue to receive treatment at pediatric thalassemia centers it become challenging for clinicians to address their changing medical needs and treat comorbidities associated with aging and complicated by thalassemia and side-effects from chronic disease management.

HRSA has provided support for programs to improve access to high quality treatment for individuals with thalassemia since 1988. In the last funding cycle, the program conducted an extensive literature review to develop expert recommended and evidence-informed guidelines in three critical treatment areas - pre-transfusion hemoglobin levels, monitoring for iron overload, and toxicity from chelation therapy. In this funding cycle, the program will focus on the dissemination and implementation of the treatment recommendations in regional networks, increasing the number of clinicians knowledgeable about treating individuals with thalassemia, especially those who are transfusion-dependent and increasing patient access to quality care through improving capacity of clinicians to manage thalassemia.

Awardees of the Thalassemia Program are expected to use collective impact and telementoring strategies to expand access to high quality thalassemia care. These concepts are addressed in detail below:

Collective Impact:

Collective impact is a framework that uses cross sector collaboration to implement strategies addressing complex social and medical problems. It is based on the premise that acting alone, a single organization lacks the resources to solve large-scale, systemic challenges. Using a collective impact framework, networks implement population level interventions by leveraging the resources and expertise of multiple organizations. Collective impact affects change by using five principles to develop alignment between stakeholders: 1) backbone and support structure; 2) common agenda; 3) continuous communication; 4) mutually reinforcing activities; and 5) shared measurement system.

⁵Vichinsky E, Levine L et al. *Standards of Care Guidelines for Thalassemia*. Oakland, California: Children's Hospital & Research Center Oakland

Telementoring:

For clinicians who see patients living in remote or medically underserved communities, telementoring expands access to high-quality disease-specific care by connecting less-experienced clinicians with geographically distant experts who facilitate case consultation and deliver specialized training. Project ECHO is an example of an evidence-based telementoring strategy.⁶ In this model, communication occurs through a combination of videoconferencing, email and teleconferencing to conduct group case reviews, generate individualized patient recommendations, and deliver brief didactic presentations on expert recommended and evidence-informed care guidelines and other topics as appropriate (e.g. navigating insurance barriers, pain management, nutrition and mental health).^{7,8}

II. Award Information

1. Type of Application and Award

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

HRSA will provide funding for the Thalassemia Program in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

HRSA Program involvement will include:

- Participate in meetings conducted during the period of the cooperative agreement;
- Review ongoing activities and procedures to be established and implemented for accomplishing the scope of work;
- Review products and project information on project activities; Assist in establishing and facilitating effective collaborative relationships with HRSA-funded grants such as the Sickle Cell Disease Treatment Demonstration Program, Regional Genetics Networks, State Title V Maternal and Child Health Programs and other entities that may be relevant to the project's mission;
- Provision of information and resources; and
- Ensure compliance with NOFO requirements and activities do not duplicate the work of other HHS-funded projects.

⁶ Arora S, Thornton K, Murata G, et al. Outcomes of treatment for hepatitis C virus infection by primary care providers. *N Engl J Med* 2011; 364: 2199-2207.

⁷ Arora S et al. *Academic Medicine*. January 2015;89(1):30-32

⁸ University of New Mexico, Health Sciences Center. *Project ECHO – Steps for Implementation*. (Accessed 2017, July 21) Retrieved from: <http://echo.unm.edu/wp-content/uploads/2014/07/ECHO-Replication-Steps-for-Implementation-Jan10-2014.pdf>

The cooperative agreement recipient's responsibilities will include:

- Completing activities proposed in response to the NOFO;
- Collaborating with HRSA on ongoing review of activities, procedures and budget items. Information/publications prior to dissemination, contracts and interagency agreements;
- Providing ongoing, timely communication and collaboration with the federal project officer;
- Providing the federal project officer opportunity to review documents and products prior to dissemination;
- Working with the federal project officer to review information on project activities as described within this award announcement; and
- Establishing contacts that may be relevant to the project's mission such as but not limited to the following: federal and state agencies; HRSA-funded projects including the Sickle Cell Disease Treatment Demonstration Program, Regional Genetics Networks, State Title V Maternal and Child Health Programs; Cooley's Anemia Foundation (CAF); and, the American Society of Hematology (ASH).

2. Summary of Funding

Approximately \$600,000 is expected to be available annually to fund three recipients. You may apply for a ceiling amount of up to \$200,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The actual amount available will not be determined until enactment of the final FY 2018 federal appropriation. 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, applications can be processed, and funds awarded in a timely manner. The project period is June 1, 2018 through May 31, 2021 (3 years). Funding beyond the first year is dependent on 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 any public or private entities. Faith-based and community-based organizations, tribes, and tribal organizations (as those terms are defined in 25 U.S.C. 450b), are eligible to apply for this federal funding opportunity.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

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

IV. Application and Submission Information

1. Address to Request Application Package

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

Effective December 31, 2017 - You **must** use the [Grants.gov Workspace](#) to complete the workspace forms and submit your application workspace package. After this date, you will no longer be able to use PDF Application Packages. HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the notice of funding opportunity (NOFO) (also known as “Instructions” on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the [Find Grant Opportunities](#) page for all information relevant to desired opportunities.*

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. Applications must be submitted in the English language and must be 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 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 application package do not count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) 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 the prospective recipient is 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 [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), please include the following:

i. Project Abstract

See Section 4.1.ix of HRSA's [SF-424 Application Guide](#).

ii. Project Narrative

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

Successful applications will contain the information below. Please use the following section headers for the narrative:

- **INTRODUCTION -- Corresponds to Section V's Review Criterion(a) 1**
Briefly describe the purpose of the proposed project.

- **NEEDS ASSESSMENT** -- *Corresponds to Section V's Review Criterion(a) 1*
Outline the needs of the community and/or organization. You must describe and document the target population and its unmet health needs. Use and cite demographic data whenever possible to support the information provided. Please discuss any relevant barriers in the region that the project hopes to overcome. 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:
 - A region of at least three contiguous states (the applicant's state plus two other states) and a justification for the selection of states/territories in the region.
 - The prevalence of thalassemia within the region, target population, its unmet health needs, and barriers to accessing expert recommended and evidence-informed treatment.
 - How individuals with thalassemia in the region access hematology care. Specifically include access to university hospitals and medical centers with hematologists and other specialty clinicians that treat thalassemia, large health center networks, and primary care provider networks in the region.
 - The current regional capacity to transition youth with thalassemia into adult care.
 - 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.
- **METHODOLOGY** -- *Corresponds to Section V's Review Criterion(a) 2*
Propose methods that you will use to address the stated needs and meet each of the previously described program goals, requirements, objectives and expectations of 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. If applicable, include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences.

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

Please describe the methods you will use to implement the following activities:

- Establishing a steering committee consisting of key regional and national stakeholders that includes patients; families; representatives of underserved populations; local and/or national patient advocacy and support organizations; thalassemia treatment centers; and community based primary and specialty care clinicians. The steering committee should:
 - Identify critical issues for thalassemia patients and barriers to accessing quality care in the region.

- Develop a strategic plan that identifies strategies to improve health outcomes for individuals with thalassemia and expand access to expert recommended and evidence-informed thalassemia care in the region.
- Develop strategies to disseminate information on expert recommended and evidence-informed care to populations of underserved thalassemia patients.
- Identify clinicians who are eligible to join the regional network.
- Establishing a regional network and infrastructure that will expand access to expert recommended and evidence-informed care within the region by:
 - a. Creating Memoranda of Agreement (MOAs) with partners in three contiguous states (federal awardee state plus two other states). State partners should be able to do the following:
 - i. Establish partnerships with primary and subspecialty clinicians, including hematologists and pediatric and adult clinicians.
 - ii. Establish partnerships with clinicians who have varying ranges of expertise treating individuals with thalassemia.
 - b. Building upon existing regional and/or national partnerships or networks.
 - c. Developing a strategic plan using collective impact strategies that:
 - i. Align resources within the region to improve patients' access to quality thalassemia care.
 - ii. Identify, outreach and link underserved populations and populations with a high prevalence of thalassemia such as Asian immigrants, Asian Americans, African immigrants, and African Americans to high quality thalassemia care within each state.
- Establishing and implementing telementoring activities and/or protocols that:
 - Utilize a diverse panel of thalassemia experts to train network clinicians on the implementation of recommended and evidence-informed treatment.
 - Train network clinicians on strategies for delivering culturally and linguistically competent care to populations of underserved thalassemia patients.
- Establishing communication strategies to share information, successes and barriers within the network and among regions outside of telementoring sessions.
 - Utilize HIPAA compliant channels of communication to foster collaboration and information sharing within and across regional networks.
 - Collaborate with other federal awardees and regional networks to identify common challenges, problem solve and disseminate resources and information to target populations including underserved thalassemia patients.
- Facilitating patient and family engagement by:
 - Involving individuals with thalassemia and their families in the development, implementation and evaluation of proposed project goals, objectives and activities.
 - Obtaining their input on strategies to disseminate information on treatment recommendations, clinical trials and other resources to the thalassemia community.
 - Obtaining patient and family feedback to identify areas for improvement to enhance care and patient support.

- Obtaining patient and family input to identify gaps in knowledge of expert recommended and evidence-informed care in the thalassemia community.
- *WORK PLAN -- Corresponds to Section V's Review Criterion(a) 2 and 4*
 - Describe the activities or steps that you will use to achieve each of the objectives proposed during the 3-year project period in the Methodology section. Use a timeline that includes each activity and identifies responsible staff.
 - Identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including development of the application.

In addition to submitting a work plan, you should submit a logic model:

- Logic model: 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., objectives, 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 staff, budget, other resources);
 - Target population (e.g., the individuals to be served);
 - Activities (e.g., approach, listing key intervention, if applicable);
 - Outputs (i.e., the direct products or deliverables of program activities); and
 - Outcomes (i.e., the results of a program, typically describing a change in people or systems).
- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion(a) 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. The discussion should include but not limit itself to challenges and proposed solutions for the following:
 - Identifying partnerships and promoting strong collaborations among clinicians with diverse specializations within the network.
 - Identifying underserved populations of thalassemia patients within the region.
 - Implementing and sustaining a regional strategy that works across state lines, engages stakeholders in diverse health care settings, and links underserved populations to expert recommended and evidence-informed thalassemia treatment.

- Including patients and families in the design of communication strategies.
 - Establishing communication strategies to share information, successes and barriers within the network and among regions.
 - Implementing the program performance evaluation and collecting data from regional partners.
- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion(a) 3 and 5*
- You must 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 staff, budget, and other resources), key processes, and expected outcomes of the funded activities.
- You must 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 from state partners (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.
- You must describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles. The program performance evaluation should include obtaining baseline measurements in the first year and monitoring progress towards goals, program requirements, and the following objectives of the project:
- By 2021, increase by 25 percent from baseline the number of clinicians in the regional network utilizing evidence-informed and expert recommendations to treat transfusion dependent thalassemia in the following areas:
 - Maintaining pre-transfusion hemoglobin levels within recommended ranges
 - Screening for iron overload
 - Using chelation therapy regimen for iron overload
 - By 2021, increase by 25 percent from baseline the number of thalassemia patients/families in the regional network states reporting knowledge of expert recommended and evidence-informed treatment recommendations.
 - By 2021, increase by 10 percent from baseline the number of unique patients served by the regional network.

The program performance evaluation should also include the collection and monitoring of process measures to assess if the program is on target for meeting requirements and goals:

- Patient demographic information that captures, race, ethnicity, age and income level.
 - Number of patients who receive regular care through a regional partner site.
 - Number of MOAs with regional partners.
 - Number of telementoring sessions.
 - Number of network partners participating in each telementoring session.
 - Topics covered during telementoring sessions.
 - Number of customized comprehensive treatment plans developed by the regional lead for patients regularly seen by regional clinicians.
 - Number of inter-regional teleconferences and topics discussed.
 - Methods developed and/or utilized to disseminate expert recommended and evidence-informed treatment recommendations to families (i.e. verbally, brochure, seminar).
 - Number of patients/families participating in advisory committees or other opportunities to provide feedback.
 - Number of clinicians utilizing expert- and evidence-informed treatment recommendations.
- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion(a) 5*
- Succinctly describe your organization's current mission and structure, scope of current activities, including an organizational chart, and describe how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.
 - Describe your current or past role in child health, blood disorders and thalassemia management. Include information on collaborative efforts with other local clinicians specifically around the care of individuals with blood disorders.
 - Provide information of your organization and key personnel's experience providing care to individuals with thalassemia.
 - Describe the roles, responsibilities and relationships between the regional network lead and state partners.
 - Provide information on how collective impact or similar strategies will be used to coordinate and lead activities within the region.
 - Describe the infrastructure and expertise to lead multi-state efforts. Provide information on the program's resources to serve as the regional telementoring hub.
 - Describe previous and current work on improving access to thalassemia care for underserved populations and application of disease management models such as the Chronic Care Model.⁹
 - Provide information on the project steering committee including fields of expertise of committee members. Describe how steering committee and regional network member's expertise and input will guide project activities.

⁹ Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Effective Clinical Practice*. 1998;1(1):2-4.

- Describe the organization or institution's current or past partnerships with thalassemia community-based organizations and patient groups. Include any mechanisms that allow your organization to receive feedback from these groups.

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.	
<u>Narrative Section</u>	<u>Review Criteria</u>
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 (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. Budget

See Section 4.1.iv of HRSA's [SF-424 Application Guide](#). Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Please follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if the application is selected for funding, you will have a well-organized plan and by carefully following the approved plan can 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) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

The Consolidated Appropriations Act, 2017 (P.L. 115-31), 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.” Please see Section 4.1.iv Budget – Salary Limitation of HRSA’s [SF-424 Application Guide](#) for additional information. Note that these or other salary limitations may apply in FY 2018, as required by law.

iv. Budget Narrative

See Section 4.1.v. of HRSA’s [SF-424 Application Guide](#).

See Section VIII of this NOFO for more information on logic models.

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. Attachments

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

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative. If applicable, also include the required logic model in this attachment. If funds will be sub-awarded or expended on contracts, describe how your organization will ensure the funds are properly documented.

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 time keeping 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 who is not yet hired, please 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. Letters of agreement must be 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, etc.).

Attachment 7: Progress Report

(FOR COMPETING CONTINUATIONS-ONLY)

A well-documented progress report is a required and important source of material for HRSA in preparing annual reports, planning programs, and communicating program-specific accomplishments. The accomplishments of competing continuation applicants are carefully considered; therefore, you are advised to include previously stated goals and objectives in your application and emphasize the progress made in attaining these goals and objectives. HRSA program staff review the progress report after the competing continuation applications are reviewed by the objective review committee. See Section V.2 Review and Selection Process for a full explanation of funding priorities and priority points.

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

- (1) The period covered (dates).
- (2) Specific Objectives - Briefly summarize the specific objectives of the project.
- (3) Results - Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachments 8 – 15: Other Relevant Documents [15 is the maximum]

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

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

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during 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)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is 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.

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](#).

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 *January 8, 2018 at 11:59 p.m. Eastern Time*.

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

You may request funding for a project period of up to 3 years, at no more than \$200,000 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.

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

Shared Staffing: If you are proposing to utilize the same director or contractual staff across multiple grants/programs (e.g., Community Integrated Service Systems (CISS), Special Projects of Regional and National Significance (SPRANS), State Title V Maternal and Child Health (MCH) block grant, Supplemental Nutrition Program for Women, Infants and Children (WIC)), you must assure that the combined funding for each position does not exceed 100 percent FTE. If such an irregularity is found, HRSA funding will be reduced accordingly.

Shared Equipment: If you are proposing to purchase equipment which will be used across multiple grants/programs (e.g., CISS, SPRANS, State Title V MCH block grant, WIC), you must pro-rate the costs of the equipment across programs and show the calculation of this pro-ration in the justification. If an irregularity is found where HRSA equipment is being used by other programs without reimbursement, HRSA funding will be reduced accordingly.

Cash Stipends/Incentives: Funds cannot be utilized for cash stipends/monetary incentives given to clients to enroll in project services. However, funds can be used to facilitate participation in project activities (e.g., daycare, transportation costs), as well as for services rendered to the project (e.g., adolescent peer mentors).

Purchase of Vehicles: Projects must not allocate funds to buy vehicles for the transportation of clients, but rather lease vehicles or contract for these services.

The General Provisions in Division H of the Consolidated Appropriations Act, 2017 (P.L. 115-31) apply to this program. Please see Section 4.1 of HRSA's [SF-424 Application Guide](#) for additional information. Note that these or other restrictions will apply in FY 2018, as required by law.

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.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. Critical indicators have been developed 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. Review criteria are outlined below with specific detail and scoring points.

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 (6) review criteria:

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

The extent to which the application demonstrates the problem and associated contributing factors to the problem. The extent to which the application describes:

- The justification of states and/or territories selected to be in the region; The prevalence of thalassemia in the region, target population, unmet health needs, and barriers to accessing expert recommended and evidence-informed treatment. (4 points)
- How individuals with thalassemia in the region access hematology care, including a description of patient access to university hospitals and medical centers with hematologists and other specialty clinicians that treat thalassemia, large health center networks, and large primary care provider networks in 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; Current regional capacity to transition youth with thalassemia to adult care. (6 points)

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology, Resolution of Challenges, and Work Plan

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives. The extent to which the applicant describes an effective approach to:

- Establishing a steering committee consisting of key regional and national stakeholders that includes patients; families; representatives of underserved populations; local and/or national patient advocacy and support organizations; thalassemia treatment centers; and community based primary care and other specialty care clinicians. The steering committee should identify critical issues for thalassemia care in the region; develop a strategic plan that identifies how to improve health outcomes for individuals with thalassemia and expand access to expert recommended and evidence-informed care in the region; identify clinicians who are eligible to join the regional network; and, develop strategies to disseminate information on expert recommended and evidence-informed care to populations of underserved thalassemia patients. (4 points)

- Developing a strategic plan using collective impact strategies to: align resources within the region to improve patients' access to quality thalassemia care; and identify, outreach, and link to underserved populations and populations with a high prevalence of thalassemia such as Asian immigrants, Asian Americans, African immigrants, and African Americans within each state. (4 points)
- Establish a regional network and infrastructure that will improve health outcomes and expand access to evidence-informed care within the region by: 1) Developing network partnerships and establishing MOAs with primary and subspecialty clinicians, including hematologists in three contiguous states (federal awardee state plus two others) and to build upon existing regional and/or national partnerships or networks; and, establishing communications strategies to disseminate expert recommended and evidence-informed treatment recommendations to patients and families. (4 points)
- Establish telementoring activities and protocols that utilize a diverse panel of thalassemia experts to train network clinicians on expert recommended and evidence-informed treatment recommendations as well as strategies for delivering culturally and linguistically competent care. (4 points)
- Establish communication strategies to share information, successes and barriers within the network and among regions outside of telementoring sessions by utilizing HIPAA compliant channels of communication to foster collaboration and information sharing within and across regional networks and collaborating with other federal awardees and regional networks to identify common challenges, problem solve and disseminate resources and information. (4 points)
- Engage thalassemia patients and their families through outreach, education and involvement with decision-making. (4 points)
- Engaging individuals with thalassemia and their families in the development, implementation and evaluation of proposed project goals, objectives and activities. (3 points)
- Resolving challenges that are likely to be encountered in designing and implementing the activities described in the work plan. Specifically addressing the following: (3 points)
 - Identifying partnerships and promoting strong collaborations among health care providers with diverse specializations within the network.
 - Identifying underserved populations of thalassemia patients within the region.
 - Implementing and sustaining a regional approach that works across state lines, engages stakeholders in diverse health care settings and links underserved populations to expert recommended and evidence-informed thalassemia treatment.
 - Including patients and families in the design of communication strategies.
 - Establishing communication strategies to share information, success and barriers within the network and among regions.
 - Implementing the program performance evaluation and collecting data from regional partners.

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

The extent to which the applicant:

- Describes the plan for the Thalassemia Program performance evaluation that monitors ongoing processes and progress towards the goals and objectives of the project; (4 points)
- Describes the evaluative methods that will be able to assess (3 points)
 - 1) To what extent the program objectives have been met, and
 - 2) To what extent these can be attributed to the project;
- Describes the systems and processes that will support performance management requirements through effective tracking of performance outcomes in a way that allows for accurate and timely reporting of performance outcomes; (4 points)
- Describe the 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. Specifically describe the plan for collecting data from regional partners. (4 points)

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Work Plan

The feasibility and effectiveness of plans for dissemination of project results, and the extent to which project results may be national in scope, and the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

Criterion 5: RESOURCES/CAPABILITIES (25 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.

- The extent to which the application describes:
 - The organization's current mission and structure, scope of current activities, including an organizational chart, and how these elements contribute to the organization's ability to conduct the program requirements and meet program expectations including: the organization and key personnel's experience providing care to individuals with thalassemia; roles, responsibilities and relationships between the regional network lead and state partners; and expertise to lead and coordinate multi-state efforts using collective impact strategies and be the regional telementoring hub. (5 points)
 - The current or past role in child health, blood disorders and thalassemia management including collaborative efforts with other local clinicians specifically around the care of individuals with blood disorders. (5 points)
 - Previous and current work on improving access to thalassemia care for underserved populations and application of disease management models such as the Chronic Care Model. (5 points)
 - Steering committee membership including the fields of expertise of committee members and how the expertise and input of the steering

- committee and members of the regional networks will be used to guide the project activities. (5 points)
- Current partnerships with thalassemia community-based organizations and patient groups. (5 points)

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 project period in relation to the objectives, the complexity of the research activities, and the anticipated results. (5 points)
- 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(5 points).

2. Review and Selection Process

The independent 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. In addition to the ranking based on merit criteria, HRSA approving officials may also apply other factors in award selection, (e.g., geographical distribution), if specified below in this NOFO. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's [SF-424 Application Guide](#) for more details.

Funding Priorities

There are no funding priorities for the Thalassemia Program.

Funding Preferences

There are no funding preferences for the Thalassemia Program.

Funding Special Considerations and Other Factors

There are no special considerations for the Thalassemia Program.

3. Assessment of Risk and Other Pre-Award Activities

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](#)).

Applications receiving a favorable objective review are reviewed 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. You may be asked 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 an award will be made. Following review of all applicable information, HRSA’s approving and business management officials will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

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

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the [Federal Awardee Performance and Integrity Information System \(FAPIS\)](#). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in [FAPIS](#) 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](#).

A determination that an applicant is not qualified will be reported by HRSA to FAPIS ([45 CFR § 75.212](#)).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of June 1, 2018.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of June 1, 2018. See Section 5.4 of HRSA’s [SF-424 Application Guide](#) for additional information.

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA’s [SF-424 Application Guide](#).

Human Subjects Protection:

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

3. Reporting

The new Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA is enhancing the DGIS and will have these improvements available for recipient reporting on October 1, 2017. Once the new DGIS has been developed, tested, and deployed, MCHB will communicate with recipients and provide instructions on how to access the system for reporting. MCHB will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

Recipients with active awards should be able to access the new DGIS between October 1, 2017 and February 28, 2018 to report their performance objectives for the remaining years of the grant/cooperative agreement. Once all recipients have reported their performance objectives, they will then return to the normal reporting schedule for reporting final 2017 performance data.

The updated and final reporting package incorporating all OMB-accepted changes (OMB Number: 0915-0298, Expiration Date: 06/30/2019) can be reviewed at:

<https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection>.

Award recipients must comply with Section 6 of HRSA's [SF-424 Application Guide](#) and the following reporting and review activities:

- 1) **Progress Report(s).** The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.
- 2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.
- 3) **Performance Reports.** HRSA has modified its reporting requirements for Special Projects of Regional and National Significance (SPRANS) projects, Community Integrated Service Systems (CISS) projects, and other grant/cooperative agreement programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). GPRA requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.

a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program can be found at https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/U1A_2.HTML

Forms			
Form 1, Project Budget Details Form 2, Project Funding Profile Form 4, Project Budget and Expenditures Form 6, Maternal & Child Health Discretionary Grant Form 7, Discretionary Grant Project Products, Publications, and Submissions Data Collection Form TA/Collaboration Form			
Updated DGIS Performance Measures, Numbering by Domain <i>(All Performance Measures are revised from the previous OMB package)</i>			
Performance Measure	New/Revised Measure	Prior PM Number (if applicable)	Topic
Core			
Core 1	New	N/A	Grant Impact
Core 2	New	N/A	Quality Improvement
Core 3	New	N/A	Health Equity – MCH Outcomes
Capacity Building			
CB 1	New	N/A	State Capacity for Advancing the Health of MCH Populations
CB 2	New	N/A	Technical Assistance
CB 3	New	N/A	Impact Measurement
CB 4	Revised	5	Sustainability
Children and Youth with Special Health Care Needs			
CSHCN 1	Revised	7	Family Engagement
CSHCN 2	Revised	40, 41	Access to and Use of Medical Home
CSHCN 3	New	N/A	Transition to Adult Health Care

b) Performance Reporting Timeline

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

Performance reporting is conducted for each year of the project period. Recipients will be required, within 120 days of the NOA, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

c) Project Period End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the project period, to electronically complete the program-specific data forms that appear for this program. The requirement includes providing expenditure data for the final year of the project period, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

VII. Agency Contacts

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

Mary Worrell
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-5181
Fax: (301) 443-5461
Email: mworrell@hrsa.gov

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

Julia Kibunja
Project Officer
Attn: Division of Services for Children with Special health Needs
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18W-9C
Rockville, MD 20857
Telephone: (301) 443-1330
Fax: (301) 594-0878
Email: jkibunja@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 Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's 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

Logic Models

Additional information on developing logic models can be found at the following website: <http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf>.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a timeline used during program implementation; the work plan provides the "how to" steps. Information on how to distinguish between a logic model and work plan can be found at the following website:

<http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf>.

Technical Assistance

The following technical assistance webinar has been scheduled:

Webinar

Day and Date: Thursday, November 16, 2017

Time: 2 p.m. – 3 p.m. ET

Call-In Number: 1-866-905-1359

Participant Code: 8898714

Weblink: <https://hrsa.connectsolutions.com/preapp18079/>

To access the archived webinar recording, please visit the HRSA MCHB Funding Opportunities Webpage: <https://mchb.hrsa.gov/fundingopportunities/Default.aspx>

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's [SF-424 Application Guide](#).