Regional Hemophilia Network

Announcement Type: New and Competing Continuation
Funding Opportunity Number: HRSA-17-074
Catalog of Federal Domestic Assistance (CFDA) No. 93.110

FUNDING OPPORTUNITY ANNOUNCEMENT
Fiscal Year 2017

Application Due Date: October 4, 2016

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

Issuance Date: August 4, 2016

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EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB)/Genetic Services Branch is accepting applications for fiscal year (FY) 2017 for the Regional Hemophilia Network (RHN). The purpose of this program is to establish integrated and collaborative regional networks to promote and improve the comprehensive care of individuals with hemophilia and related bleeding disorders or clotting disorders such as thrombophilia.

One application per region will be funded. There are a total of the eight (8) regions as defined by HRSA using a combination of the Public Health Service Regions and similarity in numbers of patients and numbers of hemophilia treatment centers and will be funded as follows:

- **Mid-Atlantic**: Delaware, DC, Maryland, Pennsylvania, Virginia, West Virginia
- **Southeast**: Alabama, Florida, Georgia, Mississippi, Kentucky, North Carolina, South Carolina, Tennessee
- **Great Lakes**: Indiana, Michigan, Ohio
- **Northern States**: Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
- **Great Plains**: Arkansas, Louisiana, Oklahoma, Texas, Iowa, Kansas, Missouri, Nebraska
- **Mountain States**: Alaska, Idaho, Oregon, Washington, Arizona, Colorado, Montana, New Mexico, Utah, Wyoming
- **Western States and Territory**: California, Hawaii, Nevada, Guam

<table>
<thead>
<tr>
<th>Funding Opportunity Title:</th>
<th>Regional Hemophilia Network</th>
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<tbody>
<tr>
<td>Funding Opportunity Number:</td>
<td>HRSA-17-074</td>
</tr>
<tr>
<td>Due Date for Applications:</td>
<td>October 4, 2016</td>
</tr>
<tr>
<td>Anticipated Total Annual Available Funding:</td>
<td>$4,000,000</td>
</tr>
<tr>
<td>Estimated Number and Type of Award(s):</td>
<td>Up to eight (8) grants</td>
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<td>Estimated Award Amount:</td>
<td>Up to $500,000 per year</td>
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<tr>
<td>Cost Sharing/Match Required:</td>
<td>No</td>
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<tr>
<td>Project Period:</td>
<td>June 1, 2017 through May 31, 2022 (five (5) years)</td>
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### Eligible Applicants:

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

[See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]

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**Application Guide**


**Technical Assistance**

MCHB will host a pre-submission technical assistance conference call for all prospective applicants on **Monday, August 22, 2016**. Call details are as follows:

**Time:** 2:00 p.m. – 4:00 p.m. ET  
**Dial-in:** 1-866-731-7986 / Passcode: 1522482  
**Web link:** [https://hrsa.connectsolutions.com/hrsa-17-074/](https://hrsa.connectsolutions.com/hrsa-17-074/)
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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for the Regional Hemophilia Network (RHN) Program. The purpose of this funding opportunity is to establish integrated and collaborative regional networks to promote and improve the comprehensive care of individuals with hemophilia and related bleeding disorders or clotting disorders such as thrombophilia.

Program Goals

Improve access to coordinated and comprehensive systems of care for patients with hemophilia and related blood or clotting disorders, strengthen hemophilia treatment centers’ (HTC) integrated care teams, and improve the health and well-being for children, youth and adults with hemophilia and related bleeding and clotting disorders.

Program Objectives

The awardee will be expected to report on program-specific objectives, which include:

- By 2022, 75 percent of the HTCs within a region will have participated in national quality improvement (QI) projects.
- By the third quarter of Year two, all HTC subawardees are expected to be reporting on select Healthy People 2020 (HP2020) measures.
- By 2022, increase by 25 percent from baseline in Discretionary Grant Information Systems (DGIS) CSHCN Measure – Family Engagement, for patients with hemophilia and related blood or clotting disorders that are seen within HTC subawardees in your region. Baseline data will be collected by the first quarter of Year two.
- By 2022, increase by 25 percent from baseline in DGIS CSHCN Measure 2 – Medical Home, for patients with hemophilia and related blood or clotting disorders that are seen within HTC subawardees in your region. Baseline data will be collected by the first quarter of Year two.
- By 2022, increase by 25 percent from baseline in DGIS CSHCN Measure 3 – Transition, for patients with hemophilia and related blood or clotting disorders that are seen within HTC subawardees in your region. Baseline data will be collected for all HTC subawardees by the first quarter of Year two.
- By 2022, increase by 25 percent from baseline the number of patients with hemophilia and related blood or clotting disorders that have had an annual comprehensive care visit within HTC subawardees in your region. Baseline data will be collected by the first quarter of Year two.
- By 2022, increase from baseline in the submission of materials to the National Hemophilia Program Coordinating Center (NHPCC) online repository in order to achieve Tier 2 of DGIS Measure CB 6 - The percent of programs supporting the development of informational products and through what means, and related outcomes.
In addition to the above program requirements and objectives, the Maternal and Child Health Bureau (MCHB) expects the successful applicant to take substantial steps to ensure that the HTCs within their region maintain full access to coordinated, integrated care in the context of a medical home model. The awardee is expected to use strategies to address hemophilia and related bleeding disorders as chronic conditions and share resources within their region, the other regions and the NHPCC) to address identified gaps.

**Program Requirements**

For the purpose of this funding opportunity announcement, HTCs are those supported by federal funds through any of the eight Regions, and are to be referred to as HTCs.

Awardees must:

1) Establish a regional infrastructure of HTCs. Each region must develop and have in place formal procedures that explain the oversight of HTCs, requirements of HTCs, procedures for approving use of program income, roles and responsibilities of the regional staff and HTC staff, and how the region will assist HTCs in accomplishing program goals and objectives.

2) Facilitate the sharing of standardized materials/practices with HTCs, other regions, and the NHPCC.

3) Provide technical assistance to strengthen the region’s HTC integrated care teams.

4) Support HTCs to participate and implement national QI projects, in conjunction with the NHPCC, that focus on the entire system of care for hemophilia and related blood or clotting patients/families. Over the course of the project period, QI projects should focus on:
   - Transition (e.g., from pediatric care to adult care, education to employment, etc.);
   - Increasing patient and family engagement in care decisions and HTC, regional, and NHPCC program activities; and
   - Ensuring access to a medical home and integrating hemophilia treatment with other systems of care.

5) Participate on NHPCC workgroups and collaborate with the NHPCC to achieve regional and national program goals, requirements, objectives, and activities.

6) Promote patients and families as partners in care at the HTCs (e.g., having patients on advisory committees, increasing availability of patient navigators within clinics, etc.).

7) Form partnerships with various stakeholders, including federal and non-federal organizations, to address emerging issues related to hemophilia and related bleeding and clotting disorders.

8) Identify, prioritize, and address emerging issues of importance, including increasing access to, and the improvement of, hemophilia and related bleeding and clotting disorder services through outreach to underserved populations in conjunction with key stakeholders.

9) Support all HTCs in reporting data on program objectives and selected Healthy People 2020 measures (HP2020).
10) Support at least one annual regional meeting for HTC staff and attend annual in-person meeting conducted by the NHPCC.

2. Background

This program is authorized by § 501(a)(2) of the Social Security Act, the Maternal and Child Health Federal Set-Aside Program: Special Projects of Regional and National Significance (SPRANS)(42U.S.C. 701(a)(2)), as amended.

Hemophilia is a group of hereditary bleeding disorders of specific blood clotting factors classified as hemophilia A and B. Classic hemophilia A is the result of a deficiency of clotting factor VIII; Hemophilia B is a deficiency of clotting factor IX. Approximately 20,000 U.S. persons, primarily males, are affected by hemophilia A or B, the most well-known and prevalent of the clotting factor deficiencies. There are also other known congenital bleeding disorders, including von Willebrand disease (VWD) which is a hereditary bleeding disorder that affects both men and women and is caused by a problem with a protein necessary for blood clotting. VWD is characterized by prolonged bleeding following trauma and during menstruation. It is estimated that up to one percent of the world population has a form of VWD, or close to four million individuals in the United States.

Individuals with hemophilia generally have chronic disease manifestations that are difficult and expensive to treat.\(^1\) Optimal care to prevent these complications requires a multi-disciplinary team approach. The National Hemophilia Foundation’s (NHF) Medical and Scientific Advisory Committee has developed guidelines for care - *Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders*.\(^2\) All HTC subawardees are required to follow these guidelines for the treatment of individuals with hemophilia and other congenital bleeding disorders. The guidelines describe the core team of allied health professionals and the integrated care services that should be provided to patients with these conditions. The guidelines emphasize family and patient education, transitional services, and psychosocial services. HTC subawardees, at a minimum, are also expected to demonstrate skills and knowledge that are used in the care of individuals with bleeding disorders, including preventive medicine, carrier detection, genetic and prenatal counseling, patient education and engagement in care, blood product use, and complications of therapy.

HRSA has funded services for individuals with hemophilia for more than 35 years. HRSA has provided funds to: 1) support the Comprehensive Hemophilia Diagnostic and Treatment programs that provide services for individuals with bleeding disorders including genetic testing, carrier testing, counseling, early identification, intervention, education, and coordinated care; 2) encourage linking patients and federally-funded

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HTCs, with systems of care and appropriate treatment interventions; 3) increase clinical knowledge of hemophilia and other bleeding and clotting disorders; 4) improve the health literacy of individuals with hemophilia and other bleeding and clotting disorder to increase understanding of their disorder as well as the benefits, risks, and limitations of genetic screening and testing, and the implications of genetic information; 5) facilitate the development of well-prepared health care and public health professionals capable of communicating the benefits, risks and limitations of genetic screening and testing and accurately interpreting and appropriately utilizing genetic information in clinical and public health practice; 6) facilitate the integration of hemophilia and other bleeding and clotting disorder services into health care systems, and; 7) build and strengthen the benign hematology workforce.

The NHPCC was developed to coordinate RHN activities on a national level and HRSA has been providing funding for the NHPCC since 2012. The NHPCC has played a key role in identifying, prioritizing, and addressing issues of importance regarding access to and utilization of hemophilia and related bleeding and clotting disorder services in the HRSA-funded infrastructure at national, state, and community levels. During the first award cycle, the NHPCC accomplished several landmark goals; including developing and implementing the first national HTC Staff Technical Assistance Needs Assessment and the first national HTC Patient Needs Assessment. Those successful efforts led to the activities of the current and second cycle of funding, developing and implementing a quality improvement (QI) project, in conjunction with the RHNs and other key stakeholders, on improving the access and care received in HTC subawardees. The third cycle of funding will focus on expanding the breadth and scope of the national quality improvement activities with the RHN that are currently underway and continuing to provide an ongoing forum for education, communication, and collaboration among the RHN and key stakeholders to address the needs of members of the bleeding and clotting community.

The 340B Drug Pricing Program

The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations (i.e., covered entities) at significantly reduced prices and enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Covered entities are defined in statute and include HRSA-supported hemophilia treatment centers (HTCs), health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children’s hospitals, and other safety net providers. To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity. Covered entities must recertify their eligibility every year and notify HRSA’s Office of Pharmacy Affairs whenever there is a change in their eligibility. If there is a change in a covered entity’s eligibility status, the covered entity has a responsibility to immediately notify OPA and should stop purchasing drugs through the 340B Drug Pricing Program.

Note: Pursuant to 45 C.F.R. § 75.307(e)(2), “Addition. With prior approval of the HHS awarding agency (except for IHEs and nonprofit research institutions, as described in paragraph (e) of this section), program income may be added to the federal award by
the federal agency and the non-federal entity. The program income must be used for the purposes and under the conditions of the federal award." Recipients are to add program income revenue to the funds committed to the project or program to “further eligible project and program objectives.” More specifically, reportable net program income is to be used for patient health, education, and supportive services necessary to provide comprehensive care to patients with hemophilia or related clotting and bleeding disorders served by the HTCs. Any proposed use of program income must be submitted to HRSA for Prior Approval through HRSA’s Electronic Handbooks (EHBs). Standard procedures for these submissions will be further elaborated during the Kick-Off Conference Call after recipients have received their Notice of Award.

Maternal and Child Health Bureau

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

MCHB recently revised its national performance measure (NPM) framework that focuses on the establishment of a set of population-based measures. The 15 NPMs address key national MCH priority areas that represent the following six MCH population domains: (1) Women/Maternal Health; (2) Perinatal/Infant Health; (3) Child Health; (4) CYSHCN; (5) Adolescent Health; and (6) Cross-cutting or Life Course. Learn more about MCHB and the six MCH population domains at http://mchb.hrsa.gov.

II. Award Information

1. Type of Application and Award

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

Funding will be provided in the form of a grant.

Data Rights

Pursuant to 45 CFR § 75.322(b), you own the copyright for materials that you develop under this grant, 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 grant and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.
2. Summary of Funding

Approximately $4,000,000 is expected to be available annually to fund up to eight (8) recipients. You may apply for a ceiling amount of up to $500,000 per year. The actual amount available will not be determined until enactment of the final FY 2017 federal budget. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is June 1, 2017 through May 31, 2022 (five (5) years). Funding beyond the first year is dependent on the availability of appropriated funds for the Regional Hemophilia Network Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

III. Eligibility Information

1. Eligible Applicants

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

You must be able to serve effectively as the regional center for hemophilia and bleeding disorders service needs (including the provision of counseling, testing, information dissemination, education and training) for one of the defined regions. Although this regional center may be multi-centered and multi-state, it must be headquartered within the region as defined by MCHB. You may NOT apply concurrently to become the lead organization for funding as both the National Hemophilia Program Coordinating Center

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Mid-Atlantic: Delaware, DC, Maryland, Pennsylvania, Virginia, West Virginia
Southeast: Alabama, Florida, Georgia, Mississippi, Kentucky, North Carolina, South Carolina, Tennessee
Great Lakes: Indiana, Michigan, Ohio
Northern States: Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Great Plains: Arkansas, Louisiana, Oklahoma, Texas, Iowa, Kansas, Missouri, Nebraska
Western States and Territory: California, Hawaii, Nevada, Guam
(NHPCC) (HRSA-17-087) and a Regional Hemophilia Network (RHN) (HRSA-17-074). If you do apply for both funding opportunities, you will be considered non-responsive and both applications will be disqualified. RHN applicants are allowed to be included as partners of any applicants for the NHPCC (HRSA-17-087).

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

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

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

NOTE: Multiple applications from an organization are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

2. Content and Form of Application Submission

Section 4 of HRSA’s SF-424 Application Guide provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. You are responsible for reading and complying with the instructions included in HRSA’s SF-424 Application Guide except where instructed in the FOA to do otherwise.
See Section 8.5 of the 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 FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

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

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

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

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

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

Use the following section headers for the Narrative:

- **INTRODUCTION** -- Corresponds to Section V’s Review Criterion 1 (Need)
  Briefly describe the purpose of the proposed project. You should briefly discuss your appropriate expertise and understanding of the issues related to this program.
- **NEEDS ASSESSMENT -- Corresponds to Section V’s Review Criterion 1 (Need)**
  Outline the needs of the bleeding and clotting community. The target population and its unmet health needs must be described and documented in this section. Disparities based on race, ethnicity, gender, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions impacting the population or communities served and those populations of patients that are not seen within HTCs should be considered. You should also consider people with disabilities; non-English speaking populations; lesbian, gay, bisexual, and transgender populations; people with limited health literacy; or populations that may otherwise be overlooked when identifying your target population. Include socio-cultural determinants of health and health disparities impacting the population or communities served and unmet. In addition, you should report on the current level of patient and family engagement within the region. You should also describe the extent to which patients have access to coordinated, integrated care in the context of a medical home model. Demographic data should be used and cited whenever possible to support the information provided. Please discuss any relevant barriers in the service area that the project hopes to overcome. This section should help reviewers understand the community and/or organization that will be served by the proposed project.

- **METHODOLOGY -- Corresponds to Section V’s Review Criterion 2 (Response)**
  Propose methods that will be used to address the stated needs and meet each of the previously described program goals, requirements, and objectives in this FOA. Be sure to describe, but do not limit yourself to:
  
  - Activities used to achieve each project goal, requirement, and objective.
  - A plan for establishing formal procedures that document oversight of HTCs and their activities. Formal, standardized procedures should describe the oversight of participating HTCs, requirements of HTCs, roles and responsibilities of the regional staff and HTC staff, and how the region will assist HTCs in accomplishing program goals and objectives. These procedures should be clearly written and widely available to HTCs and new HTC organizations interested in becoming subawardees. A draft manual of procedures should be included as Attachment 9.
  - Methods for developing, collecting and disseminating evidence-based materials, best practices, white papers, and peer-review articles that highlight results of program goals, improved care processes, and improved clinical outcomes for patients throughout their lifespan.
  - Plans for developing and implementing effective and culturally and linguistically relevant outreach to unserved and underserved people with hemophilia and other congenital bleeding disorders.
  - Plans for implementing at least one annual regional meeting for HTC staff.
  - Plans and methods to support region’s HTC subawardees in participating and implementing national QI projects, in conjunction with the NHPCC. National QI projects should focus on the entire system of care for hemophilia patients and their families and over the course of the project period address: 1) transition, 2) increasing patient/family engagement, and 3) ensuring access to a medical home and integrating the treatment of hemophilia and related bleeding
disorders or clotting disorders such as thrombophilia with other systems of care.

- Plans and methods on how the region and the HTC will collaborate with the NHPCC on: 1) national QI projects; 2) establishing and implementing evidence-based best practices for an HTC integrated care team; 3) promoting national standards of care; 4) promoting patient and family engagement, including recruiting HTC staff, patients, and families to participate on NPHCC workgroups and/or committees; and 5) populating the NPHCC online repository with regional materials.

- Methods for promoting patients and families as partners in care at the HTC (e.g., having patients on advisory committees, increasing availability of patient navigators within clinics, etc.). Activities should include plans for building capacity to track and collect data on patient and family engagement.

- Methods for identifying, prioritizing, and addressing emerging issues of importance, including increasing access to, and the improvement of, hemophilia and related bleeding and clotting disorder services through outreach to underserved populations in conjunction with key stakeholders.

- Engaging and forming partnerships with key stakeholders including: the NHPCC, the National Hemophilia Foundation (NHF), NHF’s Medical and Scientific Advisory Council, the American Thrombosis and Hemostasis Network, professional hematologic and policy organizations, bleeding and clotting researchers, consumers, and federal partners. Program activities may include:
  - Participating in collaborative efforts with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), HRSA’s MCHB-funded programs, which could include, but are not limited to, the CDC’s Community Counts Public Health Surveillance Project, and MCHB-funded programs such as the Regional Genetics Networks, the Sickle Cell Disease Demonstration Project and the Sickle Cell Newborn Screening Program.

- Activities that support all HTCs in reporting data on the program objectives and selected Healthy People 2020 measures. All HTCs within the region should have the capacity to collect patient-level data necessary to participate in quality improvement projects and to track longitudinal health care outcomes and processes, including Healthy People 2020.

- How program income, including program income from any 340B Factor Replacement Product programs, will be used and disbursed, consistent with applicable federal regulation and policies. Include any information on guidelines or policies for disbursement. Address how this information will be transmitted to HTC subawardees and how the recipient will monitor HTC compliance.

Note: Pursuant to 45 C.F.R. § 75.307(e)(2), “Addition. With prior approval of the HHS awarding agency (except for IHEs and nonprofit research institutions, as described in paragraph (e) of this section), program income may be added to the federal award by the federal agency and the non-federal entity. The program income must be used for the purposes and under the conditions of the federal award.” Recipients are to add program income revenue to the funds committed to the project or program to “further eligible project and program objectives.” More specifically, reportable net program income is to be used for
patient health, education, and supportive services necessary to provide comprehensive care to patients with hemophilia or related clotting and bleeding disorders served by the HTCs.

Reminder: If a drug is purchased at 340B discount prices by or on behalf of a Medicaid beneficiary, the amount billed may not exceed the entity’s actual acquisition cost for the drug, as charged by the manufacturer at the price consistent with the Veterans Health Care Act of 1992 (P.L. 102-585), plus a reasonable dispensing fee established by the state Medicaid agency.

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

- **WORK PLAN -- Corresponds to Section V’s Review Criteria 2 (Response) and 4 (Impact)**
  In Attachment 1 describe the activities or steps that will be used to achieve each of the objectives proposed during the entire project period in the Methodology section. Use a timeline that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application and, further, the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversity of the populations and communities served. The reviewers should clearly be able to link the overall program objectives with your specific project goals, objectives, and activities.

You must submit a logic model for designing and managing their project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this announcement the logic model should summarize the connections between the:

- Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the program will work and its supporting resources. Assumptions should be based on research, best practices, and experience.);
- Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources);
- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products or deliverables of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).
**RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion 2 (Response)**
Discuss challenges that are likely to be encountered in designing and implementing the activities described in the work plan, and approaches that will be used to resolve such challenges. The plan should address, but is not limited to, any of the following concerns: patient socioeconomic status; workforce issues, both within specialty and allied health care fields; insurance and formulary coverage trends; telehealth implementation; 340B program growth and stability within the hemophilia community, etc.

**EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V’s Review Criteria 3 (Evaluative Measures) and 5 (Resources/Capabilities)**
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, program requirements, and objectives of the project listed under Section I.1 within this FOA. 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. Specifically, describe how HTC’s QI activities will be monitored and coordinated. As a reminder, all HTCs within the region should have the capacity to collect patient-level data necessary to participate in quality improvement projects and to track longitudinal health care outcomes and processes, including Healthy People 2020.

You must describe the systems and processes that will support the organization’s performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes and addresses the program objectives.

Within the evaluation plan, regions are expected to confirm they have distributed written, standardized regional administrative processes/documents to 100 percent of HTCs in region within the first year. In addition, the plan should include a method for reporting within the non-compete continuation report:
- the number of best practices, educational materials, and white papers, articles developed and published.
- the number of HTCs participating in national QI project activities.
- the number of HTC staff that have received QI training/Technical Assistance.
- the number of regional/local QI initiatives.
- the number of patients/family members serving on advisory committees.
- the percent change (increase) from baseline in the number of patient navigators.
- the number of HTCs within region submitting data for HP2020 measures reported to HRSA, specifically Blood Disorder and Blood Safety (BDBS-15, -16 & Disability and Health (DH)-5.
- the number of regional core and HTC staff participating in NHPCC work
groups/committees.

Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze and track data to measure process and impact/outcomes, with different cultural groups (e.g., race, ethnicity, language) and explain how the data will be used to inform program development and service delivery. You must describe any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed.

- ORGANIZATIONAL INFORMATION -- Corresponds to Section V’s Review Criterion 5 (Resources/Capabilities)
  Provide information on your organization’s current mission and structure, scope of current activities, and an organizational chart, and describe how these all contribute to the ability of the organization to conduct the program requirements and meet program expectations. Provide information on the program’s resources and capabilities to support provision of culturally and linguistically competent and health literate services. Describe how the unique needs of target populations of the communities served are routinely assessed and improved. You should provide a description of the organizational structure, the decision-making process and approaches that will be employed to work cooperatively with HTCs and other partners and stakeholders. Include an effective communication plan that ensures regular meetings amongst the NHPCC. Describe responsibilities for collecting and analyzing data and how the results will be used. In addition, adequate resources should be devoted to conducting QI projects and be reflected in the budget.

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<th>NARRATIVE GUIDANCE</th>
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<td>In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.</td>
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<th>Narrative Section</th>
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<td>Introduction</td>
<td>(1) Need</td>
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<td>Needs Assessment</td>
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<td>Methodology</td>
<td>(2) Response</td>
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<td>Work Plan</td>
<td>(2) Response and (4) Impact</td>
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<td>Resolution of Challenges</td>
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<td>Evaluation and Technical Support</td>
<td>(3) Evaluative Measures and (5) Resources/Capabilities</td>
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<td>Capacity</td>
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<td>Organizational Information</td>
<td>(5) Resources/Capabilities</td>
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<tr>
<td>Budget and Budget Narrative</td>
<td>(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.</td>
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iii. **Budget**

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

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

In addition, the Regional Hemophilia Network program requires the following:

- Funding for at least one annual regional meeting for HTC subawardee staff.
- Attendance at annual in-person meeting conducted by the NHPCC.

If a drug is purchased at 340B discount prices by or on behalf of a Medicaid beneficiary, the amount billed may not exceed the entity’s actual acquisition cost for the drug, as charged by the manufacturer at the price consistent with the Veterans Health Care Act of 1992 (P.L. 102-585), plus a reasonable dispensing fee established by the state Medicaid agency.

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

iv. **Budget Narrative**

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

v. **Program-Specific Forms**

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

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

2) Performance Measures for the “Regional Hemophilia Network Program”

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

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

**vi. Attachments**

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

**Attachment 1: Work Plan**

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

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

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

**Attachment 3: Biographical Sketches of Key Personnel**

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

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

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

**Attachment 5: Project Organizational Chart**

Provide a one-page figure that depicts the organizational structure of the project.
Attachment 6: Tables, Charts, etc.
To give further details about the proposal (e.g., Gantt or PERT charts, flow charts, etc.).

Attachment 7: For Multi-Year Budgets--Fifth Year Budget (NOT counted in page limit), if applicable
After using columns (1) through (4) of the SF-424A Section B for a five-year project period, you will need to submit the budget for the fifth year as an attachment. Use the SF-424A Section B. See Section 4.1.iv of HRSA’s SF-424 Application Guide.

Attachment 8: Summary Progress Report
ACCOMPLISHMENT SUMMARY (FOR COMPETING CONTINUATIONS ONLY)
A well-planned accomplishment summary can be of great value by providing a record of accomplishments. It is an important source of material for HRSA in preparing annual reports, planning programs, and communicating program-specific accomplishments. The accomplishments of competing continuation applicants are carefully considered during the review process; therefore, you are advised to include previously stated goals and objectives in your application and emphasize the progress made in attaining these goals and objectives. Because the Accomplishment Summary is considered when applications are reviewed and scored, competing continuation applicants who do not include an Accomplishment Summary may not receive as high a score as applicants who do. The Accomplishment Summary will be evaluated as part of Review Criterion 4: IMPACT.

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

(1) The period covered (dates).

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

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

Attachment 9: Request for Funding Priority
To receive a funding preference, include a statement that you are eligible for a funding preference and identify the preference. Include documentation of this qualification. See Section V.2.
**Attachment 10: Draft Manual of Procedures**

Provide documentation of the oversight of participating HTCs, requirements of HTCs, roles and responsibilities of the regional staff and HTC staff, and how the region will assist HTCs in accomplishing program goals and objectives. Awardees will have the opportunity to finalize their documentation during the first quarter of the project period.

**Attachments 11-15: Other Relevant Documents**

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

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

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during 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://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

For further details, see Section 3.1 of HRSA’s [SF-424 Application Guide](#).

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

Application Due Date
The due date for applications under this FOA is October 4, 2016 at 11:59 P.M. Eastern Time.

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

5. Intergovernmental Review

The “Regional Hemophilia Network” 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 five (5) years, at no more than $500,000 per year. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project’s objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds (including federal award dollars and program income) under this announcement may not be used for the following purposes:

- **Foreign travel:** Any foreign travel (using federal award dollars or federal program income) must be submitted to HRSA for approval through the EHBs under Prior Approval – Other.
- **Construction and Major Alterations and Renovations:** Unless specifically authorized by law, award funds, and program income generated from award funds, may not be used to fund construction or the acquisition of title to real property. The HTC authorizing statute, 42 U.S.C. § 701(a)(2), does not provide sufficient legal authority for construction or major renovations. In addition, 45 C.F.R. § 75.307: Program Income, states that program income must be used for the same objectives/purposes/goals of the hemophilia program that are stated in the Funding Opportunity Announcement (FOA). As this FOA contains no requirement, goal, or objective regarding construction, using program income for these purposes is not allowable under the current award.

For the purposes of the Regional Hemophilia Network program, major Alteration & Renovation (A&R) project exceeding $150,000 is unallowable. Major A&R consists of a structural change (e.g., to the foundation, roof, floor, or exterior or load-bearing walls of a facility or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change function and purpose of the facility.
The General Provisions in Division H of the Consolidated Appropriations Act, 2016 (P.L. 114-113) apply to this program. Please see Section 4.1 of HRSA’s SF-424 Application Guide for additional information. Note that these or other restrictions will apply in FY 2017, as required by law.

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

All program income generated as a result of awarded funds, including program income from any 340B Factor Replacement Product programs, must be used for approved project-related activities.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which each 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 the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The Regional Hemophilia Network has six (6) review criteria:

Criterion 1: NEED (5 points) – Corresponds to Section IV’s Introduction and Needs Assessment
The extent to which the application demonstrates the problem and associated contributing factors to the problem.

Criterion 2: RESPONSE (40 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 applicant’s 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 regional collaborative approach to:

   Planning Activities (20 points)
   • Establish a regional infrastructure of HTCs via subawards, including developing formal procedures that explain the oversight of participating HTCs, requirements
of HTCs, procedures for approving use of program income, roles and responsibilities of the regional staff and HTC staff, and how the region will assist HTCs in accomplishing program goals and objectives. (4 points)

- Form partnerships with various stakeholders including federal and non-federal organizations. (3 points)
- Provide methods for developing, collecting and disseminating evidence-based materials, best practices, white papers, and peer-review articles that highlight results of program goals, improved care processes, and improved clinical outcomes for patients throughout their lifespan. (3 points)
- Support at least one annual regional meeting for HTC subawardees staff and attend annual in-person meeting conducted by the NHPCC (3 points)
- Plan for how program income, including program income from any 340B Factor Replacement Product programs, will be used and disbursed, consistent with applicable federal regulation and policies. The extent to which the applicant addressed how this information will be transmitted to HTC subawardees and how the recipient will monitor HTC compliance. (3 points)
- Develop a work plan that includes a logical, stepwise process and lists activities that support the goals, requirements and objectives of the RHN Program, including a reasonable and achievable timeline and a sustainability strategy for after the award ends without the use of HRSA funding. (4 points)

Implementation and Evaluation Activities (20 points)

- Facilitate the sharing of standardized materials/practices with HTCs and provide technical assistance to strengthen HTC integrated care teams. Describe how program income, including program income from any 340B Factor Replacement Product programs, will be used and disbursed, consistent with applicable federal regulation and policies. Include any information on guidelines or policies for disbursement. (4 points)
- Support HTCs to participate and implement national quality improvement (QI) projects, in conjunction with the National Hemophilia Program Coordinating Center (NHPCC), that focus on the entire system of care for hemophilia and related blood or clotting patients/families. (4 points) Over the course of the project period, QI projects should focus on:
  - Transition (e.g., from pediatric care to adult care, education to employment, etc.)
  - Increasing patient and family engagement in care decisions and HTC, regional, and NHPCC program activities.
  - Ensuring access to a medical home and integrating hemophilia treatment with other systems of care.
- Participate on NHPCC workgroups and collaborate with the NHPCC to achieve regional and national program goals, requirements, objectives, and activities. Activities may include recruiting HTC staff, patients, and families to participate on NPHCC workgroups and or committees, and populating the NPHCC online repository with regional materials. (3 points)
- Promote patients and families as partners in care at the HTCs (e.g., having patients on advisory committees, increasing availability of patient navigators within clinics, etc.). Activities should include plans for building capacity to track and collect data on patient and family engagement. (3 points)
• Identify, prioritize, and address emerging issues of importance, including increasing access to, and the improvement of, hemophilia and related bleeding and clotting disorder services through culturally and linguistically relevant outreach to underserved populations in conjunction with key stakeholders. Additionally, identify and address challenges that are likely to be encountered in designing and implementing the activities in the work plan including patient socioeconomic status, workforce issues, both within specialty and allied health care fields, insurance and formulary coverage trends, telemedicine implementation, 340B program stability, etc. (3 points)

• Support all HTCs in reporting data on program objectives and selected Healthy People 2020 measures. All HTCs within the region should have the capacity to collect patient-level data necessary to participate in HRSA required quality improvement projects and to track longitudinal health care outcomes and processes, including Healthy People 2020. (3 points)

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

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

• Provide an evaluation plan that monitors ongoing processes and the progress towards the goals, program requirements, and objectives of the award. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities. Describes current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. (4 points)

• Describe how the program-specific objective data will be collected, analyzed, and tracked. (3 points)

• Provide a QI performance evaluation that monitors progress towards achieving QI project goals. (3 points)

• Describe the systems and processes that will support the organization’s performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes and addresses the program objectives. (3 points)

• As appropriate, describes the data collection strategy to collect, analyze and track data to measure process and impact/outcomes, with different cultural groups (e.g., race, ethnicity, language) and explain how the data will be used to inform program development and service delivery. (4 points)

• Describes any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed. (3 points)
Criterion 4: IMPACT (20 points) – Corresponds to Section IV’s Work Plan

- The feasibility and effectiveness of plans for dissemination of project results. (4 points)
- The extent to which project results may be national in scope. (4 points)
- The degree to which the project activities are replicable. (4 points)
- The sustainability of the program beyond the federal funding. (4 points)
- The extent to which applicants describe how program income revenue is added to the funds committed to the program to further eligible project and program activities. (4 points)

Criterion 5: RESOURCES/CAPABILITIES (10 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. (4 points)
- The extent to which the applicant describes documentation of support and commitment to perform award projects from proposed HTC subawardees, and other stakeholders. (3 points)
- 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. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. (3 points)

Criterion 6: SUPPORT REQUESTED (5 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 project activities, and the anticipated results.

- The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work. The extent to which key personnel have adequate time devoted to the project to achieve project objectives. (5 points)
  - Includes funding for at least one annual regional meeting for HTC staff and attendance by the regional coordinator and director at an annual in-person meeting conducted by the NHPCC.

2. Review and Selection Process

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

Please see Section 5.3 of HRSA’s SF-424 Application Guide for more details.
Funding Priorities
This program includes a funding priority. Prior to final funding decisions, HRSA will assess all applications within the fundable range for eligibility to receive priority points. You do not need to request a funding priority. To minimize potential grant activity disruptions and maximize the effective use of federal dollars, HRSA will award priority points to competing continuation applicants according to the criteria below.

Program Compliance (5 points): HRSA will award 5 points if you are a competing continuation applicant applying to continue to serve your Region within Regional Hemophilia Network and if you have successfully achieved the previous grant goals and objectives based on progress reports submitted during the project period and a detailed accomplishment summary (submitted with this application) describing how the objectives were implemented and achieved.

3. Assessment of Risk and Other Pre-Award Activities

The Health Resources and Services Administration may elect not to fund applicants with management or financial instability that directly relates to the organization’s ability to implement statutory, regulatory or other requirements (45 CFR § 75.205). Applications receiving a favorable objective review that HRSA is considering for funding are reviewed for other considerations. These include, as applicable, cost analysis of the project/program budget, assessment of the applicant’s 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 grants information (such as an updated budget or “other support” information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that an award will be made. Following review of all applicable information, the HRSA approving 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 the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). An applicant may review and comment on any information about itself that a federal awarding agency previously entered. HRSA will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants 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 FAPIIS (45 CFR § 75.21245 CFR § 75.212).
4. Anticipated Announcement and Award Dates

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

VI. Award Administration Information

1. Award Notices

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

2. Administrative and National Policy Requirements

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

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

3. Reporting

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

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

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

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

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

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

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

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

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

   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.

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

VII. Agency Contacts

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

Mary C. Worrell
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Room 10N194B
Rockville, MD 20857
Telephone: (301) 443-5181
E-mail: mworrell@hrsa.gov

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

Kathryn McLaughlin, MPH
Director, National Hemophilia Program
MCHB/DSCSHN/Genetic Services Branch
Health Resources and Services Administration
5600 Fishers Lane, Room 18W08
Tel: (301) 443-6829
Fax: (301) 594-0878
E-mail: kmclaughlin@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, seven days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
E-mail: support@grants.gov
Successful applicants/ recipients may need assistance when working online to submit information and reports electronically through HRSA’s Electronic Handbooks (EHBs). For assistance with submitting information in HRSA’s EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET, excluding federal holidays at:

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

VIII. Other Information

Logic Models:

Additional information on developing logic models can be found at the following website: http://www.cdc.gov/nccdphp/dnpao/hwi/programdesign/logic_model.htm.

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 MCHB will host a pre-submission technical assistance conference call for all prospective applicants on Monday, August 22, 2016. Call details are as follows:

Time: 2:00 p.m. – 4:00 p.m. ET
Dial-in: 1-866-731-7986 / Passcode: 1522482
Web link: https://hrsa.connectsolutions.com/hrsa-17-074/

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA’s SF-424 Application Guide