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

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

## National Hemophilia Program Coordinating Center

Announcement Type: New and Competing Continuation Funding Opportunity Number: HRSA-17-087

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 3, 2016

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

## **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Division of Services for Children with Special Health Needs/Genetic Services Branch is accepting applications for fiscal year (FY) 2017 for the National Hemophilia Program Coordinating Center (NHPCC). The purpose of this program is to support a center that will coordinate a collaborative national infrastructure of regional hemophilia networks to promote and improve comprehensive quality care for individuals with hemophilia and related bleeding or clotting disorders such as thrombophilia.

Funding Opportunity Title:	National Hemophilia Program Coordinating
	Center
Funding Opportunity Number:	HRSA-17-087
Due Date for Applications:	October 4, 2016
Anticipated Total Annual Available	\$800,000
Funding:	
Estimated Number and Type of Award(s):	Up to one (1) cooperative agreement
Estimated Award Amount:	Up to \$800,000 per year
Cost Sharing/Match Required:	No
Project Period:	June 1, 2017, through May 31, 2022
	(five (5) years)
Eligible Applicants:	Per 42 CFR § 51a.3(a), any public or
	private entity, including an Indian tribe or
	tribal organization (as those terms are
	defined at 25 U.S.C. 450b) is eligible to
	apply. Faith-based and community-
	based organizations are eligible to apply.
	[See Section III-1 of this funding
	opportunity announcement (FOA) for
	complete eligibility information.]

#### **Application Guide**

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

#### **Technical Assistance**

MCHB will host a pre-submission technical assistance conference call for all prospective applicants on **Wednesday**, **August 24**, **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: <u>https://hrsa.connectsolutions.com/hrsa-17-087/</u>

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## I. Program Funding Opportunity Description

#### 1. Purpose

This announcement solicits applications for the National Hemophilia Program Coordinating Center (NHPCC). The purpose of the NHPCC funding opportunity is to support a center that will coordinate a collaborative national infrastructure of regional hemophilia networks to promote and improve comprehensive, quality care of individuals with hemophilia and related bleeding or clotting disorders such as thrombophilia.

#### **Program Goals**

Establish a national infrastructure to improve access to coordinated and comprehensive systems of care for patients with hemophilia and related blood or clotting disorders; strengthen the capacity of the Regional Hemophilia Network (RHN) and the hemophilia treatment centers' (HTC) integrated care teams; increase the evidence base on care for patients with hemophilia and related blood or clotting disorders; and track national, regional, and patient-level data to assess patient and health outcomes.

#### **Program Objectives**

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

- The number and type of technical assistance services provided to RHN and HTC staff.
- The number of active NHPCC workgroups/committees, the charter, and membership.
- The number of patients/families serving on NHPCC workgroups/committees and which committees.
- The number of HTC staff quality improvement (QI) trainings that were available to HTC subawardee staff.
- The number of HTC staff that completed QI trainings.
- The number of regions and HTC subawardees participating in reportable national NHPCC activities.
- The number and titles of educational materials/reports/articles disseminated from NHPCC workgroups/committees.
- The number and types of submissions of materials to NHPCC public and private access website.
  - By the fourth quarter in Year two, the percent increase from baseline in the # of submissions/materials to NHPCC online repository.
- The number and type of annual RHN leadership in-person meetings.
- National QI project data results on transition survey, increased patient/family engagement/tracking medical homes of patients for each RHN and their HTC subawardees.
- The number of HTC subawardees (and their regions) submitting data for Healthy People 2020 (HP2020) measures.
- Analysis on the RHN results for the following measures:

- Discretionary Grant Information System (DGIS) CSHCN measure 2 Medical Home
- DGIS CSCHN measure three Transition
- DGIS CSCHN measure one Family Engagement
- Analysis on the number of annual comprehensive visits recorded by Regional Hemophilia Networks (RHNs) and their HTC subawardees.

In addition to the above program requirements and objectives, the awardee is expected to use strategies to address hemophilia and related bleeding disorders as chronic conditions and share resources to address identified gaps.

#### **Program Requirements**

Awardees must:

- Provide an infrastructure that provides technical assistance and supports the work of the RHNs which results in a uniformity of practice and developing standards of care, accessible care for all patients and their families, improved quality of care, and the dissemination of bleeding and clotting disorder services and information.
- Coordinate and support national QI projects carried out by the RHNs. National QI projects will focus on the entire system of care for hemophilia patients and their families over the course of the project period and should address:
  - a. Transition (e.g., from pediatric care to adult care, education to employment, etc.)
  - b. Increasing patient/family engagement in care decisions and HTC, Regional, and NHPCC program activities.
  - c. Ensuring access to a medical home and integrating hemophilia treatment with other systems of care.
- 3) Support a national patient-level hemophilia database by collecting regional specific data, including supporting regional and national QI projects and data reporting for HP2020.
- Develop and maintain a national online repository of evidence-based articles, best practices and standards of care, and educational materials for regional and HTC subawardee staff and patients.
- 5) Work with RHNs to 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.
- 6) Support and fund at least one in-person meeting annually for all RHNs and identified staff.

### 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 involving specific blood clotting. 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 other congenital bleeding disorders, including von Willebrand disease (VWD), a hereditary bleeding disorder that affects men and women. VWD is caused by a decrease in von Willebrand factor and 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.<sup>1</sup> 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*.<sup>2</sup> All hemophilia treatment centers supported under this funding opportunity as subawardees (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 comprehensive 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 of preventive medicine, carrier detection, genetic and prenatal counseling, patient education and engagement in care, blood product use, complications of therapy, and are used in the care of individuals with bleeding disorders.

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 HTC subawardees, 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

 <sup>&</sup>lt;sup>1</sup> Guh S, Grosse SD, McAlister S, Kessler CM, Soucie JM. Health care expenditures for Medicaid-covered males with haemophilia in the United States, 2008. Haemophilia. 2012 Mar;18(2):276-83. doi: 10.1111/j.1365-2516.2011.02713.x. Epub 2011 Dec 21. Accessed May 9, 2016. Available online: <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4684173/</u>
 <sup>2</sup> National Hemophilia Foundation. Medical and Scientific Advisory Council (MASAC), MASAC Document #132: *Standards and*

<sup>&</sup>lt;sup>2</sup> National Hemophilia Foundation. Medical and Scientific Advisory Council (MASAC), MASAC Document #132: *Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders*. Revised and Approved by MASAC on March 24, 2002 and by the NHF Board of Directors on April 15, 2002. Available online: <u>https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/Standards-and-Criteria-for-the-Care-of-Persons-with-Congenital-Bleeding-Disorders.</u>

clotting disorder services into health care systems; and, 7) build and strengthen the benign hematology workforce.

This announcement is the third cycle of funding for the NHPCC. 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 QI project, in conjunction with the RHNs and other key stakeholders, on improving the access and care received from 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.

#### **Regional Hemophilia Network (RHN)**

The purpose of the Regional Hemophilia Network funding opportunity (HRSA-17-074) 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. The eight RHNs are currently made up of 135 HTC subawardees. The RHNs and their HTC subawardees work to improve hemophilia care and patient outcomes by ensuring that individuals with hemophilia and other congenital bleeding disorders and their families have access to coordinated, integrated care in the context of a medical home model. The RHN and the NHPCC are the two components of HRSA's National Hemophilia Program.

#### 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) Children and Youth with Special Health Care Needs (CYSHCN);(5) Adolescent Health; and (6) Cross-cutting or Life Course.

Learn more about MCHB and the six MCH population domains at <u>http://mchb.hrsa.gov</u>.

## II. Award Information

#### 1. Type of Application and Award

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

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

In addition to the usual monitoring and technical assistance provided under the cooperative agreement, **HRSA Program involvement shall include**:

- Participation in meetings conducted during the period of the cooperative agreement;
- Ongoing review and approval of activities and procedures to be established and implemented for accomplishing the scope of work;
- Review of project information prior to dissemination;
- Review of information on project activities;
- Assistance around establishing and facilitating effective collaborative relationships with federal and state agencies, MCHB award projects, other resource centers, and other entities that may be relevant to the project's mission;
- Participation in disseminating project information;
- Working with the recipient to ensure that they are compliant and not duplicating the work of other MCHB-funded projects; and
- Provision of information resources.

#### The cooperative agreement recipient's responsibilities shall include:

- Adhering to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds (see Acknowledgement of Federal Funding in Section 2.2 of HRSA's <u>SF-424 Application Guide</u>); );
- Meeting the deadlines for information and reports as required by the cooperative agreement;
- Ongoing communication and collaboration with HRSA;
- Providing the federal project officer opportunity to review project information prior to dissemination;
- Working with the federal project officer to review information on project activities as described within this award announcement, including QI and staff training development;
- Establishing contacts that may be relevant to the project's mission such as federal and non-federal partners, and other MCHB grant projects that may be relevant to the project's mission;
- Collaborating with MCHB-funded programs including, but not limited to, the Regional Genetics and Newborn Screening Collaboratives, the Newborn Screening Technical Assistance Center, the Clearinghouse of Newborn Screening Information, the Sickle Cell Disease Demonstration Project, and the Sickle Cell Newborn Screening Program;

- Requiring at least two key staff to attend joint meeting((s) of the National Coordinating Center/Regional Hemophilia Network Regional Leadership; and
- Holding and funding the logistical costs for at minimum one (1) joint meeting(s) per year of the National Coordinating Center/Regional Hemophilia Network Regional Leadership.

#### **Data Rights**

All publications the cooperative agreement recipient develops or purchases with funds awarded under this announcement must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the cooperative agreement recipient owns the copyright for materials that it develops under this cooperative agreement, 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 cooperative agreement and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by other researchers. The specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the Notice of Award (NoA). Data and copyright-protected works developed by a sub-recipient also are subject to the Federal Government's copyright license and data rights.

#### 2. Summary of Funding

Approximately \$800,000 is expected to be available annually to fund one (1) recipient. You may apply for a ceiling amount of up to \$800,000 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 "National Hemophilia Program Coordinating Center" 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 <u>2 CFR part 200</u> as codified by HHS at <u>45 CFR part 75</u>, which supersede 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. Faithbased and community-based organizations are eligible to apply.

You may NOT apply concurrently to become the lead organization for funding as both the National Hemophilia Program Coordinating Center (NHPCC) (HRSA-17-087) and the Regional Hemophilia Network (RHN) (HRSA-17-074). If you 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 <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

#### 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> except where instructed in the 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.
- 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 <u>SF-424 Application Guide</u> for additional information on this and other certifications.

#### **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), 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 describe 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 community and/or organization. The target population and its unmet health needs must be described and documented in this section. Disparities based on race, ethnicity, 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 HTC subawardees 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 needs of the bleeding and clotting community for transition education and planning, and the current level of patient and family engagement in the hemophilia community. 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 at the national level that the project hopes to overcome. This section should help reviewers understand the national landscape and the needs of the RHNs 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. Please describe, but do not limit to:
  - Activities used to achieve each project goal, requirement, and objective.
  - A plan for establishing formal procedures that support the work of the RHNs.
  - A plan for providing training and technical assistance to the RHNs and HTC subawardee staff to assist in accomplishing the goals and activities required for the RHNs. Training and technical assistance should focus on: the development of best practices and models of care, QI activities, educational materials for HTC subawardee staff and other groups to assist in promoting and highlighting the benefits of the HTC infrastructure, methods to improve outreach to patients not seen within the system, and addressing workforce issues.

- Methods for 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, and results of RHN and NHPCC activities, using a central, online repository. This repository should have two parts: a private module to allow the RHNs to work on documents in progress, and a public site to disseminate final materials broadly to the public.
- Plans to coordinate national and regional activities that contribute to the uniformity of practice and standards of care. Activities should include improving outreach to patients outside of the HTC subawardee system, especially those in underserved areas; addressing workforce issues; and the dissemination of bleeding and clotting disorder information and best practices.
- Plan to support an annual RHN Leadership in-person meeting. This meeting should include at minimum the regional coordinator and director of each region, NHPCC key personnel, and HRSA program staff.
- Plans to coordinate workgroups/committees to support the RHN infrastructure.
- Plans and methods to coordinate and support national QI projects carried out by the RHNs. National QI projects will 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 hemophilia treatment with other systems of care.
  - The plan should include methods to convene the RHNs to identify specific QI project and measure sets; technical assistance and training to RHN and HTC subawardee staff on QI methodologies; and how to serve as the centralized data repository for these projects, including analysis and providing data reports.
- Plans and methods to support a national patient-level hemophilia database by collecting regional- and HTC-specific data, including data required to report on Healthy People 2020 measures.<sup>3</sup> These activities should include methods of supporting the regions and HTC subawardees by having the capacity to collect, analyze, and report on aggregate HTC QI data, and the capacity to report on aggregate national data on selected Healthy People 2020 measures.
- Methods to 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. Program activities can include: providing an ongoing forum for education, communication, and collaboration among key stakeholders to identify, prioritize, and address the needs of members of the bleeding and clotting community.
- Engaging key stakeholders including: the RHNs, the National Hemophilia Foundation (NHF), NHF's Medical and Scientific Advisory Council, the American Thrombosis and Hemostasis Network, professional hematologic and

<sup>&</sup>lt;sup>3</sup> Within the Regional Hemophilia Network Funding Opportunity Announcement, HRSA-17-074, recipients are required to collect data on Healthy People 2020 Blood Disorder and Blood Safety Measures 15 and 16, and Disability & Health Measure 5.

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), and HRSA's MCHB-funded programs, which could include, but are not limited to, the CDC's Community Counts Public Health Surveillance Project and MCHBfunded programs such as the Regional Genetics Networks, the Sickle Cell Disease Demonstration Project and the Sickle Cell Newborn Screening Program.
- Provide evidence of collaborative relationships with stakeholders that clearly
  define the respective roles and responsibilities of the partners and how they will
  participate in coordinated activities with the NHPCC and the RHNs.
  Stakeholders and partners should include, but are not limited to: existing
  federal entities such as the CDC, NIH, and the National Heart, Lung and Blood
  Institute (NHLBI); hemophilia and other bleeding condition professional
  organizations (e.g., the American Society of Hematology, the Hemostasis and
  Thrombosis Research Society, etc.); nursing organizations, and allied health
  professional organizations; and family/patient organizations (e.g., the National
  Hemophilia Federation (NHF), and the Hemophilia Federation of America).

You must also propose a plan for project sustainability after the period of federal funding ends. You are expected to sustain key elements of the 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 activities proposed during the entire project period in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application and, further, the extent to which these contributors reflect the cultural, racial, linguistic and geographic diversity of the populations and communities served.

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

- Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable);
- Assumptions (e.g., beliefs about how the program will work and is supporting resources. Assumptions should be based on research, best practices, and experience.);
- Inputs (e.g., organizational profile, collaborative partners, key staff, budget,

other resources);

- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products or deliverables of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).
- RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review 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.

 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 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. Specifically, describe how the RHNs' QI activities will be monitored and coordinated. (Note: all HTCs within each RHN 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).

In regards to the central, online repository, describe the technology capacity in place to develop, implement, and host an interactive and evidence-based designed data repository for easy utility. There should have two parts: a private module to allow the RHNs to work on documents in progress and a public site to disseminate final materials broadly to the public.

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 your 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 related to the goals and objectives of the cooperative agreement.

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 outcome, process and/or balancing measures 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 the RHNs and other partners and stakeholders. Include an effective communication plan that ensures regular meetings amongst the NHPCC staff and the RHN Leadership. 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.

### NARRATIVE GUIDANCE

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

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – 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 <u>SF-424 Application Guide</u>. 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 National Hemophilia Program Coordinating Center program requires the following:

Fund an in-person annual meeting for RHN Leadership and identified staff.

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 <u>SF-424 Application Guide</u> 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 National Hemophilia Program Coordinating Center

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

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

#### vi. Attachments

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

#### Attachment 1: Work Plan

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

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

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 <u>SF-424</u> <u>Application Guide</u>.

#### 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 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) <u>Specific Objectives</u> Briefly summarize the specific objectives of the project as actually funded.
- (3) <u>Results</u> 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.

#### Attachments 10-15: 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 (<u>http://fedgov.dnb.com/webform/pages/CCRSearch.jsp</u>)
- System for Award Management (SAM) (<u>https://www.sam.gov</u>)
- Grants.gov (<u>http://www.grants.gov/</u>)

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 <u>SF-424 Application</u> <u>Guide</u> for additional information.

#### 5. Intergovernmental Review

The "National Hemophilia Program Coordinating Center" 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 <u>SF-424 Application Guide</u> for additional information.

#### 6. Funding Restrictions

You may request funding for a project period of up to five (5) years, at no more than \$800,000 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 under this announcement may not be used for the following purpose:

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

The General Provisions in Division H of the Consolidated Appropriations Act, 2016 (P.L. 114-113) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424 Application</u> <u>Guide</u> 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 must be used for approved project-related activities.

## V. Application Review Information

#### 1. Review Criteria

HRSA-17-087

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 the application. The entire proposal will be considered during objective review.

#### The National Hemophilia Program Coordinating Center 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 proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives. The extent to which the applicant describe an effective regional collaborative approach to provide:

#### Planning Activities (20 points)

- An infrastructure to support the work of the RHNs, including plans to coordinate workgroups/committees to support the RHN infrastructure. (4 points)
- Plans and methods to coordinate national and regional activities that contribute to the uniformity of practice and standards of care, including: improving outreach to patients outside of the HTC subawardee system, especially those in underserved areas; address workforce issues; and disseminating bleeding and clotting disorder information and best practices. (4 points)
- Plans to support at least one annual RHN Leadership in-person meeting. This meeting should include at minimum the regional coordinator and director of each region, NHPCC key personnel, and HRSA program staff. (3 points)
- Plans and methods for coordinating and supporting national QI projects carried out by the RHNs. National QI projects will 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 hemophilia treatment with other systems of care. (6 points)
  - The plan should include methods to convene the RHNs to identify specific QI project and measure sets; technical assistance and training to RHN and HTC subawardee staff on QI methodologies; and, how to serve as the centralized data repository for these projects, including analysis and providing data reports.

• A sustainability plan that sustains key elements of the project that improve practices and lead to improved outcomes for the target population. (3 points)

#### Implementation and Evaluation Activities (20 points)

- Methods for supporting a national patient-level hemophilia database by collecting regional- and HTC-specific data, including data required to report on Healthy People 2020 measures. These activities should include the capacity to collect, analyze, and report on aggregate HTC QI data, and the capacity to report on aggregate national data on selected Healthy People 2020 measures. (4 points)
- Methods to identify, prioritize, and address emerging issues of importance. Program activities can include: providing an ongoing forum for education, communication, and collaboration among key stakeholders to identify, prioritize, and address the needs of members of the bleeding and clotting community. (4 points)
- Support training and technical assistance plan for the RHNs and HTC subawardee staff to assist in accomplishing the goals and activities required for the RHNs. (4 points)
- Support the sharing of materials, preferably using a central, online repository which should contain materials and data on educational, quality improvement, and results of RHN and NHPCC activities. This repository should have two parts: a private module to allow the RHNs to work on documents in progress, and a public site to disseminate final materials broadly to the public. (4 points)
- Engagement of key stakeholders including: the RHNs, 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, federal partners, and other federally funded programs. Roles and responsibilities of the partners and how they will participate in coordinated activities with the RHNs should be included. (4 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 should monitor ongoing processes and the progress towards the goals and objectives of the goals and objectives of the award. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities. (6 points)
- Describe how the program objective data will be collected, analyzed, and tracked. (5 points)
- Provide a QI performance evaluation that should monitor progress towards achieving QI project goals. (5 points)
- Describe the technology capacity in place to develop, implement, and host an interactive and evidence-based designed data repository for easy utility. (4 points)

Criterion 4: IMPACT (20 points) – Corresponds to Section IV's Work Plan

- The feasibility and effectiveness of plans for dissemination of project results, preferably using a centralized electronic mechanism (5 points).
- The extent to which the applicant describes a QI process to quantitatively determine the long-term health progress and the activities of the RHNs and NHPCC (5 points).
- The capacity for, and experience in, regional and national data collection necessary to accomplish QI activities and all other program goals and objectives (5 points).
- The extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding (per Summary Progress Report in Attachment 8). (5 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 with hemophilia services and activities, quality improvement, and Regional Hemophilia Network program capacity and infrastructure to implement and carry out the project. (5 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 (per Summary Progress Report in Attachment 8). (5 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 research activities, and the anticipated results.

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

#### 2. Review and Selection Process

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

Please see Section 5.3 of HRSA's SF-424 Application Guide.

#### **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 serving the eight (8) regions 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 (<u>45 CFR § 75.205</u>).

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 <u>Federal Awardee Performance and Integrity</u> <u>Information System (FAPIIS)</u>. 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 <u>FAPIIS</u> 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 § 75.212).

#### 4. Anticipated Announcement and Award Dates

HRSA anticipates announcing 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 <u>SF-424 Application Guide</u> 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 <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</a>.

### 3. Reporting

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

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

The new reporting package can be reviewed at:

http://mchb.hrsa.gov/sites/default/files/mchb/Data/Discretionary\_Grant\_Information\_System\_Performance\_Measure\_Update.pdf

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

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

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

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

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

#### a) Performance Measures and Program Data

After the NoA is released, the Project Officer will inform grantees of the administrative forms and performances measures they must report.

#### b) Performance Reporting Timeline

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

#### c) Project Period End Performance Reporting

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

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

## **VII. Agency Contacts**

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

Mary 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: <u>mworrellmworrell@hrsa.gov</u>

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 Rockville, MD 20857 Tel: (301) 443-6829 Fax: (301) 594-0878 E-mail: <u>kmclaughlin@hrsa.gov</u>

You may need assistance when working online to submit their 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: <u>support@grants.gov</u> Self-Service Knowledge Base: <u>https://grants-</u> <u>portal.psc.gov/Welcome.aspx?pt=Grants</u>

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: <u>http://www.hrsa.gov/about/contact/ehbhelp.aspx</u>

### **VIII. Other Information**

#### Logic Models:

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

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:

MCHB will host a pre-submission technical assistance conference call for all prospective applicants on **Wednesday**, **August 24**, **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: <u>https://hrsa.connectsolutions.com/hrsa-17-087/</u>

## IX. Tips for Writing a Strong Application

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