# 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 Needs

# Regional Genetics Networks

**Announcement Type:** New **Opportunity Number:** HRSA-17-082

Catalog of Federal Domestic Assistance (CFDA) No. 93.110

#### FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2017

Letter of Intent Due Date: November 1, 2016

Application Due Date: December 14, 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: September 21, 2016

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Authority: Public Health Service Act, Title XI, § 1109(a)(2) and (4), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240) (42 U.S.C. 300b-8(a)(2) and (4)).

# **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Division of Services for Children with Special Health Needs (DSCSHN), Genetic Services Branch is accepting applications for fiscal year (FY) 2017 for Regional Genetic Networks (RGNs). The program intends to improve health equity and health outcomes in individuals with genetic conditions, reduce morbidity and mortality caused by genetic conditions (including congenital and metabolic disorders); and to improve the quality of coordinated and comprehensive genetic services to children and their families. The purpose of the RGNs is to: 1) link medically underserved populations (based on poverty, rural geographic location, and/or populations that experience health disparities)<sup>1</sup> to genetic services; 2) implement quality improvement activities to increase the connection with genetic services for the medically underserved; 3) implement evidence-based innovative models of telehealth<sup>2</sup> and/or telemedicine<sup>3</sup> with a focus on clinical genetics outreach; and 4) provide resources to genetic service providers, public health officials and families.

One application per region will be funded. A total of seven (7) Regional Genetics Networks will be funded.

- 1. **New England**: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- 2. **Mid-Atlantic:** Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Virginia, and West Virginia.
- 3. **Southeast:** Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and the Virgin Islands.
- 4. **Midwest:** Indiana, Illinois, Michigan, Minnesota, Ohio, Wisconsin, and Kentucky.
- 5. **Heartland:** Arkansas, Iowa, Kansas, Missouri, Nebraska, Oklahoma, North Dakota, and South Dakota.
- 6. **Mountain:** Arizona, Colorado, Montana, Nevada, New Mexico, Texas, Utah, and Wyoming.
- 7. Western: Alaska, California, Hawaii, Guam, Idaho, Oregon, and Washington.

HRSA-17-082

<sup>&</sup>lt;sup>1</sup> Medically Underserved Areas/Populations are areas or populations designated by HRSA/HPSA as having too few primary care providers, high infant mortality, high poverty or a high elderly population. http://www.hrsa.gov/shortage/find.html.

<sup>&</sup>lt;sup>2</sup> The Health Resources and Services Administration (HRSA) defines telehealth as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.

According to the American Telemedicine Association, telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology.

(http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VsrcU7VzIU)

Funding Opportunity Title:	Regional Genetics Networks
Funding Opportunity Number:	HRSA-17-082
Due Date for Applications:	December 14, 2016
Anticipated Total Annual Available	\$4,200,000
Funding:	
Estimated Number and Type of Award(s):	Up to seven (7) cooperative agreement(s)
Estimated Award Amount:	Up to \$600,000 per year
Cost Sharing/Match Required:	No
Project Period:	June 1, 2017 through May 31, 2020
	(three (3) years)
Eligible Applicants:	Applicants include: (1) a state or a political subdivision of a state; (2) a consortium of two or more states or political subdivisions of states; (3) a territory; (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or (5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.
	[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/">http://www.hrsa.gov/grants/apply/applicationguide/</a>.

# **Technical Assistance**

MCHB will host a pre-submission technical assistance webinar for all prospective applicants. Call details are as follows:

Day/Date: Tuesday, October 25, 2016

Time: 3:00 – 4:00 p.m. ET Dial-in: 1-/866-723-0810 Passcode: 31341820#

Web Link: https://hrsa.connectsolutions.com/rgn/

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# I. Program Funding Opportunity Description

# 1. Purpose

This announcement solicits applications for Regional Genetics Networks (RGNs) to improve health equity and health outcomes in individuals with genetic conditions (including congenital and metabolic disorders), reduce morbidity and mortality caused by genetic conditions, and strengthen and improve the quality of coordinated follow-up and treatment for comprehensive genetic services. The purpose of the RGNs is to: 1) link medically underserved populations (based on poverty, rural geographic location, and/or populations that experience health disparities)<sup>4</sup> to genetic services; 2) implement quality improvement activities to increase the connection with genetic services for the medically underserved; 3) implement evidence-based innovative models of telehealth<sup>5</sup> and/or telemedicine<sup>6</sup> with a focus on clinical genetics outreach; and 4) provide resources to genetic service providers, public health officials and families.

# **Program Goals**

Each region will establish a network of partnerships and connections to link individuals and families to genetic services. A focus will be on linking medically underserved populations (based on poverty, rural geographic location, and/or populations that experience health disparities)<sup>7</sup> to genetic service providers, and promoting efficient genetic services practices through the use of health information technologies such as telehealth/telemedicine.

One application per region will be funded. The regions are:

- 1) **New England:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- 2) **Mid-Atlantic:** Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Virginia, and West Virginia.
- 3) **Southeast:** Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and Virgin Islands.

<sup>&</sup>lt;sup>4</sup> Medically Underserved Areas/Populations are areas or populations designated by HRSA/HPSA as having too few primary care providers, high infant mortality, high poverty or a high elderly population. <a href="http://www.hrsa.gov/shortage/find.html">http://www.hrsa.gov/shortage/find.html</a>.

<sup>&</sup>lt;sup>5</sup> The Health Resources and Services Administration (HRSA) defines telehealth as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.

<sup>&</sup>lt;sup>6</sup> According to the American Telemedicine Association, telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology. (<a href="http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VsrcU\_7VzIU">http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VsrcU\_7VzIU</a>)

<sup>&</sup>lt;sup>7</sup> Medically Underserved Areas/Populations are areas or populations designated by HRSA/HPSA as having too few primary care providers, high infant mortality, high poverty or a high elderly population. http://www.hrsa.gov/shortage/find.html.

- 4) **Midwest:** Indiana, Illinois, Michigan, Minnesota, Ohio, Wisconsin, and Kentucky.
- 5) **Heartland:** Arkansas, Iowa, Kansas, Missouri, Nebraska, Oklahoma, North Dakota, and South Dakota.
- 6) **Mountain:** Arizona, Colorado, Montana, Nevada, New Mexico, Texas, Utah, and Wyoming.
- 7) Western: Alaska, California, Hawaii, Guam, Idaho, Oregon, and Washington.

# **Program Objectives**

- 1) By May 2018, each RGN will provide services to at least 250 individuals or families within the geographic area served by the RGN.<sup>8</sup>
- 2) By May 2020, each RGN will provide services to at least 1,500 individuals within the geographic area served by the RGN.
- 3) By May 2020, increase by 20 percent the number of medically underserved patients served by each RGN.
- 4) By May 2020, increase by 20 percent the percentage of clinical sites that use telehealth/telemedicine to provide genetic services.
- 5) By May 2020, increase by 20 percent the number of medically underserved patients receiving genetic services through telemedicine visits.
- 6) By May 2020, increase by 20 percent the number of primary care providers using RGN resources.

Baseline data will be collected and provided to HRSA for purposes of establishing the benchmark for this program objective by the end of year one of the award.

# **Program Requirements**

To achieve the goals of this program, each RGN must, following consultation with HRSA:

- 1) Establish a steering committee made up of stakeholders to provide guidance on meeting regional needs;
- 2) Develop a regional web-based genetics resource for primary care providers, public health professionals, and patients/families that will identify and map the availability of genetic services and resources in the region;
- 3) Implement a strategic plan to identify and link underserved populations within each state of the region served by the RGN to genetic service providers that provide services to patients within the state the plan must be included as Attachment 7, see Section IV;
- 4) In coordination with the National Coordinating Center (NCC) for the Regional Genetics Networks (RGNs) (HRSA-17-084) and other entities so as not to duplicate efforts, develop/disseminate educational resources for primary care

<sup>&</sup>lt;sup>8</sup> An individual or family directly "served" by the RGN is one for whom a genetic appointment has been facilitated through RGN resources, for example through a telehealth program, or indirectly through outreach and education to primary care or public health.

- providers that increase the ability of providers to identify, refer, and use genomic information in clinical management;
- 5) Establish partnerships and/or contracts as appropriate with regional academic institutions, health systems, or public health to coordinate access to genetic services for underserved populations;
- 6) Provide technical assistance (TA) to primary care providers and other specialists on various health information technology, such as telehealth/telemedicine, mobile health (mhealth), etc., to improve practice efficiencies and to reach underserved populations;
- 7) Facilitate telehealth/telemedicine outreach services within the region;
- 8) Establish communication strategies to share information, successes and barriers within the RGN and among regions;
- 9) Support an annual regional meeting of partners and other stakeholders and experts working within the region;
- 10) Promote patient and family engagement as partners in care by having patients and/or family members on workgroups and advisory groups and by collaborating with the National Genetics Education and Family Support Center;
- 11)Collaborate with the NCC on evidence-based quality improvement (QI) activities to achieve the aims of the award including:
  - a. Connecting underserved populations with clinical services,
  - b. Providing resources to genetic service providers, primary care, and public health agencies, and
  - c. Improving the quality of genetic care, with a focus on areas of need (e.g. integrating genetic services with primary care).
- 12) Up to \$100,000 of funding may be used for projects that address regional genetic service delivery issues. Specifically, projects must address a regional need and is limited to the following topics: long-term follow-up of individuals identified by newborn screening, access to a medical home, implementing new conditions on the recommended uniform screening panel, and transition. Performance measures that are SMART (specific, measureable, achievable, relevant, and time-bound) must be proposed for each project.
- 13) Collect RGN data and submit to the NCC;
- 14) Partner with stakeholders addressing genomic services including but not limited to: HRSA-funded programs such as the Sickle Cell Treatment Demonstration Regional Collaboratives; the Sickle Cell Newborn Screening Program; the Regional Hemophilia Network Program; the Newborn Screening Data Repository and Technical Assistance Center; the National Newborn Screening Clearinghouse; the Maternal and Child Environmental Health Network; Federally Qualified Health Centers (FQHCs); the CARES National Interdisciplinary Training Resource Center; Leadership, Education in Neurodevelopmental and Related Disabilities Program (LEND); the Catalyst Center, Improving Financing of Care for Youth and Children with Special Health Care Needs; the Association of Maternal and Child Health Programs (AMCHP); the Association of State and

Territorial Health Officials (ASTHO); and the Newborn Screening Translational Research Network (NBSTRN).

Baseline data will be collected and provided to HRSA for purposes of establishing the benchmark for this program objective by the end of year one of the award.

RGNs will be expected to provide data on how they are achieving the goals of the program, including collecting information on the following:

- 1) Number of individuals or families receiving services within each RGN;9
- 2) Number of medically underserved patients receiving services within each RGN;
- 3) Number of primary care, genetic service providers, and public health officials, participating in the regional network infrastructure;
- Number of technical assistance activities/services provided to genetic service providers;
- 5) RGN participation in QI activities to connect the medically underserved to genetic services:
- 6) Number of patients/families receiving education and resource materials;
- 7) Number of health care providers receiving education or using RGN resources;
- 8) Number of hits on RGN website and social media by stakeholders, providers and consumers:
- 9) Number of clinical sites that use telehealth/telemedicine to provide genetic services; and
- 10) Number of medically underserved patients receiving genetic services through telemedicine visits.

Quality Improvement (QI) Activities: Awardees will be expected to participate in one in-person QI meeting led by the NCC as well as share progress of QI activities through monthly conference calls with the NCC and HRSA/MCHB.

## **Recipient Requirements**

Successful RGN applicants must demonstrate an understanding of the clinical genetic service needs of populations within their region; have a strategic plan in place to identify which populations and their health care providers to target; and demonstrate the ability to develop strong partnerships with genetic service providers, primary health care provider communities, and public health officials. The successful applicant must also demonstrate an understanding of resources needed by health professionals to: identify individuals with or at-risk for genetic conditions, refer for genetic services, use genetic information in clinical management, and serve underserved population(s) in partnership with genetic services providers. All RGNs will be expected to work with the National Coordinating Center and the National Genetics Education and Family Support Center.

<sup>&</sup>lt;sup>9</sup> An individual or family directly 'served' by the RGN is one for whom a genetic appointment has been facilitated through RGN resources, for example through a telehealth program, or indirectly through outreach and education to primary care or public health.

# 2. Background

This program is authorized by Public Health Service Act, Title XI, § 1109, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240) (42 U.S.C. 300b-8(a)(2) and (4)).

From 2004 to 2017, HRSA/MCHB funded regional genetics and newborn screening collaborative awardees to provide leadership to expand, strengthen, and evaluate access to a system of genetic services. These awardees focused their work on a variety of topics including: newborn screening (NBS) laboratory quality assurance; NBS laboratory emergency preparedness; guidance to state public health officials on the addition of heritable disorders for state NBS panels; short and long-term follow-up and data collection on individuals identified through NBS and confirmatory testing; medical home and care coordination; transition from pediatric to adult care; strategic outreach via telemedicine to patients and providers; access to health care coverage for genetic testing and treatment; education of primary care providers; and engagement of families affected with genetic conditions, including education about family history. Regional activities were built upon collaboration with state public health agencies (Title V and NBS programs), community organizations, genetics specialists, primary and specialty care providers, and individuals with genetic conditions and their families.

While progress has been made in expanding and improving access and knowledge around genetic services, there are still gaps in the delivery of genetic services provided to medically underserved populations. These gaps include: geographic disparities in where the small medical genetic workforce is distributed (i.e., the workforce tends to be found in urban areas and/or academic medical centers) and health insurance reimbursement for genetic testing and counseling is limited, if covered at all. 10 Improving the integration of genetic services with primary care, particularly for underserved populations, has been a focus within the Maternal and Child Health Bureau's Children with Special Health Care Needs programs. For FY 2017, MCHB continues to focus on reducing morbidity and mortality caused by genetic conditions in newborns and children by establishing the Regional Genetics Networks (RGNs). The RGNs will address issues related to improving the access and quality of genetic service delivery. The RGNs are tasked with implementing innovative practices to connect underserved populations with clinical genetic services and provide resources to genetic service providers, primary care providers, families, and state public health workers in order to better support underserved populations. Each RGN will collaborate with the National Coordinating Center for the RGNs (NCC) and the National Genetics Education and Family Support Center.

<sup>&</sup>lt;sup>10</sup> Senier, L., Kearney, M., & Orne, J. (2015). *Using Public-Private Partnerships to Mitigate Disparities in Access to Genetic Services: Lessons from Wisconsin. Advances in Medical Sociology*, 16, 269–305. <a href="http://doi.org/10.1108/S1057-629020150000016010">http://doi.org/10.1108/S1057-629020150000016010</a>. Accessed online: August 8, 2016, at: <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4894330/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4894330/</a>

#### 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.

# The Division of Services for Children with Special Health Needs

With the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239 amended Title V of the Social Security Act to extend the authority and responsibility of MCHB to address the core elements of community-based systems of services for CYSHCN and their families. With this amendment, State Title V programs under the MCH Services Block Grant program were given the responsibility to provide and promote family-centered, community-based, coordinated care for CYSHCN and facilitate the development of community-based systems of services for such children and their families. CYSHCN are defined as "those children and youth who have or are at increased risk for chronic physical, developmental, behavioral or emotional conditions and who also require health and related services of a type or amount beyond that required by children generally." According to the National Survey of Children with Special Health Care Needs (2009/2010), 15.1 percent of children under 18 years of age in the United States, or approximately 11.2 million children, are estimated to have special health care needs. Overall, 23 percent of U.S. households with children have at least one child with special health care needs.

Through award initiatives, DSCSHN works to achieve the following six critical systems outcomes:

- 1) Family/professional partnership at all levels of decision making.
- 2) Access to coordinated ongoing comprehensive care within a medical home.
- Access to adequate private and/or public insurance and financing to pay for needed services.
- 4) Early and continuous screening for special health needs.
- 5) Organization of community services for easy use.
- 6) Youth transition to adult health care, work, and independence.

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<sup>&</sup>lt;sup>11</sup> Carman KL, Dardess P, Maurer M, Sofaer S, Adams K, Bechtel C, Sweeney J. Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies. Health Aff (Millwood). 2013 Feb;32(2):223-31. doi: 10.1377/hlthaff.2012.1133. Accessed online on August, 3, 2016, at:

http://content.healthaffairs.org/content/32/2/223.long

12 U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau. *The National Survey of Children with Special Health Care Needs Chartbook 2009–2010.* Rockville, Maryland: U.S. Department of Health and Human Services, 2013. Accessed August 3, 2016, at: http://mchb.hrsa.gov/cshcn0910/more/pdf/nscshcn0910.pdf

## **II. Award Information**

# 1. Type of Application and Award

Type(s) of applications sought: New.

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.

# As a cooperative agreement, **HRSA Program involvement will include**:

- Participating in RGN-supported meetings conducted during the period of the cooperative agreement;
- Collaborating with RGNs in developing activities and procedures to be established and implemented for accomplishing the scope of work;
- Reviewing RGNs' project information prior to dissemination;
- Providing assistance in establishing and facilitating effective collaborative relationships with federal and state agencies, and especially HRSA MCHB award projects;
- Participating in dissemination of RGNs' project information;
- Working with the RGNs to ensure they are compliant with FOA requirements and do not duplicate the work of other MCHB-funded projects; and
- Providing information resources.

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

- Adherence to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds.
- Conducting all tasks as they relate to the goals of the RGNs listed under the "Purpose" section of this funding opportunity;
- Participating in activities convened by the NCC specifically, QI activities to improve quality of care by connecting patients to services; activities on resources and education and for primary care; and other activities;
- Ensuring the integral involvement of the RGNs with the National Genetics Education and Family Support Center Family Center;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the RGNs' scope of work;
- Providing ongoing, timely communication and collaboration with the federal project officer;
- Working with the federal project officer to review information on RGN activities and products;
- Providing the federal project officer opportunity to review RGNs products prior to dissemination;
- Establishing contacts that may be relevant to the RGNs' project's mission;
- Facilitating partnerships with federal and non-federal entities and other HRSAfunded programs relevant to the RGNs cooperative agreement activities; and

 Meeting deadlines for RGN information and reports as required by the cooperative agreement.

# 2. Summary of Funding

Approximately \$4,200,000 is expected to be available annually to fund seven (7) recipients. You may apply for a ceiling amount of up to \$600,000 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, 2020 (three (3) years). Funding beyond the first year is dependent on the availability of appropriated funds for "Regional Genetics Networks" 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 supersede the previous administrative and audit requirements and cost principles that govern federal monies.

# **III. Eligibility Information**

# 1. Eligible Applicants

Eligible applicants include: (1) a state or a political subdivision of a state; (2) a consortium of two or more states or political subdivisions of states; (3) a territory; (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or (5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

You may NOT apply concurrently to become the lead organization for funding as both a Regional Genetics Network (HRSA-17-082) and the National Coordinating Center (NCC) (HRSA-17-084). If you do apply for both funding opportunities, you will be considered non-responsive and both applications will be disqualified. RGN applicants are allowed to be included as partners of any applicants for the NCC (HRSA-17-084).

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.

Non-Supplantation (also known as "Supplement Not Supplant")

Funds shall be used to supplement and not supplant other federal, state, and local public funds provided for activities described in this FOA.

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 <a href="http://www.grants.gov/applicants/apply-for-grants.html">http://www.grants.gov/applicants/apply-for-grants.html</a>.

# 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. 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) Outlines the needs within the target populations. The target population and its unmet health needs must be described and documented. Disparities based on race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions 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 their target population. Include socio-cultural determinants of health and health disparities impacting the population or communities served and unmet. 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. In addition, you should report on the current level of patient and family engagement within the region. For projects specific to long-term follow-up of individuals identified by newborn screening, access to a medical home, implementing new conditions on the recommended uniform screening panel, and transition, outline the need of the region specific activity, target population and its unmet needs that would be addressed. This section will help reviewers understand the underserved populations 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 accomplish the previously described program requirements and expectations described in Section I.1 of the FOA. In addition, the proposed methods should meet the requirements and review criteria outlined in Section V of this FOA. Be sure to describe but do not limit yourself to:
  - Activities used to achieve each project goal, requirement, and objective;
  - Plans to establish an advisory group to review progress towards meeting regional needs;
  - Plans for developing a regional web-based genetics resource for primary care providers, public health professionals, and patients/families that will identify and map genetic services and resources in the region;
  - Plans to develop/disseminate educational resources for primary care that increases the ability of providers to identify, refer, and use genomic information in clinical management in conjunction with the NCC or other entities so as not to duplicate effort;
  - Methods to prioritize/select the target populations to be included in the strategic plan and how to implement linking underserved populations within each state of the region to genetic service providers;
  - Plans for establishing partnerships and contracts as appropriate with regional academic institutions, health systems, or public health to coordinate access to genetic services for underserved populations;
  - Technical assistance activities to support genetic service providers to improve practice efficiencies, for example, on how to implement telehealth strategies or other health information technologies;
  - Methods for establishing communication strategies to share information, successes and barriers within the RGN and among the regions;
  - Plans to promote patient and family engagement as partners in care by having patients/family members on workgroups and advisory groups and by collaborating with National Genetics Education and Family Support Center;

- Methods for identifying potential evidence-based quality improvement (QI) activities and collaborating with the NCC on QI activities to achieve the aims of the award;
- Plans that address long-term follow-up of individuals identified by newborn screening, access to a medical home, implementing new conditions on the recommended uniform screening panel, or transition.
- Plans for working with the NCC;
- Methods and plans to partner with key stakeholders addressing genomic services including but not limited to: HRSA-funded programs such as the Sickle Cell Treatment Demonstration Regional Collaboratives; the Sickle Cell Newborn Screening Program; the Regional Hemophilia Network Program; the Newborn Screening Data Repository and Technical Assistance Center; the National Newborn Screening Clearinghouse; the Maternal and Child Environmental Health Network; Federally Qualified Health Centers (FQHCs); the CARES National Interdisciplinary Training Resource Center; Leadership, Education in Neurodevelopmental and Related Disabilities Program (LEND); the Catalyst Center; Improving Financing of Care for Youth and Children with Special Health Care Needs; the Association of Maternal and Child Health Programs (AMCHP); the Association of State and Territorial Health Officials (ASTHO); and the Newborn Screening Translational Research Network (NBSTRN).

You must include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences. You must also propose a plan for project sustainability after the period of federal funding ends. Recipients are expected to sustain key elements of their projects, e.g., strategies or services and interventions, which have been effective in improving practices and those that have led to improved outcomes for the target population.

WORK PLAN -- Corresponds to Section V's Review Criteria 2 (Response) and 4 (Impact)
 Submit a work plan in a table format. 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. The proposed project's goals, objectives, and activities should be clearly aligned with the stated needs and meet the previously described program goals, objectives, and requirements outlined in the Purpose section, and review criteria outlined in Section V of this FOA. Use a time allocation table, graph, or chart that includes each activity and identifies responsible staff and partners, proposed outcome, intended impact, and how the activity's outcome and impact will be measured included in Attachment 1. The reviewers should clearly be able to link the overall program objectives with your specific project goals, objectives, and activities.

Additionally, you must submit a logic model for designing and managing the project, Attachment 1. 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 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 include monitoring of ongoing processes and the progress towards the goals, program requirements, and objectives of the project listed under Section I.1 within this FOA, including specific, measurable, attainable, and realistic and time bound (SMART) objectives. 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 QI activities will be monitored and coordinated. Include a description of how you 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. Include the management of HRSA-assigned DGIS and evaluation measures and regionspecific projects. Clearly define an approach that is SMART. 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.

Within the evaluation plan, RGNs will be expected to provide data on the program objectives, how they are achieving the goals of the program and provide information on the following within the non-competing continuation report.

Baseline data will be collected by conclusion of Year 1, as follows:

- 1) Number of individuals or families receiving services within each RGN.<sup>13</sup>
- 2) Number of medically underserved patients receiving services within each RGN.
- 3) Number of primary care, genetic service providers, and public health officials, participating in the regional network infrastructure.
- 4) Number of technical assistance activities/services provided to genetic service providers.
- 5) RGN participation in QI activities to connect the medically underserved to genetic services.
- 6) Number of patients/families receiving education and resource materials.
- 7) Number of health care providers receiving education or using RGN resources.
- 8) Number of hits on RGN website and social media by stakeholders, providers and consumers.
- Number of clinical sites that use telehealth/telemedicine to provide genetic services.
- 10) Number of medically underserved patients receiving genetic services through telemedicine visits.
- ORGANIZATIONAL INFORMATION -- CORRESPONDS TO SECTION V'S REVIEW CRITERION 5 (RESOURCES/CAPABILITIES) Provide information on the applicant organization's current mission and management structure, scope of current activities, and an organizational chart (Attachment 5), and describe how these all contribute to the ability of the organization to conduct the program requirements and meet program expectations. Describe current experience, skills and knowledge, including the individuals on staff that demonstrate the capability of the organization to meet the goals of this program. Applicants should include an effective communication plan that ensures regular meetings, forums, and an annual regional meeting. Provide information on the program's resources and capabilities to support provision of culturally and linguistically competent and health literate services. Applicants should include an effective communication plan that ensures regular meetings with the NCC. Describe how the unique needs of the underserved populations of the communities served are routinely assessed and improved. In addition, adequate resources should be devoted to conducting QI projects and be reflected in the budget.

<sup>&</sup>lt;sup>13</sup> An individual or family directly "served" by the RGN is one for whom a genetic appointment has been facilitated through RGN resources, for example through a telehealth program, or indirectly through outreach and education to primary care or public health.

## 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
	(3) Evaluative Measures
	(4) Impact
	(6) Support Requested
Work Plan	(2) Response
	(4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(2) Response
Capacity	(3) Evaluative Measures
	(4) Impact
	(5) Resources/Capabilities
	(6) Evaluation and Technical Support
Organizational Information	(2) Response
	(3) Evaluative Measure
	(4) Impact
	(5) Resources/Capabilities
Budget and Budget Narrative	(5) Resources/Capabilities
	(6) 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.

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.

In addition, the Regional Genetics Networks program requires the following:

- Travel funds for designated attendees to annual RGN meetings;
- Travel Funds for Quality Improvement (QI) Activities: You will be expected to participate in one in-person QI meeting led by the NCC as well as share progress of QI activities through monthly conference calls with the NCC and HRSA/MCHB.
- Travel funds to support RGN key staff including Co-Program Directors and Program Manager, to an annual meeting of RGN Program Directors/Managers conducted by National Coordinating Center (NCC).
- Quality improvement: quality improvement activities that are required should be accounted for and included within the scope of the budget

#### 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 Genetics Networks"

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. To give more information on the strategic plan and the priority underserved populations both medically and geographically per state.

Attachment 6: Tables, Charts, etc.

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts, etc.)

Attachment 7: Strategic Plan and Medically Underserved Populations
Provide a strategic plan that includes: list of medically and geographically
underserved populations by state to be served by the RGN, a summary of the
goals for the Region, strategies to achieve goals. Please limit the plan to two
pages.

#### Attachments 8-15: Other Relevant Documents

Include here any other documents that are relevant to the application. 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 (<a href="http://www.grants.gov/">http://www.grants.gov/</a>)

For further details, see Section 3.1 of HRSA's SF-424 Application Guide.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

#### 4. Submission Dates and Times

# **Application Due Date**

The due date for applications under this FOA is *December 14, 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> Guide for additional information.

# 5. Intergovernmental Review

Regional Genetics Networks 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 three (3) years, at no more than \$600,000 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 purposes:

 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.

Per legislation, an eligible entity may not use amounts received to—

- 1) provide cash payments to or on behalf of affected individuals;
- 2) provide inpatient services;
- 3) purchase land or make capital improvements to property; or
- 4) provide for proprietary research or training.

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.

## 7. Other Submission Requirements

# **Notification of Intent to Apply**

You are eligible to apply even if no letter of intent is submitted. The letter should identify your organization and its intent to apply, and briefly describe the proposal to be submitted. The letter of intent should be no longer than one (1) page. Receipt of Letters of Intent will *not* be acknowledged.

This letter should be sent via e-mail by *November 1, 2016* to:

HRSA Digital Services Operation (DSO)
Please use HRSA opportunity number as e-mail subject (HRSA-17-082)
HRSADSO@hrsa.gov

# V. Application Review Information

#### 1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. Critical indicators have been developed for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

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

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

Criterion 1: NEED (5 points) – Corresponds to Section IV's Introduction and Needs Assessment

The extent to which the applicant demonstrates an understanding of 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, Evaluation and Technical Support Capacity and Organizational Information

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

# Planning Activities (13 Points)

- Establishes a regional infrastructure to connect underserved populations to genetic services, including an advisory group, and provides communication strategies to share information across the RGN. (4 points)
- Implements a strategic plan to identify and link underserved populations within each state of the region to genetic service providers. (5 points)
- Establishes partnerships and contracts as appropriate with regional academic institutions, health systems, or public health to coordinate access to genetic services for underserved populations and provide a plan to work with the NCC and participate on NCC workgroups. (4 points)

# Implementation and Evaluation Activities (27 points)

- Develop a regional web-based genetics resource for primary care providers, public health professionals, and patients/families that will identify and map genetic services and resources in the region. (4 points)
- Develop educational resources for primary care that increase the ability of providers to identify, refer, and use genomic information in clinical management. (4 points)
- Support technical assistance activities to support genetic service providers to improve practice efficiencies (e.g. health information technologies, such as telehealth strategies, mobile applications, etc.). (4 points)
- Promote patient and family engagement as partners in care by having patients/family members on workgroups and advisory groups and by collaborating with National Genetics Education and Family Support Center. (4 points)
- Identify potential projects on long-term follow-up of individuals identified by newborn screening, access to a medical home, implementing new conditions on the recommended uniform screening panel, or transition as well as identification of quality improvement (QI) activities for connecting medically underserved individuals to genetic services and collaborating with the NCC on QI activities to achieve the aims of the award. (4 points)
- Identify and address challenges that are likely to be encountered in designing and implementing the activities in the work plan. (4 points)
- Engage key stakeholders including HRSA-funded programs such as the Sickle Cell Treatment Demonstration Regional Collaboratives; the Sickle Cell Newborn Screening Program; the Regional Hemophilia Network Program; the Newborn Screening Data Repository and Technical Assistance Center; the National Newborn Screening Clearinghouse; the Maternal Reproductive and Child Environmental Health Network; Federally Qualified Health Centers (FQHCs); the CARES National Interdisciplinary Training Resource Center; Leadership, Education in Neurodevelopmental and Related Disabilities Program (LEND); the Catalyst Center; Improving Financing of Care for Youth and Children with Special Health Care Needs; the Association of Maternal and Child Health Programs (AMCHP); the Association of State and Territorial Health Officials (ASTHO); and the Newborn Screening Translational Research Network (NBSTRN). (3 points)

Criterion 3: EVALUATIVE MEASURES (18 points) – Corresponds to Section IV's Methodology, Evaluation and Technical Support Capacity, and Organizational Information

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:

- Provides an evaluation plan that includes monitoring ongoing processes and the progress towards the goals, program requirements, and objectives of the award. (3 points)
- Describes how the program specific objective data will be collected, analyzed, and tracked. (3 points)
- Describes 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 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. (3 points)
- Describes any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed. (3 points)
- Describes current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. (3 points)

Criterion 4: IMPACT (12 points) – Corresponds to Section IV's "Work Plan," Methodology, Evaluation and Technical Support Capacity, and Organizational Information

- 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), and
- The sustainability of the program beyond the federal funding. (4 points)

Criterion 5: RESOURCES/CAPABILITIES (16 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity, Organizational Information, and Budget

- The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. (6 points)
- The extent to which the capabilities of the applicant organization and the quality and availability of facilities and personnel fulfill the needs and requirements of the proposed project. (6 points)
- The extent to which the applicant describes the maintenance of up-to-date resources, tools, and models for sharing dissemination. (4 points.)

Criterion 6: SUPPORT REQUESTED (9 points) – Corresponds to Section IV's Methodology, Evaluation and Technical Support Capacity, 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 required resources sections, are reasonable given the scope of work. (5 points)
  - Includes funding for: at least one annual RGN meeting;
  - Attendance at an annual meeting of RGN Program Directors/Managers conducted by NCC;
  - Attendance at one in-person quality improvement meeting conducted by NCC:
  - Attendance at one in-person quality improvement meeting conducted by NCC; and
  - Adequate resources and budget allocated for quality improvement activities.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives. (4 points)

#### 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.

#### 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 § 75.212).

# 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 <a href="http://www.hhs.gov/ohrp/humansubjects/quidance/45cfr46.html">http://www.hhs.gov/ohrp/humansubjects/quidance/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 reflect 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 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: <a href="http://mchb.hrsa.gov/sites/default/files/mchb/Data/Discretionary\_Grant\_Information\_System\_Performance\_Measure\_Update.pdf">http://mchb.hrsa.gov/sites/default/files/mchb/Data/Discretionary\_Grant\_Information\_System\_Performance\_Measure\_Update.pdf</a>.

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). You 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 Notice of Award (NoA) is released, the MCHB Project Officer will inform awardees 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 <u>FAPIIS</u>, as required in <u>45 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:

Devon Cumberbatch
Grants Management Specialist
Division of Grants Management Operations, OFAM

Health Resources and Services Administration 5600 Fishers Lane, Room 10SWH03

Rockville, MD 20857

Telephone: (301) 443-7532 E-mail: DCumberbatch@hrsa.gov

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

Jill F. Shuger, ScM Project Officer

Attn: Regional Genetics Networks Maternal and Child Heath Bureau Health Resources and Services Administration

5600 Fishers Lane, Room 18W09D

Rockville, MD 20857

Telephone: (301) 443-3247 E-mail: JShuger@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: <a href="mailto:support@grants.gov">support@grants.gov</a>

Self-Service Knowledge Base: <a href="https://grants-portal.psc.gov/Welcome.aspx">https://grants-portal.psc.gov/Welcome.aspx</a>?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 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: <a href="http://www.cdc.gov/eval/resources/">http://www.cdc.gov/eval/resources/</a>.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. Information on how to distinguish between a logic model and work plan can be found at the following website: <a href="http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf">http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf</a>.

#### **Technical Assistance:**

MCHB will host a pre-submission technical assistance webinar for all prospective applicants. Call details are as follows:

Day/Date: Tuesday, October 25, 2016

Time: 3:00 – 4:00 p.m. ET Dial-in: 1- /866-723-0810 Passcode: 31341820#

Web Link: <a href="https://hrsa.connectsolutions.com/rgn/">https://hrsa.connectsolutions.com/rgn/</a>

# IX. Tips for Writing a Strong Application

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