U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



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

Quality Improvement in Newborn Screening Program

Funding Opportunity Number: HRSA-18-070
Funding Opportunity Type(s): New and Competing Continuation
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: March 20, 2018

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

Registration in all systems, including SAM.gov and Grants.gov,

may take up to 1 month to complete.

Issuance Date: January 18, 2018

Ann Ferrero, MPH Public Health Analyst

Telephone: (301) 443-3999

Fax: (301) 594-0878 Email: <u>aferrero@hrsa.gov</u>

Authority: 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).

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) 2018 for the Quality Improvement in Newborn Screening Program. The purpose of this program is to improve the outcomes of newborns with conditions identified through newborn screening (NBS) by: 1) improving the amount of time it takes to identify infants at high risk for having one of these conditions; 2) improving the processes used for detecting out-of-range results; 3) improving the procedures for reporting out-of-range results to providers; 4) improving methods NBS programs use to confirm diagnoses; and 5) addressing emerging issues, or any other NBS process or procedure that could negatively affect the quality, accuracy, or timeliness of NBS.

The FY 2018 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds a timely manner. You should note that this program may be cancelled prior to award recommendations.

Funding Opportunity Title:	Quality Improvement in Newborn		
	Screening Program		
Funding Opportunity Number:	HRSA-18-070		
Due Date for Applications:	March 20, 2018		
Anticipated Total Annual Available FY18	\$3,300,000		
Funding:			
Estimated Number and Type of Award(s):	Up to one cooperative agreement		
Estimated Award Amount:	Up to \$3,300,000 per year		
Cost Sharing/Match Required:	No		
Project Period/Period of Performance:	September 1, 2018 through		
	August 31, 2023 (5 years)		
Eligible Applicants:	A state or a political subdivision of a state; a consortium of two (2) or more states or political subdivisions of states; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or any other domestic entity with appropriate expertise in newborn screening, as determined by the Secretary.		
	See <u>Section III-1</u> of this notice of funding opportunity (NOFO), formerly known as the funding opportunity announcement (FOA), for complete eligibility information.		

Application Guide

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

Technical Assistance

HRSA has scheduled the following technical assistance webinar:

Webinar

Day and Date: Thursday, February 15, 2018

Time: 1-2 p.m. ET

Call-In Number: 1-888-826-9572 Participant Code: 77014936

Weblink: https://hrsa.connectsolutions.com/hrsa-18-070 ta webinar/

HRSA will record the technical assistance webinar and archive it at this website: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

Table of Contents

I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION	1
1. Purpose	
II. AWARD INFORMATION	4
1. TYPE OF APPLICATION AND AWARD	
III. ELIGIBILITY INFORMATION	6
1. ELIGIBLE APPLICANTS 2. COST SHARING/MATCHING 3. OTHER	6 6
IV. APPLICATION AND SUBMISSION INFORMATION	7
ADDRESS TO REQUEST APPLICATION PACKAGE CONTENT AND FORM OF APPLICATION SUBMISSION	
i. Project Abstractii. Project Narrative	
iii. Budgetiv. Budget Narrative	
v. Program-Specific Formsvi. Attachments	14
3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management	16
4. SUBMISSION DATES AND TIMES	
5. INTERGOVERNMENTAL REVIEW	
V. APPLICATION REVIEW INFORMATION	
1. Review Criteria	18
2. REVIEW AND SELECTION PROCESS	
ASSESSMENT OF RISK AND OTHER PRE-AWARD ACTIVITIES ANTICIPATED ANNOUNCEMENT AND AWARD DATES	
VI. AWARD ADMINISTRATION INFORMATION	
1. AWARD NOTICES	
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS	23
VII. AGENCY CONTACTS	26
VIII. OTHER INFORMATION	27
IV. TIDE FOR WRITING A STRONG ARRIVESTION	20

I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the Quality Improvement in Newborn Screening Program. The purpose of this program is to improve the outcomes of newborns with conditions identified through newborn screening (NBS) by: 1) improving the amount of time it takes to identify infants at high risk for having one of these conditions; 2) improving the processes used for detecting out-of-range results; 3) improving the procedures for reporting out-of-range results to providers; 4) improving methods NBS programs use to confirm diagnoses; and 5) addressing emerging issues, or any other NBS process or procedure that could negatively affect the quality, accuracy, or timeliness of NBS.

Program Goals

The overall goal of this program is to support quality improvement (QI) in newborn screening processes to ensure the optimal health and well-being of children with conditions identified through state newborn screening programs. The Quality Improvement in Newborn Screening Program will support the development and implementation of QI activities in at least 30 states identified by the end of the project period ("participating states"), focusing on timeliness, detection of out-of-range results, reporting out-of-range results to providers, confirming a diagnosis, and addressing emerging issues or any other NBS process or procedure that could negatively affect the quality, accuracy, or timeliness of NBS.

Program Objectives

The recipient will be responsible for collecting data on these objectives for the purpose of monitoring and evaluating the overall effectiveness of the program. Within the first year of the award, HRSA expects the recipient to establish baselines for these objectives.

- By 06/30/2022, 95 percent of newborn screens in participating states will meet the recommended NBS timeframes identified by the Advisory Committee on Heritable Disorders in Newborns in Children:¹
 - Presumptive positive results for time-critical conditions are communicated immediately to the child's healthcare provider but no later than five (5) days of life.
 - Presumptive positive results for all other conditions are communicated to the child's healthcare provider as soon as possible but no later than seven (7) days of life.
 - o All newborn screening results are reported within seven (7) days of life.

¹ https://www.hrsa.gov/advisory-committees/heritable-disorders/newborn-screening-timeliness.html

- By 06/30/2019, all participating states will have identified performance measures specific to their state's processes to identify and follow up on out-of-range results, specifying baseline measures and goals for each performance measure.
- By 06/30/2022, 85 percent of participating states will have met their specified goal(s) for improving identification of, and follow up on, out-of-range results.
- By 06/30/2019, all participating states will have identified performance measures specific to their state's processes for communicating screening results to providers and families and confirming diagnoses, specifying baseline measures and goals for each performance measure.
- By 06/30/2022, 85 percent of participating states will have met their specified goal(s) for improving communication of screening results to providers and families and confirming diagnoses.

Program Requirements

The Quality Improvement in Newborn Screening Program recipient will conduct the following activities:

Planning and Establishing State Teams

- Implement a plan to identify, and select at least 30 participating state teams to implement quality improvement activities focusing on one or more of the following components related to the newborn screening process: timeliness; detection of out-of-range results; reporting out-of-range results to providers; and/or confirming a diagnosis. Membership on the state teams should include NBS programs, state laboratories, hospitals and birthing centers, primary care providers, maternal and child health leaders, and other stakeholders.
- Establish a Steering Committee to help guide the project, consisting of newborn screening stakeholders including parents/families/individuals with conditions identified through NBS, State Health Departments, Newborn Screening Programs (including laboratory and follow-up personnel), MCH/Title V, public health surveillance, hospitals and birthing centers.

Coordination, Alignment, and Facilitation

- Conduct a kick-off and annual in-person meetings with all state NBS teams to advise and share strategies on innovation, best practices, data collection and reporting, and program sustainability beyond the project period.
- Maintain a web-based platform to facilitate online collaboration and learning activities for team participants.
- Create an online database to maintain, standardize, analyze, evaluate and report on NBS QI data from participating states.
- Identify and utilize an evidence-based quality improvement methodology or model for all QI activities.
- Provide leadership, education, and ongoing coaching and technical assistance (TA) to participating state teams on QI activities that improve timely diagnosis and follow-up. TA should include assistance on all of the following:
 - o Implementation of QI methodology, evidence-based strategies, and innovation practices (with emphasis on rapid cycle testing).

- Development of aims, change packages, measures to track progress, and appropriate data sources (including outcome and process measures).
- Implementation of data collection and reporting on QI measures.
- How to foster ongoing engagement of state teams.

Quality Improvement

- Support at least 30 participating state NBS teams in all of the following:
 - Developing a process map of NBS, identifying one or more of the following areas in need of improvement with respect to improving timeliness, the processes for identifying and following up on out-of-range results, removing gaps/barriers for communicating NBS results, and/or confirming diagnoses.
 - Developing performance measures and goals specific to their state's processes. (To the extent possible, measures should align with quality indicators developed by the Newborn Screening Data Repository and Technical Assistance Center, HRSA-18-080).
 - o Implementing QI activities.
 - Developing a plan of collecting and reporting data, and developing QI projects.
- Synthesize best available evidence in achieving timeliness in NBS, identifying outof-range results, communicating results to providers, and confirming a diagnosis.
- Establish method to identify and address emerging issues through QI methodology.

Dissemination and Spread

- Disseminate outcomes of activities and best practices to participating states and the newborn screening community via web, email, reports, webinars, listservs.
- Develop partnerships and facilitate information sharing with various stakeholders, including federal and non-federal organizations, and Department of Health and Human Services (HHS)-funded organizations in order to collaborate, coordinate, promote, and support these efforts and not duplicate efforts.
- Support and assist states with sustainability of QI activities and practices beyond the federal funding period. States must develop plans to sustain the goals, objectives, and improvements achieved through this program.

2. Background

NBS is a successful state and territorial public health program that saves and improves the lives of thousands of babies each year in the United States. Four million newborns each year are screened for up to 34 conditions recommended by the Secretary of Health and Human Services for states to include on their newborn screening panel. Some of these conditions can be life threatening in the first days of life, making it imperative that infants are identified in a timely way so immediate treatment can be initiated. Early intervention and treatment mitigates brain and organ damage, may affect disease severity, and may prevent life-threatening complications associated with these conditions.

Despite progress in the timely reporting of conditions, many states do not meet established recommendations.² Accuracy of reporting (reducing false-positives and false-negatives) is also important to ensure timely diagnosis.³ Interpretation of results can be impacted by age at the time of specimen collection and medical condition of the infant, making it challenging to interpret and report results, in particular borderline results, which could contribute to infants not being detected in time to initiate life-saving treatment.

The Quality Improvement in Newborn Screening Program was preceded by the Improving Timeliness of Newborn Screening Diagnosis Program, which was designed to improve the time to diagnosis and treatment for infants undergoing NBS who receive a presumptive positive result. Twenty-eight states participated in the program and reported several improvements between 2015 and 2017: median percent of specimens with a presumptive positive result for time critical disorders that were reported to the newborn's healthcare provider within 5 days of birth improved from 23 percent to 50 percent; median percent of specimens with a presumptive positive result for non-time critical disorders that were reported to the newborn's healthcare provider within 7 days of birth improved from 55 percent to 82 percent; median percent of specimens for all results reported to healthcare providers within 7 days of birth improved to 89 percent of specimens (up by 20 percent). This new program builds on lessons learned from the quality improvement work on timeliness in NBS and expands it in two ways. First, the current program will work with states that have not previously met the recommendations for NBS timeframes. Second, the program will implement quality improvement in three new areas, including identifying and following up on out-of-range results, communicating screening results to providers and families, and confirming diagnosis.

II. Award Information

1. Type of Application and Award

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

HRSA will provide funding 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.

HRSA Program involvement will include:

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

- Participation in meetings conducted during the period of the cooperative agreement.
- Ongoing review of activities and procedures to be established and implemented for accomplishing the scope of work.
- Review of project information prior to dissemination.

² https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/index.html

³ https://www.newsteps.org/quality-indicators-qi

- Assistance establishing and facilitating effective collaborative relationships with federal and state agencies, HRSA-funded grants, and other entities that may be relevant to the project's mission.
- Provision of information resources.
- Ensure compliance with NOFO requirements and ensure that activities do not duplicate the work of other HHS-funded projects.

The cooperative agreement recipient's responsibilities will include:

- Complete activities proposed in response to the NOFO.
- Collaborate with HRSA on ongoing review of activities, procedures and budget items, information/publications prior to dissemination, contracts and interagency agreements.
- Provide ongoing, timely communication and collaboration with the federal project officer.
- Provide the federal project officer opportunity to review documents and products prior to dissemination.
- Work with the federal project officer to review information on project activities as described within this funding notice.
- Establish contacts that may be relevant to the project's mission such as federal and non-federal partners, and other HRSA projects that may be relevant to the project's mission.
- Coordinate with HRSA-funded programs including, but not limited to, the Newborn Screening Data Repository and Technical Assistance Program, Sickle Cell Disease Follow Up programs, the Family-to-Family Health Information Centers, and Healthy Start and Home Visiting programs.
- Ensure that data collected is publicly available, free of charge, for use by the public without any restrictions imposed by the recipient.
- Provide HRSA or HRSA's designee the collected data, a data dictionary, and any
 other metadata that supports the usability or functionality of the collected data on a
 quarterly basis and when requested.
- Provide to HRSA or HRSA's designee all collected data, a data dictionary, source code, software and any other metadata that supports the usability or functionality of the collected data no later than the end of the project period.

Data Rights

All publications the cooperative agreement recipient develops or purchases with funds awarded under this notice 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

HRSA expects approximately \$3,300,000 to be available annually to fund one recipient. You may apply for a ceiling amount of up to \$3,300,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The actual amount available will not be determined until enactment of the final FY 2018 federal appropriation. The FY 2018 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The project period is September 1, 2018 through August 31, 2023 (5 years). Funding beyond the first year is dependent on the availability of appropriated funds for the Quality Improvement in Newborn Screening Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles and Audit Requirements at 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Eligible entities include: a State or a political subdivision of a State; a consortium of 2 or more States or political subdivisions of States; a territory; a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or any other domestic entity with appropriate expertise in newborn screening, as determined by the Secretary.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in *Section IV.4* non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

IV. Application and Submission Information

1. Address to Request Application Package

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

Effective December 31, 2017 - You **must** use the <u>Grants.gov Workspace</u> to complete the workspace forms and submit your application workspace package. After this date, you will no longer be able to use PDF Application Packages.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing the notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. Please note you are ultimately responsible for reviewing the Find Grant Opportunities page for all information relevant to desired opportunities.

2. Content and Form of Application Submission

Section 4 of HRSA's <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 NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the application package do not count in the page limitation. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- 3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment #9-15: Other Relevant Documents.

See Section 4.1 viii of HRSA's <u>SF-424 Application Guide</u> for additional information on all 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), include the following:

i. Project Abstract

See Section 4.1.ix of HRSA's SF-424 Application Guide.

ii. Project Narrative

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

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

- INTRODUCTION -- Corresponds to Section V's Review Criterion (1) Need
 - Describe the purpose of the proposed project including your experience in leading high-level state teams in effecting change though quality improvement strategies.
 - Briefly discuss your expertise working with newborn screening; state newborn screening programs; quality improvement; data collection and analysis.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) Need Outline the needs and challenges for state newborn screening programs with respect to timeliness, detection of out-of-range results, reporting out-of-range results to providers and families, and confirming diagnosis. Describe and document the target population and its unmet health needs. Use and cite demographic data whenever possible to support the information provided. Please discuss any relevant barriers that the project hopes to overcome. This section will help reviewers understand the community and/or organization that you will serve with the proposed project.

- METHODOLOGY -- Corresponds to Section V's Review Criterion (2) Response
 - Propose methods that you will use to address the stated needs and meet each of the previously described program requirements and expectations in this NOFO.
 - Describe the methods that you will use in the development of effective tools and strategies for training, outreach, collaborations, clear communication, and information sharing/dissemination.
 - Include a plan to disseminate reports, products, and/or project outputs so project information is provided to key target audiences and the public.
 - Propose a plan for sustainability for the project beyond federal project period.

Be sure to include how you will achieve the following activities:

Planning and Establishing Participating State Teams

- After award, plans to identify and select at least 30 participating state teams to implement quality improvement activities focusing on one or more of the following components related to the newborn screening process: timeliness; detection of out-of-range results; reporting out-of-range results to providers; and/or confirming a diagnosis. Membership on the state teams should include NBS programs, state laboratories, hospitals and birthing centers, primary care providers, maternal and child health leaders, and other stakeholders.
- O Plans to establish a Steering Committee to provide guidance to the project, to assist in prioritizing challenges and activities, and to provide expertise on best practices. The Steering Committee should consist of newborn screening stakeholders including parents/families/individuals with conditions identified through NBS, State Health Departments, Newborn Screening Programs (including laboratory and follow-up personnel), MCH/Title V, public health surveillance, hospitals and birthing centers.

Coordination, Alignment, and Facilitation

- Plans to conduct a kick-off and annual in-person meetings with all participating state NBS teams to advise and share strategies on innovation, best practices, data collection and reporting, and program sustainability beyond the project period.
- Plans to maintain a web-based platform to facilitate online collaboration and learning activities for team participants.
- Plans to create an online database to maintain, standardize, analyze, evaluate and report on NBS QI data from participating states.
- Plans to identify and utilize an evidence-based quality improvement methodology or model for all QI activities.
- Plans to provide leadership, education, and ongoing coaching and technical assistance (TA) to participating state teams on QI activities that improve timely diagnosis and follow-up. TA should include assistance on:
 - Implementation of QI methodology, evidence-based strategies, and innovation practices (with emphasis on rapid cycle testing).

- Development of aims, change packages, measures to track progress, and appropriate data sources (including outcome and process measures).
- Implementation of data collection and reporting on QI measures
- How to foster ongoing engagement of state teams.

Quality Improvement

- Plans to support at least 30 participating state NBS teams in:
 - Developing a process map of NBS, identifying one or more of the following areas in need of improvement with respect to improving timeliness, the processes for identifying and following up on out-ofrange results, removing gaps/barriers for communicating NBS results, and/or confirming diagnoses.
 - Developing performance measures and goals specific to their state's processes. To the extent possible, measures should align with quality indicators developed by the Newborn Screening Data Repository and Technical Assistance Center, HRSA-18-080.
 - Implementing QI activities.
 - Developing a plan of collecting and reporting data, and developing QI projects.
- Plans to synthesize best available evidence in achieving timeliness in NBS, identifying out-of-range results, communicating results to providers, and confirming a diagnosis.
- Methods to identify and address emerging issues through QI.

Dissemination and Spread

- Plans to disseminate outcomes of activities and best practices to participating states and the newborn screening community via web, email, reports, webinars, listservs.
- Plans to develop partnerships and facilitate information-sharing with various stakeholders, including federal and non-federal organizations, and HHS funded organizations in order to collaborate, coordinate, promote, and support these efforts and not duplicate efforts.
- Plans to support and assist states with developing plans to sustain the QI activities and practices, goals, objectives, and improvements achieved through this program.
- WORK PLAN -- Corresponds to Section V's Review Criteria (2) Response and (4)
 Impact
 - Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire project period in the Methodology section. Use a time line that includes each activity and identifies responsible staff.
 - Identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application.

Logic Model: Each applicant must submit a logic model.

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

- Goals of the project (e.g., objectives, reasons for proposing the intervention, if applicable)
- Assumptions (e.g., beliefs about how the program will work and support resources.
 Base assumptions on research, best practices, and experience)
- Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources)
- Target population (e.g., the individuals to be served)
- Activities (e.g., approach, listing key intervention, if applicable)
- Outputs (i.e., the direct products or deliverables of program activities), and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).
- RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion
 (2) Response
 - Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges. Specifically, discuss the approaches of resolving challenges for the following:
 - Establishing partnerships with state NBS programs, state health departments, MCH/Title V, local hospitals, and birthing centers
 - Engaging other stakeholders including professional associations, subspecialists, pediatricians/primary care providers and individuals and families living with conditions identified through newborn screening
- EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria (3) Evaluative Measures and (5) Resources/Capabilities
 - Describe the performance evaluation plan for monitoring ongoing processes and progress towards the goals and objectives of the project (listed immediately below). 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. The program performance evaluation should include monitoring of ongoing processes and the progress towards meeting the goals, program requirements, and objectives of the project listed under Section I.1 within this NOFO, including specific, measurable, attainable, and realistic and time bound (SMART) objectives:

- By 06/30/2022, 95 percent of newborn screens in participating states will meet the recommended NBS timeframes as established by the Advisory Committee on Heritable Disorders in Newborns in Children.
- By 06/30/2019, all participating states will have identified performance measures specific to their state's processes to identify and follow up on out-of-range results, specifying baseline measures and goals for each performance measure.
- By 06/30/2022, 85 percent of participating states will have met their specified goal(s) for improving identification of, and follow up on, outof-range results.
- By 06/30/2019, all participating states will have identified performance measures specific to their state's processes for communicating screening results to providers and families and confirming diagnoses, specifying baseline measures and goals for each performance measure.
- By 06/30/2022, 85 percent of participating states will have met their specified goal(s) for improving communication of screening results to providers and families and confirming diagnoses.
- Describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes.
- Describe the strategy to collect, analyze and track data to measure processes and impact/outcomes, and explain how you will use the data to inform program development and service delivery.
- Describe any potential obstacles to performance evaluation and your plan to address those obstacles.
- Describe a plan to use data to demonstrate the national impact of the Quality Improvement in Newborn Screening Program.

Technical Support Capacity:

- Describe the technology capacity in place to develop, implement, and host an online, interactive forum, organized for multiple audiences that promotes collaboration, information sharing and dissemination of authoritative and/or evidence-based information.
- Include a description and/or diagrams explaining how the quality improvement program will facilitate collaborative distance learning for multiple audiences and how you will disseminate information.
- ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion (5) Resources/Capabilities
 - Succinctly describe your organization's current mission and structure, scope of current activities, including an organizational chart, and describe how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.

- Provide information on the program's resources and capabilities to support provision of culturally and linguistically competent and health literate services.
- Demonstrate experience working with newborn screening stakeholders, including: parents, families, and individuals affected by conditions identified through NBS; State Health Departments; Newborn Screening Programs (including laboratory and follow-up personnel); MCH/Title V; public health surveillance; hospitals and birthing centers. -
- Project activities should be guided by a steering committee. Include information on the project steering committee and what expertise will be represented within the steering committee.
- Describe how the expertise and input of the members will be used to guide the project.
- Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings.
- Describe how the organization has the capacity to meet the unique needs of target populations of the communities served.

NARRATIVE GUIDANCE

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

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 and Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. Budget

See Section 4.1.iv of HRSA's <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. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan

and by carefully following the approved plan can avoid audit issues during the implementation phase.

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

The Consolidated Appropriations Act, 2017 (P.L.115-31), Division H, § 202, states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." 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 2018, as required by law.

State Teams: You are expected to dedicate a significant proportion of the budget directly to participating state NBS teams to support the activities of this program.

Meetings: You should budget funds to convene one in-person meeting per year with all participating state NBS teams in the Washington, DC area.

iv. Budget Narrative

See Section 4.1.v. of HRSA's SF-424 Application Guide.

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 201 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), Public Law 113-5 amends section 319 of the Public Health Service (PHS) Act to provide the Secretary of the Department of Health and Human Services (HHS) with discretion to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency upon request by a state or tribal organization. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to be reassigned on a voluntary basis to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with section 319(e). This authority terminates September 30, 2018. Please reference detailed information available on the Assistant Secretary for Preparedness and Response (ASPR) website via

http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

v. Program-Specific Forms

Program-specific forms are not required for application.

vi. Attachments

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

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. If you will make subawards or expend funds on contracts, describe how your organization will ensure to document the funds properly.

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. Also, please include a description of your organization's time keeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

Attachment 3: Biographical Sketches of Key Personnel

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

Attachment 4: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

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

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--5th Year Budget (NOT counted in page limit), if applicable

After using columns (1) through (4) of the SF-424A Section B for a 5-year project period, you will need to submit the budget for the 5th year as an attachment. Use the SF-424A Section B. See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>

Attachments 8 – 15: Other Relevant Documents

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

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

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

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

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

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *March 20, 2018 at 11:59 p.m. Eastern Time*.

See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 Application</u> Guide for additional information.

5. Intergovernmental Review

Program Quality Improvement in Newborn Screening Program not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100. See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information

6. Funding Restrictions

You may request funding for a project period of up to 5 years, at no more than \$3,300,000 per year (inclusive of direct **and** indirect costs). The FY 2018 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

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

- 1. Providing cash payments to or on behalf of affected individuals.
- 2. Providing inpatient services.
- 3. Purchasing land or making capital improvements to property.
- 4. Providing for proprietary research or training.

Per the PHS Act § 1109(g) SUPPLEMENT NOT SUPPLANT.— Funds appropriated under this section shall be used to supplement and not supplant other federal, state, and local public funds provided for activities of the type described in this NOFO.

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

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding, including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative(s) applied to the award(s) under the program will be addition. You can find post-award requirements for program income at 45 CFR § 75.307.

V. Application Review Information

1. Review Criteria

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

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

Review criteria are used to review and rank applications. The Quality Improvement in Newborn Screening Program has 6 review criteria:

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

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

The extent to which the applicant:

- Details their understanding of the purpose for the project
- Demonstrates an understanding of newborn screening, including the complexity of the newborn screening process, and the current barriers and challenges with respect to timeliness, detection of out-of-range results, reporting out-of-range results to providers, and confirming diagnosis.
- Discusses experience leading high-level state teams
- Describes the needs of the states that will be participating in the project
- Uses and cites data whenever possible

Criterion 2: RESPONSE (35 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.

Methodology (25 points)

The extent to which the applicant describes an effective approach to:

Planning and Establishing State Teams (5 points)

 After award, identification and selection at least 30 state teams to implement quality improvement activities focusing on one or more of the following components related to the newborn screening process: timeliness; detection of out-of-range results; reporting out-of-range results to providers; and/or

- confirming a diagnosis. Membership on the state teams should include NBS programs, state laboratories, hospitals and birthing centers, primary care providers, maternal and child health leaders, and other stakeholders.
- Establishing a Steering Committee to provide guidance to the project, to assist in prioritizing challenges and activities, and provide expertise on best practices. The Steering Committee should consist of newborn screening stakeholders including parents/families/individuals with conditions identified through NBS, State Health Departments, Newborn Screening Programs (including laboratory and follow-up personnel), MCH/Title V, public health surveillance, hospitals and birthing centers.

Coordination, Alignment, and Facilitation (5 points)

- Conducting a kick-off and annual in-person meetings with all state NBS teams to advise and share strategies on innovation, best practices, data collection and reporting, and program sustainability beyond the project period.
- Maintaining a web-based platform to facilitate online collaboration and learning activities for team participants.
- Creation of an online database to maintain, standardize, analyze, evaluate and report on NBS QI data from participating states.
- Identification and utilization of an evidence-based quality improvement methodology or model for all QI activities.
- Providing leadership, education, and ongoing coaching and technical assistance (TA) to participating state teams on QI activities that improve timely diagnosis and follow-up. TA should include assistance on:
 - Implementation of QI methodology, evidence-based strategies, and innovation practices (with emphasis on rapid cycle testing)
 - Development of aims, change packages, measures to track progress, and appropriate data sources (including outcome and process measures)
 - Implementation of data collection and reporting on QI measures
 - How to foster ongoing engagement of state teams

Quality Improvement (10 points)

- Supporting at least 30 state NBS teams in:
 - Developing a process map of NBS, identifying one or more of the following areas in need of improvement with respect to improving timeliness, the processes for identifying and following up on out-ofrange results, removing gaps/barriers for communicating NBS results, and/or confirming diagnoses.
 - Developing performance measures and goals specific to their state's processes (to the extent possible, measures should align with quality indicators developed by the Newborn Screening Data Repository and Technical Assistance Center, HRSA-18-080).
 - Implementing QI activities.
 - Developing a plan of collecting and reporting data, and developing QI projects.

- Plans to synthesize best available evidence in achieving timeliness in NBS, identifying out-of-range results, communicating results to providers, and confirming a diagnosis.
- o Plans to identify and address emerging issues through QI methodology.

Dissemination and Spread (5 points)

- Dissemination of outcomes of activities and best practices to participating states and the newborn screening community via web, email, reports, webinars, listservs.
- Developing partnerships and facilitating information-sharing with various stakeholders, including federal and non-federal organizations, and HHS funded organizations in order to collaborate, coordinate, promote, and support these efforts and not duplicate efforts.
- Supporting and assisting states with developing plans to sustain the QI activities and practices, goals, objectives, and improvements achieved through this program.

Work Plan (5 points)

The extent to which the applicant:

- Describes the activities or steps that will be used to achieve each of the objectives proposed during the entire project period in the Methodology section. Use a time line that includes each activity and identifies responsible staff.
- Identifies meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application.

Resolution of Challenges (5 points)

The extent to which the applicant:

- Discusses potential challenges and approaches to resolve such challenges, including:
 - Establishing partnerships with state NBS programs, state health departments, MCH/Title V, local hospitals, and birthing centers
 - Engaging other stakeholders including professional associations, subspecialists, pediatricians/primary care providers and individuals and families

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

The extent to which the applicant:

- Describes the performance evaluation plan for monitoring ongoing processes and progress towards the goals and objectives of the project
- 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 (e.g., assigned skilled staff, data management software) in a way that allows
 for accurate and timely reporting of performance outcomes
- Describes the methods to reach and track access by underserved and diverse populations

- Describes the data collection strategy to collect, analyze and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery
- Describes potential obstacles to performance evaluation and plans to address those obstacles
- Describes a plan to use data to demonstrate the impact of the Quality Improvement in Newborn Screening Program.

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

The extent to which:

- The applicant's plans for dissemination of project results are feasible and effective.
- Project results may be national in scope.
- Project activities are replicable.
- The program is sustainable beyond the period of federal funding.

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

The extent to which the applicant:

- Describes the technology capacity in place to develop, implement, and host an online, interactive forum organized for multiple audiences that promotes collaboration, information sharing and dissemination of information.
- Includes a description and/or diagrams explaining how the quality improvement program will facilitate collaborative distance learning for multiple audiences and how information will be disseminated.
- Describes the organization's current mission and structure, scope of current activities, including an organizational chart, and describe how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.
- Provides information on the resources and capabilities to support provision of culturally and linguistically competent and health literate services.
- Demonstrates experience working with newborn screening stakeholders, including parents, families, and individuals affected by conditions identified through NBS, State Health Departments, Newborn Screening Programs (including laboratory and follow-up personnel), MCH/Title V, public health surveillance hospitals and birthing centers..
- Describes how the expertise and input of the steering committee members will be used to guide the project.
- Describes how the organization has the capacity to meet the unique needs of target populations of the communities served.

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 required resources sections, are reasonable given the scope of work.
- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- The extent to which funds are provided to support state newborn screening programs and is reasonable given the scope of work.
- The extent to which funds are budgeted to convene one (1) in-person meeting per year with all participating state NBS teams.

2. Review and Selection Process

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

See Section 5.3 of HRSA's <u>SF-424 Application Guide</u> for more details.

Funding Priorities

This program does not include a funding priority.

3. Assessment of Risk and Other Pre-Award Activities

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

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

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

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

4. Anticipated Announcement and Award Dates

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

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 1, 2018. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA's SF-424 Application Guide.

Human Subjects Protection:

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

3. Reporting

The new Discretionary Grant Information System (DGIS) reporting system will continue to be available through the Electronic Handbooks (EHBs). HRSA enhanced the DGIS

and these improvements are available for recipient reporting as of October 1, 2017. HRSA will communicate with recipients and provide instructions on how to access the system for reporting. HRSA will also provide technical assistance via webinars, written guidance, and one-on-one sessions with an expert, if needed.

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

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

Award recipients must comply with Section 6 of HRSA's <u>SF-424 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, which should address progress against program outcomes, including any expected outcomes in the first year of the program. Further information will be provided in the award notice.
- 2) **Final Report Narrative.** The recipient must submit a final report narrative to HRSA after the conclusion of the project.
- 3) Performance Reports. HRSA has modified its reporting requirements for Special Projects of Regional and National Significance projects, Community Integrated Service Systems projects, and other grant/cooperative agreement programs to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). GPRA requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act.
 - a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program can be found at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UG8_2.HTML.

Administrative Forms

- Form 1, Project Budget Details
- Form 2, Project Funding Profile
- Form 3, Budget Details by Types of Individuals Served
- Form 4, Project Budget and Expenditures
- Form 5, Number of Individuals Served (Unduplicated)
- Form 6, Maternal & Child Health Discretionary Grant
- Form 7, Discretionary Grant Project

Updated DGIS Performance Measures, Numbering by Domain (All Performance Measures are revised from the previous OMB package)						
Performance Measure	New/Revised Measure	Prior PM Number (if applicable)	Topic			
Core						
Core 1	New	N/A	Grant Impact			
Core 2	New	N/A	Quality Improvement			
Capacity Building						
CB 1	New	N/A	State Capacity for Advancing the Health of MCH Populations			
CB 2	New	N/A	Technical Assistance			
CB 3	New	N/A	Impact Measurement			
CB 4	Revised	5	Sustainability			
CB 6	New	N/A	Products			
CB 7	New	N/A	State capacity for accessing electronic health data			
Perinatal Infant Health						
PIH 3	New	N/A	Newborn Screening			
Children and Youth with Special Health Care Needs						
CSHCN 2	Revised	40, 41	Access to and Use of Medical Home			

b) Performance Reporting Timeline

Successful applicants receiving HRSA funds will be required, within 120 days of the project period start date, to register in HRSA's EHBs and electronically complete the program-specific data forms that are required for this award. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other 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 budget period start date, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the

abstract and 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 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 45 CFR part 75 Appendix XII.

VII. Agency Contacts

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

Mary Worrell
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857

Telephone: (301)443-5181 Fax: (301) 594-6096

Email: <u>mworrell@hrsa.gov</u>

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

Ann Ferrero, MPH
Public Health Analyst
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N100C
Rockville, MD 20857

Telephone: (301) 443-3999

Fax: (301) 594-0878 Email: <u>aferrero@hrsa.gov</u>

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: support@grants.gov

Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center

Telephone: (877) 464-4772

TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Logic Models

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

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a 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: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance

HRSA has scheduled the following technical assistance webinar:

Webinar

Day and Date: Thursday, February 15, 2018

Time: 1-2 p.m. ET

Call-In Number: 1-888-826-9572 Participant Code: 77014936

Weblink: https://hrsa.connectsolutions.com/hrsa-18-070 ta webinar/

HRSA will record the technical assistance webinar and archive it at this website: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

IX. Tips for Writing a Strong Application

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