U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA

Health Resources & Services Administration

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

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Newborn Screening State Evaluation Program

Funding Opportunity Number: HRSA-18-125
Funding Opportunity Type(s): New
Catalog of Federal Domestic Assistance (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2018

Application Due Date: August 8, 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: July 5, 2018

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Authority: Public Health Service Act, § 1110 (42 U.S.C. 300b-9)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2018 for the Newborn Screening State Evaluation Program. The purpose of this program is to evaluate the effectiveness of newborn screening programs in reducing the morbidity and mortality caused by heritable disorders in newborns and children, by assessing the timeliness of screening, follow up, and referral to counseling or health care services. This will be accomplished by supporting state newborn screening programs in the implementation of a demonstration program to use newborn screening quality indicator information to evaluate the effectiveness of their state newborn screening system.

Funding Opportunity Title:	Newborn Screening State Evaluation Program
Funding Opportunity Number:	HRSA-18-125
Due Date for Applications:	August 8, 2018
Anticipated Total Annual Available FY 2018 Funding:	$1,020,000
Estimated Number and Type of Award(s):	Up to 17 grants
Estimated Award Amount:	Up to $60,000 per year dependent on the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 30, 2018 through September 29, 2019 (1 year)
Eligible Applicants:	States or political subdivisions of a state, or a consortium of two or more states or political subdivisions of states. See Section III-1 of this notice of funding opportunity (NOFO) 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.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Wednesday, July 18, 2018
Time: 1 p.m. – 2 p.m. ET
Call-In Number: 1-888-826-9572
Participant Code: 77014936
Weblink: https://hrsa.connectsolutions.com/hrsa18125/

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

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I. Program Funding Opportunity Description

1. Purpose

This notice solicits applications for the Newborn Screening State Evaluation Program.

The goal of the program is to reduce the morbidity and mortality associated with heritable disorders screened at birth. The purpose of this program is to evaluate the effectiveness of newborn screening programs by evaluating and assessing the effectiveness of screening, follow up, and referral to counseling or health care services. This will be accomplished by supporting state newborn screening programs in the implementation of a demonstration program to use quality indicator information, as determined by the HRSA-funded Newborn Screening Data Repository and Technical Assistance program (HRSA-18-080), to evaluate the effectiveness of their state newborn screening system. Quality indicators were created to provide longitudinal comparisons within newborn screening programs and to aggregate data at a national level. Quality indicators cover actions within the newborn screening system including assessing borderline results, eligible newborns, specimen collection, improper transport, and time of medical intervention.   It is expected that the Newborn Screening Data Repository Technical Assistance program will be able to accept data into their data repository by September 2019.

Program Objective

Recipients will be responsible for collecting data on the objective below for the purposes of monitoring and evaluating the overall effectiveness of the Newborn Screening State Evaluation program.

> Objective:
> By September 29, 2019, data[1] on all newborns screened in 2016 - 2018 will be collected and submitted to the Newborn Screening Data Repository.

Program Requirements

In order to achieve the goal and objective of the Newborn Screening State Evaluation Program, the recipient is expected to conduct the following activities:

1) Implement a data use agreement with the Newborn Screening Data Repository and Technical Assistance Program established under HRSA-18-080 to submit newborn screening data and information about your newborn screening program into the repository.
2) Collaborate with the Newborn Screening Data Repository and Technical Assistance Program to develop and implement policies, procedures, and

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[1] State NBS programs are expected to report on quality indicators similar to those found on the Newborn Screening Technical assistance and Evaluation Program website (https://www.newsteps.org/quality-indicators). Please note: The quality indicators are subject to change. They have been included to make applicants aware of the types of data reporting that will be required. HRSA will provide additional information at the beginning of the project period.

methods in order to enter information and provide feedback on all quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as established by the Newborn Screening Data Repository and Technical Assistance Program.

3) Enter data on all newborns screened from 2016 - 2018 into the newborn screening data repository established under HRSA-18-080 for the purposes of evaluation and assessment of the state newborn screening system. States should work with the data repository on available options for data transfer including using electronic data exchange or other data transfer capabilities.

4) Provide feedback to the Newborn Screening Data Repository and Technical Assistance Program on the usefulness of the measures and reports to evaluate their program.

5) Establish a sustainability plan that address how evaluation efforts will be sustained after federal funding ends and how will data collection be incorporated as a standard practice within the newborn screening program.

6) Collaborate and coordinate data reporting among programs and organizations that support the newborn screening system, including Title V programs, birthing hospitals, clinicians, etc.

2. Background

This program is authorized by the Public Health Service Act, § 1110 (42 U.S.C. 300b-9) which authorizes grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness, including with respect to timeliness, of screening, follow-up, counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

Newborn screening is an effective 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 tested for at least 29 conditions on the Recommended Uniform Screening Panel, a list of conditions adopted by the Secretary of Health and Human Services and recommended for states to screen for in their newborn screening programs. These conditions require early screening, intervention and treatment to mitigate brain and organ damage, severe illness, and/or life-threatening complications associated with these conditions.

Funded since 2012, the Newborn Screening Data Repository and Technical Assistance Program has standardized national newborn screening quality measures used by state newborn screening programs and allowed for consistent categorization and tracking of follow-up of identified newborns at the local, regional, and national levels.

This new funding will support state efforts in the evaluation and assessment of their state newborn screening systems and identify gaps and/or challenges within the system. Data can inform states on the validity of newborn screening results, whether infants with heritable disorders are being diagnosed and treated in a timely manner and ultimately, improving health outcomes for children with heritable disorders. Additionally, the information will help the Newborn Screening Data Repository and Technical Assistance Program assess the utility of the quality indicators and update if necessary in order to support state efforts in evaluating their programs.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a grant.

2. Summary of Funding

HRSA expects approximately $1,020,000 to be available annually to fund up to 17 recipients. You may apply for a ceiling amount of up to $60,000 total cost (includes both direct and indirect, facilities and administrative costs). The period of performance is September 30, 2018 through September 29, 2019 (1 year).

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

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include states or political subdivisions of a state, or a consortium of two or more states or political subdivisions of states. See Public Health Service Act, § 1110 (42 U.S.C. 300b-9).

HRSA is seeking one application per state.

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 a state are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

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

If you're reading this notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) and reviewing or preparing the workspace application package, you will automatically be notified in the event HRSA changes and/or republishes the NOFO 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 For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the NOFO to do otherwise. 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 **40 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 workspace application package do not count in the page limit. 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 6: Other Relevant Documents.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on all certifications.

Program-Specific Instructions
In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), 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*
  Briefly describe the purpose of the proposed project.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) Need*
  Describe and document your newborn screening program and its current data capacity. Outline the needs of the organization with respect to reporting newborn screening data and evaluating the newborn screening system within your state. Please discuss any relevant barriers to data collection and reporting that the project hopes to overcome.

- *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. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families and communities, if applicable.

Describe your plan of how you will accomplish the following activities:

- o Implement a data use agreement with the Newborn Screening Data Repository and Technical Assistance Program established under HRSA-18-080 to submit newborn screening data and information about your newborn screening program into the repository.
- o Collaborate with the Newborn Screening Data Repository and Technical Assistance Program to develop and implement policies, procedures, and methods in order to enter information on all quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as established by the Newborn Screening Data Repository and Technical Assistance Program.
- o Enter data on all newborns screened from 2016 - 2018 into the newborn screening data repository established under HRSA-18-080 for the purposes of evaluation and assessment of the state newborn screening system.[2]
- o Establish a sustainability plan to ensure data is collected and reported to the Newborn Screening Data Repository beyond the period of performance.
- o Collaborate and coordinate data reporting among programs and organizations that support the newborn screening system, including Title V programs, birthing hospitals, clinicians, etc.

- ▪ *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 program requirements during the entire period of performance as proposed in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application.

- ▪ *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.

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[2] State newborn screening programs are expected to report on quality indicators similar to those found on the Newborn Screening Technical assistance and Evaluation Program website (https://www.newsteps.org/quality-indicators). Please note: The quality indicators are subject to change. They have been included to make applicants aware of the types of data reporting that will be required. HRSA will provide additional information at the beginning of the project period.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria (3) Evaluative Measures and (5) Resources/Capabilities*
  Describe the evaluation plan to evaluate the program's performance relative to continuous quality improvement goals and activities to ensure ongoing enhancements to the program and program operations. Program approaches to ensuring the quality of performance measures/indicators should also be included within the evaluation plan, as warranted. In addition, the evaluation plan should identify any program goal(s) and/or question(s) to be addressed via the program evaluation, including any program process, output and outcome goal(s) and/or objective(s).

  As appropriate, the evaluation plan should specify (1) methodologically rigorous and appropriate measures that address each process, output and outcome program goal/objective; (2) qualitative and/or quantitative data to be collected to address each program goal/ objective; (3) program monitoring activities, including data collection and data quality activities; and (4) data analysis and reporting plans. The plan should ensure the monitoring of ongoing processes and progress towards program goal(s), purpose(s), requirement(s) and objective(s). Describe any potential obstacles for implementing the program evaluation and your plan to address those obstacles.

  Recipients are **required** to report progress on the following program objective:

  - By September 29, 2019, data on all newborns screened in 2016 - 2018 will be collected and submitted to the Newborn Screening Data Repository.

- *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. 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 current experience, skills, and knowledge of staff who will be collecting and reporting data to the Data Repository.

NARRATIVE GUIDANCE

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

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need

Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative (below)	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. Budget

See Section 4.1.iv of HRSA's *SF-424 Application Guide*. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. 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, 2018 (P.L. 115-141), 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 *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in FY 2019, as required by law.

iv. Budget Narrative

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

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. If applicable, also include the required logic
> model in this attachment. If you will make subawards or expend funds on
> contracts, describe how your organization will ensure proper documentation of
> funds.

*Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section
4.1. of* HRSA's [*SF-424 Application Guide*]*)*
> Keep each job description to one page in length as much as is possible. Include
> the role, responsibilities, and qualifications of proposed project staff. Also,
> please include a description of your organization's timekeeping 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: Project Organizational Chart
> Provide a one-page figure that depicts the organizational structure of the project.

Attachment 5: Tables, Charts, etc.
> To give further details about the proposal (e.g., Gantt or PERT charts, flow
> charts).

Attachments 6 – 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 *SF-424 Application Guide*.

UPDATED SAM.GOV ALERT: For your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018. Read the updated FAQs to learn more.

SAM.gov is experiencing high volume and delays. If you have tried to create or update your SAM.gov registration but have not been able to complete the process, you may not be able to apply for a HRSA funding opportunity via Grants.gov in a timely manner prior to the application deadline. If so, please email DGPwaivers@hrsa.gov, per the instructions in Section 3.6 of your HRSA Application Guide.

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

4. Submission Dates and Times

Application Due Date
The due date for applications under this NOFO is *August 8, 2018 at 11:59 p.m. Eastern Time*. HRSA suggests submitting applications to Grants.gov at least **3 days before the deadline** to allow for any unforeseen circumstances.

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

5. Intergovernmental Review

The Newborn Screening State Evaluation Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to 1 year, at no more than $60,000. (inclusive of direct **and** indirect costs).

The General Provisions in Division H of the Consolidated Appropriations Act, 2018 (P.L. 115-141) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in FY 2019, 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 applied to the award(s) under the program will be the addition/additive alternative. 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. Applications submitted for this program will be reviewed by external peer reviewers using a Field Review method. Reviewers will rate each sub-criterion listed below as a strength, weakness, or as meeting requirements. Points will be assigned as listed for each criterion, for a maximum of 100 points per application.

Review criteria are used to review and rank applications. The Newborn Screening State Evaluation Program has six review criteria:

Criterion 1: NEED (15 points) – Corresponds to Section IV's Introduction and Needs Assessment

- Does the application outline the needs of the organization with respect to reporting newborn screening data to the Newborn Screening Data Repository?
- Does the application describe and document the newborn screening program and its current data capacity?
- Does the application discuss any relevant barriers to data collection and reporting that the project hopes to overcome?

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

Methodology (15 points)

- Does the proposed project respond to the "Purpose" included in the program description?
- Does the application describe plans to enter into a data use agreement with the Newborn Screening Data Repository and Technical Assistance Program established under HRSA-18-080 to submit newborn screening data and information about their newborn screening program into the repository?
- Does the application describe plans to collaborate with the Newborn Screening Data Repository and Technical Assistance Program to develop and implement policies, procedures, and methods in order to enter information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as established by the Newborn Screening Data Repository and Technical Assistance Program?
- Does the application describe plans to enter quality indicator data on all newborns screened from newborns screened in 2016 - 2018 into the Data Repository?
- Does the application describe plans to establish a sustainability plan to ensure data is collected and reported to the Newborn Screening Data Repository beyond the period of performance?
- Does the application describe plans for collaborating and coordinating data reporting among programs and organizations that support the newborn screening system, including Title V programs, birthing hospitals, clinicians, etc.?

Work Plan (10 points)

- Does the application describe the activities or steps that will be used to achieve each of the objectives proposed during the period of performance?
- Does the applicant include a time line that includes each activity and identifies responsible staff?
- Does the application identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities?

<u>Resolution of Challenges (5 points)</u>
- Does the application describe the challenges that the applicant is likely to encounter in designing and implementing the work plan and approaches that will be used to resolve such challenges?

Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity
- Does the application propose a method to monitor and evaluate the project results?
- Do the evaluative measures assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project?

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Work Plan
- Does the application have a work plan with activities that are feasible to address the evaluation needs of the state newborn screening program?

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information
- Does the application describe training and/or experience that qualifies project personnel to implement and carry out the project?
- Does the application describe the capabilities of the organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project?
- Does the application describe the organization's 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?
- Does the application 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?

Criterion 6: SUPPORT REQUESTED (15 points) – Corresponds to Section IV's Budget and Budget Narrative
- Is the proposed budget reasonable for the period of performance in relation to the program goal, purpose, and requirements?
- Are the costs, as outlined in the budget sections, reasonable given the scope of work?
- Do the key personnel have adequate time devoted to the project to achieve project objectives?

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. 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 *SF-424 Application Guide* for more details.

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.

HRSA will report to FAPIIS a determination that an applicant is not qualified ([45 CFR § 75.212](#)).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of September 30, 2018.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 30, 2018. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's *SF-424 Application Guide*.

Requirements under Subawards under Grants
The terms and conditions in the Notice of Award (NOA) apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also

apply to subrecipients under grants. See [45 CFR § 75.101 Applicability](#) for more details.

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 you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

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. The agency 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:

https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (OMB Number: 0915-0298 Expiration Date: 06/30/2019).

Award recipients must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

1) **Progress Report**. 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 available 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 are at https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/E16_2.HTML and listed below.

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 6, Maternal & Child Health Discretionary Grant
Form 7, Discretionary Grant Project
Products Publications and Submissions Data Collection Form

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 4	Revised	5	Sustainability
Perinatal Infant Health			
PIH 3	New	N/A	Newborn Screening

b) Performance Reporting Timeline

Successful applicants receiving HRSA funds will be required, within 120 days of the period of performance 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 grant/cooperative agreement summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each year of the period of performance. 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 grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

c) Period of Performance End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the period of performance, 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 period of performance, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

VII. Agency Contacts

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

Djuana Gibson
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-3243
Email: DGibson@hrsa.gov

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: aferrero@hrsa.gov

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

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

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

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

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Wednesday, July 18, 2018
Time: 1 p.m. – 2 p.m. ET
Call-In Number: 1- 888-826-9572
Participant Code: 77014936
Weblink: https://hrsa.connectsolutions.com/hrsa18125/

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

Tips for Writing a Strong Application

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