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 Needs

Innovations in Newborn Screening Interoperability

Funding Opportunity Number: HRSA-20-134
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: July 1, 2020

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: May 4, 2020

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Authority: 42 U.S.C. § 300b-8(a)(2) and (a)(4)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2020 Innovations in Newborn Screening Interoperability program. The purpose of this program is to enhance data interoperability in the newborn screening (NBS) system. The recipient will accomplish this by serving as a national leader and resource on health information data interoperability and providing technical assistance, training, and education in data interoperability to state NBS programs.

Funding Opportunity Title:	Innovations in Newborn Screening Interoperability
Funding Opportunity Number:	HRSA-20-134
Due Date for Applications:	July 1, 2020
Anticipated Total Annual Available FY 2020 Funding:	$1,300,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to $1,300,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020 through August 31, 2023 (3 years)
Eligible Applicants:	Eligible applicants include: (1) a state or a political subdivision of a state; (2) a consortium of two or more states or political subdivisions of states; (3) a territory; (4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or (5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary. Per 42 U.S.C. § 201, the term "state" includes, in addition to the several states, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply.

| | 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, May 20, 2020
Time: 3–4 p.m. ET
Call-In Number: 1-888-826-9572
Participant Code: 77014936
Weblink: https://hrsa.connectsolutions.com/hrsa20134/

HRSA will record the webinar and make it available at:
https://mchb.hrsa.gov/fundingopportunities/default.aspx.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Innovations in Newborn Screening Interoperability program (INBSI). The purpose of this program is to enhance data interoperability in the newborn screening (NBS) system. The recipient will accomplish this by serving as a national leader and resource on health information data interoperability and providing technical assistance, training, and education in data interoperability to state NBS programs. Interoperability is defined as the ability of different information systems, devices, and applications ('systems') to access, exchange, integrate, and cooperatively use data in a coordinated manner, within and across organizational, regional, and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally.[1]

Goal
The goal of this program is to reduce morbidity and mortality associated with heritable disorders in newborns and children by enhancing data interoperability in the NBS system. Achieving data interoperability will improve the ability of states to conduct screening and report results in a timely manner, which increases the likelihood that infants with one of these newborn screening conditions will receive timely diagnoses and treatment.

Objectives
- By August 2021, the recipient will establish a pubic facing website for resources and materials on interoperability for use in newborn screening programs.
- By August 2023, 80 percent of newborn screening programs in the United States and territories will report use of resources and materials on interoperability developed by INBSI.
- By August 2023, the recipient will provide direct technical assistance and support to develop a comprehensive state interoperability plan to at least 20 states.
- By August 2023, 100 percent of the states receiving direct technical assistance and support from the recipient will report development of a comprehensive plan and timeline for achieving interoperability.
- By August 2023, the recipient will disseminate nationally a report on its work in supporting newborn screening interoperability, to include information and data collected from the states that use the resources and materials on interoperability that the recipient has developed and posted.

The recipient is expected to collect and report data annually to HRSA on progress toward meeting the objectives listed above.

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[1] Healthcare Information and Management Systems Society, Inc. (HIMSS). "What is Interoperability in Healthcare?" https://www.himss.org/what-interoperability (accessed January 27, 2020).

2. Background

This program is authorized by 42 U.S.C. § 300b-8(a)(2) and (4).

Newborn screening (NBS) is an effective public health program that saves and improves the lives of thousands of newborns each year in the United States. Four million newborns each year are screened for conditions that require early diagnosis, intervention, and treatment to mitigate brain and organ damage, severe illness, cognitive and developmental delays, and life-threatening complications. Some of the conditions on NBS panels can be life threatening in the first week of life, so it is crucial NBS is effective and efficient. NBS includes bloodspot screening for certain genetic, endocrine, and metabolic disorders, hearing screening, and screening for critical congenital heart defects.[2]

Effectively implementing NBS in a state requires that multiple entities work together, including hospitals, couriers, state newborn screening labs, follow-up programs, health care providers, and others. One component of a well-functioning system is the ability to process and exchange data and information that are necessary to ensure every baby is screened, specimens are transported and tested efficiently, and results are interpreted and reported in a timely manner. State NBS programs may also need to exchange data with other state databases (e.g., vital records) or national registries (e.g., birth defects), to ensure the best outcomes for newborns with conditions identified through NBS. Each entity involved in the NBS system (e.g., hospitals, birthing centers, couriers, state or private NBS labs, vital records and other state programs, health care providers, and national registries) must also have in place security and privacy policies on how data can be managed, controlled, and shared.

NBS systems that can effectively, efficiently, and securely exchange information are more likely to provide timely and accurate screening and lead to early diagnosis, intervention, and treatment. At the August 2019 meeting of the Advisory Committee on Heritable Disorders in Newborns and Children, state NBS programs identified a need for NBS systems to increase data interoperability[3] and informatics capacity. Manual data entry and not having direct electronic access to other state databases may lead to inaccurate or missing data, which could result in delays in screening or reporting results.

The need to move toward data interoperability is not unique to NBS. Hospital systems and public health systems have been working on these issues for many years. In 2020, the Department of Health and Human Services finalized two rules pertaining to interoperability in health care. The Office of the National Coordinator for Health Information Technology published the 21st Century Cures Act Final Rule on Interoperability Information Blocking, and the Office of the National Coordinator for Health Information Technology Certification Program,[4] which supports seamless and

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[2] Newborn Screening Portal, Centers for Disease Control and Prevention, https://www.cdc.gov/newbornscreening/index.html, accessed February 4, 2020.

[3] Interoperability is the ability of different information systems, devices and applications ('systems') to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally. Healthcare Information and Management Systems Society, Inc. (HIMSS), https://www.himss.org/what-interoperability

[4] Office of the National Coordinator for Health Information Technology. "ONC Cures Act Final Rule." https://www.healthit.gov/curesrule/ (accessed April 3, 2020).

secure access, exchange, and the use of electronic health information. The Centers for Medicare and Medicaid Services published the Interoperability and Patient Access Rule[5], which enables better patient access to their health information, improves interoperability, while reducing burden on payers and providers. Funding this program is an important step in achieving data interoperability within the NBS system.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

HRSA program involvement will include:
- Participating, as appropriate, in meetings conducted by the recipient during the period of the cooperative agreement, e.g., annual meetings, workgroups;
- Collaborating in the development of activities and procedures to be established and implemented for accomplishing the scope of work;
- Reviewing project information prior to dissemination;
- Participating in the dissemination of project information;
- Providing assistance in the establishment and facilitation of effective collaborative relationships with federal and state agencies, and especially HRSA MCHB-funded projects; and
- Working with the recipient to ensure they are compliant with program requirements and do not duplicate the work of other HRSA MCHB-funded projects.

The cooperative agreement recipient's responsibilities will include:
- Conducting all tasks as they relate to the goal, purpose, and objectives listed in this notice of funding opportunity (NOFO);
- Ensuring the integral involvement of state NBS programs;
- Reviewing, on a continuous basis, activities and procedures to be established and implemented for accomplishing the scope of work;
- Providing ongoing, timely communication and collaboration with the federal project officer;
- Working with the federal project officer to review information and reports prior to dissemination on project activities and products;
- Establishing contacts that may be relevant to the project's mission;
- Facilitating partnerships with federal and non-federal entities, including other HRSA-funded programs; and

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[5] Centers for Medicare and Medicaid Services. "CMS Interoperability and Patient Access final rule." https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index (accessed April 3, 2020).

2. Summary of Funding

HRSA estimates approximately $1,300,000 to be available annually to fund one recipient. You may apply for a ceiling amount of up to $1,300,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2023 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for the Innovations in Newborn Screening Interoperability 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

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

Per 42 U.S.C. § 201, the term "state" includes, in addition to the several states, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

Domestic faith-based and community-based organizations, tribes, and tribal organizations are also eligible to apply.

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.

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.

APPROVAL FACTORS
Per statute, an application for a grant under this section shall not be approved by the Secretary unless the application contains assurances (as *Attachment 7*) that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the ACHDNC and adopted by the Secretary.

SUPPLEMENT NOT SUPPLANT
Per statute, 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 section. Accordingly, recipients must ensure that they do use funds made available under this NOFO to supplement and not supplant other federal, state, and local public funds provided for activities of the type described in this NOFO.

VOLUNTARY PARTICIPATION
Per statute, the participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another federal or state program.

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.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

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 included in the page limit may not exceed the equivalent of **60 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. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-20-134, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **It is therefore important 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.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification
1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are 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 you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 8 Other Relevant Documents*.

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

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

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of the Department of Health and Human Services (HHS) with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and

local personnel during a declared federal public health emergency. 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 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 § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness (ASPR) website via http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

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, consistent with forms and attachments, 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, the proposed methods, and the expected outcomes.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (1) Need*
  Outline the needs for health information technology interoperability within state newborn screening systems. Describe needs shared by state newborn screening programs as well as the variability of need. Describe and document the target population and its unmet needs. Use and cite data whenever possible to support the information provided. Discuss any relevant barriers in the newborn screening system that the project hopes to overcome. This section will help reviewers understand state newborn screening programs and systems 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 purposes, goals, and objectives in this NOFO. As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaboration, clear communication, and information sharing/dissemination with efforts to involve patients, families, and communities. Include a plan to disseminate reports, products, and/or project outputs so key target audiences receive the project information.

Include a description of methods that you will use to address the following priorities and activities:

1. **Establish a National Resource Center on NBS Interoperability**

    a. **Support and Maintain a Public Facing Website**
        - Develop a web-based, publicly accessible portfolio of educational information and training about health information technology and interoperability in NBS programs.

    b. **Complete an Environmental Scan of Interoperability in Newborn Screening**
        - Conduct an environmental scan of the capacity for interoperability at the national and state levels.
        - Monitor and track national policy issues and standards related to data interoperability in the health care system.
        - Identify early adopter states and programs that can share lessons learned as part of a learning collaborative. Develop and sustain partnerships with relevant national organizations and key stakeholders.

    c. **Collect and Disseminate Best Practices**
        - Describe and summarize lessons learned, including activities implemented, policies developed, and tools and resources created.
        - Convene a "Lessons Learned" meeting, inviting all state and territorial newborn screening programs, during the final year of the period of performance.
        - Develop and disseminate a final report on state NBS interoperability, including recommendations for future needs.

2. **Provide Direct Technical Assistance and Support to State NBS Programs**

    a. **Plan and Establish State Teams**
        - After award, work with HRSA to identify participation criteria, and provide notification to all states, as defined above, regarding the opportunity to provide notice of interest in developing a comprehensive data interoperability plan with support through this program.
        - Work with HRSA to identify at least 20 state NBS programs of those expressing interest in developing such a plan, to participate in developing a comprehensive interoperability plan.
        - Assist each state NBS program with creation of a team that includes representation from a variety of organizations and state agencies needed to implement data interoperability within the state's newborn screening system, including but not limited to, state

newborn screening laboratory, state public health department or offices such as Vital Records, Early Hearing Detection and Intervention (EHDI) program, Maternal and Child Health Title V program, subject matter experts in health information technology experts, subject matter experts in informatics (as it relates to interoperability), laboratory information management system (LIMS), subject matter experts in data interoperability, hospitals, vendors, public health, etc.

b. Assess States' Readiness for Interoperability
- Assist state teams in completing a readiness assessment to evaluate the state's current data exchange, data interfacing, data utilization, and data interoperability infrastructure and capacity. The assessment should identify gaps and resources needed to create a system that would facilitate data interoperability within NBS systems.

c. Provide Training and Technical Assistance
- Provide individual training in informatics, as it relates to interoperability, for state teams.
- Provide assistance to state teams with developing comprehensive data interoperability plans, which may include financial support.
- Convene workgroups, learning collaboratives, and annual meetings that include state newborn screening programs and other experts and stakeholders to share best practices and collaborate on challenges.

d. Facilitate Development of State Interoperability Plans
- Assist state teams with development of a comprehensive interoperability plan that includes at minimum the following:
  o How data will be managed at all levels; resources needed to implement the plan including workforce development; and an implementation plan and timeline.
  o Data exchange and interoperability needs within the state newborn screening system (e.g., a plan to create a state data hub that can interface with the hospitals, health care providers, and federal agencies).
  o The interoperability of data systems used by other entities involved at the state level (e.g., LIMS, electronic health records (EHRs), state and national registries and databases); outlines the steps needed to improve or enable data exchanges and data interoperability; describes data exchange/interoperability needs of partners; describes the resources needed to develop a system for data exchange/interoperability including workforce needs.

3. **Develop Sustainability Plan**
   - Propose a plan for project sustainability after the period of federal funding ends. HRSA expects recipients to sustain key elements of their projects, including, but not limited to, the public facing website that includes information on interoperability for NBS programs, strategies or services and interventions which have been effective in improving practices and those that have led to improved outcomes for the target population.

- *WORK PLAN -- Corresponds to Section V's Review Criteria (2) Response and (4) Impact*
  In *Attachment 1,* describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance 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 developing the application.

Logic Models

Submit a logic model (also in *Attachment 1*) 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 personnel, 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 of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

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

- *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. Some challenges to consider may include, but are not limited to, the following: collaboration and coordination among partners, programs and agencies; sharing of data; buy-in from leadership and staff; implementation of additional software or systems to support interoperability, if necessary; staff turnover.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria (3) Evaluative Measures and (5) Resources/Capabilities*
Describe the plan for the program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

  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 current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery. Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

  The following measures should be tracked as part of the proposed evaluation plan and reported in the annual progress report during the period of performance:
  - Number of state newborn screening staff participating in training/education sessions on informatics, as it relates to interoperability
  - Number of state newborn screening staff that report increased knowledge after participating in training
  - Number of states that received technical assistance on development of interoperability plan
  - Number of educational resources developed
  - Number of webinars, conferences, or educational opportunities offered
  - Number of state NBS programs using resources developed by INBSI
  - Number of states receiving technical assistance from INBSI
  - Number of states developing an interoperability plan using information and resources provided by INBSI

- *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, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Include an organizational chart in *Attachment 5*. 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 you will routinely assess and improve the unique needs of target populations of the communities served.

iii. Budget

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in the Section 4.1.iv of HRSA's *SF-424 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, may 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) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the Innovations in Newborn Screening Interoperability program requires the following:

- *Budgeting adequate resources to support participating state NBS programs in development of interoperability plans.*
- *Convening annual national meetings of state newborn screening programs.*

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 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 the following fiscal years, as required by law.

iv. Budget Narrative

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

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. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	*Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested

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. Clearly label **each attachment**.

Attachment 1: Work Plan
Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. 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: 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).

Attachment 7: Assurances as detailed in the APPROVAL FACTORS section.
Briefly describe (not more than one page) how program activities support or will support the ACHDNC guidelines and recommendations.

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 Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)**

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. Beginning in December 2020, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update page.

You must also register with 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you

may be deemed 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.

*Currently, 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*.

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.

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.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO is *July 1, 2020 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar 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 Innovations in Newborn Screening Interoperability 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 3 years, at no more than $1,300,000 per year (inclusive of direct **and** indirect costs). 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.

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) 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 the following fiscal years, as required by law.

Per statute, you cannot use funds under this notice for the following purposes:
1) to provide cash payments to or on behalf of affected individuals;
2) to provide inpatient services;
3) to purchase land or make capital improvements to property; or
4) to provide for proprietary research or training.

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 procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has 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.

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 Innovations in Newborn Screening Interoperability program has six review criteria. See the review criteria outlined below with specific detail and scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's [Introduction](#) and [Needs Assessment](#)
- The clarity and completeness with which the application demonstrates the problem and associated contributing factors to the problem.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's [Methodology](#), [Work Plan](#), [Logic Model](#), 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 described in the application are capable of addressing the problem and attaining the project objectives.

Methodology (20 points)
The strength, completeness, and feasibility of the applicant's approach to:
1. Establishing a National Resource Center on NBS Interoperability
   a. Supporting and maintaining a public facing website that includes information on health information technology and interoperability.
      - Develop a web-based publicly accessible portfolio of educational information about health information technology and interoperability for NBS programs.

   b. Completing an Environmental Scan of Interoperability in Newborn Screening
      - Conducting an environmental scan of the capacity for interoperability at the national and state levels.
      - Monitoring and tracking national policy issues and standards related to data interoperability in the health care system.
      - Identifying early adopter states and programs that can share lessons learned as part of a learning collaborative. Developing and sustaining partnerships with relevant national organizations and key stakeholders.

   c. Collecting and Disseminating Best Practices
      - Describing and summarizing lessons learned, including activities implemented, policies developed, and tools and resources created.
      - Convening a "Lessons Learned" meeting inviting all state and territorial newborn screening programs during the final year of the period of performance.
      - Developing and disseminating a final report on state NBS interoperability, including recommendations for future needs.

2. Providing technical assistance and Support to State NBS Programs
   a. Planning and Establishing State Teams
      - After award, working with HRSA to identify participation criteria, and providing notification to all states regarding the opportunity to provide notice of interest in developing a comprehensive data interoperability plan with support through this program.

- Working with HRSA to identify at least 20 state NBS programs interested in developing a plan, to participate in developing a comprehensive interoperability plan.
- Assisting each state NBS program with creation of a team that includes representation from a variety of organizations and state agencies needed to implement data interoperability within the state's newborn screening system, including but not limited to, state newborn screening laboratory, state public health department or offices such as Vital Records, EHDI program, Maternal and Child Health Title V program, subject matter experts in health information technology, subject matter experts in informatics (as it relates to interoperability), LIMS, subject matter experts in data interoperability, hospitals, vendors, public health, etc.

b. Assessing States' Readiness for Interoperability
- Assisting state teams in completing a readiness assessment to evaluate the state's current data exchange, data interfacing, data utilization and data interoperability infrastructure and capacity. The assessment should identify gaps and resources needed to create a system that would facilitate data interoperability within NBS systems.

c. Providing Training and Technical Assistance
- Providing individual training in informatics, as it relates to interoperability, for state teams.
- Providing assistance to state teams with developing comprehensive data interoperability plans, which may include financial support.
- Convening workgroups, learning collaboratives, and annual meetings that include state newborn screening programs and other experts and stakeholders to share best practices and collaborate on challenges.

d. Facilitating Development of State Interoperability Plans
- Assisting state teams with development of a comprehensive interoperability plan that includes at minimum the following:
  o How data will be managed at all levels; resources needed to implement the plan including workforce development; and an implementation plan and timeline.
  o Data exchange and interoperability needs within the state newborn screening system (e.g., a plan to create a state data hub that can interface with the hospitals, health care providers, and federal agencies).
  o The interoperability of data systems used by other entities involved at the state level (e.g., LIMS, electronic health records (EHRs), state and national registries and databases); outlines the steps needed to improve or enable data exchanges and data interoperability; describes data exchange/interoperability needs of partners; describes the resources needed to develop a system for data exchange/interoperability including workforce needs.

3. Developing a Sustainability Plan
   - Plans for project sustainability after the period of federal funding ends.
   - Plans to sustain key elements of their projects, including, but not limited to, the public facing website that includes information on interoperability for NBS programs, strategies or services and interventions, which have been effective in improving practices and those that have led to improved outcomes for the target population.

Work Plan and Logic Model (10 points)
- The coherence between and completeness of activities or steps that will be used to achieve each of the corresponding objectives proposed in the Methodology section.
- The extent to which the application identifies meaningful support and collaboration with key stakeholders in planning, designing, and implementing activities.

Resolution of Challenges (5 points)
- The thoroughness with which the application discusses potential challenges and the feasibility of proposed approaches to resolve such challenges.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's *Evaluation and Technical Support Capacity*
- The strength and effectiveness of the method proposed to monitor and evaluate the project results.
- Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's *Work Plan* *and* *Logic Model*
- The extent to which the proposed project has a public health impact and the project will be effective, if funded. This should include: the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the period of federal funding.

Criterion 5: RESOURCES/CAPABILITIES (15 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.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's [Budget](#) and [Budget Narrative](#)

The reasonableness of the proposed budget for each year of the period of performance 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.

2. Review and Selection Process

The objective 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.

3. Assessment of Risk

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 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 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.

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

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2020. 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 of Subawards
The terms and conditions in the 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 awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability for more details.

Data Rights
All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, 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 award 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 others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

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

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

1) **DGIS Performance Reports.** Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/U2Y.html. The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	September 1, 2020 – August 31, 2023 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	September 1, 2021 – August 31, 2022	Beginning of each budget period (Years 2–4, as applicable)	120 days from the available date
c) Project Period End Performance Report	September 1, 2022 – August 31, 2023	Period of performance end date	90 days from the available date

The full OMB-approved reporting package is accessible at https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (OMB Number: 0915-0298 | Expiration Date: 06/30/2022.

2) **Progress Report(s).** The recipient must submit a progress report narrative to HRSA **annually** via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.

3) **Final Report**. The recipient must submit a final report within 90 days after the period of performance ends, which should summarize results, outcomes, lessons learned, and plans for sustainability.

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

VII. Agency Contacts

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

Kaleema Ameen
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-7061
Email: kameen@hrsa.gov

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

Ann Ferrero
Public Health Analyst
Genetic Services Branch
Division of Services for Children with Special Health Needs
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N100C
Rockville, MD 20857
Telephone: (301) 443-3999
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 EHBs. For assistance with submitting information in the 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, May 20, 2020
Time: 3–4 p.m. ET
Call-In Number: 1-888-826-9572
Participant Code: 77014936
Weblink: https://hrsa.connectsolutions.com/hrsa20134/

HRSA will record the webinar and make it available at: https://mchb.hrsa.gov/fundingopportunities/default.aspx.

Tips for Writing a Strong Application

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