

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

*Maternal and Child Health Bureau
Division of Child, Adolescent, and Family Health*

***Emergency Medical Services for Children
Data Coordinating Center***

Announcement Type: New, Competing Continuation
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FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2012

*Ensure your Grants.gov registration and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration may take up to one month to complete.*

Application Due Date: May 29, 2012

Release Date: March 30, 2012

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Tasmeen Weik, DrPH
Public Health Analyst
Emergency Medical Services for Children Program
Email: tweik@hrsa.gov
Telephone: (301) 443-8927
Fax: (301) 443-1296

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Executive Summary

Emergency Medical Services for Children (EMSC) Data Coordinating Center (DCC)

HRSA is pleased to provide you with this funding opportunity announcement (FOA) for the Emergency Medical Services for Children (EMSC) Data Coordinating Center (DCC) cooperative agreement. Support is available from the Division of Child, Adolescent, and Family Health (DCAFH), part of the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services (HHS). Please read the entire funding opportunity announcement carefully before completing the application.

The EMSC program works to ensure that critically ill and injured children receive optimal pediatric emergency care. The EMSC Program provides funding for State Partnership grantees to demonstrate programs that assure the provision of high-quality pediatric emergency care and the Pediatric Emergency Care Applied Research Network (PECARN) to demonstrate that a network infrastructure can improve the evidence base for treatments provided. The capacity to collect and analyze data is integral to both the provision of high-quality care and the generation of new knowledge of best treatment modalities.

The purpose of the EMSC-DCC is to serve two (2) major functions:

- 1) support States in the collection, analysis and utilization of data for EMSC performance measures as well as provide analytical support to grantees and national stakeholders to advance the delivery of quality pediatric emergency care; and
- 2) serve as the independent data coordinating center for the PECARN to conduct rigorous, high priority investigations;

National EMSC Data Analysis Resource Center (NEDARC): When a child is ill or injured, care is provided at a local level. The collection of data allows continual assessment of the capacity to deliver care and measure the quality of care being provided. Evaluation of such data at a national level provides information on gaps that exist in pediatric emergency care and guides future directions of the EMSC program. As such, the EMSC-DCC will serve as the national data analysis and resource center for EMSC grantees and stakeholders.

Data Center for PECARN: Pediatric research is difficult to conduct because no single hospital has enough pediatric patients to generate conclusive results. Further, methodological expertise is needed to identify the best ways to study a particular issue. In an attempt to respond to the need for well-designed clinical trials in EMSC, HRSA established the Pediatric Emergency Care Applied Research Network (PECARN) in 2001. PECARN is an infrastructure through which to conduct multi-center pediatric emergency medicine research. Further information about the currently funded PECARN projects can be found at <http://www.pecarn.org>

In order to assure the coordination of quality data collection across the multiple sites in PECARN, an independent data coordinating center is needed. The DCC cooperative agreement recipient will serve as the independent data center for PECARN. The primary objective of the data center is to provide data management and biostatistical support and consultation in the areas

of design, execution, and analysis for the Network studies. The DCC also assists in development of the study materials, including the protocols, study manuals and forms and provides site monitoring for studies. An independent data center is critical to assure the integrity of studies conducted by PECARN and assure validity of the study results. PECARN grantees include six research nodes, each with three hospital emergency department affiliates (HEDA), that design and conduct studies on a variety of issues related to emergency medical care and services for children. Collectively, the six research nodes and DCC are known as the Pediatric Emergency Care Applied Research Network (PECARN).

Eligible Applicants: State governments and accredited schools of medicine are the only eligible applicants for funding under the EMSC Program.

Number of Awards: One (1) cooperative agreement will be awarded.

Funds per year: an award of up to \$2,800,000 in total (direct and indirect) costs per year for four years

Application deadline: May 29, 2012 at 8:00 P.M. ET. Please submit your application early. Applications submitted on-line (and/or validated by Grants.gov) after the application deadline will not be accepted.

Project Period: September 1, 2012 to August 31, 2016

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

Mail: LaShawna D. Smith
Grants Management Specialist
HRSA Division of Grants Management Operations
5600 Fishers Lane, Room 11A-16
Rockville, MD 20857
Telephone: (301) 443-4241
Fax: (301) 443-6343
Email: LSmith3@hrsa.gov

Additional information related to overall program issues may be obtained by contacting:

Mail: Tasmeen Weik, DrPH
Public Health Analyst
HRSA Maternal and Child Health Bureau
Parklawn Building, Room 18A-38
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-8927
Fax: (301) 443-1296
Email: tweik@hrsa.gov

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I. Funding Opportunity Description

1. Purpose

The purpose of this funding opportunity announcement (FOA) is to invite cooperative agreement applications from State governments and accredited schools of medicine to support clinical investigators to serve the data functions for the Emergency Medical Services for Children (EMSC) Program which includes serving as the National EMSC Data Analysis Resource Center (NEDARC and the Pediatric Emergency Care Applied Research Network (PECARN) Data Coordinating Center (DCC).

There are two (2) major functions:

Function 1: Serve as the National EMSC Data Analysis Resource Center (NEDARC) to support States/Territories in the collection, analysis and utilization of data for EMSC State Partnership performance measures as well as provide analytical support to grantees and national stakeholders to advance the delivery of quality pediatric emergency care

Function 2: Serve as the independent data coordinating center (DCC) for the Pediatric Emergency Care Applied Research Network (PECARN) to conduct rigorous, high priority investigations

Function 1: National EMSC Data Analysis Resource Center (NEDARC)

The DCC cooperative agreement recipient will support States in data system development; provide data-related technical assistance to EMSC State Partnership Grantees; provide Statistical and Data Management Technical Assistance to EMSC Researchers and integrate activities with the EMSC National Resource Center (NRC) and the Federal EMSC Program staff.

The DCC plays an integral role in assisting State Partnership grantees with data collection related to the EMSC performance measures. The purpose of the State Partnership Performance Measures are to assess the ongoing quality of pediatric emergency care that is being provided in the prehospital and hospital setting. Periodic assessments by States and Territories guide the direction of EMSC. The DCC provides technical assistance and tools to facilitate the success of grantees in the performance measure assessment. The DCC also plays a vital role in modifying and developing new measures that address care delivery gaps.

Function 2: PECARN-DCC

The DCC cooperative agreement recipient will provide the Pediatric Emergency Care Applied Research Network (PECARN) grantees with data collection, data management, and data analysis guidelines; serve as a central repository for PECARN generated data; and, serve as a central resource for network data including data management, quality assurance, statistical analysis and coordination of selected PECARN activities. The purpose of the PECARN is to demonstrate the value of an infrastructure or network designed to be the platform from which to conduct investigations on the efficacy of treatments, transport, and care responses in pediatric emergency care. This infrastructure helps to overcome present difficulties in assessing efficacy and quality of care that derive from the relatively small incidence rates of pediatric emergency events. The infrastructure is a means to conduct observational and interventional studies on a variety of

issues related to EMSC, including processes involved in transferring research results to treatment settings. More information on PECARN can be found at <http://www.pecarn.org>.

Further information about the responsibilities of the EMSC-DCC can be found below.

Program Requirements: Data Coordinating Center

The DCC will need to have a staff composition that provides the relevant technical expertise described below and that meets the objectives of the two major functions described below.

Content Specific Expertise

Technical expertise in the area of data analysis and systems integration should include knowledge of data collection and integration that relates to EMS with a special focus on children. Essential to this expertise is the ability to increase the working knowledge and capacity of grantees to use available data to improve the delivery of pediatric care. Expertise includes providing support to State managers in collecting and analyzing data related to EMSC performance measures and how to use the results to inform other stakeholders. An applicant should have knowledge of how to use other State and national data systems such as the National Emergency Medical Systems Information System (NEMSIS) to promote improved delivery of pediatric care in a State or at the national level.

Technical expertise in the area of research should include experience and expertise with human subjects regulations, study design and methods, statistical methods, data management, data quality assurance, data safety monitoring boards and conducting coordinating functions including site monitoring. Expertise and experience in managing data coordinating functions for pediatric emergency care trials is essential.

Function specific objectives:

Function 1: National EMSC Data Analysis Resource Center (NEDARC)

Support States/Territories in Data System Development:

- Support State/territory and national capacity and infrastructure to collect, analyze and utilize data related to pediatric emergency care
- Assist State/territories in linking state performance data with other national data sets focused on emergency medical services in the prehospital and hospital setting

Provide Data-related Technical Assistance to EMSC State Partnership Grantees:

- Support learning communities among States/territories to achieve performance measures through facilitated workshops, expert panels and networking opportunities
- Collaborate with the National Resource Center (NRC) to assist States/territories in establishing the permanence of EMSC in their respective jurisdictions
- Assist the Federal EMSC program in the development of program performance measures

Provide Statistical and Data Management Technical Assistance to EMSC Researchers:

- Provide technical assistance in protocol development to EMSC Researchers

- Provide data management and statistical expertise ad hoc to targeted issue grantees

Integrate Activities with the Overall Goals of the EMSC

- Collaborate with the EMSC-NRC on strategic level planning for the EMSC program
- Schedule monthly updates with dissemination and implementation center to review ongoing projects
- Participate in the engagement of the EMSC stakeholder group
- Participate in the annual EMSC grantee meetings
- Disseminate results from state partnership performance measure assessment in the form of peer-reviewed articles for the field and general publications for the public

Function 2: PECARN-DCC

Provide Coordination for Study Design, Implementation and Data Analysis for PECARN studies;

- Assist investigators with the design and implementation of studies approved by the PECARN steering committee or Executive committee
- Provide statistical analysis of data for all studies (including secondary analysis) of studies approved by the PECARN steering committee or Executive committee
- Utilize electronic technology to design and produce data collection systems that are conducive to efficient functioning of PECARN
- Provide appropriate and capable leadership and expertise in biostatistics, developmental study design, data management, data analysis, clinical data review, and project management, including, but not limited to, staff and site training and quality assurance procedures
- Provide research support activities in designing data collection modules, operational and procedural manuals, quality control systems, and an electronic mail/communications systems for research nodes and their respective HEDAs

Assist with Dissemination of PECARN Studies;

- Assist in preparing abstracts for presentation at scientific meetings
- Assist in preparing manuscripts for publication
- Create and execute public use datasets as directed

Coordinate Regulatory and Clinical Coordination Functions;

- Coordinate and support for Data Safety Monitoring Boards (DSMB)
- Assure network wide compliance with human subjects regulations
- Facilitate communication between data center staff and other components of PECARN, including MCHB, DSMB, and RNCs and their respective HEDAs
- Provide an operational structure capable of coordinating data center functions for several protocols simultaneously
- Provide support for the regulatory functions and requirements associated with the study protocols, procedures and IRB approvals process
- Organize and conduct multi-site monitoring activities in conjunction with MCHB project officer or designee
- Revise and maintain network policies and procedures that support the network's mission and comply with Federal rules and regulations

- Provide training for RNCs and their respective HEDAs, as needed for standardization of PECARN study protocols across sites

2. Background

The mission of HRSA/MCHB is to provide national leadership and to work, in partnership with States, communities, public-private partners, and families to strengthen the maternal and child health (MCH) infrastructure, assure the availability and use of medical homes, and build the knowledge and human resources, in order to assure continued improvement in the health, safety and well-being of the MCH population. The MCH population includes all of America's women, infants, children, adolescents and their families, including fathers and children with special health care needs (CSHCN).

The Emergency Medical Services for Children (EMSC) program is administered by the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB). The program is authorized by the Public Health Service Act, Title XIX, § 1910(42 U.S.C. 300w-9), as amended by the Patient Protection and Affordable Care Act, § 5603 (P.L. 111-148).

This Federal initiative evolved out of a growing recognition that children have unique needs in emergency situations -- needs that often vary from those of adults due to physiological, developmental and psychological differences. The goal of the EMSC program is to reduce child and youth mortality and morbidity sustained as a result of severe illness or injury. The EMSC program does not intend to promote the development of a separate EMS system for children, but rather to enhance the pediatric capability of EMS systems originally designed primarily for adults. "EMS for children" is understood broadly as a continuum of care that includes the following components: prevention, prehospital care, hospital-based emergency care, and rehabilitation and reentry of the child from the emergency care environment into the community.

Historically, the EMSC program has supported projects which:

- 1) Assist States and territories (State Partnership grants) to expand and improve their capacity to provide comprehensive quality pediatric emergency care with the goal of reducing and ameliorating pediatric emergencies. Special care is taken to include children with special health care needs, culturally distinct populations and historically under-represented groups, including American Indian/Alaska Natives, and Native Hawaiians;
- 2) Focus on initiatives that address gaps in our knowledge of best practices for emergency medical services for children (Targeted Issues Grants). Knowledge generation focuses on direct patient care in the prehospital or hospital setting, education of health care providers, and systems of care that can improve the delivery of care;
- 3) Support a multi-institution Pediatric Emergency Care Applied Research Network (PECARN) that provides the infrastructure for rigorous scientific studies of pediatric emergency care.

The Need to Support State/Territory Data Systems:

Pediatric emergencies are of two types: (1) injury related and (2) non-injury related. Injury is the leading cause of death among children between the ages of 1 and 19, claiming more than 20,000

lives each year. Nonfatal injuries occur far more frequently. It is estimated that 20 million children ages 18 and under experienced injuries; 93% of these children required some type of medical attention. Approximately 75% of childhood injuries stem from unintentional causes such as motor vehicle crashes, burns, drowning, drug overdose, and poisoning. The remainder can be attributed to suicide, homicide, child abuse and neglect.

Non-injury emergencies (illnesses), medical and otherwise, constitute the remaining component of the pediatric emergencies equation. Annual incidence figures are in the millions. This includes emergencies prompted by the exacerbation of underlying chronic conditions such as asthma, chronic cognitive and physical impairments, as well as those related to infectious diseases and to non-specific symptoms interpreted by physicians and/or parents to require prompt diagnostic evaluation and resolution through hospital-based medical care.

Adding complexities to the care and overall management of pediatric emergencies is the uniqueness of childhood. It is more difficult to assess the severity of illness or injury in children than in adults. Important anatomic, physiologic, and developmental differences exist between children and adults: children are smaller and proportioned differently; normal respiratory rates, heart rates, and blood pressure differ; characteristic changes in vital signs that signal deterioration in adults may not occur in children; and, stages in children's physiologic, emotional, and behavioral development affect their responses to medical care and their risk of injury and illness.

Despite the many advances in creating and improving EMS systems and incorporating pediatric components into them, relatively little empirical data has been collected about how EMS and EMSC systems operate, about the efficacy of the clinical procedures being employed at the hospital level to treat and manage children who have experienced an emergency event, nor about the efficacy of the transport systems and clinical procedures used to treat and manage children prior to their arrival at the hospital. Information on the cost effectiveness of the various EMS and EMSC system configurations and of the various ways being used to handle clinical pediatric emergencies is also lacking.

The ultimate goal of the EMSC program is to ensure that quality pediatric emergency care is available to all children no matter where they are in the United States. The program measures the success of State Partnership grantees through ten performance measures that address: 1) quality of care provided in the prehospital and hospital setting, and 2) the sustainability and permanence of EMSC in a State or territory, (http://www.childrensnational.org/EMSC/ForGrantees/Performance_Measures.aspx). Furthermore, EMSC grantees strategically align their activities to successfully achieve MCHB Performance Measures associated with their grant. (Appendix A)

In order for EMSC grantees to accomplish the above goals effectively, they need to build successful coalitions across healthcare, public health and public safety systems, obtain and manage data on essential quality measures and strategically develop projects to address the performance measures.

Note: Specific information about the requirements of the applicant is included later in this section under "Data Coordinating Center."

The Need for an Independent DCC for PECARN:

There is a dearth of science-based knowledge about pediatric emergencies and how to best manage them. The issue has been raised by many professionals in the field who have found that it constitutes a major barrier to the prevention and reduction of the annual toll in mortality and morbidity. Calls by experts to mount a nationwide research initiative in emergency medical services were made in 1991 and 1993. In addition, in 2006, the Institute of Medicine published three reports on the emergency care system in the U.S. The three reports focused on emergency medical services, hospital-based care and pediatric care. Of particular importance to this competition is the pediatric report and the gaps in research identified by that report. See reference below:

Emergency Care for Children: Growing Pains. 2006 *Institute of Medicine* (Available at: <http://www.iom.edu/CMS/3809/16107/35002.aspx>)

Barriers to research: As described above, despite the need for research, there are challenges to conducting meaningful EMSC research. These include:

- Incidence rates of pediatric emergency events are relatively small, requiring pooling of sites and treatment experiences to conduct research;
- Large numbers of children are required to attain diverse and representative study samples;
- There is difficulty in maintaining data quality, integrity, and consistency. Emergency care providers take care of patients in a chaotic setting and may not have time for collecting data for research purposes.

Need for an independent data center: The aforementioned barriers are addressed by the creation of the Pediatric Emergency Care Applied Research Network (PECARN). By providing a multi-site framework, PECARN addresses the challenge of pooling patients to achieve enough patient numbers to conduct a study. However, in order to assure that quality data is collected, an independent data center is needed. Typical functions of a data center include:

- Providing expertise in how to conduct multi-center research. Very few pediatric emergency medicine researchers have experience conducting multi-site research and in order to ensure high quality studies, an independent data center can provide needed expertise in study design and methods. Further, the data center can provide technical assistance for complex statistical analysis of large datasets and assure that data are analyzed appropriately.
- Quality of study implementation and data collection. When studies are implemented across multiple sites, explicit instructions from Manual of Operations and other controls are needed to assure that all sites will implement a standard protocol with fidelity.
- There are several Federal regulations¹ that dictate the conduct of human subjects research. A data center provides administrative oversight of compliance with such Federal regulations by tracking institutional review board approvals at all sites, reviewing

¹ Including but not limited to: 45 CFR 46 Protection Of Human Subjects. **Guidelines**, 21 CFR part 50, Protection of Human Subjects, 21 CFR part 56, Institutional Review Boards, 21 CFR part 312, Investigational New Drug Application, 21 CFR part 812, Investigational Device Exemptions

informed consent documentation, conducting site monitoring, etc. A data center also works, as appropriate, with Data Safety Monitoring Boards.

- Since research data often contains personally identifiable information, a data center assures that information is collected, stored and released in compliance with Federal regulations to protect health information, as appropriate.
- Data centers also provide analyzable datasets for both internal use by investigators and external use to the public of data generated with Federal funding.

Thus, an independent data center is key to a research infrastructure to produce high-quality evidence to better treatments for ill and injured children.

The following information provides the background necessary to understand the conceptual framework of PECARN and the integration of individual awardees into the PECARN. **Specific information about the requirements of the applicant is included later in this section under “Data Coordinating Center.”**

PECARN and DCC

The Pediatric Emergency Care Applied Research Network (PECARN) was established in response to the above concerns in 2001. Six cooperative agreements were awarded to Research Node Centers in 2001 along with an award for a Data Coordinating Center (DCC)² to support PECARN data functions in 2002. Collectively, the six Research Node Centers and DCC are known as the Pediatric Emergency Care Applied Research Network (PECARN). Four interrelated reasons support the continuation of PECARN: 1) Incidence rates of pediatric emergency events are relatively small, requiring pooling of sites and treatment experiences to conduct research; 2) large numbers of children are required to attain diverse and representative study samples; 3) an infrastructure is needed to test the efficacy of treatments and of the transport and care responses that precede the arrival of children to hospital emergency departments; and 4) a mechanism is required by which to study the processes involved in transferring research results to treatment settings. The network is expected to forge partnerships among Federal agencies, EMSC researchers, and EMS and EMSC treatment providers. Establishment of strong partnerships between researchers and emergency care practitioners is essential to assure that new treatments and systems management approaches address the critical needs of community and regional emergency medical services systems and are suitable for those settings. Through this joint effort, the gaps in current treatments and systems management approaches will be addressed, yielding treatments and systems approaches proven in real life emergency medical services systems ready for adoption into practices everywhere.

Applicants are encouraged to visit the PECARN website to understand the structure of the network and about prior and current studies at <http://www.pecarn.org>.

² Note: in previous FOAs the DCC was referred to as the Central Data Management Coordinating Center (CDMCC).

Specific aspects that relate to the DCC are provided below:

Quality Control and Monitoring

For protocols requiring an investigational new drug application (IND), the principal investigator or study-specific sponsor is primarily responsible for study control and monitoring as defined by FDA rules and regulations. All PECARN participants cooperate with HRSA and the DCC to review RNC operations and advise investigators of specific requirements concerning investigational drug management.

With regards to laboratory quality control and data management issues, the sites agree to participate in protocol-defined measures to follow methodological and analytic guidelines established by the DCC or PECARN and HRSA.

Subject Safety/Oversight

The sites adhere to protocol-specific measures established by the DCC to assure the safety and protection of the rights of volunteers who may participate in clinical trials and observational studies to be conducted as a result of this cooperative agreement.

All sites and the DCC are required to consult their Institutional Review Board (IRB) for any project that may utilize human subjects or data from human subjects or the Federal Office of Human Research Protection (website: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>) for the requirements of IRB review. The principal investigator and all HEDA investigators assume and accept the primary responsibility for ensuring PECARN studies are conducted in compliance with all Federal regulations and PECARN policies and procedures. Since the DCC is responsible for storing, analyzing and publishing data, as required by Federal regulations, the DCC is responsible for submitting all PECARN protocols through its parent IRB to obtain approval for the DCC role in each study.

The DCC also assures there is documentation of IRB approval from all sites prior to submission of data to the DCC. All investigators agree and assure that adequate records will be maintained, and that access to these records will be available to enable outside monitors (including DCC staff) to assess compliance with applicable Federal laws and regulations.

Adverse Experience Reporting

All PECARN sites adhere to an adverse event tracking system operated by the DCC. The DCC also provides guidance and training to sites on adverse events reporting.

Data Confidentiality

Pursuant to 42 USC 299c-3(c), information obtained in the course of any HRSA-supported study that identifies an individual or entity must be treated as confidential in accordance with any explicit or implicit promises made regarding the possible uses and disclosures of such data. PECARN and the DCC provide procedures for ensuring the confidentiality of the identifying information to be collected, including who will be permitted access to this information, both raw data and machine readable files, and how personal identifiers and other identifying or identifiable data will be restricted and safeguarded. Identifiable patient health

information collected by awardees under this funding will be managed in accordance with 45 CFR Parts 160 and 164, the Federal Privacy Rule developed by the Department of Health and Human Services (DHHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These regulations serve to limit the disclosure of personally identifiable patient information by covered entities and define when and how such information can be disclosed. Thus, health care plans ordinarily will require either patient authorization for disclosures of identifiable information to be made to researchers or waivers of such authorizations obtained from an IRB or Privacy Board (defined in the regulations), which will involve review to ensure that identifiable health information will be appropriately safeguarded by the investigators. The DHHS Office of Civil Rights is the enforcement body for this regulation. Additional information about the regulations, their implementation, and alternative methods of permissible disclosures to researchers (limited data sets with data use agreements, de-identified data sets, data about deceased persons, and data use to develop protocols) can be obtained from: <http://www.hhs.gov/ocr/hipaa/>.

The awardee should ensure that computer systems containing confidential data have a level and scope of security that equals or exceeds that established by the HIPAA Security Rules, if applicable, and that established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems. The National Institute of Standards and Technology (NIST) has published several implementation guides for this circular. They are: “An Introduction to Computer Security: The NIST Handbook;” “Generally Accepted Principles and Practices for Securing Information Technology Systems;” and the “Guide for Developing Security Plans for Information Technology Systems.” The circular and guides are available on the web at <http://csrc.nist.gov/publications/nistpubs/800-12/>. The applicability and intended means of applying these confidentiality and security standards to subcontractors and vendors, if any, should be addressed in the application.

Sharing Research Resources: Rights in Data

HRSA awardees may copyright, unless otherwise provided in the Notice of Award, or seek patents for, as appropriate, final and interim products and materials developed in whole or in part with HRSA funds, including, but not limited to, methodological tools, measures, software with documentation, literature searches, and analyses. With respect to **copyrightable material** that might be developed as a part of the award activity, please note that in accordance with 45 CFR 74.36, the HHS Grants Policy Statement provides that if any copyrightable material (e.g., audiovisuals, software, publications, curricula and training materials, etc.) is developed under this cooperative agreement (by the awardee or contractor) the Department of Health and Human Services (HHS) shall have a royalty-free nonexclusive and irrevocable right to reproduce, publish or otherwise use, and authorize others to use, the work, for purposes which further the objectives of HHS, HRSA, and MCHB. In accordance with its legislative dissemination mandate, HRSA purposes may include, subject to statutory confidentiality protections, making project materials, databases, results, and algorithms available for verification or replication by other researchers. All contracts or other arrangements entered into by the awardee for purpose of developing or procuring such material shall specifically reference and reserve the rights of HHS with respect to the material. The awardee shall provide a master electronic or digital file and four final reproducible copies of all such copyrightable material upon the request of the MCHB.

Specific to data collected by PECARN, a de-identified dataset will be made available by the DCC three (3) **years after the last patient completed the study.**

Subject to HRSA budget constraints, final products may be made available to the health care community and the public by HRSA or its agents if such distribution would significantly increase access to a product and thereby produce substantial or valuable public health benefits.

Publication of Data

Prompt and timely presentation and publication in the scientific literature of findings resulting from research undertaken in the PECARN is required. The DCC assists investigators with manuscript preparation and statistical analysis. A primary publication from the research should be published no later than two (2) years after the last patient has been enrolled or data collection completed. The DCC is responsible for assisting investigators in submitting manuscripts for publication in a timely manner. The DCC may also write manuscripts on data management and analysis techniques or other manuscripts as appropriate to their role. All manuscript authors must agree to abide by HRSA and PECARN policies concerning all publication of PECARN studies. Prior to the submission of manuscripts for publication, awardees agree to provide preprint copies to the MCHB Project Officer and PECARN steering committee.

HRSA's Office of Communications will be consulted in advance of publication in order to coordinate announcements of new HRSA-supported research results with other HRSA dissemination activities.

Acknowledgement of Funding Support

As required in the general terms and conditions outlined in the HHS Grants Policy Statement, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal funds. Recipients are required to state: (1) the percentage and dollar amounts of the total program or project costs financed with Federal funds, and (2) the percentage and dollar amount of the total costs financed by non-Federal sources.

II. Award Information

1. Type of Award

Funding will be provided in the form of a cooperative agreement, in which substantial MCHB scientific and/or programmatic involvement with awardees is anticipated during the performance of the project. Under the cooperative agreement, MCHB will support and/or stimulate awardee activities by working with the awardee in a non-directive, partnership role.

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

- 1) Assurance of the availability of the services of MCHB personnel to participate in the planning and development of all phases of both functions of the DCC;

- 2) Participation in PECARN wide programmatic meetings and seminars conducted during the period of the cooperative agreement;
- 3) Review and of the work plan;
- 4) Assistance in establishing and maintaining Federal interagency and interorganizational contacts necessary to carry out the project;
- 5) Participation in the dissemination of information about project activities; and
- 6) Facilitation of effective communication and accountability to HRSA/MCHB regarding the project with special attention to new program initiatives and policy development in the public health field relating to maternal and child health.
- 7) Consulting in the planning of any conferences and meetings conducted during the period of the cooperative agreement;
- 8) Participating, when appropriate, as observer of any advisory group established by the awardee;
- 9) Providing ongoing review of procedures for accomplishing the objectives of the project funded under his cooperative agreement;
- 10) Participation and review of project activities, products and publications at key stages in its development.

In collaboration with the MCHB Program Officer, the cooperative agreement recipient's responsibilities shall include:

Function 1: Support States/Territories and National Stakeholders in collection, analysis and data utilization

The recipient will collaborate with HRSA/MCHB in assisting EMSC grantees to improve their data collection, analysis and utilization capabilities, including quality improvement (QI) capabilities through the provision of expert consultative assistance in the following areas:

Support State/territory awardees' capacity and infrastructure to collect, analyze and utilize pediatric emergency care data which includes, but is not limited to, the following:

- Develop electronic templates to assist State partnership grantees with data collection and sampling strategies for data collection as needed for reporting on Program performance measures;
- Support on-line mechanism to collect survey data for States and territories;
- Analyze data with State EMSC managers from performance measure for use by States;
- Conduct site visits to EMSC awardees and State EMS Offices in order to facilitate State EMS data system evaluation and quality improvement;
- Assess information gathered from site visits to monitor trends and needs in EMS data systems development to share with stakeholders;
- Support survey development, data collection and analysis for **emerging** pediatric emergency care quality improvement indicators of national significance (i.e., emergency department pediatric readiness, pediatric disaster preparedness, and regionalization of pediatric care).

Assist State/territories in linking State performance data with other national data sets focused on emergency medical services in the prehospital and hospital setting which include, but are not limited to, the following:

- Provide expertise in linkage of EMS and other health care data sets;
- Provide expertise in areas of data design, program evaluation, data communication and development of on-line analytical processing system capability;
- Develop and maintain on-line information and educational material in the fields of data analysis and linkages.

Support the development and maintenance of learning collaboratives among States/territories to support achievement of Program performance measures through facilitated workshops, expert panels and networking opportunities to include, but not limited to, the following:

- Support collaborative initiatives with awardees to focus on partnering with essential stakeholders to advance Program goals and objectives. These could be in the form of learning collaboratives that focus on grantees' needs. Examples include strengthening partnerships with EMS directors, MCH Title V programs, hospital associations;
- Provide technical assistance through learning collaborative such as webinars, workshops or other means directed toward EMSC awardees and State EMS office personnel to improve their understanding and capabilities in areas such as quality improvement in EMSC, statistical analysis of EMS data, uses of data in EMSC injury prevention initiatives, program evaluation, data communication, and coalition building among EMS stakeholders;
- Assist States/territories in establishing the permanence of EMSC by facilitating partnership with other State and national EMS entities via webinars, site visits or workshops.

Support research training opportunities for grantees regarding the development, implementation and evaluation of a concept as well as strategies to fund to include, but not limited to, the following:

- Provide support to grantees by providing assistance with statistical methodologies, evaluation plans, clarity and completeness of proposals;
- Provide assistance with sample size and power calculations;
- Provide technical assistance in the understanding and interpretation of Institutional Review Board (IRB) requirements and the Health Insurance Portability and Accountability Act (HIPAA) especially as they apply to research and data collection within the EMS system; and
- Foster research capacity of State Partnership and targeted issue grantees through training and mentoring in the areas of data analysis, publications, etc.

Integrate activities with the overall goal of the Federal EMSC Program:

- Participate in national, regional and professional meetings in which the content of such meetings relates to the goals and objectives of the EMSC Program;
- Participate as presenters and/or moderators at meetings with a focus on, but not limited to, sessions that disseminate knowledge and information on data collection, data analysis, data linkage, program evaluation, survey design and development, data communication principles, and State and national EMS data systems development status;
 - Supporting educational documentation to grantees on purpose and long-term impact of performance measures;

- Technical assistance to States when collecting data for performance measures.
- Collaborate with national groups, including Federal agencies, in providing expert opinion and consultation that informs national planning, program and policy development around issues of pediatric emergency care, data collection and evaluation to insure the inclusion of pediatric emergency care
- Develop various products for target audiences that may include, but are not limited to background papers and briefs, written issue analyses, technical assistance memoranda or briefs, organizational policy statements, fact sheets, and audiovisual and electronic presentations;
- Provide the Federal project officer with the opportunity to review, provide input, and approve at the program level any publications, audiovisuals, and other materials, produced, as well as meetings/conferences planned, under the auspices of this cooperative agreement. Such reviews should start as part of the concept development and include reviews of drafts and final products;
- Participate in and utilize the EMSC stakeholder group coordinated by the Program and NRC to serve as an advisory board for joint resource consortium activities;
- Undertake joint projects with the Program's NRC to address the goals of the Federal EMSC program.

Provide Statistical and Data Management Technical Assistance to EMSC Researchers:

- Provide technical assistance in protocol development to EMSC Researchers through the aforementioned learning collaboratives.
- Provide data management and statistical expertise ad hoc to targeted issue grantees
- Participate in site visits to targeted issue grantees as needed

Function 2: PECARN-DCC

- 1) Close collaboration with the Research Nodes in the design, conduct, data analysis, and data management of collaborative clinical trials and observational studies in pediatric populations (with a focus on pediatric emergencies in the pre- and in-hospital setting) ages birth to 21. This includes the special pediatric issues of consent.
- 2) Utilization of electronic technology to design and produce data collection systems that are conducive to efficient functioning of PECARN.
- 3) Provision of appropriate and capable leadership and expertise in biostatistics, developmental study design, data management, data analysis, clinical data review, and project management, including, but not limited to, staff and site training and quality assurance procedures. This support should be initiated for all concepts and proposals approved by the PECARN steering committee.
- 4) Designing data collection modules, operational and procedural manuals, and quality control systems for the research undertaken in the PECARN.
- 5) Preparation of abstracts for presentation at scientific meetings.
- 6) Prompt and timely presentation and publication in the scientific literature of findings resulting from research undertaken in the PECARN.
- 7) Facilitating communication between data center staff and other components of PECARN, including MCHB, Data Safety Monitoring Boards (DSMB), and RNCs and their respective HEDAs.
- 8) Provision of an operational structure capable of coordinating data center functions for several protocols simultaneously.

- 9) Provision of support for the regulatory functions and requirements associated with the study protocols, procedures and IRB approvals process.
- 10) Organization and conduct of multi-site monitoring activities to assure quality data collection and comply with Federal Human Subjects regulations.
- 11) Revise and maintain appropriate and current network data collection policies and procedures that adhere to applicable Federal rules and regulations related to human subjects protections.
- 12) Participate in and staff steering committee, executive committee and respective subcommittees as appropriate to the function of the data coordinating center.
- 13) Provide advice on study design, data collection, study conduct, data analysis, and publication development in all PECARN research projects.
- 14) Prepare, design, and disseminate protocols, operations manuals, data collection forms, databases, and results reporting summaries for Network projects.
- 15) Compile for the steering committee, Data Safety Monitoring Boards (DSMB), and the MCHB project officer, site visit reports, monthly, quarterly reports of research undertaken in the PECARN including, but not limited to, subject enrollment, and other reports as requested by the PECARN steering committee or Study DSMB or MCHB project officer.
- 16) Provide training for RNCs and their respective HEDAs for personnel as needed for standardization of PECARN study protocols across sites.
- 17) Assist nodes with education of sites related to data quality, GCP and other study implementation training. Provide periodic, on-site data quality monitoring and/or remote monitoring at the RNCs and HEDAs as needed based on site specific characteristics and performance (example, if a site needs additional training because of a high rate of protocol deviations or has staff turnover).
- 18) Provide data management and assessment of data quality throughout each PECARN study.
- 19) Provide statistical analysis for all main study data and subsequent substudies.
- 20) Creation and execution of public use datasets as directed by the PECARN steering committee.

2. Summary of Funding

This program will provide funding during **Federal fiscal years 2012–2015**. Approximately \$2,800,000 is expected to be available annually to fund one (1) awardee. Applicants may apply for a ceiling amount of up to \$2,800,000 per year. The project period is four (4) years. Funding beyond the first year is dependent on the availability of appropriated funds for the “EMSC Program” in subsequent fiscal years, awardee satisfactory performance, and a decision that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

1. Eligible Applicants

Applications may be submitted by State governments and accredited schools of medicine. The term “school of medicine” for the purpose of this application funding opportunity announcement is defined as having the same meaning as set forth in section 799B(1)(A) of the Public Health Service Act (42 U.S.C. 295p(1)(A)) which defines it as an accredited public or nonprofit private school in the State that provides training leading, respectively, to a doctor of medicine and including advanced training related to such training provided by any such school. “The term accredited” in this context has the same meaning as set forth in section 799B(1)(E) of the Public Health Service Act (42 U.S.C. 295p(1)(E)) which when applied to a school of medicine defines it to mean a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education, except that a new school or program that, by reason of an insufficient period of operation, is not, at the time of application for a grant or contract under this subchapter, eligible for accreditation by such a recognized body or bodies, shall be deemed accredited for purposes of this subchapter, if the Secretary of Education finds, after consultation with appropriate accreditation body or bodies, that there is reasonable assurance that the school or program will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of the first entering class in such school or program.

Applicants must have experience and demonstrable success in conducting data center functions as described in this FOA.

2. Cost Sharing/Matching

Cost Sharing/Matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement.

NOTE: Multiple applications from an organization are not allowable.

IV. Application and Submission Information

1. Address to Request Application Package

Application Materials and Required Electronic Submission Information

HRSA *requires* applicants for this funding opportunity announcement to apply electronically through Grants.gov. This robust registration and application process protects applicants against fraud and ensures that only authorized representatives from an organization can submit an application. Applicants are responsible for maintaining these registrations, which should be completed well in advance of submitting your application. All applicants *must* submit in this manner unless they obtain a written exemption from this requirement in advance by the Director of HRSA's Division of Grants Policy. Applicants must request an exemption in writing from DGPWaivers@hrsa.gov, and provide details as to why they are technologically unable to submit electronically through the Grants.gov portal. Your email must include the HRSA announcement number for which you are seeking relief, the organization's DUNS number, the name, address, and telephone number of the organization and the name and telephone number of the Project Director as well as the Grants.gov Tracking Number (GRANTXXXX) assigned to your submission along with a copy of the "Rejected with Errors" notification you received from Grants.gov. **HRSA and its Digital Services Operation (DSO) will only accept paper applications from applicants that received prior written approval.** However, the application must still be submitted by the deadline. Suggestion: submit application to Grants.gov at least two days before the deadline to allow for any unforeseen circumstances.

Note: Central Contractor Registration (CCR) information must be updated at least every 12 months to remain active (for both grantees and sub-recipients). As of August 9, 2011, Grants.gov began rejecting submissions from applicants with expired CCR registrations.

Although active CCR registration at time of submission is not a new requirement, this systematic enforcement will likely catch some applicants off guard. According to the CCR Website it can take 24 hours or more for updates to take effect, so ***check for active registration well before your grant deadline.***

An applicant can view their CCR Registration Status by visiting <http://www.bpn.gov/CCRSearch/Search.aspx> and searching by their organization's DUNS. The [CCR Website](#) provides user guides, renewal screen shots, FAQs and other resources you may find helpful.

Applicants that fail to allow ample time to complete registration with CCR and/or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

All applicants are responsible for reading the instructions included in HRSA's *Electronic Submission User Guide*, available online at <http://www.hrsa.gov/grants/apply/userguide.pdf>. This Guide includes detailed application and submission instructions for both Grants.gov and HRSA's Electronic Handbooks. Pay particular attention to Sections 2 and 5 that provide detailed information on the competitive application and submission process.

Applicants are also responsible for reading the Grants.gov Applicant User Guide, available online at <http://www.grants.gov/assets/ApplicantUserGuide.pdf>. This Guide includes detailed information about using the Grants.gov system and contains helpful hints for successful submission.

Applicants must submit proposals according to the instructions in the Guide and in this funding opportunity announcement in conjunction with Application Form SF-424. The forms contain additional general information and instructions for applications, proposal narratives, and budgets. The forms and instructions may be obtained by:

- 1) Downloading from <http://www.grants.gov>, or
- 2) Contacting the HRSA Digital Services Operation (DSO) at:
HRSADSO@hrsa.gov

Each funding opportunity contains a unique set of forms and only the specific forms package posted with an opportunity will be accepted for that opportunity. Specific instructions for preparing portions of the application that must accompany Application Form SF-424 appear in the “Application Format Requirements” section below.

2. Content and Form of Application Submission

Application Format Requirements

The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA. The total file size may not exceed 10 MB. The 80-page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support. Standard forms are NOT included in the page limit. **We strongly urge you to print your application to ensure it does not exceed the 80-page limit. Do not reduce the size of the fonts or margins to save space. See the formatting instructions in Section 5 of the Electronic Submission User Guide referenced above.**

Applications must be complete, within the 80-page limit, within the 10 MB limit, and submitted prior to the deadline to be considered under this announcement.

Application Format

Applications for funding must consist of the following documents in the following order:

SF-424 Non-Construction – Table of Contents

- 🔔 It is mandatory to follow the instructions provided in this section to ensure that your application can be printed efficiently and consistently for review.
- 🔔 Failure to follow the instructions may make your application non-responsive. Non-responsive applications will not be considered under this funding opportunity announcement.
- 🔔 For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.
- 🔔 For electronic submissions, no Table of Contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Application for Federal Assistance (SF-424)	Form	Pages 1, 2 & 3 of the SF-424 face page.	Not counted in the page limit
Project Summary/Abstract	Attachment	Can be uploaded on page 2 of SF-424 - Box 15	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions.
Additional Congressional District	Attachment	Can be uploaded on page 3 of SF-424 - Box 16	As applicable to HRSA; not counted in the page limit.
Project Narrative Attachment Form	Form	Supports the upload of Project Narrative document	Not counted in the page limit.
Project Narrative	Attachment	Can be uploaded in Project Narrative Attachment form.	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions. Provide table of contents specific to this document only as the first page.
SF-424A Budget Information - Non-Construction Programs	Form	Pages 1–2 to support structured budget for the request of Non-construction related funds.	Not counted in the page limit.
Budget Narrative Attachment Form	Form	Supports the upload of Project Narrative document.	Not counted in the page limit.
Budget Narrative	Attachment	Can be uploaded in Budget Narrative Attachment form.	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions.
SF-424B Assurances - Non-Construction Programs	Form	Supports assurances for non-construction programs.	Not counted in the page limit.
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in the SF-424 Performance Site Location(s) form. Single document with	Not counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
		all additional site location(s)	
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.
Other Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list.	Not counted in the page limit.
Attachment 1-15	Attachment	Can be uploaded in Other Attachments form 1-15.	Refer to the attachment table provided below for specific sequence. Counted in the page limit.

- 🔔 To ensure that attachments are organized and printed in a consistent manner, follow the order provided below. Note that these instructions may vary across programs.
- 🔔 Evidence of Non-Profit status and invention related documents, if applicable, must be provided in the other attachment form.
- 🔔 Additional supporting documents, if applicable, can be provided using the available rows. Do not use the rows assigned to a specific purpose in the program funding opportunity announcement.
- 🔔 Merge similar documents into a single document. Where several pages are expected in the attachment, ensure that you place a table of contents cover page specific to the attachment. The Table of Contents page will not be counted in the page limit.
- 🔔 Limit the file attachment name to under 50 characters. Do not use any special characters (e.g., %, /, #) or spacing in the file name or word separation. (The exception is the underscore (_) character.) Your attachment will be rejected by Grants.gov if you use special characters or attachment names greater than 50 characters.

Attachment Number	Attachment Description (Program Guidelines)
Attachment 1	Tables, Charts, etc that supplement the narrative.
Attachment 2	Job Descriptions of Key Personnel
Attachment 3	Biographical Sketches of Key Personnel.
Attachment 4	Letters of Agreement and/or Description(s) of Proposed/Existing Contracts specific to this project.
Attachment 5	Project Organizational Chart
Attachment 6	Summary Progress Report – Accomplishment Summary for COMPETING CONTINUATIONS ONLY
Attachments 7–15	Other Relevant Documents

Application Format

i. Application Face Page

Complete Application Form SF-424 provided with the application package. Prepare according to instructions provided in the form itself. Important note: enter the name of the **Project Director** in 8.f. “Name and contact information of person to be contacted on matters involving this application.” If, for any reason, the Project Director will be out of the office, please ensure their email Out of Office Assistant is set so HRSA will be aware if any issues arise with the application and a timely response is required. For information pertaining to the Catalog of Federal Domestic Assistance, the CFDA Number is 93.127.

DUNS Number

All applicant organizations (and subrecipients of HRSA award funds) are required to have a Data Universal Numbering System (DUNS) number in order to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a unique nine-character identification number provided by the commercial company, Dun and Bradstreet. There is no charge to obtain a DUNS number. Information about obtaining a DUNS number can be found at <http://fedgov.dnb.com/webform> or call 1-866-705-5711. Please include the DUNS number in item 8c on the application face page. Applications **will not** be reviewed without a DUNS number. Note: A missing or incorrect DUNS number is the number one reason for applications being “Rejected for Errors” by Grants.gov. HRSA will not extend the deadline for applications with a missing or incorrect DUNS number. Applicants should take care in entering the DUNS number in the application.

Additionally, the applicant organization (and any subrecipient of HRSA award funds) is required to register annually with the Central Contractor Registration (CCR) in order to do electronic business with the Federal Government. CCR registration must be maintained with current, accurate information at all times during which an entity has an active award or an application or plan under consideration by HRSA. It is extremely important to verify that your CCR registration is active and your Marketing Partner ID Number (MPIN) is current. Information about registering with the CCR can be found at <http://www.ccr.gov>.

ii. Table of Contents

The application should be presented in the order of the Table of Contents provided earlier. Again, for electronic applications no table of contents is necessary as it will be generated by the system. (Note: the Table of Contents will not be counted in the page limit.)

iii. Budget

Complete Application Form SF-424A Budget Information – Non-Construction Programs provided with the application package.

Please complete Sections A, B, E, and F, and then provide a line item budget for each year of the project period. In Section A use rows 1 - 4 to provide the budget amounts for the first four years of the project. Please enter the amounts in the “New or Revised Budget” column- not the “Estimated Unobligated Funds” column. In Section B Object Class Categories of the SF-424A, provide the object class category breakdown for the annual amounts specified in

Section A. In Section B, use column (1) to provide category amounts for Year 1 and use columns (2) through (4) for subsequent budget years (up to four years).

Salary Limitation:

The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is \$179,700. This amount reflects an individual’s base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under a HRSA grant or cooperative agreement.

As an example of the application of this limitation: If an individual’s base salary is \$350,000 per year plus fringe benefits of 25% (\$87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to \$179,700 plus fringe of 25% (\$44,925) and a total of \$112,312.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

Individual’s <i>actual</i> base full time salary: \$350,000 50% of time will be devoted to project	
Direct salary	\$175,000
Fringe (25% of salary)	\$43,750
Total	\$218,750
Amount that may be claimed on the application budget due to the legislative salary limitation: Individual’s base full time salary <i>adjusted</i> to Executive Level II: \$179,700 50% of time will be devoted to the project	
Direct salary	\$89,850
Fringe (25% of salary)	\$22,462.50
Total amount	\$112,312.50

iv. Budget Justification

Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of proposed objectives. The budget period is for ONE year. However, the applicant **must** submit one-year budgets for each of the subsequent budget periods within the requested project period (usually one to four years) at the time of application. Line item information must be provided to explain the costs entered in the SF-424A. Be very careful about showing how each item in the “other” category is justified. For subsequent budget years, the justification narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the project period. The budget justification **MUST** be concise. Do NOT use the justification to expand the project narrative.

This announcement is inviting applications for project periods up to four (4) years. Awards, on a competitive basis, will be made for a one-year budget period; although the project period may be

for up to four (4) years. Submission and HRSA approval of your Progress Report(s) and any other required submission or report is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the four-year project period is subject to availability of funds, satisfactory progress of the awardee and a determination that continued funding would be in the best interest of the Federal Government.

Include the following in the Budget Justification narrative:

Personnel Costs: Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. Reminder: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or \$179,700. An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to HRSA grants and cooperative agreements. Please provide an individual's actual base salary if it exceeds the cap. See the sample below.

Sample:

Name	Position Title	% of FTE	Annual Salary	Amount Requested
J. Smith	Chief Executive Officer	50	\$179,700*	\$89,850
R. Doe	Nurse Practitioner	100	\$75,950	\$75,950
D. Jones	Data/AP Specialist	25	\$33,000	\$8,250

*Actual annual salary = \$350,000

To ensure oversight of the program a dedicated principal investigator/project director must be identified for each of the functions of the DCC (function 1 and function 2 described under "purpose") who will be responsible for the management of daily activities and monitor the center's accomplishment of stated purpose of work. The principal investigator for each function should be clearly listed and described in the narrative and budget sections. Note: Form 424 only allows one project director to be listed. One of the two principal investigators can be listed.

Fringe Benefits: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plan, tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project. (If an individual's base salary exceeds the legislative salary cap, please adjust fringe accordingly.)

Travel: List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. The budget should also reflect the travel expenses associated with participating in meetings and other proposed trainings or workshops.

At a minimum, the following travel is **required** to be budgeted.

- Travel expenses associated with relevant staff to attend up to two in-person PECARN Steering Committee meetings a year. At least one meeting will be held in the Washington, DC metro area with an additional meeting in a major city in the US. Travel expenses for the principal investigator and DCC manager (or equivalent) to travel to one executive committee meeting a year in the Washington, DC area.

PECARN Steering Committee Meeting (up to 2 Steering Committee meetings per year for an anticipated total of 8 meetings during the cooperative agreement period of Sept 1, 2012 – August 31, 2016)

Lodging: 3 nights

Travel: Airfare

- At least one meeting per year will be held in the Washington, DC area.

Registration/Meeting Expenses: the DCC should budget an estimated \$5,000 per meeting (total of \$10,000 per year) to cover PECARN meeting expenses such as room rental, AV costs etc.

In addition, specific travel expenses should include;

- Expenses for annual meeting of a group supporting the maintenance and development of EMSC performance measures. Anticipate a meeting for 20 individuals in a major city in the US for EMSC Program needs. The exact content and invitee list for the meeting will be determined in conjunction with the Federal Program
- Expenses for site visits to State Partnership grantees to provide technical assistance.
- Expenses for an annual trip of key staff dedicated from both functions of the DCC to Washington DC to meet with Federal Program staff.

It is also recommended that travel for presentation at scientific meetings and other training meetings be budgeted as appropriate.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of computers and furniture items that meet the definition of equipment (a unit cost of \$5,000 or more and a useful life of one or more years).

Supplies: List the items that the project will use. In this category, separate office supplies from medical and educational purchases. Office supplies could include paper, pencils, and the like; medical supplies are syringes, blood tubes, plastic gloves, etc., and educational supplies may be pamphlets and educational videotapes. Remember, they must be listed separately.

Contractual: Applicants are responsible for ensuring that their organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Applicants must provide a clear

explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables. Reminder: recipients must notify potential subrecipients that entities receiving subawards must be registered in the CCR and provide the recipient with their DUNS number.

Consultants can also be listed in this section. For each consultant, specify the scope of work for the consultant, the hourly rate, and the number of hours of expected effort. Note: This program allows awardees to utilize contractors but not to issue subgrants

Other: Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.

Applicants may include the cost of access accommodations as part of their project's budget, including sign interpreters, plain language and health literate print materials in alternate formats (including Braille, large print, etc.); and cultural/linguistic competence modifications such as use of cultural brokers, translation or interpretation services at meetings, clinical encounters, and conferences, etc.

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For institutions subject to OMB Circular A-21, the term "facilities and administration" is used to denote indirect costs. If an organization applying for an assistance award does not have an indirect cost rate, the applicant may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at <http://rates.psc.gov/> to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them.

Please note that if indirect costs are requested, the applicant must submit a copy of the latest negotiated rate agreement. **This program supports an infrastructure from which to conduct research, but is not a research project in and of itself, therefore, it is not eligible for research indirect rates.** The indirect costs rate refers to the "Other Sponsored Program/Activities" rate and to neither the research rate, nor the education/training program rate. Those applicants without an established indirect cost rate for "other sponsored programs" may only request 10% of salaries and wages, and must request an "other sponsored programs" rate from DCA. Direct cost amounts for equipment (capital expenditures), tuition and fees, and contracts in excess of \$25,000 are excluded from the actual direct cost base for purposes of this calculation.

v. *Staffing Plan and Personnel Requirements*

Applicants must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in Attachment 2. Biographical sketches for any key employed personnel that will be assigned to work on the proposed project must be included in Attachment 3. When applicable, biographical sketches should

include training, language fluency and experience working with the cultural and linguistically diverse populations that are served by their programs.

vi. Assurances

Complete Application Form SF-424B Assurances – Non-Construction Programs provided with the application package.

vii. Certifications

Use the Certifications and Disclosure of Lobbying Activities Application Form provided with the application package.

viii. Project Abstract

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed services, and the population group(s) to be served.

Please place the following at the top of the abstract:

- Project Title
- Applicant Organization Name
- Address
- Project Director Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

Abstract content:

PROBLEM: Briefly (in one or two paragraphs) state the principal needs and problems which are addressed by the project.

GOAL(S) AND OBJECTIVES: Identify the major goal(s) and objectives for the project period. Typically, the goal is stated in a sentence or paragraph, and the objectives are presented in a numbered list.

METHODOLOGY: Describe the programs and activities used to attain the objectives and comment on innovation, cost, and other characteristics of the methodology. This section is usually several paragraphs long and describes the activities which have been proposed or are being implemented to achieve the stated objectives. Lists with numbered items are sometimes used in this section as well.

COORDINATION: Describe the coordination planned with appropriate national, regional, State and/or local health agencies and/or organizations in the area(s) served by the project.

EVALUATION: Briefly describe the evaluation methods used to assess program outcomes and the effectiveness and efficiency of the project in attaining goals and objectives. This section is usually one or two paragraphs in length.

ANNOTATION: Provide a three- to five-sentence description of your project that identifies the project's purpose, the needs and problems, which are addressed, the goals and objectives of the project, the activities, which will be used to attain the goals and the materials which will be developed.

The project abstract must be **single-spaced and limited to one page in length**.

ix. Project Narrative

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

Use the following section headers for the Narrative:

BACKGROUND AND SIGNIFICANCE:

In this section, the applicant should demonstrate a thorough knowledge and understanding of EMSC. The applicant should demonstrate their understanding of the needs of the EMSC grantees and the need to make EMSC system improvements. The applicant should identify areas for further development to improve the overall mission of the EMSC program. The applicant's past experience that makes them qualified for the work described in this funding opportunity announcement should be highlighted in this section, specifically successful collaboration with EMSC grantees, government entities and national organizations in integrating EMSC into the nation's healthcare system.

This section should also describe the purpose of the proposed project focusing on the purpose of a data coordinating center within the context of a multi-site pediatric research network. Discuss any relevant barriers in the field of pediatric emergency care that the project hopes to overcome. This section should help reviewers understand the: 1) role of a data center in a research network; 2) applicant's understanding of the issues related to emergency care research (including issues related to human subjects protections); and 3) general infrastructure needs of a data center (for example, software/hardware needs to assure secure transmission and storage of private health information).

GOALS, METHODOLOGY AND WORKPLAN:

Propose goals and methods that will be used to meet the previously-described scope of activities and expectations for Function 1 and Function 2 in this funding opportunity announcement. Describe specific activities or steps that will be used to achieve each of the goals proposed. Use a detailed time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaborations with key stakeholders in planning, designing, and implementing all activities. This section should also include a plan for publishing lessons learned and contributing to the dissemination of EMSC work.

Each goal should include an evaluative measure to assess achievement. Evaluation and self-assessment are critically important for quality improvement and assessing the value-added contribution of HRSA/MCHB investments. Consequently, all MCHB discretionary grant projects and EMSC projects are expected to incorporate a carefully designed and well-planned evaluation protocol capable of demonstrating and documenting measurable progress toward

achieving the stated goals. The measurement of progress toward goals should focus on systems and health and performance indicators, rather than solely on intermediate process measures. The evaluation protocol should be based on a clear rationale relating to the identified needs of the target population with award activities, project goals, and evaluation measures. A project lacking a complete and well-conceived evaluation protocol may not be funded.

RESOLUTION OF CHALLENGES:

Discuss challenges that are likely to be encountered in designing and implementing the activities described in the Work Plan, and approaches that will be used to resolve such challenges.

TECHNICAL SUPPORT CAPACITY:

Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. Specifically describe the availability of content expertise needed for both functions of the DCC.

ORGANIZATIONAL INFORMATION:

Discuss the resources of the applicant to accomplish the proposed goals and methods and scope of activities described in Section II. Provide information on the applicant's structure, resources and infrastructure available at the applicant institution to conduct the scope of current activities, and describe how these all contribute to the ability of the organization to serve as a data coordinating center for EMSC. Describe previous work of a similar nature in the past 5-10 years that demonstrates the applicant's ability to serve as a data center.

x. Program Specific Forms

1) Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects

The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant programs administered by the Maternal and Child Health Bureau (MCHB) to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for States have also been established under the Block Grant provisions of Title V of the Social Security Act, the MCHB's authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) Performance Measures for the **EMSC Program** and Submission of Administrative Data

To prepare applicants for reporting requirements, administrative data collection requirements are presented in Appendix A of this funding opportunity announcement.

xi. Attachments

Please provide the following items to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Unless otherwise noted, attachments count toward the application page limit. **Each attachment must be clearly labeled.**

Required Attachments:

Attachment 1: Tables, Charts, etc.

These should be supplementary to provide illustration to concepts described in the narrative.

Attachment 2: Job Descriptions of Key Personnel

Keep each to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff.

Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch. The principal investigator and other staff must have appropriate expertise and capability in biostatistics, data management, data analysis, and project management

Attachment 4: Letters of Agreement and/or Description(s) of Proposed/Existing Contracts specific to this project

Provide any documents that describe working relationships between the applicant agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverable. Letters of agreements must be dated.

Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project, including subcontractors and other significant collaborators.

Attachment 6: Summary Progress Report

ACCOMPLISHMENT SUMMARY (FOR COMPETING CONTINUATIONS ONLY)

A well-planned accomplishment summary can be of great value by providing a record of accomplishments. It is an important source of material for HRSA in preparing annual reports, planning programs, and communicating program specific accomplishments. The accomplishments of competing continuation applicants are carefully considered during

the review process; therefore, applicants are advised to include previously stated goals and objectives in their application and emphasize the progress made in attaining these goals and objectives. Because the Accomplishment Summary is considered when applications are reviewed and scored, **competing continuation applicants who do not include an Accomplishment Summary may not receive as high a score as applicants who do**

The accomplishment summary should be a brief presentation of the accomplishments, in relation to the objectives of the program during the current project period. The report should include:

- (1) The period covered (dates).
- (2) Specific Objectives- Briefly summarize the specific objectives of the project as actually funded. Because of peer review recommendations and/or budgetary modifications made by the awarding unit, these objectives may differ in scope from those stated in the competing application.
- (3) Results- Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.

Attachments 7–15: Other Relevant Documents

Include here any other documents that are relevant to the application. Examples include:

- Letters of supports-- letters of support must be dated. Include only letters of support which specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.) List all other support letters on one page.
- Supplementary documents describing data infrastructure (network security policies, physical setup etc)

3. Submission Dates and Times

Application Due Date

The due date for applications under this funding opportunity announcement is *May 29, 2012 at 8:00 P.M. ET*. Applications completed online are considered formally submitted when the application has been successfully transmitted electronically by your organization's Authorized Organization Representative (AOR) through Grants.gov and has been validated by Grants.gov on or before the deadline date and time.

Receipt acknowledgement: Upon receipt of an application, Grants.gov will send a series of email messages advising you of the progress of your application through the system. The first will confirm receipt in the system; the second will indicate whether the application has been successfully validated or has been rejected due to errors; the third will be sent when the application has been successfully downloaded at HRSA; and the fourth will notify the applicant of the Agency Tracking Number assigned to the application.

The Chief Grants Management Officer (CGMO) or designee may authorize an extension of published deadlines when justified by circumstances such as natural disasters (e.g., floods or

hurricanes) or other disruptions of services, such as a prolonged blackout. The CGMO or designee will determine the affected geographical area(s).

Late applications:

Applications which do not meet the criteria above are considered late applications and will not be considered in the current competition.

4. Intergovernmental Review

The Emergency Medical Services for Children Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100.

5. Funding Restrictions

Applicants responding to this announcement may request funding for a project period of up to 4 years, at no more than \$2,800,000 per year. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Salary Limitation: The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is \$179,700. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under a HRSA grant or cooperative agreement.

Per Division F, Title V, Section 503 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011 (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. (b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive

branch of that government. (c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

Per Division F, Title V, Section 523 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

6. Other Submission Requirements

As stated in Section IV.1, except in very rare cases HRSA will no longer accept applications in paper form. Applicants submitting for this funding opportunity are **required** to submit **electronically** through Grants.gov. To submit an application electronically, please use the APPLY FOR GRANTS section at <http://www.grants.gov>. When using Grants.gov you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site.

It is essential that your organization **immediately register** in Grants.gov and become familiar with the Grants.gov site application process. If you do not complete the registration process you will be unable to submit an application. The registration process can take up to one month.

To be able to successfully register in Grants.gov, it is necessary that you complete all of the following required actions:

- Obtain an organizational Data Universal Numbering System (DUNS) number
- Register the organization with Central Contractor Registration (CCR)
- Identify the organization's E-Business Point of Contact (E-Biz POC)
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password
- Register and approve an Authorized Organization Representative (AOR)
- Obtain a username and password from the Grants.gov Credential Provider

Instructions on how to register, tutorials and FAQs are available on the Grants.gov web site at <http://www.grants.gov>. Assistance is also available 24 hours a day, 7 days a week (excluding Federal holidays) from the Grants.gov help desk at support@grants.gov or by phone at 1-800-518-4726. Applicants should ensure that all passwords and registration are current well in advance of the deadline.

It is incumbent on applicants to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will not accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline. Therefore, you are urged to submit your application in advance of the deadline. If your application is rejected by Grants.gov due to errors, you must correct the application and resubmit it to Grants.gov before the deadline date and time. Deadline extensions will not be provided to applicants who do not correct errors and resubmit before the posted deadline.

If, for any reason, an application is submitted more than once prior to the application due date, HRSA will only accept the applicant’s last validated electronic submission prior to the application due date as the final and only acceptable submission of any competing application submitted to Grants.gov.

Tracking your application: It is incumbent on the applicant to track their application by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking your application can be found at <https://apply07.grants.gov/apply/checkApplStatus.faces>. Be sure your application is validated by Grants.gov prior to the application deadline.

V. Application Review Information

1. Review Criteria

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

<u>Narrative Section</u>	<u>Review Criteria</u>
Background and Significance	(1) Need
Goals, Methodology and Workplan	(2) Response (3) Evaluative measures (4) Impact
Resolution of Challenges	(2) Response
Technical Support Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

Review Criteria are used to review and rank applications. The EMSC Program has five (5) review criteria:

Criterion 1: NEED (5 points) The extent to which the application demonstrates understanding of the EMSC Program, the role of a data coordinating center to support State/Territory EMSC data collection systems. Further, within the context of multi-site research studies involving children, the applicant demonstrates an understanding of the issues involved in pediatric emergency care trials.

Criterion 2: RESPONSE (40 points) The clarity of the proposed goals and objectives and their relationship to the identified project. The extent to which there is a clearly described methodology to address activities described in the application. Quality of the applicant's plan for the DCC, as described in this funding opportunity announcement, and the nature and technical quality of the data coordinating center proposed. Adequacy of the proposed plans for overall DCC management and operations, including those factors that will contribute to collaborative interactions. Applicants should address the requirements for both Function 1 and Function 2 of the data center.. Specifically;

- The extent to which an adequate plan for data collection with appropriate safeguards (e.g. secure electronic storage with backup) is presented
- The extent to which a plan for data management (established process to assure uniformity of data collection) is presented.
- Specific to Function 1: State/Territory data assistance
 - The extent to which the applicant will provide meaningful technical assistance to States/Territories to build data capacity
 - The extent to which the applicant will assist States/Territories with data collection related to EMSC performance measures
 - The extent to which the applicant will provide data related assistance and training to investigators and national stakeholders
- Specific to Function 2: PECARN DCC
 - The extent to which an appropriate plan for data analysis of PECARN studies is presented.
 - The extent to which an adequate plan for data management includes quality assurance procedures.
 - The extent to which an appropriate plan for creating public use data sets is presented that includes appropriate procedures for de-identifying datasets and secure procedures for providing data to external investigators.
 - The extent to which there is an adequate plan for coordinating multiple sites and multiple studies (i.e. tracking IRB approvals, providing assistance to site investigators, monitoring site performance).
 - The extent to which there is an adequate plan to train (including re-training) of study personnel.
 - The extent to which applicant demonstrates an understanding of the challenges inherent in collecting and processing multi-center data and presents meaningful solutions to address such barriers.

Criterion 3: EVALUATIVE MEASURES (5 points)

The effectiveness of the method proposed to monitor and evaluate the project results. Evaluative measures must be able to assess: 1) to what extent the project objectives have been met, and 2) what specific measures the applicant will use to monitor the services they provide to the PECARN and EMSC grantees.

Criterion 4: IMPACT (5 points)

This section of the narrative should describe the extent and effectiveness of this application in improving the success of EMSC grantees and EMSC stakeholders (those involved in the delivery of emergency care to children or systems that support this effort) in furthering the EMSC mission. Applicants should describe the significance of the project in terms of its potential impact for improving EMSC nationally, specifically focusing on data collection, analysis and utilization.

Criterion 5: RESOURCES/CAPABILITIES (35 points) Adequacy of the available resources and personnel for administration of the DCC. The applicant should provide evidence of infrastructure capabilities in State data system development, research, administration, operational management, protocol development, clinical data information systems and management of regulation documents. The extent to which **listed personnel or proposed personnel demonstrate content area expertise**. Biographical sketches should document education, skills, and experience that are relevant and necessary for the proposed project.

Specifically for Function 1: NEDARC;

- Applicant's ability to provide technical assistance to EMSC grantees, government entities and national organizations as it relates to successful implementation of EMSC projects
- Applicant's ability to understand and provide assistance related to the EMSC performance measures
- Applicant's ability in survey development, deployment and analysis
- Applicant's content expertise in training to support EMSC grantees in achieving performance measures (ie:assessment, dissemination of data to stakeholders, use of other data sources)

Specifically for Function 2: PECARN DCC;

- The extent to which the applicant demonstrates successful experience in the design, conduct, data analysis, and data management of major collaborative research projects involving pediatric populations.
- The extent to which the applicant demonstrates successful performance as a data coordinating center for multi-site research in children during the previous five to ten years.
- The extent to which the principal investigator and staff demonstrate appropriate expertise and capabilities in biostatistics, study design, development and support, as well as data analysis, project management, and staff site training and quality assurance procedures.
- The extent to which the applicant has the existing resources/facilities to successfully support the project.

- The extent to which the setting/parent institution of the applicant has the appropriate infrastructure to achieve project objectives.
- The extent to which the organizational and physical environment is supportive of the investigator and the project.
- The extent to which the applicant provides evidence of the ability to assist in designing protocols, data collection forms, manuals of operation, and data collection systems for multi-site research studies involving children.

Criterion 6: SUPPORT REQUESTED (10 points) The reasonableness of the proposed budget in relation to the objectives, the complexity of the activities, and the anticipated results.

- The extent to which costs outlined in the budget are reasonable given the scope of work
- The extent to which the budget line items are well described and justified in the budget justification
- The extent to which key personnel have adequate time devoted to the project to achieve the project objective

2. Review and Selection Process

The Division of Independent Review is responsible for managing objective reviews within HRSA. Applications competing for Federal funds receive an objective and independent review performed by a committee of experts qualified by training and experience in particular fields or disciplines related to the program being reviewed. In selecting review committee members, other factors in addition to training and experience may be considered to improve the balance of the committee, e.g., geographic distribution. Each reviewer is screened to avoid conflicts of interest and is responsible for providing an objective, unbiased evaluation based on the review criteria noted above. The committee provides expert advice on the merits of each application to program officials responsible for final selections for award.

Applications that pass the initial HRSA eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in Section V. 1. Review Criteria of this funding opportunity announcement. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of September 1, 2012.

VI. Award Administration Information

1. Award Notices

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

The Notice of Award sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer, it is sent to the applicant's Authorized Organization Representative, and reflects the only authorizing document. It will be sent prior to the start date of September 1, 2012.

2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 [Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations](#) or 45 CFR Part 92 [Uniform Administrative Requirements For Grants And Cooperative Agreements to State, Local, and Tribal Governments](#), as appropriate.

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable based on recipient type and purpose of award. This includes, as applicable, any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at <http://www.hrsa.gov/grants/>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award).

Human Subjects Protection

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

Financial Conflict of Interest

HHS requires awardees and investigators to comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS

Funding is Sought." A Final Rule amending this PHS regulation (and the companion regulation at 45 CFR part 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). An Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the rule must be in full compliance with all of the revised regulatory requirements no later than August 24, 2012, and immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described in the regulation.

Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to <http://www.hrsa.gov/grants/trafficking.html>. If you are unable to access this link, please contact the Grants Management Specialist identified in this funding opportunity to obtain a copy of the Term.

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Cultural and Linguistic Competence

HRSA programs serve culturally and linguistically diverse communities and multiple cultures. Although race and ethnicity are often thought to be dominant elements of culture, HRSA funded programs embrace a broader definition to include language, gender, socio-economic status, sexual orientation and gender identity, physical and mental capacity, age, religion, housing status, and regional differences. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients and students served. HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, materials delivered by competent providers in a manner that factors in the language needs, cultural richness, and diversity of populations served. Quality also means that, where appropriate, data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS) published by HHS and available online at <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15>. Additional cultural competency and health literacy tools, resources and definitions are available online at <http://www.hrsa.gov/culturalcompetence> and <http://www.hrsa.gov/healthliteracy>.

Healthy People 2020

Healthy People 2020 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has four overarching goals: (1) attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; (2) achieve health equity, eliminate disparities, and improve the health of all groups; (3) create social and physical environments that promote good health for all; and (4) promote quality of life, healthy development, and healthy

behaviors across all life stages. The program consists of over 40 topic areas, containing measurable objectives. HRSA has actively participated in the work groups of all the topic areas and is committed to the achievement of the Healthy People 2020 goals. More information about Healthy People 2020 may be found online at <http://www.healthypeople.gov/>.

National HIV/AIDS Strategy (NHAS)

The National HIV/AIDS Strategy (NHAS) has three primary goals: 1) reducing the number of people who become infected with HIV, 2) increasing access to care and optimizing health outcomes for people living with HIV, and 3) reducing HIV-related health disparities. The NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically deployed. Further, the NHAS recognizes the importance of early entrance into care for people living with HIV to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention, care and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to identify people who are HIV-positive but do not know their serostatus and reduce stigma and discrimination against people living with HIV.

To the extent possible, program activities should strive to support the three primary goals of the NHAS. As encouraged by the NHAS, programs should seek opportunities to increase collaboration, efficiency, and innovation in the development of program activities to ensure success of the NHAS. Programs providing direct services should comply with Federally-approved guidelines for HIV Prevention and Treatment (see <http://www.aidsinfo.nih.gov/Guidelines/Default.aspx> as a reliable source for current guidelines). More information can also be found at <http://www.whitehouse.gov/administration/eop/onap/nhas>

Health IT

Health information technology (Health IT) provides the basis for improving the overall quality, safety and efficiency of the health delivery system. HRSA endorses the widespread and consistent use of health IT, which is the most promising tool for making health care services more accessible, efficient and cost effective for all Americans.

Related Health IT Resources:

- [Health Information Technology \(HHS\)](#)
- [What is Health Care Quality and Who Decides? \(AHRQ\)](#)

3. Reporting

The successful applicant under this funding opportunity announcement must comply with the following reporting and review activities:

a. Audit Requirements

Comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at http://www.whitehouse.gov/omb/circulars_default.

b. **Payment Management Requirements**

Submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System. The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to <http://www.dpm.psc.gov> for additional information.

c. **Status Reports**

1) **Federal Financial Report.** The Federal Financial Report (SF-425) is required within 90 days of the end of each budget period. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically through EHB. More specific information will be included in the Notice of Award.

2) **Progress Report(s).** The awardee must submit a progress report to HRSA on an annual basis. Submission and HRSA approval of your Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates awardee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the award notice.

3) **Final Report(s).** A final report is due within 90 days after the project period ends. The final report collects program-specific goals and progress on strategies; core performance measurement data; impact of the overall project; the degree to which the awardee achieved the mission, goal and strategies outlined in the program; awardee objectives and accomplishments; barriers encountered; and responses to summary questions regarding the awardee's overall experiences over the entire project period. The final report must be submitted on-line by awardees in the Electronic Handbooks system at <https://grants.hrsa.gov/webexternal/home.asp>

4) **Performance Reports.** The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by the Maternal and Child Health Bureau (MCHB) to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for States have also been established under the Block Grant provisions of Title V of the Social Security Act, the MCHB's authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect.

d. Transparency Act Reporting Requirements

New awards (“Type 1”) issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252, and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier subaward of \$25,000 or more in Federal funds and executive total compensation for the recipient’s and subrecipient’s five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (FFATA details are available online at <http://www.hrsa.gov/grants/ffata.html>).

Competing continuation awardees, etc. may be subject to this requirement and will be so notified in the Notice of Award.

VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this funding opportunity announcement by contacting:

LaShawna D. Smith
Grants Management Specialist
HRSA Division of Grants Management Operations
5600 Fishers Lane, Room 11A-16
Rockville, MD 20857
Telephone: (301) 443-4241
Fax: (301) 443-6343
Email: LSmith3@hrsa.gov

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

Tasmeen Weik, DrPH
Public Health Analyst
HRSA Maternal and Child Health Bureau
Parklawn Building, Room 18A-38
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-8927
Email: tweik@hrsa.gov

Applicants may need assistance when working online to submit their application forms electronically. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding Federal holidays at:

Grants.gov Contact Center
Phone: 1-800-518-4726
E-mail: support@grants.gov
iPortal: <http://grants.gov/iportal>

VIII. Other Information

Definitions and Abbreviated Terms

The following definitions and abbreviated terms are provided as guidance for applicants:

- "**Children**" means youths from birth through age 21.
- "**DCC**" Data Coordinating Center. Serves as a central data collection, data management, data analysis, and repository for the Pediatric Emergency Care Applied Research Network.
- "**Cultural Competence**" means a set of values, behaviors, attitudes, and practices within a system, organization, or program or among individuals that enables them to work effectively cross culturally. Further, it refers to the ability to honor and respect the beliefs, language, interpersonal styles and behaviors of individuals and families receiving services, as well as staff who are providing such services. Cultural competence is a dynamic, ongoing, developmental process that requires a long-term commitment and is achieved over time.
- "**Data Safety Monitoring Board**" or "**DSMB**" is an independent group of experts that advises the study investigators and reviews data to assure safety. Standards for DSMB's are provided in Good Clinical Practice (GCP) guidelines.
- "**Emergency Medical Services**" or "**EMS**" means services used in responding to an adult or child's need for immediate medical care in order to prevent loss of life and to prevent aggravation of physiological or psychological illness or injury and disability by appropriate intervention at the very early stages of the event.
- "**Emergency Medical Services System**" means an arrangement of personnel, facilities, and equipment for the effective and coordinated delivery of health care services in an appropriate geographical area, under emergency conditions (occurring either as a result of the patient's condition or of natural disasters or similar situations), and which has the authority and the resources to provide effective administration of the system. An "appropriate geographical area" means an area which is of sufficient size, population, and economic diversity so that an efficient and economically feasible EMS project can be established, taking into consideration existing medical service areas and health service areas. The EMS system is a continuum encompassing primary prevention, pre-hospital and emergency department care, critical care and acute hospitalization, rehabilitation, and return to the community.
- "**Family-Centered**" includes the following key elements of care: maximum possible involvement of families in all phases of the EMSC continuum of care; clear and continuous communication between family members and the emergency care team; attention to the psychological needs of all family members; cultural competence of providers; consumer (parental) involvement in planning and needs assessment; organizational support for the formation of parent advocacy groups; and ongoing partnerships with such groups.

- “**HEDA**” – Hospital Emergency Department Affiliate: Serves as a functional component of the Research Node, participates in the observational studies and randomized clinical trials and takes part in the development of and implementation of concept and protocol of these studies.
- “**Manual of Operations**” – this is a manual that details study procedures and provides instructions for sites on how to conduct a study.
- “**PECARN**” – Pediatric Emergency Care Applied Research Network: Functions as a collaborative group of Research Nodes. PECARN is the operational name of the six research nodes (and their HEDAs) and the DCC. The website <http://www.pecarn.org> denotes general information on current network activity.
- “**RNC**” – Research Node Center: Serves as a local operation center for the Research Node, provides a core of administrative and study operations services as well as scientific leadership and management of observational and randomized studies.
- “**State**” means one of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of Northern Mariana Islands.

VIII. Tips for Writing a Strong Application

A concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed online at:

<http://www.hhs.gov/asrt/og/grantinformation/apptips.html>.

Appendix A: MCHB Administrative Forms and Performance Measures

The following Administrative Forms and Performance Measures are assigned to this MCHB program.

- Form 1, MCHB Project Budget Details
- Form 2, Project Funding Profile
- Form 4, Project Budget and Expenditures by Types of Services—(Use Infrastructure Building for this Application)
- Form 6, MCH Abstract
- Form 7, Discretionary Grant Project Summary Data
- Performance Measures 03, The percentage of MCHB-funded projects submitting and publishing findings in peer-reviewed journals
- Performance Measure 10, The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training
- Performance Measure 24, The degree to which MCHB-funded initiatives contribute to infrastructure development through core public health assessment, policy development and assurance functions
- Performance Measure 27, The degree to which awardees have mechanisms in place to ensure quality in the design, development, and dissemination of new information resources that they produce each year
- Performance Measure 33, The degree to which MCHB-funded initiatives work to promote sustainability of their programs or initiatives beyond the life of MCHB funding
- Data Forms: Products, Publications and Submissions Data Collection Form

FORM 1
MCHB PROJECT BUDGET DETAILS FOR FY _____

1. MCHB GRANT AWARD AMOUNT	\$ _____
2. UNOBLIGATED BALANCE	\$ _____
3. MATCHING FUNDS	\$ _____
(Required: Yes [] No [] If yes, amount)	
A. Local funds	
B. State funds	\$ _____
C. Program Income	\$ _____
D. Applicant/Grantee Funds	\$ _____
E. Other funds: _____	\$ _____
4. OTHER PROJECT FUNDS (Not included in 3 above)	\$ _____
A. Local funds	\$ _____
B. State funds	\$ _____
C. Program Income (Clinical or Other)	\$ _____
D. Applicant/Grantee Funds (includes in-kind)	\$ _____
E. Other funds (including private sector, e.g., Foundations)	\$ _____
5. TOTAL PROJECT FUNDS (Total lines 1 through 4)	\$ _____
6. FEDERAL COLLABORATIVE FUNDS	\$ _____
(Source(s) of additional Federal funds contributing to the project)	
A. Other MCHB Funds (Do not repeat grant funds from Line 1)	
1) Special Projects of Regional and National Significance (SPRANS)	\$ _____
2) Community Integrated Service Systems (CISS)	\$ _____
3) State Systems Development Initiative (SSDI)	\$ _____
4) Healthy Start	\$ _____
5) Emergency Medical Services for Children (EMSC)	\$ _____
6) Traumatic Brain Injury	\$ _____
7) State Title V Block Grant	\$ _____
8) Other: _____	\$ _____
9) Other: _____	\$ _____
10) Other: _____	\$ _____
B. Other HRSA Funds	
1) HIV/AIDS	\$ _____
2) Primary Care	\$ _____
3) Health Professions	\$ _____
4) Other: _____	\$ _____
5) Other: _____	\$ _____
6) Other: _____	\$ _____
C. Other Federal Funds	
1) Center for Medicare and Medicaid Services (CMS)	\$ _____
2) Supplemental Security Income (SSI)	\$ _____
3) Agriculture (WIC/other)	\$ _____
4) Administration for Children and Families (ACF)	\$ _____
5) Centers for Disease Control and Prevention (CDC)	\$ _____
6) Substance Abuse and Mental Health Services Administration (SAMHSA)	\$ _____
7) National Institutes of Health (NIH)	\$ _____
8) Education	\$ _____
9) Bioterrorism	
10) Other: _____	\$ _____
11) Other: _____	\$ _____
12) Other: _____	\$ _____
7. TOTAL COLLABORATIVE FEDERAL FUNDS	\$ _____

INSTRUCTIONS FOR COMPLETION OF FORM 1
MCH BUDGET DETAILS FOR FY ____

- Line 1. Enter the amount of the Federal MCHB grant award for this project.
- Line 2. Enter the amount of carryover (e.g, unobligated balance) from the previous year's award, if any. New awards do not enter data in this field, since new awards will not have a carryover balance.
- Line 3. If matching funds are required for this grant program list the amounts by source on lines 3A through 3E as appropriate. Where appropriate, include the dollar value of in-kind contributions.
- Line 4. Enter the amount of other funds received for the project, by source on Lines 4A through 4E, specifying amounts from each source. Also include the dollar value of in-kind contributions.
- Line 5. Displays the sum of lines 1 through 4.
- Line 6. Enter the amount of other Federal funds received on the appropriate lines (A.1 through C.12) **other** than the MCHB grant award for the project. Such funds would include those from other Departments, other components of the Department of Health and Human Services, or other MCHB grants or contracts.
- Line 6C.1. Enter only project funds from the Center for Medicare and Medicaid Services. Exclude Medicaid reimbursement, which is considered Program Income and should be included on Line 3C or 4C.
- If lines 6A.8-10, 6B .4-6, or 6C.10-12 are utilized, specify the source(s) of the funds in the order of the amount provided, starting with the source of the most funds. .
- Line 7. Displays the sum of lines in 6A.1 through 6C.12.

FORM 2
PROJECT FUNDING PROFILE

	<u>FY</u>		<u>FY</u>		<u>FY</u>		<u>FY</u>		<u>FY</u>	
	<u>Budgeted</u>	<u>Expended</u>								
1 <u>MCHB Grant</u> <u>Award Amount</u> <i>Line 1, Form 2</i>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
2 <u>Unobligated</u> <u>Balance</u> <i>Line 2, Form 2</i>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
3 <u>Matching Funds</u> <u>(If required)</u> <i>Line 3, Form 2</i>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
4 <u>Other Project</u> <u>Funds</u> <i>Line 4, Form 2</i>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
5 <u>Total Project</u> <u>Funds</u> <i>Line 5, Form 2</i>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
6 <u>Total Federal</u> <u>Collaborative</u> <u>Funds</u> <i>Line 7, Form 2</i>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____

**INSTRUCTIONS FOR THE COMPLETION OF FORM 2
PROJECT FUNDING PROFILE**

Instructions:

Complete all required data cells. If an actual number is not available, use an estimate. Explain all estimates in a note.

The form is intended to provide funding data at a glance on the estimated budgeted amounts and actual expended amounts of an MCH project.

For each fiscal year, the data in the columns labeled Budgeted on this form are to contain the same figures that appear on the Application Face Sheet (for a non-competing continuation) or the Notice of Award (for a performance report). The lines under the columns labeled Expended are to contain the actual amounts expended for each grant year that has been completed.

FORM 4
PROJECT BUDGET AND EXPENDITURES
By Types of Services

<u>TYPES OF SERVICES</u>	FY _____		FY _____	
	<u>Budgeted</u>	<u>Expended</u>	<u>Budgeted</u>	<u>Expended</u>
I. <u>Direct Health Care Services</u> (Basic Health Services and Health Services for CSHCN.)	\$ _____	\$ _____	\$ _____	\$ _____
II. <u>Enabling Services</u> (Transportation, Translation, Outreach, Respite Care, Health Education, Family Support Services, Purchase of Health Insurance, Case Management, and Coordination with Medicaid, WIC and Education.)	\$ _____	\$ _____	\$ _____	\$ _____
III. <u>Population-Based Services</u> (Newborn Screening, Lead Screening, Immunization, Sudden Infant Death Syndrome Counseling, Oral Health, Injury Prevention, Nutrition, and Outreach/Public Education.)	\$ _____	\$ _____	\$ _____	\$ _____
IV. <u>Infrastructure Building Services</u> (Needs Assessment, Evaluation, Planning, Policy Development, Coordination, Quality Assurance, Standards Development, Monitoring, Training, Applied Research, Systems of Care, and Information Systems.)	\$ _____	\$ _____	\$ _____	\$ _____
V. <u>TOTAL</u>	\$ _____	\$ _____	\$ _____	\$ _____

**INSTRUCTIONS FOR THE COMPLETION OF FORM 4
PROJECT BUDGET AND EXPENDITURES BY TYPES OF SERVICES**

Complete all required data cells for all years of the grant. If an actual number is not available, make an estimate. Please explain all estimates in a note. Administrative dollars should be allocated to the appropriate level(s) of the pyramid on lines I, II, III or IV. If an estimate of administrative funds use is necessary, one method would be to allocate those dollars to Lines I, II, III and IV at the same percentage as program dollars are allocated to Lines I through IV.

Note: Lines I, II and III are for projects providing services. If grant funds are used to build the infrastructure for direct care delivery, enabling or population-based services, these amounts should be reported in Line IV (i.e., building data collection capacity for newborn hearing screening).

Line I Direct Health Care Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

Direct Health Care Services are those services generally delivered one-on-one between a health professional and a patient in an office, clinic or emergency room which may include primary care physicians, registered dietitians, public health or visiting nurses, nurses certified for obstetric and pediatric primary care, medical social workers, nutritionists, dentists, sub-specialty physicians who serve children with special health care needs, audiologists, occupational therapists, physical therapists, speech and language therapists, specialty registered dietitians. Basic services include what most consider ordinary medical care, inpatient and outpatient medical services, allied health services, drugs, laboratory testing, x-ray services, dental care, and pharmaceutical products and services. State Title V programs support - by directly operating programs or by funding local providers - services such as prenatal care, child health including immunizations and treatment or referrals, school health and family planning. For CSHCN, these services include specialty and sub-specialty care for those with HIV/AIDS, hemophilia, birth defects, chronic illness, and other conditions requiring sophisticated technology, access to highly trained specialists, or an array of services not generally available in most communities.

Line II Enabling Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

Enabling Services allow or provide for access to and the derivation of benefits from, the array of basic health care services and include such things as transportation, translation services, outreach, respite care, health education, family support services, purchase of health insurance, case management, coordination of with Medicaid, WIC and educations. These services are especially required for the low income, disadvantaged, geographically or culturally isolated, and those with special and complicated health needs. For many of these individuals, the enabling services are essential - for without them access is not possible. Enabling services most commonly provided by agencies for CSHCN include transportation, care coordination, translation services, home visiting, and family outreach. Family support activities include parent support groups, family training workshops, advocacy, nutrition and social work.

Line III Population-Based Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

Population Based Services are preventive interventions and personal health services, developed and available for the entire MCH population of the State rather than for individuals in a one-on-one situation. Disease prevention, health promotion, and statewide outreach are major components. Common among these services are newborn screening, lead screening, immunization, Sudden Infant Death Syndrome counseling, oral health, injury prevention, nutrition and outreach/public education. These services are generally available whether the mother or child receives care in the private or public system, in a rural clinic or an HMO, and whether insured or not.

Line IV Infrastructure Building Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

Infrastructure Building Services are the base of the MCH pyramid of health services and form its foundation. They are activities directed at improving and maintaining the health status of all women and children by providing support for development and maintenance of comprehensive health services systems and resources including development and maintenance of health services standards/guidelines, training, data and planning systems. Examples include needs assessment, evaluation, planning, policy development, coordination, quality assurance, standards development, monitoring, training, applied research, information systems and systems of care. In the development of systems of care it should be assured that the systems are family centered, community based and culturally competent.

Line V Total – Displays the total amounts for each column, budgeted for each year and expended for each year completed.

FORM 6
MATERNAL & CHILD HEALTH DISCRETIONARY GRANT
PROJECT ABSTRACT
FOR FY_____

PROJECT: _____

I. PROJECT IDENTIFIER INFORMATION

1. Project Title:
2. Project Number:
3. E-mail address:

II. BUDGET

- | | |
|---|----------|
| 1. MCHB Grant Award
(Line 1, Form 2) | \$ _____ |
| 2. Unobligated Balance
(Line 2, Form 2) | \$ _____ |
| 3. Matching Funds (if applicable)
(Line 3, Form 2) | \$ _____ |
| 4. Other Project Funds
(Line 4, Form 2) | \$ _____ |
| 5. Total Project Funds
(Line 5, Form 2) | \$ _____ |

III. TYPE(S) OF SERVICE PROVIDED (Choose all that apply)

- Direct Health Care Services
- Enabling Services
- Population-Based Services
- Infrastructure Building Services

IV. PROJECT DESCRIPTION OR EXPERIENCE TO DATE

- A. Project Description
1. Problem (in 50 words, maximum):

 2. Goals and Objectives: (List up to 5 major goals and time-framed objectives per goal for the project)
 - Goal 1:
 - Objective 1:
 - Objective 2:
 - Goal 2:
 - Objective 1:
 - Objective 2:
 - Goal 3:
 - Objective 1:
 - Objective 2:

B. Continuing Grants ONLY

1. Experience to Date (For continuing projects ONLY):

2. Website URL and annual number of hits

V. KEY WORDS

VI. ANNOTATION

INSTRUCTIONS FOR THE COMPLETION OF FORM 6 PROJECT ABSTRACT

NOTE: All information provided should fit into the space provided in the form. The completed form should be no more than 3 pages in length. Where information has previously been entered in forms 1 through 5, the information will automatically be transferred electronically to the appropriate place on this form.

Section I – Project Identifier Information

Project Title: Displays the title for the project.

Project Number: Displays the number assigned to the project (e.g., the grant number)

E-mail address: Displays the electronic mail address of the project director

Section II – Budget - These figures will be transferred from Form 1, Lines 1 through 5.

Section III - Types of Services

Indicate which type(s) of services your project provides, checking all that apply.

Section IV – Program Description OR Current Status (DO NOT EXCEED THE SPACE PROVIDED)

A. New Projects only are to complete the following items:

1. A brief description of the project and the problem it addresses, such as preventive and primary care services for pregnant women, mothers, and infants; preventive and primary care services for children; and services for Children with Special Health Care Needs.
2. Provide up to 5 goals of the project, in priority order. Examples are: To reduce the barriers to the delivery of care for pregnant women, to reduce the infant mortality rate for minorities and “services or system development for children with special healthcare needs.” MCHB will capture annually every project’s top goals in an information system for comparison, tracking, and reporting purposes; you must list at least 1 and no more than 5 goals. For each goal, list the two most important objectives. The objective must be specific (i.e., decrease incidence by 10%) and time limited (by 2005).
3. Displays the primary Healthy People 2010 goal(s) that the project addresses.
4. Describe the programs and activities used to attain the goals and objectives, and comment on innovation, cost, and other characteristics of the methodology, proposed or are being implemented. Lists with numbered items can be used in this section.
5. Describe the coordination planned and carried out, in the space provided, if applicable, with appropriate State and/or local health and other agencies in areas(s) served by the project.
6. Briefly describe the evaluation methods that will be used to assess the success of the project in attaining its goals and objectives.

B. For continuing projects ONLY:

1. Provide a brief description of the major activities and accomplishments over the past year (not to exceed 200 words).
2. Provide website and number of hits annually, if applicable.

Section V – Key Words

Provide up to 10 key words to describe the project, including populations served. Choose key words from the included list.

Section VI – Annotation

Provide a three- to five-sentence description of your project that identifies the project’s purpose, the needs and problems, which are addressed, the goals and objectives of the project, the activities, which will be used to attain the goals, and the materials, which will be developed.

FORM 7
DISCRETIONARY GRANT PROJECT
SUMMARY DATA

- 1. Project Service Focus**
 Urban/Central City Suburban Metropolitan Area (city & suburbs)
 Rural Frontier Border (US-Mexico)

- 2. Project Scope**
 Local Multi-county State-wide
 Regional National

- 3. Grantee Organization Type**
 State Agency
 Community Government Agency
 School District
 University/Institution Of Higher Learning (Non-Hospital Based)
 Academic Medical Center
 Community-Based Non-Governmental Organization (Health Care)
 Community-Based Non-Governmental Organization (Non-Health Care)
 Professional Membership Organization (Individuals Constitute Its Membership)
 National Organization (Other Organizations Constitute Its Membership)
 National Organization (Non-Membership Based)
 Independent Research/Planning/Policy Organization
 Other _____

- 4. Project Infrastructure Focus (from MCH Pyramid) if applicable**
 Guidelines/Standards Development And Maintenance
 Policies And Programs Study And Analysis
 Synthesis Of Data And Information
 Translation Of Data And Information For Different Audiences
 Dissemination Of Information And Resources
 Quality Assurance
 Technical Assistance
 Training
 Systems Development
 Other

5. Demographic Characteristics of Project Participants

Indicate the service level:

<input type="checkbox"/> Direct Health Care Services	<input type="checkbox"/> Population-Based Services
<input type="checkbox"/> Enabling Services	<input type="checkbox"/> Infrastructure Building Services

	RACE (Indicate all that apply)							ETHNICITY				
	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Other Pacific Islander	White	More than One Race	Unrecorded	Total	Hispanic or Latino	Not Hispanic or Latino	Unrecorded	Total
Pregnant Women (All Ages)												
Infants <1 year												
Children and Youth 1 to 25 years												
CSHCN Infants <1 year												
CSHCN Children and Youth 1 to 25 years												
Women 25+ years												
Men 25+												
TOTALS												

6. Clients' Primary Language(s)

7. Resource/TA and Training Centers ONLY

Answer all that apply.

- a. Characteristics of Primary Intended Audience(s)
 - Policy Makers/Public Servants
 - Consumers
- Providers/Professionals
- b. Number of Requests Received/Answered: _____/_____
- c. Number of Continuing Education credits provided: _____
- d. Number of Individuals/Participants Reached: _____
- e. Number of Organizations Assisted: _____
- f. Major Type of TA or Training Provided:
 - continuing education courses,
 - workshops,
 - on-site assistance,
 - distance learning classes
 - other

INSTRUCTIONS FOR THE COMPLETION OF FORM 7 PROJECT SUMMARY

Section 1 – Project Service Focus

Select all that apply

Section 2 – Project Scope

Choose the one that best applies to your project.

Section 3 – Grantee Organization Type

Choose the one that best applies to your organization.

Section 4 – Project Infrastructure Focus

If applicable, choose all that apply.

Section 5 – Demographic Characteristics of Project Participants

Indicate the service level for the grant program. Multiple selections may be made. Infrastructure cannot be selected by itself; it must be selected with another service level. Please fill in each of the cells as appropriate.

Direct Health Care Services are those services generally delivered one-on-one between a health professional and a patient in an office, clinic or emergency room which may include primary care physicians, registered dietitians, public health or visiting nurses, nurses certified for obstetric and pediatric primary care, medical social workers, nutritionists, dentists, sub-specialty physicians who serve children with special health care needs, audiologists, occupational therapists, physical therapists, speech and language therapists, specialty registered dietitians. Basic services include what most consider ordinary medical care, inpatient and outpatient medical services, allied health services, drugs, laboratory testing, x-ray services, dental care, and pharmaceutical products and services. State Title V programs support - by directly operating programs or by funding local providers - services such as prenatal care, child health including immunizations and treatment or referrals, school health and family planning. For CSHCN, these services include specialty and sub-specialty care for those with HIV/AIDS, hemophilia, birth defects, chronic illness, and other conditions requiring sophisticated technology, access to highly trained specialists, or an array of services not generally available in most communities.

Enabling Services allow or provide for access to and the derivation of benefits from, the array of basic health care services and include such things as transportation, translation services, outreach, respite care, health education, family support services, purchase of health insurance, case management, coordination of with Medicaid, WIC and educations. These services are especially required for the low income, disadvantaged, geographically or culturally isolated, and those with special and complicated health needs. For many of these individuals, the enabling services are essential - for without them access is not possible. Enabling services most commonly provided by agencies for CSHCN include transportation, care coordination, translation services, home visiting, and family outreach. Family support activities include parent support groups, family training workshops, advocacy, nutrition and social work.

Population Based Services are preventive interventions and personal health services, developed and available for the entire MCH population of the State rather than for individuals in a one-on-one situation. Disease prevention, health promotion, and statewide outreach are major components. Common among these services are newborn screening, lead screening, immunization, Sudden Infant Death Syndrome counseling, oral health, injury prevention, nutrition and outreach/public education. These services are generally available whether the mother or child receives care in the private or public system, in a rural clinic or an HMO, and whether insured or not.

Infrastructure Building Services are the base of the MCH pyramid of health services and form its foundation. They are activities directed at improving and maintaining the health status of all women and children by providing support for development and maintenance of comprehensive health services systems and resources including development and maintenance of health services standards/guidelines, training, data and planning systems. Examples include needs assessment, evaluation, planning, policy development, coordination, quality assurance, standards development, monitoring, training, applied research, information systems and systems of care. In the

development of systems of care it should be assured that the systems are family centered, community based and culturally competent.

Section 6 – Clients Primary Language(s)

Indicate which languages your clients speak as their primary language, other than English, for the data provided in Section 6. List up to three languages.

Section 7 – Resource/TA and Training Centers (Only)

Answer all that apply.

03 PERFORMANCE MEASURE

The percentage of MCHB-funded projects submitting and publishing findings in peer-reviewed journals.

**Goal 1: Provide National Leadership for MCHB
(Strengthen the MCH knowledge base and support scholarship within the MCH community)**

Level: Grantee

Category: Information Dissemination

GOAL

To increase the number of MCHB-funded research projects that publish in peer-reviewed journals.

MEASURE

The percent of MCHB-funded projects submitting articles and publishing findings in peer-reviewed journals.

DEFINITION

Numerator: Number of projects (current and completed within the past three years) that have submitted articles for review by refereed journals.

Denominator: Total number of current projects and projects that have been completed within the past three years.

And

Numerator: Number of projects (current and completed within the past 3 years) that have published articles in peer reviewed journals

Denominator: Total number of current projects and projects that have been completed within the past three years.

Units: 100 **Text:** Percent

HEALTHY PEOPLE 2010 OBJECTIVE

Related to Goal 1: Improve access to comprehensive, high-quality health care services (Objectives 1.1-1.16).

DATA SOURCE(S) AND ISSUES

Attached data collection form will be sent annually to grantees during their funding period and three years after the funding period ends. Some preliminary information may be gathered from mandated project final reports

SIGNIFICANCE

To be useful, the latest evidence-based, scientific knowledge must reach professionals who are delivering services, developing programs and making policy. Peer reviewed journals are considered one of the best methods for distributing new knowledge because of their wide circulation and rigorous standard of review.

DATA COLLECTION FORM FOR DETAIL SHEET #03

Please use the space provided for notes to detail the data source and year of data used.

Number of articles submitted for review by refereed journals but not yet published in this reporting year _____

Number of articles published in peer-reviewed journals this reporting year _____

NOTES/COMMENTS:

10 PERFORMANCE MEASURE

**Goal 2: Eliminate Health Barriers & Disparities
(Develop and promote health services and
systems of care designed to eliminate disparities
and barriers across MCH populations)**

Level: Grantee

Category: Cultural Competence

The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training.

GOAL

To increase the number of MCHB-funded programs that have integrated cultural and linguistic competence into their policies, guidelines, contracts and training.

MEASURE

The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training.

DEFINITION

Attached is a checklist of 15 elements that demonstrate cultural and linguistic competency. Please check the degree to which the elements have been implemented. The answer scale for the entire measure is 0-45. Please keep the completed checklist attached.

Cultural and linguistic competence is a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in cross-cultural situations. 'Culture' refers to integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. 'Competence' implies having the capacity to function effectively as an individual and an organization within the context of the cultural beliefs, behaviors, and needs presented by consumers and their communities. (Adapted from Cross, 1989; cited from DHHS Office of Minority Health--
<http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlid=11>)

Linguistic competence is the capacity of an organization and its personnel to communicate effectively, and convey information in a manner that is easily understood by diverse audiences including persons of limited English proficiency, those who have low literacy skills or are not literate, and individuals with disabilities. Linguistic competency requires organizational and provider capacity to respond effectively to the health literacy needs of populations served. The organization must have policy, structures, practices, procedures, and dedicated resources to

support this capacity. (Goode, T. and W. Jones, 2004. National Center for Cultural Competence; <http://www.ncccurricula.info/linguisticcompetence.html>)

Cultural and linguistic competency is a process that occurs along a developmental continuum. A culturally and linguistically competent program is characterized by elements including the following: written strategies for advancing cultural competence; cultural and linguistic competency policies and practices; cultural and linguistic competence knowledge and skills building efforts; research data on populations served according to racial, ethnic, and linguistic groupings; participation of community and family members of diverse cultures in all aspects of the program; faculty and other instructors are racially and ethnically diverse; faculty and staff participate in professional development activities related to cultural and linguistic competence; and periodic assessment of trainees' progress in developing cultural and linguistic competence.

HEALTHY PEOPLE 2010 OBJECTIVE

Related to the following HP2010 Objectives:

16.23: Increase the proportion of States and jurisdictions that have service systems for children with or at risk for chronic and disabling conditions as required by Public Law 101-239.

23.9: (Developmental) Increase the proportion of schools for public health workers that integrate into their curricula specific content to develop competency in the essential public health services.

23.11:(Developmental) Increase the proportion of State and local public health agencies that meet national performance standards for essential public health services.

23.15: (Developmental) Increase the proportion of Federal, Tribal, State, and local jurisdictions that review and evaluate the extent to which their statutes, ordinances, and bylaws assure the delivery of essential public health services.

DATA SOURCE(S) AND ISSUES

Attached data collection form is to be completed by grantees.

There is no existing national data source to measure the extent to which MCHB supported programs have incorporated cultural competence elements into their policies, guidelines, contracts and training.

SIGNIFICANCE

Over the last decade, researchers and policymakers have emphasized the central influence of cultural

values and cultural/linguistic barriers: health seeking behavior, access to care, and racial and ethnic disparities. In accordance with these concerns, cultural competence objectives have been: (1) incorporated into the MCHB strategic plan; and (2) in guidance materials related to the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), which is the legislative mandate that health programs supported by MCHB Children with Special Health Care Needs (CSHCN) provide and promote family centered, community-based, coordinated care.

DATA COLLECTION FORM FOR DETAIL SHEET #10

Using a scale of 0-3, please rate the degree to which your grant program has incorporated the following cultural/linguistic competence elements into your policies, guidelines, contracts and training.

Please use the space provided for notes to describe activities related to each element, detail data sources and year of data used to develop score, clarify any reasons for score, and or explain the applicability of elements to program.

0	1	2	3	Element
				1. Strategies for advancing cultural and linguistic competency are integrated into your program's written plan(s) (e.g., grant application, recruiting plan, placement procedures, monitoring and evaluation plan, human resources, formal agreements, etc.).
				2. There are structures, resources, and practices within your program to advance and sustain cultural and linguistic competency.
				3. Cultural and linguistic competence knowledge and skills building are included in training aspects of your program.
				4. Research or program information gathering includes the collection and analysis of data on populations served according to racial, ethnic, and linguistic groupings, where appropriate.
				5. Community and family members from diverse cultural groups are partners in planning your program.
				6. Community and family members from diverse cultural groups are partners in the delivery of your program.
				7. Community and family members from diverse cultural groups are partners in evaluation of your program.
				8. Staff and faculty reflect cultural and linguistic diversity of the significant populations served.
				9. Staff and faculty participate in professional development activities to promote their cultural and linguistic competence.
				10. A process is in place to assess the progress of your program participants in developing cultural and linguistic competence.

- 0 = Not Met
- 1 = Partially Met
- 2 = Mostly Met
- 3 = Completely Met

Total the numbers in the boxes (possible 0-30 score) _____

NOTES/COMMENTS:

24 PERFORMANCE MEASURE

Goal 4: Improve the Health Infrastructure and Systems of Care
(Assist States and communities to plan and develop comprehensive, integrated health service systems)
Level: State, Community, or Grantee
Category: Infrastructure

The degree to which MCHB-funded initiatives contribute to infrastructure development through core public health assessment, policy development and assurance functions.

GOAL

To develop infrastructure that supports comprehensive and integrated services.

MEASURE

The degree to which MCHB-supported initiatives contribute to the implementation of the 10 MCH Essential Services and Core Public Health Program Functions of assessment, policy development and assurance.

DEFINITION

Attached is a checklist of 10 elements that comprise infrastructure development services for maternal and child health populations. Please score the degree to which each your program contributes to the implementation of each of these elements Each element should be scored 0-2, with a maximum total score of 20 across all elements.

HEALTHY PEOPLE 2010 OBJECTIVE

Related to Healthy People Goal 23, Objective 12 (23.12): Increase the proportion of tribes, States, and local health agencies that have implemented a health improvement plan and increase the proportion of local health jurisdictions that have a health improvement plan linked with their State plan.

DATA SOURCE(S) AND ISSUES

Attached data collection form to be completed by grantees based on activities they are directly engaged in or that they contribute to the implementation of by other MCH grantees or programs.

SIGNIFICANCE

Improving the health infrastructure and systems of care is one of the five goals of MCHB. There are five strategies under this goal, all of which are addressed in a number of MCHB initiatives which focus on system-building and infrastructure development. These five strategies follow:

Build analytic capacity for assessment, planning,

and evaluation.

Using the best available evidence, develop and promote guidelines and practices that improve services and systems of care.

Assist States and communities to plan and develop comprehensive, integrated health service systems.

Work with States and communities to assure that services and systems of care reach targeted populations.

Work with States and communities to address selected issues within targeted populations.

The ten elements in this measure are comparable to the 10 Essential Public Health Services outlined in Grason H, Guyer B, 1995. *Public MCH Program Functions Framework: Essential Public Health Services to Promote Maternal and Child Health in America*. Baltimore, MD: The Women's and Children's Health Policy Center, The Johns Hopkins University.

DATA COLLECTION FORM FOR DETAIL SHEET #24

Use the scale below to describe the extent to which your program or initiative has contributed to the implementation of each of the following Public MCH Program core function activities at the local, State, or national level. Please use the space provided for notes to clarify reasons for score

0	1	2	Element
Assessment Function Activities			
			1. Assessment and monitoring of maternal and child health status to identify and address problems, including a focus on addressing health disparities [Examples of activities include: developing frameworks, methodologies, and tools for standardized MCH data in public and private sectors; implementing population-specific accountability for MCH components of data systems, and analysis, preparation and reporting on trends of MCH data and health disparities among subgroups.]
			2. Diagnosis and investigation health problems and health hazards affecting maternal and child health populations [Examples of activities include conduct of population surveys and reports on risk conditions and behaviors, identification of environmental hazards and preparation of reports on risk conditions and behaviors.]
			3. Informing and educating the public and families about MCH issues.
Policy Development Function Activities			
			4. Mobilization of community collaborations and partnerships to identify and solve MCH problems. [Examples of stakeholders to be involved in these partnerships include: policymakers, health care providers, health care insurers and purchasers, families, and other MCH care consumers.]
			5. Provision of leadership for priority setting, planning and policy development to support community efforts to assure the health of maternal and child health populations.
			6. Promotion and enforcement of legal requirements that protect the health and safety of maternal and child health populations.
Assurance Function Activities			
			7. Linkage of maternal and child health populations to health and other community and family services, and assuring access to comprehensive quality systems of care
			8. Assuring the capacity and competency of the public health and personal health workforce to effectively and efficiently address MCH needs.
			9. Evaluate the effectiveness, accessibility and quality of direct, enabling and population-based preventive MCH services
		\	10. Research and demonstrations to gain new insights and innovative solutions to MCH-related issues and problems

0 = Grantee does not provide or contribute to the provision of this activity.
 1 = Grantee sometimes provides or contributes to the provision of this activity.
 2 = Grantee regularly provides or contributes to the provision of this activity
 Total the numbers in the boxes (possible 0–20 score): _____

NOTES/COMMENTS:

27 PERFORMANCE MEASURE

Goal 4: Improve the Health Infrastructure and Systems of Care by Improving MCH Knowledge and Available Resources
Level: Grantee
Category: Infrastructure

The degree to which grantees have mechanisms in place to ensure quality in the design, development, and dissemination of new information resources that they produce each year.

GOAL

To improve the dissemination of new knowledge to the MCH field by increasing the quality of informational resources produced, including articles, chapters, books, and other materials produced by grantees, and by addressing the quality in design and development. This includes consumer education materials, conference presentations, and electronically available materials.

MEASURE

The degree to which grantees have mechanisms in place to ensure quality in the design, development, and dissemination of new informational resources they produce each year.

DEFINITION

Publications are articles, books, or chapters published during the year being reported. Products include electronic Web-based resources, video training tapes, CD ROMs, DVD, materials created for consumers (parents, children, and community agencies). Products and publications also include outreach and marketing materials (such as presentations, alerts, and HRSA clearinghouse materials).

Details on these publications and products are reported on a data collection form. These products are summed by category and the total number of all publications and products are reported on a PM tracking form for a reporting year.

This measure can be applicable to any MCHB grantee.

HEALTHY PEOPLE 2010 OBJECTIVE

Related to Goal 1: Improve access to comprehensive, high-quality health care services. Specific objective: 1.3.

Related to Goal 7 – Educational and community-based programs: Increase the quality, availability and effectiveness of educational and community-based programs designed to prevent disease and improve health and quality of life. Specific objectives: 7.7 through 7.12.

Related Goal 11 – Use communication strategically to improve health. Specific objective: 11.3.

Related to Goal 23 – Public Health Infrastructure:
Ensure that Federal, tribal, State, and local health agencies have the infrastructure to provide essential public health services effectively.
Specific objective: 23.2.

DATA SOURCE(S) AND ISSUES

Data will be collected by grantees throughout the year and reported in their annual reports and via this measure's data collection form.

SIGNIFICANCE

Advancing the field of MCH based on evidence-based, field-tested quality products. Collection of the types of and dissemination of MCH products and publications is crucial for advancing the field. This PM addresses the production and quality of new informational resources created by grantees for families, professionals, other providers, and the public.

DATA COLLECTION FORM FOR DETAIL SHEET #27

Using the 0–3 scale below indicate the degree to which your grant has incorporated each of the design, dissemination, and continuous quality improvement activities into MCH information resources that you have developed within the past year. Please use the space provided for notes to describe activities related to each element and clarify any reasons for the score

0	1	2	3	Element
Mechanisms in Place to Ensure Quality in Design of Informational Resources				
				<p>1. Obtain input from the target audience or other experts to ensure relevance. The grantee conducts activities to ensure the information resource is relevant to the target audience with respect to knowledge, issues, and best practices in the MCH field. [Example: Obtain target audience, user, or expert input in the design of informational resources, the testing or piloting of products with the potential users/audience, and the use of expert reviews of new products.]</p>
				<p>2. Obtain input from the target audience or other experts to ensure cultural and linguistic appropriateness. The grantee specifically employs mechanisms to ensure that resources are culturally and linguistically appropriate to meet the needs and level of the target audience(s).</p>
				<p>3. Build on Existing Information Resources and Expertise, and Ensure Up-to-Date Content. As part of the development of information resources, the grantee conducts activities (such as reviewing existing bibliographies, information resources, or other materials) to ensure that the information provided in newly developed information resources is up to date with standard practice; based on research-, evidence-, and best practice-based literature or materials in the MCH field; and is aligned with local, State, and/or Federal initiatives. Grantee uses these mechanisms to ensure that information resource content does not duplicate existing resources available to the same audience. Also include in the design and development expert review panels (experts may include target audience members).</p>
Mechanisms in Place to Track Dissemination and Use of Resources or Products				
				<p>4. The grantee has a system to track, monitor, and analyze the dissemination and reach of products. The grantee implements a mechanism for tracking and documenting dissemination of products, and uses this information to ensure the target audience(s) is reached. Grantees with a Web site should include mechanisms for tracking newly created resources disseminated through their Web sites and are encouraged to detail Web-related dissemination mechanisms and the use of Web-based products in the Notes section below. Grantee ensures that format is accessible to diverse audiences and conforms to ADA guidelines and to Section 508 of the Rehabilitation Act.</p>
				<p>5. The grantee has a system in place to track, monitor, and analyze the use of products. The grantee routinely collects data from the recipients of its products and resources to assess their satisfaction with products, and whether products are useful, share new and relevant information, and enhance MCH knowledge. [An example of data collection is assessments.]</p>

0	1	2	3	Element
Mechanisms in Place to Promote Grantee's Information Resources				
				<p>6. Conduct Culturally Appropriate Outreach and Promotion to Ensure Target Audience is Aware of Information Resources The grantee routinely uses mechanisms to reach out to MCHB grantees and other target audiences such as provider or family organizations, consumers of MCH services, and the public, to make sure that target audiences know the resources are available. [Examples of outreach methods include promotion of services through list serves, exhibits at meetings, and targeted outreach to representatives of individual organizations or MCHB grantees.]</p>
Use of Evaluation Data for Quality Improvement				
				<p>7. Use of Feedback for Quality Improvement. The degree to which the grantee has used the results of satisfaction and other feedback mechanisms to improve the content, reach, and effectiveness of their products/information resources.</p>

0=Not Met
 1=Partially Met
 2=Mostly Met
 3=Completely Met

Total the numbers in the boxes (possible 0–21 score): _____

NOTES/COMMENTS:

33 PERFORMANCE MEASURE

The degree to which MCHB-funded initiatives work to promote sustainability of their programs or initiatives beyond the life of MCHB funding.

Goal 4: Improve the Health Infrastructure and Systems of Care (Assist States and communities to plan and develop comprehensive, integrated health service systems)

Level: Grantee

Category: Infrastructure

GOAL

To develop infrastructure that supports comprehensive and integrated systems of care for maternal and child health at the local and/or state level.

MEASURE

The degree to which MCHB grantees are planning and implementing strategies to sustain their programs once initial MCHB funding ends.

DEFINITION

Attached is a checklist of nine actions or strategies that build toward program sustainability. Please check the degree to which each of the elements is being planned or carried out by your program, using the three-point scale. The maximum total score for this measure would be 45 across all elements.

HEALTHY PEOPLE 2010 OBJECTIVE

Related to Healthy People Goal 23, Objective 12 (23.12): Increase the proportion of Tribes, States, and local health agencies that have implemented a health improvement plan and increase the proportion of local health jurisdictions that have a health improvement plan linked with their State plan.

DATA SOURCE(S) AND ISSUES

Attached is a data collection form to be completed by grantees. Since these actions and their outcomes are necessarily progressive over time from the beginning to the end of a program funding period, grantees' ratings on each element are expected to begin lower in the first year of grant award and increase over time.

SIGNIFICANCE

In recognition of the increasing call for recipients of public funds to sustain their programs after initial funding ends, MCHB encourages grantees to work toward sustainability throughout their grant periods. A number of different terms and explanations have been used as operational components of sustainability. These components

fall into four major categories, each emphasizing a distinct focal point as being at the heart of the sustainability process: (1) adherence to program principles and objectives, (2) organizational integration, (3) maintenance of health benefits, and (4) State or community capacity building. Specific recommended actions that can help grantees build toward each of these four sustainability components are included as the data elements for this PM.

DATA COLLECTION FORM FOR DETAIL SHEET #33

Use the scale below to rate the degree to which your program has taken the following actions to promote sustainability of your program or initiative. Since these actions and their outcomes are necessarily progressive over the funding period, the ratings are expected to begin lower and progress over the grant period.

Please use the space provided for notes to clarify reasons for score.

0	1	2	3	Element
				1. A written sustainability plan is in place within two years of the MCHB grant award, with goals, objectives, action steps, and timelines to monitor plan progress.
				2. Staff and leaders in the organization engage and build partnerships with consumers, and other key stakeholders in the community, in the early project planning, and in sustainability planning and implementation processes.
				3. There is support for the MCHB-funded program or initiative within the parent agency or organization, including from individuals with planning and decision making authority.
				4. There is an advisory group or a formal board that includes family, community and state partners, and other stakeholders who can leverage resources or otherwise help to sustain the successful aspects of the program or initiative.
				5. The program's successes and identification of needs are communicated within and outside the organization among partners and the public, using various internal communication, outreach and marketing strategies.
				6. The grantee identified, actively sought, and obtained other funding sources and in-kind resources to sustain the program or initiative.
				7. Policies and procedures developed for the successful aspects of the program or initiative are incorporated into the parent or another organization's system of programs and services.
				8. The responsibilities for carrying out key successful aspects of the program or initiative have begun to be transferred to permanent staff positions in other ongoing programs or organizations.
				9. The grantee has secured financial or in-kind support from within the parent organization or external organizations to sustain the successful aspects of the MCHB-funded program or initiative.

- 0 = Not Met
- 1 = Partially Met
- 2 = Mostly Met
- 3 = Completely Met

Total the numbers in the boxes (possible 0–27 score): _____

NOTES/COMMENTS:

Products, Publications and Submissions Data Collection Form

Part 1

Instructions: Please list the number of products, publications and submissions addressing maternal and child health that have been published or produced by your staff during the reporting period (counting the original completed product or publication developed, not each time it is disseminated or presented). Products and Publications include the following types:

Type	Number
Peer-reviewed publications in scholarly journals – published (including peer-reviewed journal commentaries or supplements)	
Peer-reviewed publications in scholarly journals – submitted	
Books	
Book chapters	
Reports and monographs (including policy briefs and best practices reports)	
Conference presentations and posters presented	
Web-based products (Blogs, podcasts, Web-based video clips, wikis, RSS feeds, news aggregators, social networking sites)	
Electronic products (CD-ROMs, DVDs, audio or videotapes)	
Press communications (TV/Radio interviews, newspaper interviews, public service announcements, and editorial articles)	
Newsletters (electronic or print)	
Pamphlets, brochures, or fact sheets	
Academic course development	
Distance learning modules	
Doctoral dissertations/Master’s theses	
Other	

Part 2

Instructions: For each product, publication and submission listed in Part 1, complete all elements marked with an “*.”

Data collection form: Peer-reviewed publications in scholarly journals – published

*Title: _____

*Author(s): _____

*Publication: _____

*Volume: _____ *Number: _____ Supplement: _____ *Year: _____ *Page(s): _____

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL): _____

Key Words (No more than 5): _____

Notes: _____

Data collection form: Peer-reviewed publications in scholarly journals – submitted

*Title: _____

*Author(s): _____

*Publication: _____

*Year Submitted: _____

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

Key Words (No more than 5): _____

Notes: _____

Data collection form: Books

*Title: _____

*Author(s): _____

*Publisher: _____

*Year Published: _____

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

Key Words (No more than 5): _____

Notes: _____

Data collection form for: Book chapters

Note: If multiple chapters are developed for the same book, list them separately.

*Chapter Title: _____

*Chapter Author(s): _____

*Book Title: _____

*Book Author(s): _____

*Publisher: _____

*Year Published: _____

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

Key Words (no more than 5): _____

Notes: _____

Data collection form: Reports and monographs

*Title: _____

*Author(s)/Organization(s): _____

*Year Published: _____

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____

Data collection form: Conference presentations and posters presented

(This section is not required for MCHB Training grantees.)

*Title: _____

*Author(s)/Organization(s): _____

*Meeting/Conference Name: _____

*Year Presented: _____

*Type: Presentation Poster

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____

Data collection form: Web-based products

*Product: _____

*Year: _____

*Type: blogs podcasts Web-based video clips
 wikis RSS feeds news aggregators
 social networking sites Other (Specify)

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL): _____

Key Words (no more than 5): _____

Notes: _____

Data collection form: Electronic Products

*Title: _____

*Author(s)/Organization(s): _____

*Year: _____

*Type: CD-ROMs DVDs audio tapes
 videotapes Other (Specify)

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____

Data collection form: Press Communications

*Title: _____

*Author(s)/Organization(s): _____

*Year: _____

*Type: TV interview Radio interview Newspaper interview
 Public service announcement Editorial article Other (Specify)

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____

Data collection form: Newsletters

*Title: _____
*Author(s)/Organization(s): _____
*Year: _____
*Type: Electronic Print Both
*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___
*To obtain copies (URL or email): _____
*Frequency of distribution: weekly monthly quarterly annually Other (Specify)
Number of subscribers: _____
Key Words (no more than 5): _____
Notes: _____

Data collection form: Pamphlets, brochures or fact sheets

*Title: _____
*Author(s)/Organization(s): _____
*Year: _____
*Type: Pamphlet Brochure Fact Sheet
*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___
*To obtain copies (URL or email): _____
Key Words (no more than 5): _____
Notes: _____

Data collection form: Academic course development

*Title: _____
*Author(s)/Organization(s): _____
*Year: _____
*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___
*To obtain copies (URL or email): _____
Key Words (no more than 5): _____
Notes: _____

Data collection form: Distance learning modules

*Title: _____
*Author(s)/Organization(s): _____

*Year: _____

*Media Type: blogs podcasts Web-based video clips
 wikis RSS feeds news aggregators
 social networking sites CD-ROMs DVDs
 audio tapes videotapes Other (Specify)

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____

Data collection form: Doctoral dissertations/Master's theses

*Title: _____

*Author: _____

*Year Completed: _____

*Type: Doctoral dissertation Master's thesis

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____

Other

(Note, up to 3 may be entered)

*Title: _____

*Author(s)/Organization(s): _____

*Year: _____

*Describe product, publication or submission: _____

*Target Audience: Consumers/Families ___ Professionals ___ Policymakers ___ Students ___

*To obtain copies (URL or email): _____

Key Words (no more than 5): _____

Notes: _____