

TABLE 1—Continued

Meeting address	Dates and local time	FDA contact person
South San Francisco Conference Center, 255 South Airport Blvd., South San Francisco, CA 94080, 650-877-8787.	June 26, 2002, from 9 a.m. to 5 p.m.	Do.

**Contact Persons:**

For information about this notice:

Michael D. Anderson, Center for Biologics Evaluation and Research (CBER) (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6210, FAX 301-594-1944, e-mail: Andersonm@cber.fda.gov.

For information about the workshop and registration: Kathy Eberhart, Center for Biologics Evaluation and Research (HFM-42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000, FAX 301-827-3079, e-mail eberhart@cber.fda.gov.

**Procedure:** Mail or fax your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Kathy Eberhart, Center for Biologics Evaluation and Research (HFM-42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000, FAX 301-827-3079, by May 17, 2002, for the May 29, 2002, workshop, and by June 14, 2002, for the June 26, 2002, workshop. There is no registration fee for the public workshops. Space is limited, therefore interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Kathy Eberhart (see *Contact Persons*) at least 7 days in advance.

CBER is requesting that you submit your issues related to application deficiencies and approval times before the workshop. There will be an opportunity to submit additional issues and questions at the end of the morning sessions. Mail or fax your issues to Kathy Eberhart (see *Contact Persons*) by May 17, 2002, for the May 29, 2002, workshop and by June 14, 2002, for the June 26, 2002, workshop.

Dated: April 26, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-11062 Filed 5-2-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Emergency Medical Services for Children; National Trauma Registry for Children Demonstration Project

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of availability of funds.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that up to \$400,000 in fiscal year (FY) 2002 funds is available to fund two grants to assess the feasibility and value of developing a National Trauma Registry for Children (NTRC) as part of the Emergency Medical Services for Children (EMSC) program. Two grant awards are planned for 2002. One award of up to \$150,000 will be made for a Data Identification, Collection and Use Planning Project to identify and prioritize data elements necessary for a pediatric trauma registry, develop sustainable data collection procedures that take into account the needs of all potential users, including but not limited to, State Emergency Medical Services (EMS) Offices, pediatric trauma surgeons, pre-hospital and hospital health care providers; and develop procedures for accessing the data. A second award of up to \$250,000 will be for a Registry Design and Technology Planning Project to assess existing trauma registries, assess the feasibility of obtaining and linking information from them, and assess the feasibility of collecting additional data elements identified by the Data Identification, Collection and Use Planning Project. A pediatric trauma registry could be useful to clinicians and program planners for understanding the epidemiology and improving the clinical management of pediatric trauma. These demonstration project grants will be awarded under the program authority of the Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w-9), and will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Projects will be approved for up to a 2-year period. However, funding beyond FY

2002 is contingent upon the availability of funds.

**DATES:** Applicants are expected to notify MCHB's Division of Child, Adolescent, and Family Health of their intent by June 14, 2002. The deadline for receipt of applications is July 15, 2002. Applications will be considered "on time" if they are either received on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 3, 2002.

**ADDRESSES:** To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1-877-477-2123 (1-877-HRSA-123) or register on-line at: [http://www.hrsa.gov/g\\_order3.htm](http://www.hrsa.gov/g_order3.htm) directly. The Emergency Medical Services for Children program uses the standard Form PHS 5161-1 (rev. 7/00) for applications (approved under OMB No. 0920-0428). Applicants must use Catalog of Federal Domestic Assistance (CFDA) #93.127 when requesting application kits. The CFDA is a Government wide compendium of enumerated Federal programs, project services, and activities that provide assistance. All applications must be mailed or delivered to Grants Management Officer, MCHB: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879; telephone 1-877-477-2123; E-mail: [hrsagac@hrsa.gov](mailto:hrsagac@hrsa.gov).

Necessary application forms and an expanded version of this **Federal Register** notice may be downloaded in either Microsoft Office 2000 or Adobe Acrobat format (.pdf) from the MCHB Home Page at <http://www.mchb.hrsa.gov>. Please contact Joni Johns, at 301-443-2088, or [jjohns@hrsa.gov](mailto:jjohns@hrsa.gov), if you need technical assistance in accessing the MCHB Home Page via the Internet.

This notice will appear on the HRSA Home Page at <http://www.hrsa.gov/>. **Federal Register** notices are found on the World Wide Web by following instructions at: [http://www.access.gpo.gov/su\\_docs/aces/aces140.html](http://www.access.gpo.gov/su_docs/aces/aces140.html).

**LETTER OF INTENT:** Notification of intent to apply can be made in one of three ways: Cindy Doyle, RN, telephone, 301-443-3888; email: [cdoyle@hrsa.gov](mailto:cdoyle@hrsa.gov), mail,

HRSA/EMSC Program, Parklawn Building, Room 18A-38; 5600 Fishers Lane; Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Cindy Doyle, RN, 301-443-3888, email: cdoyle@hrsa.gov (for questions specific to project objectives and activities of the program; or the required Letter of Intent, which is further described in the application kit); Mickey Reynolds, 301-443-0724, email mreynolds@hrsa.gov (for grants policy, budgetary, and business questions).

**SUPPLEMENTARY INFORMATION:**

**Program Background and Objectives**

Section 1910 of the Public Health Service Act authorizes the implementation of a program of grants to States or accredited schools of medicine in States to develop and evaluate improved emergency procedures and protocols for children. It covers the entire spectrum of emergency medical care, including education of emergency providers about pediatric care, primary prevention, acute clinical care, and rehabilitation, and is a critical component of the President's initiative to combat terrorism and bioterrorism.

The standard emergency medical services (EMS) system was developed primarily for adults, to address cardiac arrest. Because children suffer from a different spectrum of disease and injuries than adults, emergency medical services for adults differ significantly from those that are needed by children. Children are smaller, often respond with different symptoms than adults display in similar traumatic circumstances, and require specialized equipment and provider training. EMSC is specialized care for children who experience a serious injury or an acute illness. EMSC is integrated into the standard EMS system, and enhances its capability to address the special needs of children.

Each year, well over 31 million children and adolescents are seen in emergency departments. Fewer than half of all hospitals (46%) with emergency departments have all the necessary equipment for the stabilization of ill and injured children. Only five States currently require that advanced life support ambulances carry all the recommended equipment needed to stabilize a child. The most seriously ill and injured children may require care in pediatric specialty centers and access to rehabilitation services. Yet, no more than 11 States have guidelines for the identification of pediatric acute care facilities, to ensure that children get to the right hospital in a timely manner.

EMS systems depend on successful coordination of services from many

separate components, including pre-hospital care, emergency department care, inpatient care, and rehabilitation. Linking data across these different systems involves both technical challenges, and access issues. Other issues include a lack of common definitions across systems, a lack of consensus on needed data elements, a lack of validated measures of severity and acuity, a lack of validated measures of patient outcomes, and a lack of consensus on what outcomes to measure and when to measure them. Mortality is the most readily available and most widely used outcome, but relatively few children needing or receiving emergency care die. Other outcomes include the presence or absence of diseases, impairments, functional limitations, or disabilities interfering with age-appropriate activities; physical mobility and functioning; social and role functioning; and emotional and mental well-being. Measuring these reliably in children is a challenge. The purpose of the National Trauma Registry for Children Demonstration Project is to assess the feasibility of addressing some of these issues.

**Authorization**

Title XIX, Section 1910, Public Health Service Act (42 U.S.C. 300w-9).

**Purpose**

This announcement invites proposals to demonstrate the feasibility and the value of developing a nationwide repository of information on the epidemiology and optimal clinical management of pediatric injury and trauma, which has the potential to improve the quality of care for children who have experienced traumatic injury. This demonstration project is structured into two parts:

(a) Data Identification, Collection and Use Planning Grant. The purpose of this grant is to devise a process to identify and define a uniform set of variables that describe the type of pediatric trauma, clinical course and outcomes. Proposed data elements should ensure comparability across state and regional registries. MCHB assumes that the clinical data necessary to examine and enhance the care of injured children in the U.S. already exists as a subset of all data collected by hospitals on patient care. There are, however, barriers that hinder or even prohibit the aggregation of data from existing systems. One of the more obvious barriers is the lack of a standardized or common set of data elements.

The grantee will be expected to propose data elements drawn from pre-hospital, emergency department,

inpatient, rehabilitation, outcome, and vital statistics records. In the selection and justification of these data elements, the grantee will be expected to weigh the value and the cost of collection costs for each element. A list of data elements previously identified as possible candidates for a trauma registry is included in the grant guidance.

The grantee will also be expected to address ideas for long-term sustainability, and patient privacy and confidentiality concerns that may arise as a result of data collection and linkage.

(b) Registry Design and Technology Planning Grant. The purpose of this grant is to develop a pediatric trauma information system that will result in reliable and valid data for a variety of research and policy uses. Current trauma registry software packages are proprietary, and data are not easily exchanged across different platforms. The grantee will be expected to work with popular registry vendors to devise an export algorithm that will allow vendor data, using divergent platforms, to be downloaded to a central repository.

Other issues to be addressed by the grantee include designing a system that can easily be adapted to add new data elements, obtaining voluntary participation by hospitals in providing data to the registry, electronic submission of data, and sample design considerations. MCHB's intent is to develop a registry system that is nationally representative, and large enough to enable analysis by specific type of pediatric injury.

**Eligibility**

State governments and accredited schools of medicine are eligible for these grants. The term "schools of medicine" for the purpose of this solicitation is defined as having the same meaning as set forth in section 799B(1)(A) of the PHS Act (42 U.S.C. 295p(1)(A)). "Accredited" in this context has the same meaning as set forth in section 799B(1)(E) of the PHS Act (42 U.S.C. 295p(1)(E)).

**Funding Categories**

(1) Data Identification, Collection, and Use Planning Grant: MCHB expects to award one grant of up to \$150,000 in this category to identify and prioritize data elements necessary for a trauma registry; develop sustainable data collection procedures that take into account the needs of all potential users, including but not limited to, State EMS Offices, pediatric trauma surgeons, pre-hospital and hospital health care providers; and develop procedures for

accessing the data. For the purposes of this demonstration project a registry is defined as the recording and compilation of predetermined data elements for the reporting and descriptive analysis of injury patterns, treatment and quality of care.

(2) Registry Design and Technology Planning Grant: MCHB expects to award one grant of up to \$250,000 in this category for a project to assess existing trauma registries; and to analyze the feasibility of obtaining and linking information from them, and to assess the feasibility of collecting data elements recommended by the recipient of the Data Identification, Collection, and Use Planning Grant, but not currently being collected.

Applicants must specify the category of grant for which they are applying. Those applying for both types of grants must complete a separate application for each.

#### Funding Level/Project Period

Approximately \$400,000 in FY2002 funds is available to support two (2) awards. One award of up to \$150,000 will be made for a Data Identification, Collection and Use Planning project, and one award of up to \$250,000 will be made for a Registry Design and Technology Planning project. The initial budget period will be 12 months, with a subsequent budget period of 12 months. Continuation of any project from one budget period to the next is subject to satisfactory performance, program priorities, and availability of funds.

#### Review Criteria

MCHB staff will screen applications for completeness and responsiveness to the program guidance. Applications that are incomplete or non-responsive will be returned to the applicant without review. Applications that are complete and responsive to the guidance will be evaluated for technical merit by a peer review group convened specifically for this solicitation and in accordance with HRSA grants management policies and procedures. As part of the initial merit review, all applications will receive a written critique.

Technical merit will be assessed using the following criteria:

(a) Applicants' ability to accurately describe the significance of the injury and trauma problems facing the children of our nation and the rationale for establishing the NTRC;

(b) Applicants' ability to clearly articulate the project's goals and the corresponding time-framed, measurable (e.g. quantified) objectives and activities to achieve these goals;

(c) Applicants' ability to clearly articulate and identify a process for evaluating the outcome of this project;

(d) Applicants' ability to successfully carry out the project as evidenced by a sufficient number of qualified project personnel and resources; and

(e) Reasonableness of the proposed budget and soundness of the arrangement for fiscal management and ability to complete the proposed activities within the project period.

Additional criteria used to review and rank applications for this competition are included in the application kit.

Applicants should pay strict attention to addressing these criteria, as they are the basis upon which their applications will be judged.

#### Paperwork Reduction Act

OMB approval for any data collection in connection with these grants will be sought, as required under the Paperwork Reduction Act of 1995.

#### Executive Order 12372

This program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice will contain a listing of States that have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their

State SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date. ( See part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements).

Dated: April 29, 2002.

**Elizabeth M. Duke,**  
Administrator.

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**BILLING CODE 4165-15-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Substance Abuse and Mental Health Services Administration

#### Fiscal Year (FY) 2002 Funding Opportunities

**AGENCY:** Substance Abuse and Mental Health Services Administration, DHHS.

**ACTION:** Notice of funding availability.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Mental Health Services (CMHS) announces the availability of FY 2002 funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants *must* obtain a copy of the Guidance for Applicants (GFA), including Part I, SAMHSA/HRSA Collaboration to Link Health Care for the Homeless Programs and Community Mental Health Agencies (SM 02-013), and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing and submitting an application.

Activity	Application deadline	Estimated funds FY 2002	Estimated number of awards	Project period
SAMHSA/HRSA Collaboration to Link Health Care for the Homeless Programs and Community Mental Health Agencies.	June 19, 2002 ..	\$3,100,000	15-19	3 years.

The actual amount available for the award may vary, depending on

unanticipated program requirements and the number and quality of

applications received. FY 2002 funds for the activity discussed in this