

(HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Subpart D—Private Contracts and Supporting Regulations in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, and 424.24;

Form No.: HCFA-R-234 (OMB # 0938-0730);

Use: Section 4507 of the BBA of 1997 amended section 1802 of the Social Security Act to permit certain physicians and practitioners to opt-out of Medicare and to provide through private contracts services that would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the Supporting Regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455, counters the effect of certain provisions of Medicare law that, absent section 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits;

Frequency: Biennially;

Affected Public: Business or other for-profit;

Number of Respondents: 26,820;

Total Annual Responses: 26,820;

Total Annual Hours: 7,197.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed

within 30 days of this notice directly to the OMB Desk Officer designated at the following address:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 22, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Groups, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Emergency Medical Service for Children; Cooperative Agreements for Emergency Medical Services for Children Network Development Demonstration Projects

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 \$1.8 million in fiscal year (FY) 2001 funds is available to fund up to three cooperative agreements for demonstration projects to develop and potentially replicate a system of regional applied pediatric emergency medical services research centers designed to expand and improve emergency services for children who need treatment for trauma or critical care. These regional centers will be linked together, as nodes in a network, with their affiliated hospital emergency departments, to demonstrate a capacity to conduct observational studies and clinical trials on issues relating to the management of emergency pediatric events that occur in medical settings as well as in transport to and from such settings. Substantial HRSA scientific and/or programmatic involvement in the administration of network activities is anticipated. All of the cooperative agreements will be made under the program authority of the Public Health Service Act, Title XIX, Section 1910 (42 U.S.C. 300w-9), Emergency Medical Services for Children, and will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Projects will be approved for up to a 3-year period, with average yearly awards varying from \$350,000 to \$600,000. However, funding for Emergency

Medical Services for Children (EMSC) Network Development Cooperative Agreements (CFDA #93.127L) beyond FY 2001 is contingent upon the availability of funds. Announcements may be made after the initial 3-year project period to demonstrate the effectiveness of expanding the number of regional centers in the network.

DATES: Entities which intend to submit an application for this program are expected to notify MCHB's Division of their intent by July 2, 2001. The deadline for receipt of applications is August 1, 2001. 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 30, 2001.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1-877-477-2123 (1-877-HRSA-123) beginning May 29, 2001, or register on-line at: <http://www.hrsa.gov/order3.htm> directly. The Pediatric Emergency Medical Services Network Development 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) #93.127L when requesting application kits. The CFDA is a Government wide compendium of enumerated Federal programs, project services, and activities which provide assistance. All applications must be mailed or delivered to Grants Management Officer, MCHB: HRSA Grants Application Center, 1815 N. Fort Meyer Drive, Suite 300, Arlington, Virginia 22209; telephone 1-877-477-2123; E-mail: 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, if you need technical assistance in accessing the MCHB Home Page via the Internet.

This notice will appear in the **Federal Register** and/or HRSA Home Page at <http://www.hrsa.dhhs.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.

Letter of Intent: Notification of intent to apply can be made in one of three ways: Telephone, 301-443-2190; email, kwadhwani@hrsa.gov; mail, Research Branch, MCHB Division of Research,

Training and Education; Parklawn Building, Room 18A-55; 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kishena Wadhvani, 301/443-4842, email: kwadhvani@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); Jamie King, 301/443-1123, email jkking@hrsa.gov/ (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION: Improving the care of ill and injured pediatric patients has been a major goal of the EMSC program since its inception in 1984. This program is administered by MCHB in collaboration with the National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation. Almost every State has received EMSC funding for demonstration projects to expand and improve pediatric emergency care and many new methods have been implemented, including system development, education of emergency providers, integration of pediatric components into adult emergency medical services (EMS) systems, and data collection and analysis to delineate existing and emergent problems and develop cause-and-effect hypotheses.

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, or 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 dearth of science-based knowledge about pediatric emergencies and how to best manage them has not gone unnoticed. The issue has been raised by professionals in the field, who have found that it constitutes a major barrier to the reduction of the annual toll in mortality and morbidity. Calls by experts to mount a nation wide research initiative in emergency medical services were made in 1991 and 1993. These led to the publication of comprehensive research agenda reports for researchers working independently. More recently, in 2001, a joint report from the National

Association of EMS Physicians and NHTSA delineates what areas of research—unspecified as to adult or children—need to be addressed. This report alludes to the nationwide scarcity of available funds for research in EMS and EMSC. The same report emphasizes that because the incidence rates for all emergency events are relatively small, more so for children, the pooling of sites and treatment experiences for applied research is highly desirable.

The encouragement of a research focus for the EMSC program was also reflected by the Senate Appropriations Committee in its FY 2001 committee report language (S.Report No. 106-293, at 73 (2000)). In it, the Committee encourages MCHB's EMSC program to "develop * * * quality of care assessment and enhancement initiatives" and "to develop a means of collecting data to ensure accountability and to better track accomplishments and needs." *Id.*

The EMSC Network Development Demonstration Projects described in this announcement are a measured response to the national concerns outlined above. Within five years, the intent is to demonstrate that: (1) A well-conceived and fully-operational infrastructure can be put in place to conduct clinical trials and observational studies on EMSC using rigorous study designs and methodologies; (2) a consensus-derived and well-informed research agenda can be developed and used to actively guide the network's activities; (3) a research and development process can be instituted fully within the network to develop proposals, conduct pilot studies, and carry out full-blown investigation with support from MCHB and other Federal agencies; and (4) a plan to study and encourage the transfer of network findings to EMSC practices can be designed and instituted.

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

Purpose

The purpose of this program is to design and evaluate an infrastructure to test the efficacy of treatments, transport and care responses that precede the arrival of children to hospital emergency departments. Creation of a successful infrastructure will help overcome present difficulties in assessing the efficacy and quality of care and ensuring accountability in State EMSC programs that result from the relatively small incidence rates of pediatric emergency events and the lack of a current mechanism to pool sites and treatment experiences and can also be expected to facilitate observational

studies on a variety of issues related to EMSC, including the processes involved in transferring research results to treatment settings.

Eligibility

Applications may be submitted by State governments and accredited schools of medicine. 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 Mechanism

The administrative and funding instrument to be used for this program will be the 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 stimulate awardees' activities by working with the awardees in a partnership role. Federal involvement may include, but is not limited to, planning, guidance, coordination and participation in programmatic activities. Periodic meetings and/or communications with the award recipient may be held to review mutually agreed upon goals and objectives and to assess progress. Details of the responsibilities of MCHB, awardees, and their expected relationships under these cooperative agreements are included in the "Terms and Conditions of Award" section of the application guidance material, which is part of the application kit sent to prospective applicants upon request, or downloaded by prospective applicants from the MCHB web site.

Funding Level/Project Period

Approximately \$1.8 million in FY 2001 funds is available to support the EMSC Network Development Demonstration Projects. This level of support is dependent on the receipt of a sufficient number and diversity of applications of high scientific merit.

Three awards are anticipated in FY 2001, for project periods of up to three years. Because the nature and scope of activities proposed in response to this announcement may vary, it is anticipated that the size of individual awards will also vary. The initial budget period is expected to be 12 months, with subsequent budget periods being 12 months. Continuation of any project from one budget period to the next is subject to satisfactory performance,

availability of funds, and program priorities.

Competing continuation applications may be invited upon expiration of the initial funding period. Any awards made subsequent to the initial 3-year project period would be expected to demonstrate the feasibility of adding sites to the Network.

Review Criteria

Applications will be screened by MCHB staff for completeness and programmatic responsiveness to the program guidance. Those judged to be 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 scientific and technical merit by an appropriate peer review group specifically convened 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. All applications recommended for approval will be discussed fully by the ad hoc peer review group and assigned a priority score for funding.

Applications will be reviewed for scientific and technical merit using a set of criteria covering the following areas:

- (1) Quality of plan for the establishment of the cooperative regional research center and the nature and technical quality of the investigations proposed;
- (2) Principal investigator's documented history of leadership in the conduct of complex multi-site clinical trials and observational investigations and substantial publication record in the field of emergency medical services;
- (3) Infrastructure to conduct research;
- (4) Collaboration between hospital emergency departments and regional center;
- (5) Administrative and management plan;

(6) Budget. Budget requests should be commensurate with the complexities involved in what is being proposed and carefully justified;

(7) Positive evaluation of pre-award site visits to all applicants.

Final 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

If the cooperative agreements described in this announcement involve data collection activities that fall under the purview of the Paperwork Reduction Act of 1995, OMB clearance will be sought prior to collection of data.

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 which 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 SPECS 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: June 7, 2001.

Betty James Duke,
Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2001 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

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 2001 funds for cooperative agreements 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, Cooperative Agreements to Develop a National Infrastructure for the Improvement of Treatment and Services for Children and Adolescents Who Experience Trauma, 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	Est. funds FY 2001 (in millions)	Est. number of awards	Project period (in yrs.)
Child Traumatic Stress Initiative	July 30, 2001	*\$9.5 ...	*18	*3

*See the text below for more details on the funding, number of awards, and the project period. This will vary with the three types of awards.

The actual amount available for the award may vary, depending on unanticipated program requirements and the number and quality of application received. FY 2001 funds for the activity discussed in this

announcement were appropriated by Congress under Public Law No. 106-310. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement application were

published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

General Instructions: Applicants must use application form PHS 5161-1 (Rev. 7/00). The application kit contains the two-part application materials