899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMICA Facts, at second voice prompt press 2, and then enter the document number (791) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains a home page at http://www.fda.gov/cdrh on the Internet for easy access to information that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts; **Federal Register** reprints; information on premarket submissions, including lists of approved applications and manufacturers' addresses; small manufacturers' assistance; information on video conferencing and electronic submissions; Mammography Matters, and other medical device oriented information. The CDRH home page also includes the document ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA'' which may be accessed at http://www.fda.gov/cdrh/ode/guidance/791.html. A search capability for all guidance documents may be found at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

Dated: April 15, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–10427 Filed 4–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal and Child Health Federal Set-Aside Program; Special Projects of Regional and National Significance; Sickle Cell Disease and Newborn Screening Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately $3.6 million in fiscal year (FY) 2002 funds is available to fund (1) a single cooperative agreement with a national sickle cell disease organization for a national coordinating center, and (2) up to 15 grants for community-based sickle cell disease projects to enhance the Sickle Cell Disease and Newborn Screening program through provision of outreach and counseling efforts. Eligibility is open to any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450(b)). Awards will be made under the program authority of section 501(a)(2) of the Social Security Act, the Maternal and Child Health (MCH) Federal Set-Aside Program (42 U.S.C. 701(a)(2)), or ''SPRANS.'' Funds for these awards were appropriated under Public Law 107–116. Up to $750,000 will be available for one cooperative agreement; up to $2.87 million will be available for community-based grants. Awards are made for a grant period of one year.

DATES: Applicants for this program are expected to notify the Maternal and Child Health Bureau (MCHB) by May 20, 2002. Notification of intent to apply can be made in one of three ways: telephone: 301–443–1080; email *cdiener@hrsa.gov;* mail, MCHB, HRSA; Division for Children with Special Health Care Needs, Parklawn Building, Room 18A–19; 5600 Fishers Lane; Rockville, MD 20857. The deadline for receipt of applications is June 29, 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 1, 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) beginning April 29, 2002, or register on-line at: *http://www.hrsa.gov/,* or by accessing *http://www.hrsa.gov/g_order3.htm* directly. This program uses the standard Form PHS 5161–1 (rev. 7/00) for applications (approved under OMB No. 0920–0428). Applicants must use the appropriate Catalog of Federal Domestic Assistance (CFDA) number 93.110A when requesting application materials. The CFDA is a Government wide compendium of enumerated Federal programs, projects, services, and activities that provide assistance. All applications should be mailed or delivered to: Grants Management Officer (MCHB), HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg MD, telephone: 1–877–HRSA–123 (477–2123), e-mail: *hrsagac@hrsa.gov.*

This application guidance and the required form for the Sickle Cell Disease and Newborn Screening grant program may be downloaded in either WordPerfect 6.1 or Adobe Acrobat format (.pdf) from the MCHB HomePage 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 announcement will appear on the HRSA Home Page at: *http://www.hrsa.gov/.* **Federal Register** notices are found by following instructions at: *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

FOR FURTHER INFORMATION CONTACT: Michele A. Lloyd-Puryear, M.D., Ph.D. 301–443–1080, e-mail: *mpuryear@hrsa.gov* (for questions specific to project activities of the program, program objectives, or the Letter of Intent described above); and Jacquelyn Whitaker, 301/443–1440; e-mail, *jwhitaker@hrsa.gov* (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

Sickle cell disease (SCD) is an inherited red blood cell condition characterized primarily by chronic anemia and periodic episodes of pain. In affected individuals, the abnormal red blood cells break easily and clog blood vessels to block blood flow to organs and tissues. This process results in anemia, periodic pain episodes, and ultimately can damage tissues and vital organs and lead to increased infections and early death. In the United States, most cases of SCD occur among people of African ancestries. People of Mediterranean, Middle Eastern, and Indian background are also affected. It is estimated that more than 2 million Americans have the sickle cell trait and over 70,000 have the disease. Annually approximately 1,000 newborns are identified with the disease through state newborn screening programs.

Early diagnosis of SCD is critical so that children who have the condition can receive proper interventions. Newborn screening for SCD followed by parental health education, enrollment in comprehensive care, initiation of penicillin prophylaxis and anti-pneumococcal vaccination within the first two months of life can prevent death from severe infections.

The Federal MCHB has long recognized the significance of SCD. In the mid 1960s, MCHB developed and disseminated SCD educational materials nationally. Following passage of the National Sickle Cell Anemia Control Act in 1972, MCHB, with initial funding from the National Institutes of Health (NIH), provided support for community

based sickle cell clinics to conduct testing, counseling, and education. In the mid 1980s, the Federal MCHB supported the development and implementation of State newborn screening programs for SCD. By 1990, 30 States and jurisdictions had implemented programs with direct Federal support. Although most States and jurisdictions currently have State wide screening programs, the 1987 Consensus Development Conference on Newborn Screening for Sickle Cell and Other Hemoglobinopathies recommendation for universal screening has not been realized.

All State SCD screening programs include a follow-up component. Some, however, fall short of the guidelines recommended by the Council of Regional Networks for Genetic Services (CORN). There are infants with SCD who do not enter into appropriate programs of comprehensive care and do not receive the requisite interventions. Further, follow-up of infants with sickle cell trait or carriers is sub-optimal. While the benefit of carrier notification leads to increased knowledge for the affected infant's family, problems of misunderstanding (infant with the trait perceived as defective), stigmatization, and issues of paternity can also result from carrier notification. It is thus imperative that trait notification and counseling be undertaken with sensitivity and accuracy. In many State SCD programs, parents are notified of the carrier infant's abnormal test results but are left on their own to seek education, genetic counseling, and testing. Many parents do not receive counseling and testing.

Just as important as follow-up in a SCD program is the education component. Patients and families need to remain well informed and be empowered as active participants in service delivery. State SCD programs need to enlist partners in this effort, including primary care providers, subspecialists, and community-based support organizations. In some communities, the staff of the community-based organization can make the initial contact with the affected family and maintain subsequent contact and provide support and education.

Authorization

Section 501(a)(2) of the Social Security Act (42 U.S.C. 701(a)(2)).

Purpose

The purpose of the Sickle Cell Disease and Newborn Screening Program is to support newborns diagnosed with SCD or trait and their families, relying on partnerships among the State newborn screening programs, community-based SCD organizations, comprehensive SCD treatment centers, and health care professionals. Specifically, the program will enhance the follow up component of State SCD screening programs and support community-based projects that provide SCD related education, carrier counseling, and support services.

Through a cooperative agreement, a national SCD organization will partner with families, community based SCD organizations, health care professionals, State agencies and MCHB, and assist in the coordination and implementation of community-based SCD projects funded by this initiative. Further, it will provide an organizational forum for interaction between MCHB and the SCD community to identify and prioritize issues of importance to the SCD community.

The funded community-based SCD projects will partner with State newborn screening programs, comprehensive sickle cell treatment centers, and health care professionals to provide support to infants screened positive for SCD and trait and their families; as well as working cooperatively with each other and the funded national SCD organization to implement a model program of SCD carrier follow-up to include notification, extended family testing, counseling and education of affected individuals and families.

Eligibility

Under SPRANS project grant regulations at 42 CFR part 51a.3, any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450(b)), is eligible to apply for grants and cooperative agreements covered by this announcement. Under the President's initiative, community-based and faith-based organizations that are otherwise eligible and believe they can contribute to HRSA's program objectives are urged to consider this initiative.

Funding Levels/Project Periods

The administrative and funding instrument to be used for the national SCD coordinating center will be a cooperative agreement, in which substantial MCHB scientific and/or programmatic involvement with the awardee is anticipated during the performance of the project. Under the terms of this cooperative agreement, in addition to the required monitoring and technical assistance, Federal responsibilities will include:

(1) Provision of services of experienced federal personnel as participants in the planning and development of all phases of this activity.

(2) Participation, as appropriate, in meetings conducted during the period of the cooperative agreement.

(3) Ongoing review and concurrence with activities and procedures to be established and implemented for accomplishing the scope of work.

(4) Participation in the preparation of project information prior to dissemination.

(5) Participation in the presentation of information on project activities.

(6) Assistance with the establishment of contacts with Federal and State agencies, MCHB grant projects, and other contacts that may be relevant to the project's mission; and referrals to these agencies.

Up to $750,000 will be used to fund the national coordinating center through a cooperative agreement. Up to $2.87 million will be used to fund up to 15 community-based grants within the program. Grantees will be expected to work cooperatively with the national coordinating center also described in this announcement. All awards will be made for one year.

Funding Priorities

Funding priority for the cooperative agreement will be given to an established national SCD organization with clearly demonstrated expertise and national capacity for addressing issues relevant to SCD patients and their families and in which community-based programs play an integral role in its mission.

Funding priority for community-based grants will be given to existing local community-based SCD organizations meeting one of following two priority factors:

(1) A collaborative relationship with the State Title V and newborn screening program and a partnership with a local comprehensive sickle cell treatment center; or

(2) Participation in a cooperative relationship with the national SCD coordinating center and fellow grantees funded by this initiative to collect information and standardize the education and counseling to be offered by the network of local, community-based projects.

An applicant meeting one of these priority factors will be given a 5 point favorable adjustment to the ranking score assigned to that application, on a 100 point scale. There is a maximum of 2 awards per State.

Review Criteria

Applications that are complete and responsive to the guidance will be

evaluated by an objective review panel specifically convened for this solicitation and in accordance with HRSA grants management policies and procedures.

Cooperative agreement applications will be reviewed using the following criteria:

1. Understanding of the problem, solutions, and desired outcome;
2. Quality of the proposal for the coordination and support to be provided to the community-based SCD projects to be funded by MCHB under this initiative;
3. Collaboration between the organization and State newborn screening programs and sickle cell treatment centers and health care professionals;
4. Infrastructure, including sound administrative and management components, necessary to carry out the proposed activities;
5. Expertise and experience of the project staff;
6. Budget request to be commensurate with the proposed activities and well justified;

Applications for community-based grants will be evaluated using the following criteria:

1. Experience in providing outreach, education, and support to parents of newborns determined by newborn screening to have SCD or sickle cell trait;
2. Willingness to engage in a collaborative relationship with the State newborn screening program and a comprehensive sickle cell treatment center;
3. Willingness to participate in a cooperative relationship with the national SCD organization and fellow grantees funded by this initiative to collect information and standardize the education and counseling to be offered by the grantees;
4. Quality of plan for collaboration with partners and conduct of outreach, education, and counseling activities;
5. Infrastructure, including sound administrative and management components, necessary to carry out the proposed plan;
6. Budget request to be commensurate with the proposed plan and well justified;

Additional criteria may be used to review and rank applications for this competition. Any such criteria will be identified in the program guidance included in the application kit. Applicants should pay strict attention to addressing these criteria, in addition to those referenced above. Also, to the extent that regulatory review criteria generally applicable to all Title V programs (at 42 CFR part 51a) are relevant to this specific project, such factors will be taken into account.

Paperwork Reduction Act

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

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 424).

(b) A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372

The MCH Federal Set-Aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

Dated: April 23, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–10429 Filed 4–26–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal and Child Health Federal Set-Aside Program; Special Projects of Regional and National Significance; Oral Health Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately $350,000 in fiscal year (FY) 2002 funds is available to fund one competitive grant to establish a new National Maternal and Child Oral Health Resource Center (NMCOHRC). This new center is intended to continue, in part, activities carried out by an earlier oral health resource center funded by the Maternal and Child Health Bureau (MCHB). The purpose of the NMCOHRC is to collect maternal and child oral health information and materials that are not readily available elsewhere, and make them available to the public for easy reference and retrieval in a variety of print and media formats. Eligibility is open to any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b). The award will be made under the program authority of section 501(a)(2) of the Social Security Act, the Maternal and Child Health (MCH) Federal Set-Aside Program (42 U.S.C. 701(a)(2)). Funds for this award were appropriated under Public Law 107–116. The award will be made for a project period of up to five years. Funding beyond the first year is subject to grantee performance and the availability of funds.

DATES: Applicants for this program are requested to notify MCHB of their intent by May 10, 2002. Notification of intent to apply can be made in one of three ways: telephone: 301–443–3449; email: *mnehring@hrsa.gov* or; mail: MCHB/HRSA; Division for Child, Adolescent and Family Health; Oral Health Program; Parklawn Building, Room 18A–39; 5600 Fishers Lane; Rockville, MD 20857. The deadline for receipt of applications is June 14, 2002. Applications will be considered ''on time'' if they are either received at the Grants Application Center on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 1, 2002.

ADDRESSES: To receive a complete application kit, applicants may