

person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 15, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96-17956 Filed 7-15-96; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

Program Announcement, Proposed Project Requirements, Review Criteria, and Funding Preference for Regional Nursing Partnerships to Provide Continuing Education in Nursing Informatics for Faculty in Medically Underserved Communities

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1996 Cooperative Agreements for Regional Nursing Partnerships to Provide Continuing Education in Nursing Informatics for Faculty in Medically Underserved Communities. These cooperative agreements will be funded for one year under the Public Health Service Act, as amended by Nurse Education and Practice Improvement Amendments of 1992, Title II, Public Law 102-408, dated October 13, 1992, Section 820 (c), Continuing Education for Nurses in Medically Underserved Communities. It is anticipated that \$280,000 will be available to support up to three competitive one-year awards.

Purpose

The purpose of the cooperative agreements is to support the formation of partnerships between recognized regional nursing organizations and nursing entities qualified to provide continuing education in nursing informatics for nursing faculty in schools located in, or preparing students to serve in, medically underserved communities. Nursing informatics is defined as the integration of nursing science, computer science, and information science applied to the identification, collection, analysis, and management of data for nursing education, practice, and research. Increasing the number of nurses in the workforce who are knowledgeable about nursing informatics, especially those practicing in underserved or rural communities, will enhance clinical proficiency and improve access to and quality of health care for increasing numbers in the population. For the purpose of these cooperative agreements, regional nursing organizations are those regionally based nursing organizations whose members must include schools of nursing in institutions of higher education located within the designated region, and whose members may also include health care agencies and other health care entities.

Applicants must establish and maintain effective partnerships to implement sound continuing education

programs designed to meet the identified nursing faculty needs in nursing informatics. Continuing education program curricula must be based on regional assessments of undergraduate and graduate nursing faculty proficiency in computer technology and nursing informatics.

Eligibility and Proposed Funding Preference

Eligible applicants include public and non-profit entities. A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories or groups of approved applications in a discretionary program. It is proposed that a funding preference will be given to recognized regional nursing organizations who enter partnerships with nursing entities experienced in teaching nursing informatics. These entities may include, but are not limited to, schools of nursing. The partner providing the nursing informatics expertise must be located within the recognized regional nursing organization's designated region. It is highly unlikely that any applicant not meeting the funding preference will be supported under this cooperative agreement.

Proposed Project Requirements

1. Develop a formalized partnership between the regional nursing organization and nursing entities qualified to provide continuing education in nursing informatics.

2. Establish an Advisory Board to oversee the development, administration, and evaluation of the project. The Advisory Board must include at least one non-academically based nurse practicing in a medically underserved community.

3. Utilize an existing assessment of undergraduate and graduate nursing programs within the region to determine:

(a) The availability of computer-based systems;

(b) Faculty knowledge, skills, and abilities in the use of computer-based systems; and

(c) The ability of faculty to prepare students for practice in technologically advanced practice environments.

4. Based on analysis of the assessment in #3, develop and implement four regionally-based nursing informatics continuing education programs during the 1997 academic year. Each continuing education program must be designed to:

(a) Enhance faculty knowledge, skills, and abilities in nursing informatics in the areas of computer technology;

human factors; information and database management; professional practice, trends, and issues; system analysis and design; system implementation and support; system testing and evaluation; and theoretical frameworks;

(b) Include a computer lab practicum;

(c) Be completed in a one-week, 30–36 hour session;

(d) Be provided in two or more different geographic locations to facilitate participation by faculty from distant areas within the region;

(e) Enroll a minimum of 14 nursing faculty from schools of nursing located in or experienced in preparing nurses to serve in medically underserved communities;

(f) Provide participants a syllabus and reading materials prior to the session; and

(g) Award continuing education credit in nursing informatics.

6. Project must be documented in a format to facilitate replication by other organizations.

Substantial Federal Programmatic Involvement

Personnel in the Bureau of Health Professions, Division of Nursing will have substantial programmatic involvement with the planning, development, administration, and evaluation of the Regional Nursing Partnerships to Provide Continuing Education in Nursing Informatics for Faculty in Medically Underserved Communities and their outputs by:

1. Participating in the identification and selection of an Advisory Board. This includes participation in the selection of co-chair(s), one of whom will be the Division of Nursing representative, Meribeth Reed, PhD, RN.

2. Providing guidance for obtaining an existing regional assessment on the availability of computer-based systems; faculty knowledge, skills, and abilities in the use of computer-based systems; and the ability of faculty to prepare students for practice in technologically advanced practice environments.

3. Providing technical assistance, guidance, and recommendations for project modifications.

4. Reviewing and advising on curricula content, selection of participants, methodologies, and teaching techniques.

5. Reviewing and advising on program evaluation methods.

6. Reviewing and advising on documenting project activities and experiences for dissemination and replication.

7. Providing data and information about Federal programs that may impact the project.

National Health Objectives for the year 2000

The HRSA urges applicants to submit work plans that address specific objectives of *Healthy People 2000*. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017–001–00474–0) or *Healthy People 2000* (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (Telephone 202–783–3238).

Education and Service Linkage

As part of its long-range planning, HRSA will be targeting its efforts to strengthening linkages between HRSA education programs and programs which provide comprehensive primary care services to the underserved.

Smoke-Free Workplace

The HRSA strongly encourages all grant recipients to provide a smoke-free workplace; to promote the non-use of all tobacco products; and to promote Public Law 103–227, the Pro-Children Act of 1994, which prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Proposed Review Criteria

The review of applications will take into consideration the following criteria:

1. The need for the proposed project.
2. The potential effectiveness of the proposed project in carrying out the stated purpose.
3. The administrative and managerial capability of the applicant to carry out the proposed project.
4. The efficacy of the proposed partnership.
5. The adequacy of the facilities and resources available to the applicant to carry out the proposed project.
6. The qualifications of the project director and proposed staff.
7. The feasibility of the proposed budget in relation to the proposed project.
8. The potential of the project to continue on a self-sustaining basis after the period of Federal support.

Additional Information

Interested persons are invited to comment on the proposed project requirements; review criteria; and funding preference for recognized nursing organizations in partnership with nursing entities qualified to provide continuing education in nursing informatics. The comment period is 30

days. All comments received on or before August 15, 1996 will be considered before the final project requirements and review criteria are established. The final project requirements and review criteria will be included in the final notice published in the Federal Register. Written comments should be addressed to Marla Salmon, ScD, RN, FAAN, Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9–35, 5600 Fishers Lane, Rockville, Maryland 20857. All comments received will be available for public inspection and copying at the Division of Nursing, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m., Eastern Standard Time.

Application Availability

Application materials, including Supplemental Instructions and Training Application Form PHS 6025–1, are available on the World Wide Web at: <http://www.os.dhhs.gov/hrsa/bhpr>. To obtain the supplemental instructions, click on the file named “NICE.EXE” to download to your computer. Click on “save to disk.” The file will be saved as a self-extracting WordPerfect 5.1 file named NICE.EXE. Once the file is downloaded to your disk or hard drive, you may exit the web site.

The NICE.EXE file will be a compressed file. To decompress or expand the file in DOS, go to the DOS directory where the file has been downloaded and type in “NICE.EXE”, then “enter.” The file will expand into a WordPerfect 5.1 file, now named “NICE.”

To decompress the file in Windows, go to “program manager,” then click on “file,” then “run.” The file will expand to a Windows file now named “NICE.” Note that in DOS or in Windows, you will retain a file with the extension “.EXE,” and one without the extension, but with considerably larger disk size. The expanded file is the one you will use. To obtain the PHS 6025–1, follow the same instructions, after clicking on “PHS 6025–1.”

Questions regarding grants policy and business management issues should be directed to Ms. Wilma Johnson, Acting Chief, Centers and Formula Grants Section (wjohnson@hrsa.ssw.dhhs.gov), Grants Management Branch, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8C–26, 5600 Fishers Lane, Rockville, Maryland 20857. Applicants are strongly encouraged to obtain application materials from the

World Wide Web via the Internet. However, if you are unable to obtain the application materials electronically, you may obtain application materials in the mail by sending a written request to the Grants Management Branch at the address above. Written requests may also be sent via FAX (301) 443-6343 or via the internet listed above. Completed applications should be returned to the Grants Management Branch at the above address.

If additional programmatic information is needed, please contact Meribeth Reed, PhD, RN, Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9-35, 5600 Fishers Lane, Rockville, Maryland 20857. Dr. Reed may be reached by telephone at (301) 443-5763, by fax at (301) 443-8586, or by e-mail at: (mreed@hrsa.ssw.dhhs.gov).

Paperwork Reduction Act

The standard application form PHS 6025-1, HRSA Competing Training Grant Application, has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB Clearance Number is 0915-0060.

The deadline date for receipt of applications is August 19, 1996. Applications will be considered to be "on time" if they are either:

- (1) *Received on or before* the established deadline date, or
- (2) *Sent on or before* the established deadline date and received in time for orderly processing. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

Late applications not accepted for processing will be returned to the applicant. In addition, applications which exceed the page limitation and/or do not follow format instructions will not be accepted for processing and will be returned to the applicant.

This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is also not subject to the Public Health System Reporting Requirements.

Dated: July 10, 1996.

Ciro V. Sumaya,
Administrator.

[FR Doc. 96-17998 Filed 7-15-96; 8:45 am]

BILLING CODE 4160-15-P

Availability of Funds for Cooperative Agreement to Create a Primary Care Resource Center

AGENCY: Health Resources and Services Administration.

ACTION: Notice of available funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted in fiscal year (FY) 1996 to create a university-based Primary Care Resource Center. The purpose of the Center is to study the organization, financing, and delivery of primary health care services to underserved and vulnerable populations, in order to develop materials and information which will assist and benefit Community Health Centers (CHCs) in their analysis of the need for primary health services, the development of clinical practices, and the refinement of fiscal and administrative systems. Funding of this activity is authorized under Section 330(f)(1) of the Public Health Service (PHS) Act.

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. HRSA programs, and CHCs in particular, are related to the objectives cited for special populations, particularly minorities, people with low income, and other types of vulnerable populations. Potential applicants may obtain a copy of *Healthy People 2000—Full Report* (Stock No. 017-001-00474-0) or *Healthy People 2000—Summary Report* (Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, 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, day care, health care, or early childhood development services are provided to children.

DUE DATES: Applications are due August 30, 1996. Applications will be considered to have met the deadline if they are: (1) Received on or before the deadline date; or (2) postmarked on or before the established deadline date and received in time for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal

Service. Private metered postmarks are not acceptable as proof of timely mailing. Applications received after the announced deadline will not be considered for funding.

ADDRESSES: Application kits (Form PHS 5161-1) with revised face sheet DHHS Form 424, as approved by the Office of Management and Budget under control number 0937-0189, may be obtained from, and completed applications should be mailed to: BPHC Grants Management Officer, c/o Houston Associates, Inc., 1010 Wayne Avenue, Suite 1200, Silver Spring, MD 20910, Telephone 800/523-2192.

FOR FURTHER INFORMATION CONTACT: For information on programmatic and research issues, contact: Ms. Bonnie Lefkowitz, Associate Bureau Director, Office of Data, Evaluation, Analysis, and Research, Bureau of Primary Health Care, HRSA, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone 301/594-4280 (FAX 301/594-4986).

For information on business management issues, please contact Nancy Benson in the Office of Grants Management, Bureau of Primary Health Care, 301/594-4232.

SUPPLEMENTARY INFORMATION:

Program Requirements

HRSA's Bureau of Primary Health Care (BPHC) is seeking to enter into a cooperative agreement with a university or university-based organization for the purpose of operating a Primary Care Resource Center. The activities to be performed under this cooperative agreement are intended to assure that relevant knowledge about the health care environment and about methods of clinical and management improvement is made available to the health centers and other primary care providers; and that this knowledge is disseminated throughout those programs, and is conveyed to policymakers, program planners and administrators, care providers, and the user populations. Toward that goal, the Primary Care Resource Center will communicate effectively and regularly with these audiences through instruments it develops and disseminates.

Areas and topics for study will be determined jointly by BPHC and the Center, with emphasis on the ability to respond to changing needs of BPHC programs. The Center will be responsible for:

1. Producing short-term (e.g., 3-4 weeks turn-around) analytic reports, white papers, and monographs, for dissemination, as appropriate, to the public;