

hearing under 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 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 22, 1997, 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 5, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 97-19247 Filed 7-22-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Program Requirements and Review Criteria for a Cooperative Agreement for a Center for Health Workforce Distribution Studies: A Federal-State Partnership Cooperative Agreement Program for Fiscal year 1997

The Health Resources and Services Administration (HRSA) announces that

applications will be accepted for a fiscal year (FY) 1997 Cooperative Agreement for a Center for Health Workforce Distribution Studies: A Federal-State Partnership Cooperative Agreement Program. The cooperative agreement will be funded under the authority of section 792 (42 USC 295k) of the Public Health Service Act, which authorizes research on health professions personnel.

Research and studies for this cooperative agreement program will focus on the workforce distributional aspects of the legislation at the state (one or a few states) level for allied health personnel, dentists, nurses, physicians, and public health personnel as specified below.

A proposed three-year period of support beginning in fiscal year 1997 is anticipated, with approximately \$250,000 per year. This is a one time competition and is not expected to be an ongoing cooperative agreement program. Applicants may request up to \$250,000 per year in total costs (direct plus indirect costs), for up to three years.

#### Purpose

The purpose of this cooperative agreement for a Center for Health Workforce Distribution Studies is to support research and analysis at the state level for one state or a few states only, including issues regarding the impact of federal initiatives aimed at improving the training of health professionals and meeting national workforce goals pertaining to:

(1) Allied health data and distributional issues consistent with the (1995) recommendations of the National Commission on Allied Health and in close coordination with the activities of the Allied Health Data Collaborative Project;

(2) Distribution of dentists, with emphasis on trends relating to educational background (for example, those with postdoctoral training in advanced general dentistry and/or public health dentistry) and practice in settings principally serving residents of medically underserved communities;

(3) The designation of nursing shortage areas at the state level and, through a pilot exploration of a model approach, build a methodologic bridge to other states for applicability across the Nation;

(4) The distribution of physicians, with emphasis on underserved areas and specialty services, including, for example OB/GYN, maternal and child health, general surgery, emergency medicine, and mental health; and addressing issues of substitution, using available tools such as the HRSA/BHPr

Integrated Requirements Model (IRM), as applicable, and

(5) The establishment of collaboration(s) between schools of public health and state and local public health agencies to assess public health workforce supply and distribution and to develop educational strategies to address imbalances; and to develop the nature of workforce planning for public health personnel at the state level.

The cooperative agreement is to fund either the establishment and the operation of a new research center, or the operation of an existing research of a new research center, for the conduct of such research. The center must conduct high-quality research and disseminate findings to colleagues and policy-makers at the institutional, Federal and state levels.

The successful applicant must have or establish the Center for Health Workforce Distribution Studies as an identifiable entity. This must be more than a set of discrete, investigator-initiated research projects proposed in one application. The center must have a director; a coherent, widely-recognized research agenda; and researchers who function as a team. The principal investigator must be an experienced researcher who will be primarily responsible for the organization and operation of the center and will provide research leadership. The center's researchers must collectively possess multidisciplinary skills, and have experience in health services research. There must be sufficient core staff with significant time commitments to the center, although the center will of necessity share common resources with other components of the applicant institution, including technical, clerical, and administrative personnel, and library and computer resources.

The cooperative agreement funds will be available to provide basic support for the center, including: the development and implementation of the center's research agenda, administrative and research staff support, researcher time (although not necessarily 100% of researcher time), and dissemination of center research products through articles in peer-reviewed journals as well as center-sponsored publications. This cooperative agreement must not be the sole source of support for this type of enterprise. The applicant institution must demonstrate a commitment (including a matching contribution—see "Program Requirements" below) to support the organizational and management structure of the center, and its investigators should seek other funds for support of its research agenda.

**Substantial Programmatic Involvement**

Personnel of the Bureau of Health Professions will have substantial programmatic involvement with the planning, developing and administering of the Center for Health Workforce Distribution Studies and its outputs. The program officer will be assisted by the work in close coordination with program staff of the divisions contributing to this cooperative agreement. Federal guidance and involvement will include:

1. Participating in identification of workforce study priorities;
2. Assisting in the selection of research projects. This includes, but is not limited to, providing substantial guidance on Federal policy-relevant issues, and issues of particular national interest, that require research;
3. Participating in the approval of study protocols and methodologies;
4. Participating in review and selection of sub-contracts awarded under the cooperative agreement. If sub-contracts are awarded via a competitive process, a representative of the Bureau will serve on the review panel which will evaluate applications;
5. Supplying data in areas relevant to studies of the health professions workforce. When data are not directly available from the Bureau of Health Professions, Bureau personnel will assist in identifying sources of data such as other Federal agencies, and other public and private organizations;
6. Assisting with the preparation of project results for publication in peer-reviewed journals;
7. Providing information about numerous Federal programs that impact health workforce studies.

**Eligibility**

Eligible applicants include public and non-profit private entities. The applicant must bring together allied/dental/medical/nursing/public health schools and state agencies, must have experience in all five component areas, the assessment and evaluation of unmet need/underserved areas, and in issues of non-physician provider substitution, and must have access to the allied and public health workforce data base in the state. Development of a methodology for the assessment of nursing shortage areas and of public health requirements and supply in a state must involve a state agency.

**Proposed Program Requirements**

The award recipient's institution must share in the cost of the program as follows: For each year funds are awarded under this program, the matching contribution shall be at least one-third of the amount of the Federal award for that year. Up to 50% of the

recipient's matching contribution may be in the form of in-kind donations of faculty time, staff time, use of computers or other shared resources.

Applicants are urged to submit applications that address specific objectives of HRSA/BHPr. Health workforce surveillance reveals significant gaps in the Nation's health workforce ability to meet the population's needs. In some cases, these gaps are exacerbated by market forces. The BHPr attempts to address these in its four health workforce goals to improve the distribution, diversity, supply, and competence/quality. Specifically,

*Distribution:* there has been little progress in reducing the number of underserved areas, and access to generalist providers varies widely across states and counties;

*Diversity:* few health professions reflect the diversity of the Nation's population, also there is strong evidence that underrepresented minority providers are more likely to serve vulnerable populations;

*Supply:* shortages of some allied and public health providers coincide with a surfeit of specialist physicians

*Competence:* most training is hospital-based and ill-suited to ambulatory health care delivery, which occurs in an increasingly managed care environment and requires skills in providing cost-effective quality care. Also, an aging population created an unmet need for geriatric training.

**Proposed Review Criteria**

Applications for this cooperative agreement will be evaluated on the basis of the following criteria:

- (1) The qualification and achievements of the proposed center's principal investigator and senior researchers, including level of productivity and quality of research in health workforce issues;
- (2) Demonstration of an understanding of the particular subject areas of health professions workforce research that are relevant to Federal policies and evidence of ability to manage research in such areas;
- (3) The appropriations of the time commitments of the principal investigator and senior researchers;
- (4) The strength of the applicant's plan to actively promote dissemination of research findings to all health professionals involved in health services research and to relevant national and state policy makers;
- (5) The appropriateness of the proposed budget;

The planned level of commitment to the center from the applicant

institution, as evidenced by specific plans for the type of financial support that will be offered, and for support of the organizations structure of the center. Evidence of a prior institutional commitment to generalizable research in health workforce studies will also be sought;

(7) The past success and the future potential of the proposed center's researchers in receiving funding from other sources; and

(8) The likely effectiveness of the organizational and management arrangements to operate the proposed center.

**National Health Objectives for the Year 2000**

The Public Health Service 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).

**Academic and Community Partnerships**

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

**Smoke-Free Workplace**

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products and Pub. L. 103-227, the Pro-Children Act of 1994, 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.

**Additional Information**

Interested persons are invited to comment on the proposed program requirements and review criteria. The comment period is 30 days. All comments received on or before August 22, 1997 will be considered before the final program requirements and review criteria are established. Written comments should be addressed to: Mr. B. Jerald McClendon, Director, Office of Research and Planning, Bureau of Health Professions, Health Resources and Services Administration, Parklawn

Building, Room 8-47, 5600 Fishers Lane, Rockville, Maryland 20857.

All comments receive will be available for public inspection and copying at the Office of Research and Planning, 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.

#### Application Requests

Application materials are available on the World Wide Web at address: "http://www.hrsa.dhhs.gov/bhpr/grants.html". In fiscal year 1997, the Bureau of Health Professions (BHPr) will use Adobe Acrobat to publish the grants documents on the Web page. In order to download, view and print these grants documents, you will need a copy of Adobe Acrobat Reader. This can be obtained without charge from the Internet by going to the adobe Web page ("http://www.adobe.com") and downloading the version of the Adobe Acrobat Reader which is appropriate for your operating system, i.e., Windows, Unix, Macintosh, etc. A set of more detailed instructions on how to download and use the Adobe Acrobat Reader can be found on the BHPr Grants Web page under "Notes on this WWW Page."

For applicants who are unable to access application materials electronically, a hard copy will be provided by contacting the HRSA Grants Application Center. The Center may be contacted by:

*Telephone Number:* 1-888-300-HRSA.

*FAX Number:* 301-309-0579.

*Email Address:*

hrsa.gac@ix.netcom.com.

*Completed applications should be returned to:* Grant Management Officer (CFDA#), HRSA Grants Applications Center, 40 West Gude Drive, Suite 100, Rockville, Maryland 20850.

Questions regarding grants policy and business management issues should be directed to: Ms. Diane Murray, Grants Management Specialist, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857, *Telephone:* (301) 443-6857, *FAX:* (301) 443-6343, *Email:* dmurray@hrsa.dhhs.gov

If additional programmatic information is needed, please contact: Herbert Traxler, Ph.D., Office of Research and Planning, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8-47, 5600 Fishers Lane, Rockville, Maryland 20857, *Telephone:* (301) 443-6662 or 3148,

*FAX:* (301) 443-8003 *Email:* htraxler@hrsa.dhhs.gov

#### Paperwork Reduction Act

The standard application form PHS 398, Application for Public Health Service Grant, will be used for this program and has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB Clearance Number is 0925-0001.

The deadline date for receipt of applications is August 22, 1997. 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 shall not be acceptable as proof of timely mailing.)

Late applications not accepted for processing will be returned to the applicant.

Dated: July 16, 1997.

**Claude Earl Fox,**

*Acting Administrator.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Substance Abuse and Mental Health Services Administration

##### Center for Substance Abuse Prevention; Cancellation of Advisory Committee Meeting

**SUMMARY:** Public notice was given in the **Federal Register** on June 13, 1997, Volume 62, No. 114, on pages 32360-32361 that the Center for Substance Abuse Prevention's Drug Testing Advisory Board (DTAB) would be meeting on August 5-6, 1997. This meeting has been canceled and will be rescheduled at a later date.

Date: July 17, 1997.

**Jeri Lipov,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 97-19244 Filed 7-22-97; 8:45 am]

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#### DEPARTMENT OF THE INTERIOR

##### Bureau of Land Management

[UT-030-1020]

##### Notice of Intent To Prepare a Management Plan and an Environmental Impact Statement; Correction

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of correction.

**SUMMARY:** The Bureau of Land Management wishes to advise the public of a correction of a phone number previously published in the **Federal Register** in the document announcing a notice of intent to prepare a management plan and associated environmental impact statement for the Grand Staircase-Escalante National Monument, Kane and Garfield Counties, Utah.

**SUPPLEMENTARY INFORMATION:** Please note that the telephone number stated in **FOR FURTHER INFORMATION CONTACT** in the **Federal Register** of July 8, 1997 (62 FR 36570), is incorrect. The correct telephone number for Pete Wilkins, Planning Coordinator of the Grand Staircase-Escalante National Monument, is (801) 865-5100.

Dated: July 10, 1997.

**Thom Slater,**

*Acting Deputy State Director, Division of Natural Resources.*

[FR Doc. 97-18680 Filed 7-22-97; 8:45 am]

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#### DEPARTMENT OF THE INTERIOR

##### Bureau of Land Management

[AK-910-0777-51]

##### Iditarod Advisory Council Meeting

**AGENCY:** Bureau of Land Management, Interior

**ACTION:** Notice of Iditarod Advisory Council Meeting

**SUMMARY:** The Iditarod Advisory Council will conduct an open meeting Tuesday, August 19, 1997, from 8 a.m. to 5 p.m. The purpose of the meeting is to discuss the formation of a non-profit foundation to assist in the management of the Iditarod National Historic Trail. The meeting will be held at the Campbell Creek Science Center off Abbott Loop Road in Anchorage, AK.

Public comments pertaining to management of the Iditarod National Historic Trail will be taken from 1-2 p.m. Written comments may be