

will exclude 510(k)'s that require clinical data for a decision. Clear review criteria must also be available, in the form of FDA guidance documents, consensus standards, or other appropriate assessment tools. FDA has prepared a preliminary list of devices that may be included in the pilot (see section IV. of this document for information on obtaining a copy).

Third party review organizations will be individually accepted by FDA. FDA will establish and apply requirements covering personnel qualifications as well as controls over potential conflicts of interest. FDA believes it is essential that third party review organizations maintain adequate independence from the device industry. FDA is also considering additional safeguards to ensure the quality and impartiality of third party reviews. Among the safeguards being considered are: FDA examination, acceptance, and oversight of third party review organizations; provision of training and standard operation procedures for third parties; audits of third party reviews; having FDA personnel serve as on site advisors to third party review bodies; and database checks to track ongoing reviews.

FDA expects that applicants who submit a 510(k) to a third party during the pilot will pay a fee directly to the third party. FDA does not expect to take part in setting fees, but rather intends to leave this to be negotiated between the third party review organization and the applicant.

The full range of general controls (current good manufacturing practices (CGMP's), medical device reporting, prohibition against adulteration and misbranding, etc.) and, where appropriate, special controls (device tracking, postmarket surveillance, etc.) will be applicable to devices included in the pilot program.

III. Purpose and Tentative Agenda of the Workshop

The purpose of the workshop is to obtain public comments and suggestions that will help FDA refine its plans for a pilot program for third party review of selected 510(k)'s.

Joseph A. Levitt, Deputy Director for Regulations and Policy, Center for Devices and Radiological Health, FDA, will preside. Mr. Levitt will be assisted by other FDA officials.

FDA will open the workshop with a summary of the framework for the proposed pilot program. This presentation will provide information on the impetus, objectives, and scope of the proposed pilot program. Following FDA's presentation, other participants

will make presentations. After reviewing the notices of participation, FDA will allocate the time available for presentations among those persons who properly file a written notice of participation. FDA will schedule each appearance and will notify each participant by mail or telephone of the time allotted to him or her and the approximate time his or her presentation is scheduled to begin. The full schedule will be available at the workshop and will subsequently be placed on file in the Dockets Management Branch under the docket number found in brackets in the heading of this document. Time permitting, the workshop will also include an opportunity for interested persons who did not submit a notice of participation to make brief statements or comments. The workshop will then proceed to a panel discussion of specific issues that FDA must resolve before third party reviews of 510(k)'s can begin. Among the topics to be discussed are the following: Which devices should be eligible for third party review; criteria for selection or acceptance of private sector organizations to perform reviews, including conflict of interest protections; safeguards necessary to ensure a fair and impartial review by a third party; and funding of third party reviews.

FDA is making available a list of specific topics for written comment and discussion at the workshop. (See section IV. of this document for information on how to obtain a copy.)

The workshop is informal, and the rules of evidence will not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question participants at the conclusion of their presentations.

IV. Obtaining Additional Information on the Workshop

Information on the June 19, 1995, workshop, including a more detailed listing of the topics and issues on which FDA is inviting comment and a list of the devices proposed for inclusion in the pilot, can be obtained from the Dockets Management Branch (address above) or by calling FDA's Facts-on-Demand system. The Facts-on-Demand system can be reached by calling 1-800-899-0381 or 301-827-0111 on a touch-tone phone. Follow the instructions provided, and request DSMA shelf number 150. The requested materials will be sent by FAX.

Dated: May 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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Health Resources and Services Administration

RIN 0905-ZA89

Program Announcement and Proposed Review Criteria for Grants for the Minority Faculty Fellowship Program for Fiscal Year 1995

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1995 Grants for the Minority Faculty Fellowship Program (MFFP) under the authority of section 738(b), title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102-408, dated October 13, 1992. Comments are invited on the proposed review criteria.

Approximately \$210,000 will be available in FY 1995 for this program. It is anticipated that \$210,000 will be available to support about five competing awards to schools and other eligible entities averaging \$42,000 which will cover the cost of the following: stipend in an amount not exceeding 50 percent of the regular salary of a similar faculty member or \$30,000, whichever is less, and tuition, fees and travel, where appropriate.

Purpose

The purpose of the MFFP is to increase the number of underrepresented minority faculty members in health professions schools, i.e., schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, health administration, clinical psychology, and other public or private nonprofit health or educational entities.

Specifically, these grant awards are intended to allow institutions an opportunity to provide a fellowship to individuals who have the potential for teaching, administering programs, or conducting research as faculty members. Institutions must demonstrate a commitment and ability to identify, recruit, and select underrepresented minorities in health professions. The institutions' training programs provide the fellows with the techniques and skills needed to secure an academic career including competence in: pedagogical skills, research methodology, development of research

grant proposals, writing and publication skills, and the ability to work with minority populations and provide health services to medically underserved communities. In addition, the fellows must work under the direct supervision of a senior level faculty member engaged in the disciplines mentioned above, and upon successful completion of the program would be assured a teaching position at the institution.

Period of Support

The period of Federal support will not exceed one year for each fellowship award to an applicant institution. However, a fellowship award to an individual recipient must be for a minimum of two years. The program does not contribute to the support of the fellow in the second year. The applicant institution (school) will be required to support the fellow for the second year at a level not less than the total of federal and institutional funds awarded for the first year.

Eligibility Requirements for the Applicant Institution

Eligible applicants for this program are schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, health administration, clinical psychology, and other public or private nonprofit health or educational entities.

In addition, to receive a fellowship award, an applicant institution must demonstrate to the Secretary that it has the commitment and ability to:

- * Identify, recruit and select individuals from underrepresented minorities in health professions who have the potential for teaching, administering programs, or conducting research at a health professions institution;
- * Provide such individuals with the skills necessary to enable them to secure an academic career. Training may include: pedagogical skills, program administration, the design and conduct of research, grant writing, and the preparation of articles suitable for publication in peer reviewed journals;
- * Provide services designed to assist such individuals in their preparation for an academic career, including the provision of mentors; and
- * Provide health services to rural or medically underserved populations.

In Addition, the Applicant Institution Shall Agree to the Following Assurances

- * Provide an assurance that the applicant institution will make available

(directly through cash donations) \$1 for every \$1 of Federal funds received under the fellowship (Each fellowship must include a stipend in an amount not exceeding 50 percent of the regular salary of a similar faculty member, or \$30,000, whichever is less);

- * Provide an assurance that institutional support will be provided for the individual for a second year at a level not less than the total amount of Federal and institutional funds provided in the year in which the grant was awarded;

- * Provide an assurance that the fellowship recipient is from an underrepresented minority in the health professions; has at a minimum, appropriate advanced preparation (such as a master's or doctoral degree in a health profession) and special skills necessary to enable that individual to teach and practice;

- * Provide an assurance that the recipient of the fellowship will be a member of the faculty of the applicant institution; and

- * Provide an assurance that the recipient of the fellowship has not been a member of the faculty of any school at any time during the 18-month period preceding the date on which the individual submits a request for the fellowship.

Eligibility Requirements for the Fellows

Fellowship awards must be for two years, and are provided for an individual who meets the following criteria:

- * Individual must be from an underrepresented minority in the health professions;
- * Individual must have appropriate advanced preparation (such as a master's or doctoral degree in a health profession) and special skills necessary to enable that individual to teach and practice;
- * Individual must not have been a member of the faculty of any school at any time during the 18-month period preceding the date on which the individual submits a request for the fellowship;
- * Individual must have completely satisfied any other obligation for health professional service which is owed under an agreement with the Federal Government, State Government, or other entity prior to beginning the period of service under this program;
- * Individual must be a U.S. citizen, noncitizen national, or foreign national who possesses a visa permitting permanent residence in the United States.

Breach of Fellowship Funds

The school will be required to return fellowship funds received if it fails to honor the terms of the fellowship award. Such sums must be paid within 1 year from the day the Secretary determines that the breach occurred. If payment is not received by the payment date, additional interest, penalties and administrative charges will be assessed in accordance with Federal Law (45 CFR 30.13).

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, DC 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 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 promote the non-use of all tobacco products, and Public Law 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.

Proposed Review Criteria

The following criteria are proposed for review of applications for this program:

1. The extent to which the institution demonstrates that it has the commitment and ability to identify, recruit, and select underrepresented minority faculty, and its ability to provide health services to rural or medically underserved populations;
2. The extent to which the institution's training program will provide the fellow with the preparation, training and skills needed to secure an academic career. Training may include: pedagogical skills, program administration, grant writing and publication skills, research methodology

and development of research grant proposals, and community service abilities;

3. The degree to which the institution's senior faculty are involved in the training and preparation of fellows pursuing an academic career, and the potential of the institution to continue the program without Federal support beyond the approved project period; and

4. The extent to which the institution meets the eligibility requirements set forth in section 738(b) of the Public Health Service Act.

In determining awards, the Secretary will also take into consideration equitable distribution among health disciplines and geographic areas.

Additional Information

Interested persons are invited to comment on the proposed review criteria. The comment period is 30 days. All comments received on or before July 3, 1995 will be considered before the final review criteria are established. Written comments should be addressed to: Mr. William J. Holland, Acting Director, Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-09, 5600 Fishers Lane, Rockville, Maryland 20857.

All comments received will be available for public inspection and copying at the Division of Disadvantaged Assistance, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

Application Requests

Requests for application materials and 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.

Completed applications should be returned to the Grants Management Branch at the above address.

If additional programmatic information is needed, please contact: Mr. Lafayette Gilchrist, Analysis and Evaluation Branch, Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-09, 5600 Fishers Lane, Rockville, Maryland 20857,

Telephone: (301) 443-3680 FAX: (301) 443-5242.

Paperwork Reduction Act

The application form for this program has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB Clearance Number is 0915-0150.

Deadline Date

The deadline date for receipt of applications is July 14, 1995. 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.

This program, Grants for the Minority Faculty Fellowship Program, is listed at 93.923 in the Catalog of Federal Domestic Assistance. It 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 not subject to the Public Health System Reporting Requirements.

Dated: May 26, 1995.

Ciro V. Sumaya,
Administrator.

[FR Doc. 95-13424 Filed 5-31-95; 8:45 am]
BILLING CODE 4160-15-P

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Availability of Funds for the Nursing Education Loan Repayment Program for Service in Certain Health Facilities

AGENCY: Health Resources and Services Administration, PHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately \$2,025,000 will be available in fiscal year (FY) 1995 for awards under section 846 of the Public Health Service (PHS) Act to repay up to 85 percent of the nursing education loans of registered nurses who agree to serve for up to 3 years as nurse employees in certain health facilities.

The HRSA, through this notice, invites applications for participation in this loan repayment program. With these funds, the HRSA estimates that approximately 218 loan repayment awards may be made.

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting health priorities. These programs will contribute to the Healthy People 2000 objectives by improving access to primary health care services through coordinated systems of care for medically underserved populations in both rural and urban areas. Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-01) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-01) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone number: 202 783-3238).

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

DATES: To receive consideration for funding, individuals must submit their applications by September 1, 1995.

Applications shall be considered as meeting the deadline if they are either:

- (1) received on or before the deadline date; or
- (2) sent on or before the deadline and received in time for submission to the reviewing program official.

(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 will not be considered for funding in FY 1995, but may be kept on file for consideration in FY 1996.

ADDRESSES: Application materials with a list of counties (parishes) with the greatest shortage of nurses may be obtained by calling or writing to: Joyce Washington, Acting Chief, Loan Repayment Programs Branch, Division of Scholarships and Loan Repayments, Bureau of Primary Health Care, HRSA, 4350 East-West Highway, 10th Floor, Bethesda, MD 20814, (301-594-4400). The 24-hour toll-free phone number is 1-800-435-6464 and the FAX number is (301) 594-4981. Completed