Class III devices require premarket approval.

Under the new categorization process to assist HCFA, the Food and Drug Administration assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories: Experimental/Investigational (Category A) Devices, or Non-Experimental/Investigational (Category B) Devices. Under this categorization process, an experimental/investigational (Category A) device is an innovative device in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the Food and Drug Administration is unsure whether the device type can be safe and effective). A non-experimental/investigational (Category B) device is a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained Food and Drug Administration approval for that device type. The criteria the Food and Drug Administration uses to categorize an investigational device under Category B include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/currently legally marketed device.

(2) Class III devices whose technological characteristics and indication for use are comparable to a Pre-Market Approval (PMA)-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required.

(5) Pre-amendments Class III devices that become the subject of an investigational device exemption after the Food and Drug Administration requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the Food and Drug Administration required the submission of an investigational device exemption. The following information presents the device number, category (in this case, A), and criterion code.

G950158 A1
G950168 A2
G950175 A2
G960060 A1
G960066 A2
G960074 A2
G960078 A1
G960101 A2
G960113 A2

The following information presents the device number, category (in this case, B), and criterion code.

G950194 B1
G950210 B1
G950218 B1
G960003 B4
G960021 B2
G960040 B4
G960041 B4
G960043 B1
G960046 B1
G960048 B3
G960052 B2
G960054 B3
G950056 B5
G960057 B2
G960059 B2
G960062 B2
G950100 B1
G950224 B3
G960047 B3
G960064 B2
G960067 B4
G960068 B4
G960069 B4
G960071 B2
G960076 B4
G960083 B3
G960084 B4
G960085 B1
G960086 B1
G960087 B3
G960088 B4
G960090 B1
G960091 B1
G960094 B1
G960095 B1
G960097 B1
G950205 B3
G960044 B3
G960045 B4
G960099 B1
G960100 B1
G960102 B1
G960103 B1
G950104 B1
G960105 B1
G960108 B3
G960109 B3
G960111 B2
G960112 B4
G960134 B4

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the Food and Drug Administration will agree on the additional criteria to be used. The Food and Drug Administration will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 96–32016 Filed 12–17–96; 8:45 am]

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Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden.

Proposed Project

1. *AIDS Education and Training Centers Program: National Program and Service Record Data Reporting Form (OMB No. 0915–0154)*—Extension, No change—Under section 2692(a) of the Public Health Service Act, information on training programs and training participants is obtained from 15 AIDS Education Training Centers (ETCs) currently operating in health professions schools and academic health science centers. The goal of the AIDS ETC program is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat and manage individuals with HIV infection and to assist in the prevention of high risk

behaviors which may lead to infection. The National Program and Service Record Data Reporting (NPSR) Form will be used by ETCs to provide standardized reporting of project activities for Federal program monitoring. The burden estimates are as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
NPSR	15	2	84	2,520

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 12, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–32073 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–15–P

Program Announcement for Grant Programs Administered by the Division of Disadvantaged Assistance, Bureau of Health Professions for Fiscal Year 1997

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for two grant programs for fiscal year (FY) 1997 under the authority of title VII of the Public Health Service (PHS) Act (herein referred to as the Act). These programs include:

Grants for Health Careers Opportunity Program (HCOP) (section 740, PHS Act, 42 CFR, part 57, subpart S)

Grants for the Minority Faculty Fellowship Program (MFFP) (section 738(b), PHS Act)

For the Health Careers Opportunity Program, it is anticipated that $7 million will be available to support approximately 38 competitive (new and renewal) projects. The average cost for each competitive award is estimated to be $184,210.

For the Minority Faculty Fellowship Program, it is estimated that $200,000 will be available to support approximately 6 fellowship awards. The average cost for each fellow is estimated to be $35,000.

Health Careers Opportunity Program (HCOP) (Catalog of Federal Domestic Assistance No. 93.822)

Eligibility and Purpose: Section 740 authorizes the Secretary to make grants to and enter into contracts with schools of allopathic medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic and podiatric medicine, and public and non-profit private schools which offer graduate programs in clinical psychology and other public or private nonprofit health or educational entities to carry out programs which assist individuals from disadvantaged backgrounds to enter and graduate from such schools.

Grant funds may be used to:

(1) Identify, recruit, and select individuals from disadvantaged backgrounds for education and training in a health profession;

(2) Provide, for a period prior to the entry of such individuals into the regular course of education of such a school, preliminary education designed to assist them to complete successfully, such regular course of education at such a school or referring such individuals to institutions providing such preliminary education;

(3) Facilitate the entry of such individuals in health and allied health professions schools;

(4) Provide counseling or other services designed to assist such individuals to successfully complete their education at such a school; and

(5) Inform such individuals of sources of financial aid available to assist them in their health professions education.

Applicants must carry out at least 2 of the five purposes, even if grant funds are requested or awarded for only one of them. It is permissible to request grant support for only one of the purposes if other purposes are financed with non-Federal funds. The project period of Federal support will not exceed 3 years.

Comprehensive HCOP Programs

HHS encourages the consolidation into one proposal HCOP grants among existing HCOP projects in the same institution or among entities in a geographic area of the applicant institution. Grant funds may also support comprehensive HCOP programs-involving formal linkages among several community-based entities and educational institutions in a defined geographic area to achieve an educational continuum. Comprehensive HCOP programs may include: A designated geographic area with recognized minority/disadvantaged demographics; a program building on existing strengths; and formal linkages among educational institutions, community health care entities, and community organizations.

Eligible Student Participants

Individuals participating in HCOP programs must:

(1) Be from disadvantaged backgrounds;

(2) Have completed the junior year of high school (or its equivalent);

(3) Be a resident of the United States and either a U.S. citizen, a U.S. national, an alien lawfully admitted for permanent residence in the U.S., a citizen of the Commonwealth of the Northern Mariana Islands, or a citizen of the Republic of Palau, or a citizen of the Republic of the Marshall Islands, or a citizen of the Federated States of Micronesia; and

(4) Must be enrolled and in good standing at the grantee institution or participating school(s).

Review Criteria: The review of applications will take into consideration the following factors:

(1) The degree to which the proposed project adequately provides for the requirements in 42 CFR, § 57.1805;

(2) The number and types of individuals who can be expected to benefit from the project;

(3) The administrative and management ability of the applicant to carry out the proposed project in a cost effective manner, including the validity of the proposed methodology, attainability of objectives, their measurability and outcomes;

(4) The adequacy of the staff and faculty, including experience and academic background relevant to the training of disadvantaged background students;

(5) The appropriateness of budget for assuring effective use of Federal funds; and

(6) The potential of the project to continue without further support under this program.

Statutory Funding Priorities: Section 740 provides that the Secretary shall give funding priority to the following schools: