to successful applicants by mail or will be transmitted electronically.

2. Administrative Requirements

Applicants must adhere to the requirements of this notice. Special terms and conditions regarding FDA regulatory requirements and adequate progress of the study may be part of the award notice.

3. Reporting

A. Reporting Requirements

The original and two copies of the annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. For continuing grants, an annual program progress report is also required. For such grants, the noncompeting continuation application (PHS 2590) will be considered the annual program progress report. Also, all new and continuing grants must comply with all regulatory requirements necessary to keep the status of their IND/IDE ''active'' and ''in effect,'' that is, not on ''clinical hold.'' Failure to meet regulatory requirements will be grounds for suspension or termination of the grant.

B. Monitoring Activities

The program project officer will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project officer/grants management officer and the principal investigator. Information including but not limited to study progress, enrollment, problems, adverse events, changes in protocol, and study monitoring activities will be requested. Periodic site visits with officials of the grantee organization also may occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the grant, including those which state that future funding of the study will depend on recommendations from the OPD project officer. The scope of the recommendations will confirm that: (1) There has been acceptable progress toward enrollment, based on specific circumstances of the study, (2) there is an adequate supply of the product/device, and (3) there is continued compliance with all FDA regulatory requirements for the trial. The grantee must file a final program progress report, FSR, and invention statement within 90 days after the end date of the project period as noted on the notice of grant award.

VII. Agency Contacts

For issues regarding the administrative and financial management aspects of this notice: Cynthia Polit (see Addresses to Request Application in section IV.1 of this document).

For issues regarding the programmatic aspects of this notice: Debra Y. Lewis, Director, Orphan Products Grants Program, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6A–55, Rockville, MD 20857, 301–827–3666, e-mail: *debra.lewis@fda.gov* or *dlewis@oc.fda.gov*.

VIII. Other Information

Data included in the application may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of HHS, by a court, or required by another Federal law, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: December 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24164 Filed 12–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Sentinel Centers Network (SCN) Core Data Set (OMB No. 0915–0268)—Extension

HRSA's Bureau of Primary Health Care (BPHC) established the Sentinel Centers Network (SCN) to assist in addressing critical quality, programmatic, and policy issues. Health centers identified as having adequate infrastructure and commitment through the competitive contract process have generated data for quality and program analyses and for projects on topics that have immediate programmatic impact. Health centers submit core data periodically extracted from existing information systems. These core data comprise patient, encounter, and practitioner level information including patient demographics, insurance status, clinical diagnoses and procedures, outcomes, and practitioner characteristics. Since all data obtained from the participant health centers are extracted/compiled from existing information systems and not through primary data collection, burden is minimized. In addition, each participant site receives technical assistance as needed to reduce burden and facilitate data submission.

The annual burden estimate for this activity is as follows:

Type of respondent	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Sites	43	2	86	8	688

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 13, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E5–7488 Filed 12–16–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Loan Repayment Program for Repayment of Health Professions Educational Loans

Announcement Type: Initial.

CFDA Number: 93.164.

Key Dates: Beginnning of 2006 Award Period: January 20, 2006; Ending of 2006 Award Period: September 30, 2006.

1. Funding Opportunity Description

The Indian Health Service (IHS) estimated budget request for Fiscal Year (FY) 2006 includes $11,698,754 for the Indian Health Service (IHS) Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs.

This program announcement is subject to the appropriation of funds. This notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals.

This program is authorized by Section 108 of the Indian Health Care Improvement Act (IHCIA) as amended, 25 U.S.C. 1601 *et.seq.* The IHS invites potential applicants to request an application for participation in the LRP.

Funds appropriated for the LRP in FY 2006 will be distributed among the health professions as follows: Allopathic/osteopathic practitioners will receive 27 percent, registered nurses 20 percent, mental health professionals 10 percent, dentists 12 percent, pharmacists 10 percent, optometrists 5 percent, physician assistants/advanced practice nurses 6 percent, podiatrists 4 percent, physical therapists 2 percent, other professions 4 percent. This requirement does not apply if the number of applicants from these groups, respectively, is not sufficient to meet the requirement.

H. Award Information

It is anticipated that $11,698,754 will be availabe to support approximately 253 competing awards averaging $46,250 per award for a two year contract. One year contract continuations will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2006 program cycle will be expected to begin their service period no later than September 30, 2006.

III. Eligibility Information

1. Eligible Applicants

Pursuant to Section 108(b), to be eligible to participate in the LRP, an individual must:

(1) (A) Be enrolled—

(i) In a course of study or program in an accredited institution, as determined by the Secretary, within any State and be scheduled to complete such course of study in the same year such individual applies to participate in such program; or

(ii) In an approved graduate training program in a health profession; or

(B) Have a degree in a health profession and a license to practice in a state; and

(2)(A) Be eligible for, or hold an appointment as a Commissioned Officer in the Regular or Reserve Corps of the Public Health Service (PHS); or

(B) Be eligible for selection for civilian service in the Regular or Reserve Corps of the (PHS); or

(C) Meet the professional standards for civil service employment in the IHS: or

(D) Be employed in an Indian health program without service obligation; and

(E) Submit to the Secretary an applicant for a contract to the Loan Repayment Program. The Secretary must approve the contract before the disbursement of loan repayments can be made to the participant. Participants will be required to fulfill their contract service agreements through full-time clinical practice at an Indian health program site determined by the Secretary. Loan repayment sites are characterized by physical, cultural, and professional isolation, and have histories of frequent staff turnover. All Indian health program sites are annually prioritized within the Agency by discipline, based on need or vacancy.

Section 108 of the IHCIA, as amended by Public Laws 100–713 and 102–573, authorizes the IHS LRP and provides in pertinent part as follows:

(a)(1) The Secretary, acting through the Service, shall establish a program to be known as the Indian Health Service Loan Repayment Program (hereinafter referred to as the ''Loan Repayment Program'') in order to assure an adequate supply of trained health professionals necessary to maintain accreditation of, and provide health care services to Indians through, Indian health programs.

Section 4(n) of the IHCIA, as amended by the Indian Health Care Improvement Technical Corrections Act of 1996, Public Law 104–313, provides that:

''Health Profession'' means *allopathic medicine,* family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, pediatric medicine, nursing, public health nursing, dentistry, psychiatry, osteopathy, optometry, pharmacy, psychology, public health, social work, marriage and family therapy, chiropractic medicine, environmental health and engineering, and allied health profession, *or any other health profession.*

For the purposes of this program the term ''Indian health program'' is defined in Section 108(a)(2)(A), as follows:

(A) The term ''Indian health program'' means any health program or facility funded, in whole or in part, by the Service for the benefit of Indians and administered—

(i) Directly by the Service;

(ii) By any Indian tribe or tribal or Indian organization pursuant to a contract under—

(I) The Indian Self-Determination Act, or

(II) Section 23 of the Act of April 30, 1908, (25 U.S.C. 47), popularly known as the Buy Indian Act; or

(iii) By an urban Indian organization pursuant to title V of this act.

Section 108 of the IHCIA, as amended by Public Laws 100–713 and 102–573, authorizes the IHS to determine specific health professions for which Indian Health Loan Repayment contracts will be awarded. The list of priority health professions that follow are based upon the needs of the IHS as well as upon the needs of the American Indians and Alaska Natives.

(a) Medicine: Allopathic and Osteopathic
(b) Nurse: Associate and B.S. Degree
(c) Clinical Psychology: Ph.D. only
(d) Social Work: Masters level only (concentration in Mental Health)
(e) Chemical Dependency Counseling: Baccalaureate and Masters level
(f) Dentistry
(g) Dental Hygiene
(h) Pharmacy: B.S., Pharm.D.
(i) Optometry
(j) Physician Assistant
(k) Advanced Practice Nurses: Nurse Practitioner, Certified Nurse