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The Program goals are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the extension of the Program to BsUFA II is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The

BsUFA II Commitment Letter specifies that an independent contractor can conduct the assessments and specifies that they include interviews of sponsors who submit 351(k) BLAs to the Program in BsUFA II. In accordance with the PDUFA V and BsUFA II Commitment Letters, we contracted Eastern Research Group, Inc. (ERG) to conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from

applicants on the success of the Program in increasing transparency and communication of reviews during the review process. ERG will anonymize and aggregate sponsor responses before inclusion in the assessments and presentation materials at public meetings. We will publish in the **Federal Register** for public comment ERG's assessments with interview results and findings.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-test .....	5	1	5	1.5	7.5
Interviews .....	75	1	75	1.5	112.5
<b>Total</b> .....					<b>120</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Since last OMB approval of the information collection, we have adjusted our estimate downward by 60 survey respondents. We base our estimate on the most recent number of annual surveys. ERG interviews between one and three sponsor representatives for each 351(k) BLA first-cycle action issued for applications reviewed under the Program. ERG also conducts a pretest of the interview protocol with five respondents. Assuming it will take 1.0 to 1.5 hours to complete the pretest, we calculate a total of 7.5 annual burden hours. We estimate that up to 75 respondents will take part in the post-action interviews each year. Assuming each interview will last 1.0 to 1.5 hours, we calculate a total of 112.5 annual burden hours.

Dated: March 6, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

[CFDA NUMBER: 93.164]

**Loan Repayment Program for Repayment of Health Professions Educational Loans; Announcement Type: Initial**

*Key Dates:* March 15, 2019, first award cycle deadline date; August 15, 2019, last award cycle deadline date;

September 15, 2019, last award cycle deadline date for supplemental loan repayment program funds; September 30, 2019, entry on duty deadline date.

**I. Funding Opportunity Description**

The Indian Health Service (IHS) estimated budget for fiscal year (FY) 2019 includes \$27,500,000 for the IHS Loan Repayment Program (LRP) for health professional educational loans (undergraduate and graduate) in return for full-time clinical service as defined in the IHS LRP policy at <https://www.ihs.gov/loanrepayment/policiesandprocedures/> in Indian health programs.

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 the Indian Health Care Improvement Act (IHCA) Section 108, codified at 25 U.S.C. 1616a.

**II. Award Information**

The estimated amount available is approximately \$17,750,000 to support approximately 384 competing awards averaging \$46,205 per award for a two-year contract. The estimated amount available is approximately \$9,750,000 to support approximately 392 competing awards averaging \$24,840 per award for a one-year extension. One-year contract extensions will receive priority consideration in any award cycle. Applicants selected for participation in the FY 2019 program cycle will be

expected to begin their service period no later than September 30, 2019.

**III. Eligibility Information**

*A. Eligible Applicants*

Pursuant to 25 U.S.C. 1616a(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 Corps of the Public Health Service (PHS); or
- (B) Be eligible for selection for service in the Regular 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
- (3) Submit to the Secretary an application for a contract to the LRP. 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. Indian health program sites are annually prioritized within the Agency by discipline, based on need or vacancy. The IHS LRP's ranking system gives high site scores to those sites that are most in need of specific health professions. Awards are given to the applications that match the highest priorities until funds are no longer available.

Any individual who owes an obligation for health professional service to the Federal Government, a State, or other entity, is not eligible for the LRP unless the obligation will be completely satisfied before they begin service under this program.

25 U.S.C. 1616a 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.

For the purposes of this program, the term "Indian health program" is defined in 25 U.S.C. 1616a(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 [the Indian Health Care Improvement Act].

25 U.S.C. 1616a, authorizes the IHS to determine specific health professions for which IHS LRP contracts will be awarded. Annually, the Director, Division of Health Professions Support, sends a letter to the Director, Office of Clinical and Preventive Services, IHS Area Directors, Tribal health officials, and Urban Indian health programs directors to request a list of positions for which there is a need or vacancy. The list of priority health professions that follows is based upon the needs of the IHS as well as upon the needs of American Indians and Alaska Natives.

(a) Medicine—Allopathic and Osteopathic doctorate degrees.  
 (b) Nursing—Associate Degree in Nursing (ADN) (Clinical nurses only).

(c) Nursing—Bachelor of Science (BSN) (Clinical nurses only).

(d) Nursing (NP, DNP)—Nurse Practitioner/Advanced Practice Nurse in Family Practice, Psychiatry, Geriatric, Women's Health, Pediatric Nursing.

(e) Nursing—Certified Nurse Midwife (CNM).

(f) Certified Registered Nurse Anesthetist (CRNA).

(g) Physician Assistant (Certified).

(h) Dentistry—DDS or DMD degrees.

(i) Dental Hygiene.

(j) Social Work—Independent Licensed Master's degree.

(k) Counseling—Master's degree.

(l) Clinical Psychology—Ph.D. or PsyD.

(m) Counseling Psychology—Ph.D.

(n) Optometry—OD.

(o) Pharmacy—PharmD.

(p) Podiatry—DPM.

(q) Physical/Occupational/Speech Language Therapy or Audiology—MS, Doctoral.

(r) Registered Dietician—BS.

(s) Clinical Laboratory Science—BS.

(t) Environmental Health (Sanitarian): BS and Master's level.

(u) Engineering (Environmental): BS and MS (Engineers must provide environmental engineering services to be eligible.).

#### *B. Cost Sharing or Matching*

Not applicable.

#### *C. Other Requirements*

Interested individuals are reminded that the list of eligible health and allied health professions is effective for applicants for FY 2019. These priorities will remain in effect until superseded.

### **IV. Application and Submission Information**

#### *A. Content and Form of Application Submission*

Each applicant will be responsible for submitting a complete application. Go to <http://www.ihs.gov/loanrepayment> for more information on how to apply electronically. The application will be considered complete if the following documents are included:

- Employment Verification—Documentation of your employment with an Indian health program as applicable:
  - Commissioned Corps orders, Tribal employment documentation or offer letter, or Notification of Personnel Action (SF-50)—For current Federal employees.

- License to Practice—A photocopy of your current, non-temporary, full and unrestricted license to practice (issued by any State, Washington, DC, or Puerto Rico).

- *Loan Documentation*—A copy of all current statements related to the loans submitted as part of the LRP application.

- Transcripts—Transcripts do not need to be official.

- If applicable, if you are a member of a federally recognized Tribe or an Alaska Native (recognized by the Secretary of the Interior), provide a certification of Tribal enrollment by the Secretary of the Interior, acting through the Bureau of Indian Affairs (BIA) (Certification: Form BIA-4432 Category A—Members of federally Recognized Indian Tribes, Bands or Communities or Category D—Alaska Native).

#### *B. Submission Dates and Address*

Applications for the FY 2019 LRP will be accepted and evaluated monthly beginning March 15, 2019, and will continue to be accepted each month thereafter until all funds are exhausted for FY 2019 awards. Subsequent monthly deadline dates are scheduled for the fifteenth of each month until August 15, 2019.

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

(1) Received on or before the deadline date; or

(2) Received after the deadline date, but with a legible postmark dated on or before the deadline date. (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 are not acceptable as proof of timely mailing).

Applications submitted after the monthly closing date will be held for consideration in the next monthly funding cycle. Applicants who do not receive funding by September 30, 2019, will be notified in writing.

Application documents should be sent to: IHS Loan Repayment Program, 5600 Fishers Lane, Mail Stop: OHR (11E53A), Rockville, Maryland 20857.

#### *C. Intergovernmental Review*

This program is not subject to review under Executive Order 12372.

#### *D. Funding Restrictions*

Not applicable.

#### *E. Other Submission Requirements*

New applicants are responsible for using the online application. Applicants requesting a contract extension must do so in writing by March 15, 2019, to ensure the highest possibility of being funded a contract extension.

## V. Application Review Information

### A. Criteria

The IHS will utilize the Health Professional Shortage Area (HPSA) score developed by the Health Resources and Services Administration for each Indian health program for which there is a need or vacancy. At each Indian health facility, the HPSA score for mental health will be utilized for all behavioral health professions, the HPSA score for dental health will be utilized for all dentistry and dental hygiene health professions, and the HPSA score for primary care will be used for all other approved health professions.

In determining applications to be approved and contracts to accept, the IHS will give priority to applications made by American Indians and Alaska Natives and to individuals recruited through the efforts of Indian Tribes or Tribal or Indian organizations.

### B. Review and Selection Process

Loan repayment awards will be made only to those individuals serving at facilities with have a site score of 17 or above through March 1, 2019, if funding is available.

One or all of the following factors may be applicable to an applicant, and the applicant who has the most of these factors, all other criteria being equal, will be selected.

(1) An applicant's length of current employment in the IHS, Tribal, or Urban program.

(2) Availability for service earlier than other applicants (first come, first served).

(3) Date the individual's application was received.

### C. Anticipated Announcement and Award Dates

Not applicable.

## VI. Award Administration Information

### A. Award Notices

Notice of awards will be mailed on the last working day of each month. Once the applicant is approved for participation in the LRP, the applicant will receive confirmation of his/her loan repayment award and the duty site at which he/she will serve his/her loan repayment obligation.

### B. Administrative and National Policy Requirements

Applicants may sign contractual agreements with the Secretary for two years. The IHS may repay all, or a portion, of the applicant's health profession educational loans (undergraduate and graduate) for tuition

expenses and reasonable educational and living expenses in amounts up to \$20,000 per year for each year of contracted service. Payments will be made annually to the participant for the purpose of repaying his/her outstanding health profession educational loans. Payment of health profession education loans will be made to the participant within 120 days, from the date the contract becomes effective. The effective date of the contract is calculated from the date it is signed by the Secretary or his/her delegate, or the IHS, Tribal, Urban, or Buy Indian health center entry-on-duty date, whichever is more recent.

In addition to the loan payment, participants are provided tax assistance payments in an amount not less than 20 percent and not more than 39 percent of the participant's total amount of loan repayments made for the taxable year involved. The loan repayments and the tax assistance payments are taxable income and will be reported to the Internal Revenue Service (IRS). The tax assistance payment will be paid to the IRS directly on the participant's behalf. LRP award recipients should be aware that the IRS may place them in a higher tax bracket than they would otherwise have been prior to their award.

### C. Contract Extensions

Any individual who enters this program and satisfactorily completes his or her obligated period of service may apply to extend his/her contract on a year-by-year basis, as determined by the IHS. Participants extending their contracts may receive up to the maximum amount of \$20,000 per year plus an additional 20 percent for Federal withholding.

## VII. Agency Contact

Please address inquiries to Ms. Jacqueline K. Santiago, Chief, IHS Loan Repayment Program, 5600 Fishers Lane, Mail Stop: OHR (11E53A), Rockville, Maryland 20857, Telephone: 301/443-3396 [between 8:00 a.m. and 5:00 p.m. (Eastern Standard Time) Monday through Friday, except Federal holidays].

## VIII. Other Information

Indian Health Service area offices and service units that are financially able are authorized to provide additional funding to make awards to applicants in the LRP, but not to exceed the maximum allowable amount authorized by statute per year, plus tax assistance. All additional funding must be made in accordance with the priority system outlined below. Health professions given priority for selection above the

\$20,000 threshold are those identified as meeting the criteria in 25 U.S.C. 1616a(g)(2)(A), which provides that the Secretary shall consider the extent to which each such determination:

(i) Affects the ability of the Secretary to maximize the number of contracts that can be provided under the LRP from the amounts appropriated for such contracts;

(ii) Provides an incentive to serve in Indian health programs with the greatest shortages of health professionals; and

(iii) Provides an incentive with respect to the health professional involved remaining in an Indian health program with such a health professional shortage, and continuing to provide primary health services, after the completion of the period of obligated service under the LRP.

Contracts may be awarded to those who are available for service no later than September 30, 2019, and must be in compliance with 25 U.S.C. 1616a. In order to ensure compliance with the statutes, area offices or service units providing additional funding under this section are responsible for notifying the LRP of such payments before funding is offered to the LRP participant.

Should an IHS area office contribute to the LRP, those funds will be used for only those sites located in that area. Those sites will retain their relative ranking from their Health Professions Shortage Areas (HPSA) scores. For example, the Albuquerque Area Office identifies supplemental monies for dentists. Only the dental positions within the Albuquerque Area will be funded with the supplemental monies consistent with the HPSA scores within that area.

Should an IHS service unit contribute to the LRP, those funds will be used for only those sites located in that service unit. Those sites will retain their relative ranking from their HPSA scores.

**Chris Buchanan,**

*RADM, Assistant Surgeon General, U.S. Public Health Service, Deputy Director, Indian Health Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60-Day Comment Request; National Institute on Drug Abuse Summer Research Internship Program

**AGENCY:** National Institutes of Health, HHS.