

§ 25.11 Prohibited activities and penalties.

(a) State or local agencies, FFLs, or individuals violating this subpart A shall be subject to a fine not to exceed \$10,000 and subject to cancellation of NICS inquiry privileges.

(b) Misuse or unauthorized access includes, but is not limited to, the following:

(1) State or local agencies', FFLs', or individuals' purposefully furnishing incorrect information to the system to obtain a "Proceed" response, thereby allowing a firearm transfer;

(2) State or local agencies', FFLs', or individuals' purposefully using the system to perform a check for unauthorized purposes; and

(3) Any unauthorized person's accessing the NICS.

Dated: October 27, 1998.

Janet Reno,

Attorney General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 68a

RIN 0925-AA09

National Institutes of Health Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is issuing regulations to implement provisions of the Public Health Service Act authorizing the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds. The purpose of the program is the recruitment and retention of highly qualified health professionals, who are from disadvantaged backgrounds, to conduct clinical research as employees of the NIH by providing repayment of qualified educational loans.

EFFECTIVE DATE: This final rule is effective on November 30, 1998.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, 6011 Executive Blvd., Suite 601, MSC 7669, Rockville, MD 20852; telephone 301-496-4607 (not a toll-free number); Fax 301-402-0169; or E-mail (jm40z@nih.gov). For program

information contact: Marc S. Horowitz, telephone 301-402-5666 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The NIH Revitalization Act of 1993 (Pub. L. 103-43) was enacted June 10, 1993, adding section 487E of the Public Health Service (PHS) Act, 42 U.S.C. 288-5. Section 487E authorizes the Secretary to carry out a program of entering into contracts with appropriately qualified health professionals from disadvantaged backgrounds with substantial educational loan debt relative to income. Under such contracts, qualified health professionals agree to conduct clinical research as NIH employees for a minimum of two years, in consideration of the Federal Government agreeing to repay a maximum of \$20,000 annually of the principal and the interest of the educational loans of such health professionals. This program is known as the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds. The NIH is amending title 42 of the Code of Federal Regulations by adding a new part 68a to govern the administration of this loan repayment program.

The regulations specify the scope and purpose of the program, who is eligible to apply, how individuals apply to participate in the program, how participants are selected, and the terms and conditions of the program.

The NIH announced its plans to issue the regulations in a notice of proposed rulemaking (NPRM) published in the **Federal Register**, February 10, 1997 (62 FR 5953). The NPRM provided for a 60-day comment period. The NIH received no comments. Consequently, the final regulations are the same as those originally proposed in February 1997, except for an editorial change reflecting the NIH Medical Board's change of name to the "Medical Executive Committee."

The following is provided as public information.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate, and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If a regulatory action is deemed to fall within the scope of the definition of the term "significant regulatory action" contained in section 3(f) of the Order, pre-publication review by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) is necessary. This final rule has been reviewed under

Executive Order 12866 by OIRA and has been deemed not significant.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires that regulatory actions be analyzed to determine whether they create a significant impact on a substantial number of small entities. I certify that this final rule will not have any such impact.

Paperwork Reduction Act

This final rule does not contain any information collection requirements which are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The application forms used by the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds have been reviewed and approved by OMB under OMB No. 0925-0361 (expires September 30, 1998).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered program affected by the proposed regulation is:

93.220—NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds

List of Subjects in 42 CFR Part 68a

Health—clinical research, medical research; Loan programs—health.

Dated: September 18, 1998.

Harold Varmus,

Director, National Institutes of Health.

For the reasons presented in the preamble, title 42 of the Code of Federal Regulations is amended by adding a new part 68a to read as set forth below.

PART 68a—NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL RESEARCH LOAN REPAYMENT PROGRAM FOR INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS (CR-LRP)

Sec.

68a.1 What is the scope and purpose of the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP)?

68a.2 Definitions.

68a.3 Who is eligible to apply?

68a.4 Who is eligible to participate?

68a.5 Who is ineligible to participate?

68a.6 How do individuals apply to participate in the CR-LRP?

68a.7 How are applicants selected to participate in the CR-LRP?

68a.8 What does the CR-LRP provide to participants?

68a.9 What loans qualify for repayment?

68a.10 What does an individual have to do in return for loan repayments received under the CR-LRP?

68a.11 How does an individual receive loan repayments beyond the initial two-year contract?

68a.12 What will happen if an individual does not comply with the terms and conditions of participation in the CR-LRP?

68a.13 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

68a.14 When can a CR-LRP payment obligation be discharged in bankruptcy?

68a.15 Additional conditions.

68a.16 What other regulations and statutes apply?

Authority: 42 U.S.C. 288–5.

§ 68a.1 What is the scope and purpose of the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP)?

This part applies to the award of educational loan payments under the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) authorized by section 487E of the Public Health Service Act (42 U.S.C. 288–5). The purpose of this program is to recruit and retain appropriately qualified health professionals, who are from disadvantaged backgrounds and have substantial educational debt relative to income, to conduct clinical research as NIH employees.

§ 68a.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

Applicant means an individual who applies to, and meets the eligibility criteria for the CR-LRP.

Approved clinical research means clinical research approved by the Clinical Research Loan Repayment Committee.

Clinical privileges means the delineation of privileges for patient care granted to qualified health professionals by the NIH Medical Executive Committee or other appropriate credentialing board.

Clinical research means activities which qualify for inclusion as clinical research in the CR-LRP as determined by the Clinical Research Loan Repayment Committee.

Clinical Research Loan Repayment Committee (CR-LRC) means the scientific board assembled to review, rank, and approve or disapprove Clinical Research Loan Repayment Program applications. The CR-LRC is composed of NIH scientific staff and co-chaired by the Associate Director for Clinical Research, NIH, and the Associate Director for Research on Minority Health, NIH. Members are nominated by the Deputy Director, Intramural Research, NIH, and the co-

chairs, and appointed by the Director, NIH.

Clinical Research Loan Repayment Program (CR-LRP or Program) means the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds authorized by section 487E of the Act, as amended.

Clinical Research Loan Repayment Program (CR-LRP or Program) contract refers to the agreement, which is signed by an applicant and the Secretary, wherein the applicant from a disadvantaged background agrees to engage in clinical research as an employee of the NIH and the Secretary agrees to repay qualified educational loans for a prescribed period as specified in this part.

Clinical researcher means an NIH employee with clinical privileges who is conducting approved clinical research.

Commercial loans means loans made by banks, credit unions, savings and loan associations, not-for-profit organizations, insurance companies, schools, and other financial or credit institutions which are subject to examination and supervision in their capacity as lending institutions by an agency of the United States or of the State in which the lender has its principal place of business.

Current payment status means that a qualified educational loan is not past due in its payment schedule as determined by the lending institution.

Debt threshold refers to the minimum amount of qualified educational debt an individual must have, on his/her program eligibility date, in order to be eligible for Program benefits and, for purposes of eligibility under this part, debt threshold means that the qualified educational debt must equal or exceed 20 percent of an individual's annual NIH salary on his/her program eligibility date.

Educational expenses means the cost of the health professional's education, including the tuition expenses and other educational expenses such as fees, books, supplies, educational equipment and materials, and laboratory expenses.

Government loans means loans made by Federal, State, county, or city agencies which are authorized by law to make such loans.

Individual from disadvantaged background means an individual who:

(1) Comes from an environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or

(2) Comes from a family with an annual income below a level based on low-income thresholds according to

family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels in the **Federal Register**.

Institute, Center, or Agency (ICA) means an institute, center, or agency of the National Institutes of Health.

Living expenses means the reasonable cost of room and board, transportation and commuting costs, and other reasonable costs incurred during an individual's attendance at an educational institution.

Participant means an individual whose application to the CR-LRP has been approved and whose Program contract has been executed by the Secretary.

Program means the NIH Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds.

Program eligibility date means the date on which an individual's Program contract is executed by the Secretary and that individual is engaged in approved clinical research as an employee of the NIH.

Qualified educational loans and interest/debt include Government and commercial educational loans and interest for:

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(3) reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses incurred.

Reasonable educational and living expenses means those educational and living expenses which are equal to or less than the sum of the school's estimated standard student budget for educational and living expenses for the degree program and for the year(s) during which the participant was enrolled in school. If there is no standard budget available from the school or if the participant requests repayment for educational and living expenses which exceed the standard student budget, reasonableness of educational and living expenses incurred must be substantiated by additional contemporaneous documentation, as determined by the Secretary.

Repayable debt means the portion, as established by the Secretary, of an individual's total qualified educational debt relative to the NIH salary, which can be paid by the CR-LRP. Specifically, qualifying educational debt amounts in excess of 50 percent of the debt threshold will be considered for repayment.

Salary means base pay plus quarters, subsistence, and variable housing allowances, if applicable.

School means undergraduate, graduate, and health professions schools which are accredited by a body or bodies recognized for accreditation purposes by the Secretary of Education.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service means the Public Health Service.

State means one of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

Withdrawal means a request by a participant, prior to the Program making payments on his or her behalf, for withdrawal from Program participation. A withdrawal is without penalty to the participant and without obligation to the Program.

§ 68a.3 Who is eligible to apply?

To be eligible to apply to the CR-LRP, an individual must be a citizen, national, or permanent resident of the United States; hold a M.D., Ph.D., D.O., D.D.S., D.M.D., A.D.N./B.S.N., or equivalent degree; have, on his/her program eligibility date, qualified educational debt equal to or in excess of the debt threshold; and be an individual from a disadvantaged background.

§ 68a.4 Who is eligible to participate?

To be eligible to participate in the CR-LRP, an applicant must have the recommendation of the employing ICA Scientific Program Director, the concurrence of the employing ICA Director, and the approval of the CR-LRC. Since participation in the Program is contingent, in part, upon employment with NIH, a Program contract may not be awarded to an applicant until an employment commitment has been made by the employing ICA Personnel Department.

§ 68a.5 Who is ineligible to participate?

The following individuals are ineligible for CR-LRP participation:

(a) Persons who are not eligible applicants as specified under section 68a.3;

(b) Persons who owe an obligation of health professional service to the Federal Government, a State, or other entity, unless a deferral is granted for the length of his/her service obligation under the CR-LRP. The following are examples of programs which have a service obligation: Physicians Shortage Area Scholarship Program, National Research Service Award Program, Public Health Service Scholarship, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program, Indian Health Service Scholarship Program, and the NIH AIDS Research Loan Repayment Program.

(c) Persons who are not NIH employees, such as Intramural Research Training Award (IRTA) recipients, Visiting Fellows, National Research Service Award (NRSA) recipients, Guest Researchers or Special Volunteers, NIH-National Research Council (NRC) Biotechnology Research Associates Program participants, and Intergovernmental Personnel Act (IPA) participants; or

(d) Persons who do not have clinical privileges.

§ 68a.6 How do individuals apply to participate in the CR-LRP?

An application for participation in the CR-LRP shall be submitted to the NIH office which is responsible for the Program's administration, in such form and manner as the Secretary may prescribe.

§ 68a.7 How are applicants selected to participate in the CR-LRP?

To be selected for participation in the CR-LRP, applicants must satisfy the following requirements:

(a) Applicants must meet the eligibility requirements specified in § 68a.3 and § 68a.4.

(b) Applicants must not be ineligible for participation as specified in § 68a.5.

(c) Applicants must be selected for approval by the CR-LRC, based upon a review of their applications.

§ 68a.8 What does the CR-LRP provide to participants?

(a) Loan repayments: For each year of service the individual agrees to serve, with a minimum of 2 years of obligated service, the Secretary may pay up to \$20,000 per year of a participant's repayable debt.

(b) Under § 68a.8(a), the Secretary will make payments in the discharge of debt to the extent appropriated funds are available for these purposes.

§ 68a.9 What loans qualify for repayment?

(a) The CR-LRP will repay participants' lenders the principal, interest, and related expenses of qualified Government and commercial educational loans obtained by participants for the following:

(1) Undergraduate, graduate, and health professional school tuition expenses;

(2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and

(3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other living expenses as determined by the Secretary.

(b) The following educational loans are ineligible for repayment under the CR-LRP:

(1) Loans obtained from other than a government entity or commercial lending institution;

(2) Loans for which contemporaneous documentation is not available;

(3) Loans or portions of loans obtained for educational or living expenses which exceed the standard of reasonableness as determined by the participant's standard school budget for the year in which the loan was made, and are not determined by the Secretary to be reasonable based on additional documentation provided by the individual;

(4) Loans, financial debts, or service obligations incurred under the following programs: Physicians Shortage Area Scholarship Program (Federal or State), National Research Service Award Program, Public Health and National Health Service Corps Scholarship Training Program, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program, Indian Health Service Program, and similar programs, upon determination by the Secretary, which provide loans, scholarships, loan repayments, or other awards in exchange for a future service obligation;

(5) Any loan in default or not in a current payment status;

(6) Loan amounts which participants have paid or were due to have paid prior to the program eligibility date; and

(7) Loans for which promissory notes have been signed after the program eligibility date.

§ 68a.10 What does an individual have to do in return for loan repayments received under the CR-LRP?

Individuals must agree to be engaged in approved clinical research, as employees of the NIH, for a minimum initial period of two consecutive years.

§ 68a.11 How does an individual receive loan repayments beyond the initial two-year contract?

An individual may apply for and the Secretary may grant extension contracts for one-year periods, if there is sufficient debt remaining to be repaid and the individual is engaged in approved clinical research as an NIH employee.

§ 68a.12 What will happen if an individual does not comply with the terms and conditions of participation in the CR-LRP?

(a) Absent withdrawal (see § 68a.2) or termination under paragraph (d) of this section, any participant who fails to complete the minimum two-year service obligation required under the Program contract will be considered to have breached the contract and will be subject to assessment of monetary damages and penalties as follows:

(1) Participants who leave during the first year of the initial contract are liable for amounts already paid by the NIH on behalf of the participant plus an amount equal to \$1,000 multiplied by the number of months of the original service obligation.

(2) Participants who leave during the second year of the contract are liable for amounts already paid by the NIH on behalf of the participant plus \$1,000 for each unserved month.

(b) Payments of any amount owed under paragraph (a) of this section shall be made within one year of the participant's breach (or such longer period as determined by the Secretary).

(c) Participants who sign a continuation contract for any year beyond the initial two-year period and fail to complete the one-year period specified are liable for the pro rata amount of any benefits advanced beyond the period of completed service.

(d) Terminations will not be considered a breach of contract in cases where such terminations are beyond the control of the participant as follows:

(1) Terminations for cause or for convenience of the Government will not be considered a breach of contract and monetary damages will not be assessed.

(2) Occasionally, a participant's research assignment may evolve and change to the extent that the individual is no longer engaged in approved clinical research. Similarly, the research needs and priorities of the ICA and/or the NIH may change to the extent that

a determination is made that the health professional's skills may be better utilized in a non-clinical research assignment. Under these circumstances, the following will apply:

(i) Program participation and benefits will cease as of the date an individual is no longer engaged in approved clinical research; and

(ii) Normally, job changes of this nature will not be considered a breach of contract on the part of either the NIH or the participant. Based on the recommendation of the ICA Director and concurrence of the Secretary, the participant will be released from the remainder of his or her service obligation without assessment of monetary penalties. The participant in this case will be permitted to retain all Program benefits made or owed by NIH on his/her behalf up to the date the individual is no longer engaged in approved clinical research, except the pro rata amount of any benefits advanced beyond the period of completed service.

§ 68a.13 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

(a) Any obligation of a participant for service or payment to the Federal Government under this part will be canceled upon the death of the participant.

(b) The Secretary may waive or suspend any service or payment obligation incurred by the participant upon request whenever compliance by the participant:

(1) Is impossible,

(2) Would involve extreme hardship to the participant, or

(3) If enforcement of the service or payment obligation would be against equity and good conscience.

(4) The Secretary may approve a request for a suspension of the service or payment obligations for a period of 1 year. A renewal of this suspension may also be granted.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of such information and documentation as may be required, that the participant suffers from a physical or mental disability resulting in the permanent inability of the participant to perform the service or other activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of such

information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as a physical or mental disability or terminal illness in the immediate family, which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 68a.14 When can a CR-LRP payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68a.12 may be discharged in bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment is required and only if the bankruptcy court finds that a nondischarge of the obligation would be unconscionable.

§ 68a.15 Additional conditions.

When a shortage of funds exists, participants may be funded partially, as determined by the Secretary. However, once a CR-LRP contract has been signed by both parties, the Secretary will obligate such funds as necessary to ensure that sufficient funds will be available to pay benefits for the duration of the period of obligated service unless, by mutual written agreement between the Secretary and the applicant, specified otherwise. Benefits will be paid on a quarterly basis after each service period unless specified otherwise by mutual written agreement between the Secretary and the applicant. The Secretary may impose additional conditions as deemed necessary.

§ 68a.16 What other regulations and statutes apply?

Several other regulations and statutes apply to this part. These include, but are not necessarily limited to:

Debt Collection Act of 1982, Pub. L. 97-365 (5 U.S.C. 5514);

Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*);

Federal Debt Collection Procedures Act of 1990, Pub. L. 101-647 (28 U.S.C. 1); and Privacy Act of 1974 (5 U.S.C. 552a).

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