

subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 28, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(g), 346a and 371.

■ 2. In § 180.568, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Artichoke, globe	0.02
* * * * *	
Cabbage	0.02
Cabbage, Chinese, napa	0.02
* * * * *	
Olive	0.02
* * * * *	
Pomegranate	0.02
Prickly pear, fruit	0.07
Prickly pear, pads	0.06
* * * * *	
* * * * *	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 68

[Docket No. NIH-2008-0003]

RIN 0905-AA43

National Institutes of Health Loan Repayment Programs

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: As a part of the Department of Health and Human Services (HHS)'s ongoing retrospective review initiative,

the National Institutes of Health (NIH) is rescinding the existing regulations for two of its eight loan repayment programs and issuing in their place a new consolidated set of regulations governing all of the NIH Loan Repayment Programs (LRPs). There are currently eight programs, including three for researchers employed by the NIH (Intramural LRPs) and five for non-NIH scientists (Extramural LRPs). The Intramural LRPs include the Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome (or AIDS Research LRP); Loan Repayment Program for General Research (or General Research LRP), which includes a program for the Accreditation Council for Graduate Medical Education (ACGME) Fellows; and Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds). The Extramural LRPs include the Loan Repayment Program for Contraception and Infertility Research (or Contraception and Infertility Research LRP); Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds); Loan Repayment Program for Clinical Research (or Clinical Research LRP); Loan Repayment Program for Pediatric Research (or Pediatric Research LRP); and Loan Repayment Program for Health Disparities Research (or Health Disparities Research LRP).

DATES: This final rule is effective May 6, 2013.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20892; by email at MooreJ@mail.nih.gov; by fax on 301-402-0169 (not a toll-free number); or by telephone 301-496-4607 (not a toll-free number) for information about the rulemaking process. For program information, contact: NIH Division of Loan Repayment by email lrp@nih.gov or telephone 866-849-4047. For information regarding the requirements, the application deadline dates, and an online application for the NIH Loan Repayment Programs, refer to the NIH Loan Repayment Program Web site, www.lrp.nih.gov.

SUPPLEMENTARY INFORMATION: On November 4, 1988, Congress enacted the Health Omnibus Programs Extension of 1988, (Pub. L. 100-607). Title VI of this law amended the Public Health Service (PHS) Act by adding section 487A (42

U.S.C. 288–1) entitled Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome. Subsequently, in the NIH Revitalization Act of 1993 (Pub. L. 103–43), Congress enacted the Loan Repayment Program for Research with Respect to Contraception and Infertility (section 487B; 42 U.S.C. 288–2); the Loan Repayment Program for Research Generally (section 487C; 42 U.S.C. 288–3); and the Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (section 487E; 42 U.S.C. 288–5). The Children’s Health Act of 2000 (Pub. L. 106–310), which was enacted on October 17, 2000, added the Pediatric Research Loan Repayment Program (section 487F; ¹ 42 U.S.C. 288–6). On November 13, 2000, the Clinical Research Enhancement Act, contained in the Public Health Improvement Act of 2000 (Pub. L. 106–505), enacted the Loan Repayment Program for Clinical Research (section 487F; ² 42 U.S.C. 288–5a). On November 22, 2000, the Minority Health and Health Disparities Research and Education Act of 2000 (Pub. L. 106–525) enacted the Loan Repayment Program for Health Disparities Research (section 485G, re-designated 464z–5 by Pub. L. 111–148; ³ 42 U.S.C. 285t–2).

Sections 487A, 487B, 487C, 487E, and 487F of the PHS Act authorize the Secretary of Health and Human Services to enter into contracts with qualified health professionals under which such professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$35,000 of the principal and interest of the qualified educational loans of such professionals. Section 464z–5 authorizes the Director, National Institute on Minority Health and Health Disparities (NIMHD) to do the same.

In return for these loan repayments, applicants must agree to participate in qualifying research for an initial period of not less than two years (or a minimum of three years for the General Research LRP) as one of the following:

(a) An NIH employee (for Intramural LRPs), or

(b) A health professional engaged in qualifying research supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local).

The purpose of the LRP programs is to recruit and retain highly qualified health professionals as biomedical and behavioral researchers. LRP programs offer educational loan repayment for participants who agree, by written contract, to engage in qualifying domestic nonprofit-supported research at a qualifying non-NIH institution, or as an NIH employee, for a minimum of two years (or three years for the Intramural General Research LRP).

Currently, the Clinical Research LRP for Individuals from Disadvantaged Backgrounds and the Contraception and Infertility Research LRP are governed by their own individual regulations while the other LRPs are without regulations. We are consolidating the regulations into a single set of regulations governing all the LRPs. More specifically, we are rescinding the current regulations codified at 42 CFR Part 68a, entitled “National Institutes of Health Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR–LRP),” and 42 CFR Part 68c, entitled “National Institute of Child Health and Human Development Contraception and Infertility Research Loan Repayment Program,” and issuing a new consolidated set of regulations at 42 CFR Part 68, entitled “National Institutes of Health Loan Repayment Programs (LRPs),” to govern each of the eight individual NIH Loan Repayment Programs, the three that are for researchers employed by the NIH (Intramural LRPs) and the five that are for non-NIH scientists (Extramural LRPs). The three Intramural LRPs include the AIDS Research LRP, General Research LRP, and Clinical Research LRP for Individuals from Disadvantaged Backgrounds. The five Extramural LRPs include the Contraception and Infertility Research LRP, Clinical Research LRP for Individuals from Disadvantaged Backgrounds, Clinical Research LRP, Pediatric Research LRP, and Health Disparities Research LRP.

We announced our intentions to take these rulemaking actions in the notice of proposed rulemaking (NPRM) “National Institutes of Health Loan Repayment Programs,” that we published in the **Federal Register** on February 22, 2012 (77 FR 10455–10461). In the NPRM we provided a 60-day public comment

period. The public comment period expired April 23, 2012. We received only one public comment. Because the comment did not address the regulations per se, but simply questioned the need for any loan repayment, we did not view the comment as relevant to this rulemaking action. Consequently, the final NIH LRP regulations that are set forth in this final rule are essentially identical to the proposed regulations that we set forth in the NPRM. We provide the following as public information.

Regulatory Impact Analysis

We have examined the impacts of this rule as required by E.O. 12866, “Regulatory Planning and Review” (September 30, 1993), E.O. 13563, “Improving Regulation and Regulatory Review” (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and E.O. 13132, “Federalism” (August 4, 1999).

Executive Order 12866

E.O. 12866, as supplemented by Executive Order 13563, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). Based on our analysis, we believe the rulemaking does not constitute an economically significant regulatory action.

The Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For the purpose of this analysis, small entities include small business concerns as defined by the Small Business Administration (SBA), usually businesses with fewer than 500 employees. Applicants who are eligible to apply for the loan repayment awards are individuals, not small entities. The Secretary certifies that this rule will not have a significant impact on a significant number of small entities.

¹ So in law. There are two sections 487F. Section 1002(b) of Public Law 106–310 (114 Stat. 1129), inserted section 487F above. Subsequently, section 205 of Public Law 106–505 (114 Stat. 2329), which relates to the Loan Repayment Program for Clinical Researchers, inserted a section 487F after section 487E.

² 205 of Public Law 106–505 (114 Stat. 2329), inserted section 487F after section 487E. Previously, section 1002(b) of Public Law 106–310 (114 Stat. 1129), which relates to the Pediatric Research Loan Repayment Program, inserted section 487F after section 487E.

³ Section 485G of the PHS Act, enacted by Public Law 106–525, was redesignated section 464z–5 by Public Law 111–148.

Section 202(a) of the Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement that includes an assessment of anticipated costs and benefits before proposing “any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal organizations, in the aggregate, or by the private sector, of “\$100,000,000 or more (adjusted annually for inflation with base year of 1995) in any one year.” The current inflation-adjusted threshold for 2012 is approximately \$145.5 million. The Secretary certifies that this rule does not mandate any spending by State, local or tribal government in the aggregate or by the private sector. Participation in the NIH loan repayment programs is voluntary and not mandated.

Executive Order 13132

E.O. 13132, Federalism, requires that Federal agencies consult with state and local government officials in the development of regulatory policies with federalism implications. We reviewed the rule as required under the Order, and determined that it does not have “federalism implications” because it will not have substantial direct effect on the states, the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, under E.O. 13132, no further Agency action or analysis is required.

Paperwork Reduction Act

This proposed rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 35). More specifically, § 68.6 of this rule is a reporting requirement, but the specifics of the burden are determined in the approved application forms used by the NIH Loan Repayment Programs and have been approved under OMB No. 0925–0361, Expiration Date: June 30, 2014. Additionally, §§ 68.3(c), 68.3(e), 68.11(c), 68.14(c), 68.14(d), and 68.16(a) of this rule are reporting requirements and/or recordkeeping requirements, but they are also covered under OMB No. 0925–0361.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered programs affected by the proposed regulations are:

- 93.209—Contraception and Infertility Research Loan Repayment Program
- 93.220—Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
- 93.232—Loan Repayment Program for General Research
- 93.280—NIH Loan Repayment Program for Clinical Researchers
- 93.285—NIH Pediatric Research Loan Repayment Program
- 93.307—Minority Health and Health Disparities Research
- 93.308—Extramural Loan Repayment for Individuals from Disadvantaged Backgrounds Conducting Clinical Research
- 93.936—NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program

List of Subjects

42 CFR Parts 68, 68a, and 68c

Health professions, Loan repayment programs—health, Medical research.

For reasons presented in the preamble, and under the authority of 5 U.S.C 301 and 42 U.S.C. 216, HHS amends Title 42 of the Code of Federal Regulations by removing parts 68a and 68c and adding part 68 to read as follows:

PART 68—NATIONAL INSTITUTES OF HEALTH (NIH) LOAN REPAYMENT PROGRAMS (LRPs)

Sec.

- 68.1 What is the scope and purpose of the NIH LRPs?
- 68.2 Definitions.
- 68.3 Who is eligible to apply?
- 68.4 Who is eligible to participate?
- 68.5 Who is ineligible to participate?
- 68.6 How do individuals apply to participate in the NIH LRPs?
- 68.7 How are applicants selected to participate in the NIH LRPs?
- 68.8 What do the NIH LRPs provide to participants?
- 68.9 What loans qualify for repayment?
- 68.10 What loans are ineligible for repayment?
- 68.11 What does an individual have to do in return for loan repayments received under the NIH LRPs?
- 68.12 How does an individual receive loan repayments beyond the initial applicable contract period?
- 68.13 What will happen if an individual does not comply with the terms and conditions of participation in the NIH LRPs?
- 68.14 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?
- 68.15 When can an NIH LRP payment obligation be discharged in bankruptcy?
- 68.16 Additional conditions.
- 68.17 What other regulations and statutes apply?

Authority: 42 U.S.C. 254o, 42 U.S.C. 288–1, 42 U.S.C. 288–2, 42 U.S.C. 288–3, 42

U.S.C. 288–5, 42 U.S.C. 288–5a, 42 U.S.C. 288–6, 42 U.S.C. 285t–2.

§ 68.1 What are the scope and purpose of the NIH LRPs?

The regulations of this part apply to the award of educational loan payments authorized by sections 487A, 487B, 487C, 487E, 487F,¹ and 464z–5 of the Public Health Service Act (42 U.S.C. 288–1, 42 U.S.C. 288–2, 42 U.S.C. 288–3, 42 U.S.C. 288–5, 42 U.S.C. 288–5a, 42 U.S.C. 288–6, 42 U.S.C. 285t–2). The purpose of these programs is to address the need for biomedical and behavioral researchers by providing an economic incentive to appropriately qualified health professionals who are engaged in qualifying research supported by domestic nonprofit funding or as employees of the NIH. The NIH Loan Repayment Programs include eight separate programs, three that are Intramural (for NIH researchers) and five that are Extramural (for non-NIH researchers).

(a) The Intramural LRPs include:

(1) Loan Repayment Program for Research with Respect to Acquired Immune Deficiency Syndrome (or AIDS Research LRP);

(2) Loan Repayment Program for General Research (or General Research LRP), including a program for Accreditation Council for Graduate Medical Education (ACGME) Fellows; and

(3) Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds). This program is also included as a separate program under the Extramural LRPs.

(b) The Extramural LRPs include:

(1) Loan Repayment Program for Contraception and Infertility Research (or Contraception and Infertility Research LRP);

(2) Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds (or Clinical Research LRP for Individuals from Disadvantaged Backgrounds);

(3) Loan Repayment Program for Clinical Researchers (or Clinical Research LRP);

(4) Loan Repayment Program for Pediatric Research (or Pediatric Research LRP); and

(5) Loan Repayment Program for Health Disparities Research (or Health Disparities Research LRP).

¹ There are two sections 487F. Section 1002(b) of Public Law 106–310 added section 487F, 42 U.S.C. 288–6, the Pediatric Research Loan Repayment Program. Subsequently, section 205 of Public Law 106–505 also added section 487F, 42 U.S.C. 288–5a, enacting the Loan Repayment Program for Clinical Researchers.

§ 68.2 Definitions.

As used in this part:

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

AIDS Research means research activities related to the Acquired Immunodeficiency Syndrome that qualify for inclusion in the AIDS Research LRP.

Applicant means an individual who applies to and meets the eligibility criteria for the NIH LRPs.

Breach of contract results when a participant fails to complete the research service or other obligation(s) required under the contract and may be subject to assessment of monetary damages and penalties as defined by statute.

Clinical research is patient-oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

Commercial loans means loans made for educational purposes by banks, credit unions, savings and loan associations, not-for-profit organizations, insurance companies, schools, and other financial or credit institutions that 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.

Contraception research is defined as research with the ultimate goal of providing new or improved methods of preventing pregnancy.

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 means the minimum amount of qualified educational debt an individual must have, on their program eligibility date, in order to be eligible for LRP benefits, as established by the Secretary.

Director means the Director of the National Institute on Minority Health and Health Disparities (NIMHD) or designee.

Educational expenses means the cost of the health professional's undergraduate, graduate, and health

professional school's education, including the tuition expenses and other educational expenses such as living expenses, fees, books, supplies, educational equipment and materials, and laboratory expenses.

Extramural LRPs refers to those programs for which health professionals, who are not NIH employees and have program-specified degrees and domestic nonprofit support, are eligible to apply. The Extramural LRPs include:

(1) Contraception and Infertility Research LRP;

(2) Clinical Research LRP for Individuals from Disadvantaged Backgrounds;

(3) Clinical Research LRP;

(4) Pediatric Research LRP; and

(5) Health Disparities Research LRP.

General research pertains to research that falls within the basic science or clinical research parameters and is not targeted toward a specific area (e.g., AIDS) or type of research (e.g., clinical research). The focus is on biomedical and behavioral research studies and investigations across a variety of scientific disciplines within the mission of the NIH.

Government loans means educational loans made by U.S. Federal, state, county, or city agencies that are authorized by law to make such loans.

Health disparities population: a population is a health disparity population if, as determined by the Director after consultation with the Director of the Agency for Healthcare Research and Quality, there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

Individual from disadvantaged background. (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 HHS programs. The Secretary periodically publishes these income levels in the **Federal Register**.

Infertility research is defined as research with the long-range objective of evaluating, treating, or ameliorating conditions that result in the failure of couples to either conceive or bear young.

Institute or Center (IC) means an Institute or Center of the National Institutes of Health (NIH).

Intramural LRPs refers to those programs for which applicants must be employed by the NIH. The intramural LRPs include:

(1) AIDS Research LRP;

(2) General Research LRP; and

(3) Clinical Research LRP for Individuals from Disadvantaged Backgrounds.

Institutional base salary or salary is the annual income or compensation that the organization pays for the applicant's appointment, whether the time is spent on research, teaching, patient care, or other activities.

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 and is part of the educational loan.

Loan Repayment Programs (LRPs) refers to the NIH Loan Repayment Programs, including those authorized by sections 487A, 487B, 487C, 487E, 487F, and 464z-5 of the Act, as amended.

Loan Repayment Program contract refers to the agreement signed by an applicant and the Secretary or Director (for the following extramural LRPs: Health Disparities Research LRP and Clinical Research LRP for Individuals from Disadvantaged Backgrounds only). Under such an agreement, an Intramural LRP applicant agrees to conduct qualified research as an NIH employee, and an Extramural LRP applicant agrees to conduct qualified research supported by domestic nonprofit funding, in exchange for repayment of the applicant's qualified educational loan(s) for a prescribed period.

NIH refers to the National Institutes of Health.

Nonprofit funding/support: applicants must conduct qualifying research supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local). A domestic foundation, professional association, or institution is considered to be nonprofit if exempt from Federal tax under the provisions of Section 501 of the Internal Revenue Code (26 U.S.C. 501).

Participant means an individual whose application to any of the NIH LRPs has been approved and whose Program contract has been executed by the Secretary or the Director.

Pediatric research is defined as research directly related to diseases, disorders, and other conditions in

children, including pediatric pharmacology.

Program refers to the NIH Loan Repayment Program, or LRP.

Program eligibility date means the date on which an individual's LRP contract is executed by the Secretary or the Director.

Qualified Educational Loans and Interest/Debt (see *Educational Expenses*) as established by the Secretary, 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 that 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 that 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 proportion, as established by the Secretary, of an individual's total qualified educational debt that can be paid by an NIH LRP.

Salary has the same meaning as *institutional base salary*.

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

Secretary means the Secretary of Health and Human Services or designee.

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 Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Waiver means a waiver of the service obligation granted by the Secretary when compliance by the participant is impossible or would involve extreme hardship, or where enforcement with respect to the individual would be unconscionable. (See *Breach of contract*.)

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.

§ 68.3 Who is eligible to apply?

To be eligible for consideration for the NIH LRPs, applicants must meet the following criteria:

(a) Be citizens, nationals, or permanent residents of the United States;

(b) Have the necessary degree from an accredited institution as determined by the NIH to be consistent with the needs of the LRP;

(c)(1) For Intramural LRPs only: Applicants must be employed by the NIH and engage in qualified full-time research as specified by the LRP and be recommended by the employing IC or have a firm commitment of employment from an authorized official of the NIH;

(2) For Extramural LRPs only: Applicants must be conducting qualified research for an average of at least 20 hours per week that is supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local);

(d) Have total qualifying educational loan debt as determined on the program eligibility date;

(e) The NIH or the employing institution must provide an assurance that the applicant will be employed/appointed and provided research support for the applicable term of the LRP contract; and

(f) Recipients of LRP awards must conduct their research in accordance with applicable Federal, state, and local law (e.g., applicable human subject protection regulations).

(g) For Clinical Research for Individuals from Disadvantaged Background only: Individual must be from a disadvantaged background. (See § 68.2, Definitions, *Individual from disadvantaged background*.)

§ 68.4 Who is eligible to participate?

To be eligible to participate in the NIH LRPs, individuals must:

(a) Meet the eligibility requirements specified in § 68.3 of this part;

(b) Not be ineligible for participation as specified in § 68.5 of this part;

(c) Engage in qualified research for the contractual period;

(d) Engage in such research for the percentage of time specified for the particular LRP; and

(e) Comply with all other terms and conditions of the applicable Loan Repayment Program.

§ 68.5 Who is ineligible to participate?

The following individuals are ineligible for NIH LRP participation:

(a) Persons who do not meet the eligibility requirements as specified under § 68.3 of this part;

(b) Any individual who has or had a Federal judgment lien against his/her property arising from Federal debt;

(c) Persons who owe an obligation of health professional service to the Federal Government, a state, or other entity, unless deferrals or extensions are granted for the length of the service of their LRP contract. The following are examples of programs that have a service obligation:

(1) Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program,

(2) Exceptional Financial Need (EFN) Scholarship Program,

(3) Financial Assistance for Disadvantaged Health Professions Students (FADHPS),

(4) Indian Health Service (IHS) Scholarship Program,

(5) National Health Service Corps (NHSC) Scholarship Program,

(6) National Research Service Award (NRSA) Program, and/or Loan Repayment Programs, NURSE Corps Scholarship and Loan Repayment Programs,

(7) NIH Undergraduate Scholarship Program (UGSP),

(8) Physicians Shortage Area Scholarship Program,

(9) Primary Care Loan (PCL) Program, and

(10) Public Health Service Scholarship (PHS) Program;

(d) For extramural LRPs only: Individuals who receive any research funding support or salary from a for-profit institution or organization, or Federal Government employees working more than 20 hours per week;

(e) Current recipients of NIH intramural training awards, e.g., NIH Intramural Research Training Awards (IRTA) or Cancer Research Training Awards (CRTA);

(f) Individuals conducting research for which funding is precluded by Federal law, regulation, or HHS/NIH policy or that does not comply with applicable Federal, state, and local law regarding the conduct of the research (e.g.,

applicable human subject protection regulations);

(g) Individuals with only ineligible loans or loans that are not educational; and

(h) Individuals who do not have sufficient qualifying educational debt to meet the debt threshold.

§ 68.6 How do individuals apply to participate in the NIH LRPs?

An application for participation in an NIH LRP shall be submitted to the NIH, which is responsible for the Program's administration, in such form and manner as the Secretary prescribes.

§ 68.7 How are applicants selected to participate in the NIH LRPs?

The NIH LRP awards are competitive. To be selected for participation in an NIH LRP, applicants must satisfy the following requirements:

(a) Applicants must meet the eligibility requirements specified in §§ 68.3 and 68.4 of this part.

(b) Applicants must not be ineligible for participation as specified in § 68.5 of this part.

(c) Upon receipt, applications for any of the NIH LRPs will be reviewed for eligibility and completeness by the NIH Division of Loan Repayment. Incomplete or ineligible applications will not be processed or reviewed further.

(d)(1) Applications for the Intramural LRPs that are deemed eligible and complete are submitted to the Loan Repayment Committee (LRC), which reviews, ranks, and approves/disapproves LRP awards. The LRC is composed of senior intramural scientists, including basic (bench) and clinical researchers and science policy administrators. Since LRP participation in the Intramural programs is contingent upon NIH employment, applicants must be recommended by the employing IC of the NIH to be considered by the LRC.

(2) Applications for the Extramural LRPs that are deemed eligible and complete will be referred by the NIH Center for Scientific Review (CSR) to an appropriate NIH IC for peer review. In evaluating the application, reviewers are directed to consider the following components and how they relate to the likelihood that the applicant will continue in a research career:

(i) Applicant's potential to pursue a career in research as defined by the appropriate LRP:

(A) Appropriateness of the applicant's previous training and experience to prepare for a research career.

(B) Appropriateness of the proposed research activities during the LRP contract to foster a career in research.

(C) Commitment to a research career, as reflected by the personal statement of long-term career goals and plan to achieve those goals.

(D) Strength of the letters of recommendations attesting to the applicant's potential for a successful career in research.

(ii) Quality of the overall environment to prepare the applicant for a research career:

(A) Quality and availability of appropriate scientific mentors and colleagues to help achieve or enhance the applicant's research independence, including the mentors' record in mentoring researchers, funding history, and research productivity.

(B) Quality and appropriateness of institutional resources and facilities.

(iii) For the Health Disparities Research LRP, at least 50 percent of the contracts are required by statute to be for appropriately qualified health professionals who are members of a health disparity population.

§ 68.8 What do the NIH LRPs provide to participants?

(a) Loan repayments: For each year of the applicable service period the individual agrees to serve, the NIH may pay up to \$35,000 per year of a participant's repayable debt.

(b) Payments are made directly to a participant's lender(s). If there is more than one outstanding qualified educational loan, the NIH will repay the loans in the following order, unless the NIH determines significant savings would result from paying loans in a different order of priority:

(1) Loans guaranteed by the U.S. Department of Health and Human Services;

(2) Loans guaranteed by the U.S. Department of Education;

(3) Loans made or guaranteed by a state;

(4) Loans made by a school; and

(5) Loans made by other entities.

(c) Tax liability payments: In addition to the loan repayments, the NIH shall make tax payments in an amount equal to 39 percent of the total annual loan repayment to the Internal Revenue Service on the participant's behalf. The NIH may make additional payments to those participants who show increased Federal, State, and/or local taxes as a result of loan repayments.

(d) Under paragraphs (a), (b), and (c) of this section, the NIH will make loan and tax liability payments to the extent appropriated funds are available for these purposes.

§ 68.9 What loans qualify for repayment?

The NIH LRPs will repay participants' lenders the principal, interest, and

related expenses of qualified U.S. Government and commercial educational loans obtained by participants for the following:

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

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

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

§ 68.10 What loans are ineligible for repayment?

The following loans are ineligible for repayment under the NIH LRPs:

(a) Loans not obtained from a bank, credit union, savings and loan association, not-for-profit organization, insurance company, school, and other financial or credit institution that is subject to examination and supervision in its capacity as a lending institution by an agency of the United States or of the state in which the lender has its principal place of business;

(b) Loans for which supporting documentation is not available;

(c) Loans that have been consolidated with loans of other individuals, such as spouses or children;

(d) Loans or portions of loans obtained for educational or living expenses that 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 NIH to be reasonable based on additional documentation provided by the individual;

(e) Loans, financial debts, or service obligations incurred under the following programs, or similar programs, which provide loans, scholarships, loan repayments, or other awards in exchange for a future service obligation:

(1) Armed Forces (Army, Navy, or Air Force) Professions Scholarship Program,

(2) Exceptional Financial Need (EFN) Scholarship Program,

(3) Financial Assistance for Disadvantaged Health Professions Students (FADHPS),

(4) Indian Health Service Scholarship Program,

(5) National Health Service Corps Scholarship Program,

(6) National Institutes of Health Undergraduate Scholarship Program (UGSP),

(7) National Research Service Award (NRSA) Program,

(8) Physicians Shortage Area Scholarship Program;

(9) Primary Care Loans (PCL), and

(10) Public Health Service Scholarship Program;

(f) Any loan in default, delinquent, or not in a current payment status;

(g) Any Federal educational loan debt—including debt arising from the conversion of a service obligation to a loan—that has been in default or written off as uncollectible is ineligible for repayment under the Program, even if currently considered to be in good standing;

(h) Loan amounts that participants were due to have been paid prior to the LRP contract start date;

(i) Parents PLUS loans (except the Graduate PLUS loans for students);

(j) Loans for which promissory notes have been signed after the LRP contract start date (with the exception of qualifying student loan consolidations); and

(k) Home equity loans or other noneducational loans.

§ 68.11 What does an individual have to do in return for loan repayments received under the NIH LRPs?

Individuals must agree to:

(a) Engage in qualified research for the applicable contract service period;

(b)(1) For Intramural LRPs: Engage in such research full-time as employees of NIH, or;

(2) For Extramural LRPs: Engage in such research for an average of 20 hours per week supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local);

(c) Keep all loan accounts in good standing, provide timely documentation as needed, including payment verification, service verification, change of research, change of institution, etc. Failure to provide such documentation may result in early termination, and the individual may be subject to statutory financial penalties; and

(d) Satisfy all of the other terms and conditions of the LRP and the LRP Contract (e.g., Obligations of the Participant). Failure to adhere to the terms and conditions of the LRP contract may result in early termination, and the individual may be subject to statutory financial penalties.

§ 68.12 How does an individual receive loan repayments beyond the initial applicable contract period?

An individual may apply for a competitive extension contract for at least a one-year period if the individual

is engaged in qualifying research and satisfies the eligibility requirements specified under §§ 68.3 and 68.4 of this part for the extension period and has remaining repayable debt as established by the Secretary.

§ 68.13 What will happen if an individual does not comply with the terms and conditions of participation in the NIH LRPs?

Program participants who breach their Loan Repayment Program Contracts will be subject to the applicable monetary payment provisions set forth at section 338E of the Act (42 U.S.C. 254o).

Payment of any amount owed under section 338E of the Act shall be made within one year of the date the participant breached his or her Loan Repayment Program Contract, unless the NIH specifically authorizes a longer period. Terminations will not be considered a breach of contract in cases where such terminations are beyond the control of the participant as follows:

(a) Terminations for convenience of the government will not be considered a breach of contract and monetary damages will not be assessed.

(b) Occasionally, a participant's research assignment or funding may evolve and change to the extent that the individual is no longer engaged in approved research. Similarly, the research needs and priorities of the IC and/or the NIH may change to the extent that a determination is made that a health professional's skills may be better utilized in a nonresearch assignment. Normally, job changes of this nature will not be considered a breach of contract on the part of either the NIH or the participant. Under these circumstances, the following will apply:

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

(2) Based on the approval of the NIH, the participant will be released from the remainder of his or her service obligation without assessment of damages or monetary penalties. The participant in this case will be permitted to retain all Program benefits made or owed by the NIH on his/her behalf up to the date the individual is no longer engaged in research, less the pro rata portion of any benefits advanced beyond the period of completed service.

§ 68.14 Under what circumstances can the service or payment obligation be canceled, waived, or suspended?

(a) Any obligation of a participant for service or payment will be canceled upon the death of the participant.

(b)(1) The NIH may waive or suspend any service or payment obligation

incurred by the participant upon request whenever compliance by the participant:

- (i) Is impossible;
- (ii) Would involve extreme hardship to the participant; or
- (iii) If enforcement of the service or payment obligation would be unconscionable.

(2) The NIH may approve a request for a suspension of the service or payment obligations for a period of up to one (1) year.

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

§ 68.15 When can an NIH LRP payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68.13 of this part may be discharged in bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the seven-year period beginning on the first date that payment is required and only if the bankruptcy court finds that a non-discharge of the obligation would be unconscionable.

§ 68.16 Additional conditions.

(a) When a shortage of funds exists, participants may be funded only partially, as determined by the NIH. However, once an NIH LRP contract has been signed by both parties, the NIH 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, the parties specify otherwise.

(b) Additional conditions may be imposed as deemed necessary.

§ 68.17 What other regulations and statutes apply?

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

(a) Debt Collection Act of 1982 (31 U.S.C. 3701 note);

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

(c) Federal Debt Collection Procedures Act of 1990 (28 U.S.C. 176); and

(d) Privacy Act of 1974 (5 U.S.C. 552a).

Dated: January 16, 2013.

Francis S. Collins,

Director, National Institutes of Health.

Approved: March 27, 2013.

Kathleen Sebelius,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 60 and 61

RIN 0906-AA87

National Practitioner Data Bank

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises existing regulations under sections 401–432 of the Health Care Quality Improvement Act of 1986 and section 1921 of the Social Security Act, governing the National Practitioner Data Bank, to incorporate statutory requirements under the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). The Department of Health and Human Services (HHS) also is removing regulations which implemented the Healthcare Integrity and Protection Data Bank. Section 6403 of the Affordable Care Act, the statutory authority for this regulatory action, was designed to eliminate duplicative data reporting and access requirements between the Healthcare Integrity and Protection Data Bank (HIPDB) (established under section 1128E of the Social Security Act) and the National Practitioner Data Bank (NPDB). It requires the Secretary to establish a transition period to transfer all data in the Healthcare Integrity and Protection Data Bank to the National Practitioner

Data Bank, and, once completed, to cease operations of the Healthcare Integrity and Protection Data Bank. Information previously collected and disclosed to eligible parties through the HIPDB will then be collected and disclosed to eligible parties through the NPDB. This regulatory action consolidates the collection and disclosure of information from both data banks into one part of the CFR.

DATES: The effective date of this rule is May 6, 2013.

FOR FURTHER INFORMATION CONTACT: Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 8-103, Rockville, MD 20857; telephone number: (301) 443-2300.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Authorities Governing the Data Banks

The paragraphs below provide a summary of the legal authorities governing the NPDB and the HIPDB.

(1) The Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.)

The NPDB was established by the Health Care Quality Improvement Act of 1986 (HCQIA), as amended (42 U.S.C. 11101 et seq.). The HCQIA authorizes the NPDB to collect reports of adverse licensure actions against physicians and dentists (including revocations, suspensions, reprimands, censures, probations, and surrenders); adverse clinical privileges actions against physicians and dentists; adverse professional society membership actions against physicians and dentists; Drug Enforcement Administration (DEA) certification actions; Medicare/Medicaid exclusions; and medical malpractice payments made for the benefit of any health care practitioner. Organizations that have access to this data system include hospitals, other health care entities that have formal peer review processes and provide health care services, state medical or dental boards and other health care practitioner state boards. Individual practitioners may self-query. Information under the HCQIA is reported by medical malpractice payers, state medical and dental boards, professional societies with formal peer review, and hospitals and other health care entities (such as health maintenance organizations).

(2) Section 1921 of the Social Security Act (42 U.S.C. 1396r-2) (Prior to the Passage of the Affordable Care Act)

Section 1921 of the Social Security Act (herein referred to as section 1921), as amended by section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, and as amended by the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508, expanded the scope of the NPDB. Section 1921 requires each state to adopt a system for reporting to the Secretary certain adverse licensure actions taken against health care practitioners and entities by any authority of the state responsible for the licensing of such practitioners or entities. It also requires each state to report any negative action or finding that a state licensing authority, a peer review organization, or a private accreditation entity had taken against a health care practitioner or health care entity.

Groups with access to this information include all organizations eligible to query the NPDB under the HCQIA (hospitals, other health care entities that have formal peer review and provide health care services, state medical or dental boards, and other health care practitioner state boards), other state licensing authorities, agencies administering government health care programs (including private entities administering such programs under contract), state agencies administering or supervising the administration of government health care programs, state Medicaid fraud control units, certain law enforcement agencies, and utilization and quality control Quality Improvement Organizations (QIOs). Individual health care practitioners and entities may self-query. Information under section 1921 is reported by state licensing and certification authorities, peer review organizations, and private accreditation entities.

Final regulations implementing section 1921 were issued on January 28, 2010 (75 FR 4656). The NPDB began collecting and disclosing section 1921 information on March 1, 2010.

(3) Section 1128E of the Social Security Act (42 U.S.C. 1320a-7e) (Prior to the Passage of the Affordable Care Act)

Section 1128E of the Social Security Act (herein referred to as section 1128E), as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, directed the Secretary to establish and maintain a national health care fraud and abuse data collection