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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 68b

RIN 0925-AA10

[Docket No. NIH-2007-0930]

National Institutes of Health Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH), through the Department of Health and Human Services (HHS), is issuing regulations to implement provisions of the Public Health Service Act authorizing the NIH Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes (UGSP). The purpose of the program is to recruit appropriately qualified undergraduate students from disadvantaged backgrounds to conduct research in the intramural research program as employees of the NIH by providing scholarship support.

DATES: This final rule is effective [*Federal Register*: insert the date 30 days following the date of publication].

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville MD 20852; by email at jm40z@nih.gov; by fax on 301-402-0169 (not a toll-free number); or by telephone on 301-496-4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On June 10, 1993, the NIH Revitalization Act of 1993 (Public Law 103-43) was enacted. Section 1631 of this law amended the Public Health Service (PHS) Act by adding section 487D (42 U.S.C. 288-4). Section 487D authorizes the Secretary, acting through the Director of the NIH, to carry out a program of entering into contracts with individuals under which the Director agrees to provide scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the NIH. In return, the individuals agree to serve as employees of the NIH in positions that are needed by the NIH and for which the individuals are qualified. The individuals must be enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education and must be from disadvantaged backgrounds. Section 487D of the PHS Act further states that, concerning penalties for breach of scholarship contract, the provisions of section 338E of the PHS Act shall apply to the program to the same extent

and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 338B.

The 1993 amendment of the PHS Act led to the establishment of the UGSP. The purpose of the program, since it began selecting participants in 1997, is to recruit appropriately qualified undergraduate students from disadvantaged backgrounds to conduct research in the intramural research program as employees of the NIH by providing scholarship support. The UGSP provides a diverse and highly qualified cadre of individuals seeking careers compatible with NIH employment opportunities.

The NIH is amending title 42 of the Code of Federal Regulations by adding Part 68b governing the administration of the UGSP. This final rule establishes program regulations necessary to implement and enforce important aspects of the UGSP. In general, this final rule specifies the scope and purpose of the program, the eligibility criteria, the application process, the selection criteria, and the terms and conditions of the program.

The rationale used by the NIH in developing the eligibility and selection criteria of this final rule is explained as follows. For eligibility, the definition for “Individual from Disadvantaged Background” used in section § 68b.2 of this proposed rule is the same definition used for other similar programs in HHS such as the NIH Loan Repayment Program and the Health Resources and Services Administration Scholarships for Disadvantaged Students Program. That is, an individual from a disadvantaged background, as section § 68b.2 states, means “an individual who: (1) comes from an environment that inhibited (but did not prevent) him or her from obtaining the

knowledge, skills, and abilities required to enroll in an undergraduate institution; or (2) comes from a family with an annual income below established low-income thresholds. These low-income thresholds are based on 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.” Previously, the UGSP used this definition, but switched to another definition that did not take into consideration any other factors other than economics in defining “Individual from a Disadvantaged Background.” The program used that approach for several UGSP cycles and noted a decrease in the qualifications of applicants. The NIH believes that returning to the original definition, stated above, will ensure the largest, most diverse pool of applicants for the UGSP.

Regarding selection criteria, the applications are prioritized in § 68b.5 to give preference to students that have already completed two years of undergraduate studies and have excellent grades in the core science courses because the NIH wants to ensure a pool of candidates that likely possess the traits required to complete their undergraduate training and their required service obligation to the NIH.

The NIH announced its intentions to take this rulemaking action, through HHS, in the notice of proposed rulemaking (NPRM) titled “National Institutes of Health Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes” published in the Federal Register on May 28, 2014 (79 FR 30531-30535). In the NPRM we provided a sixty day public comment period. The comment period expired July 28, 2014. We received a total of two comments. One respondent

questioned the need for the program, and expressed concerns about the impact of government spending on taxpayers. This respondent stated that the program was “an unnecessary gouging of taxpayers” and that “graduate students can pay their own way and do not need to be coddled by taking tax dollars from working people making \$30,000 a year.” We disagree with these comments and did not consider other comments made by the respondent as relevant because the comments did not specifically address the proposed regulations. The UGSP does not provide scholarship support to graduate or professional school students. Furthermore, for the past 15 years, the UGSP has been instrumental in funding over 200 undergraduate students from disadvantaged backgrounds. With the support of the UGSP, 59 percent of these students have gone onto acquire a terminal graduate degree and 23 percent are currently pursuing terminal graduate degrees. Many of these students could not foresee completing their undergraduate academic training without UGSP support. The UGSP has been very successful at creating a very high caliber cadre of professionals who effectively support the ongoing biomedical research and public health goals of NIH.

The second respondent expressed concern that the rule might have an internal conflict between eligibility and selection criteria set forth in § 68b.2 and § 68b.5, respectively. The respondent suggested that matriculating through the first two years of undergraduate studies and achieving junior and senior class undergraduate status indicates that an individual has overcome obstacles that would have rendered the individual disadvantaged, therefore placing priority on recruiting undergraduate students

at the junior and senior year grade levels would be contradictory and it undermines the program's initiative to recruit students from disadvantaged backgrounds.

We disagree with the respondent's reasoning. Accomplishing academic success and research experience does not preclude or nullify environmental or financial disadvantage. Disadvantaged backgrounds affect individuals at a host of training levels, which is evidenced by the NIH Loan Repayment Programs and other Federal aid programs for professionals that recognize and award individuals from disadvantaged backgrounds after achieving a fair amount of success, i.e., matriculation into and graduation from professional school).

The UGSP has very specific reasons for placing priority on recruiting upperclassman candidates. First, students who have matriculated into their junior and senior years of undergraduate study have usually completed the challenging core courses required to pursue research-specific careers. Since students selected into the UGSP are under contract to maintain a minimum 3.5 GPA, this achievement minimizes the potential for attrition due to academic performance below the required eligible GPA. Additionally, this early achievement also greatly solidifies a candidate's choice to seek a research-centered career. Furthermore, these upperclassman students also are more likely already to have had a research experience, giving them an opportunity to explore whether they enjoy research and are committed to a career path where a post-graduation work commitment at NIH would be beneficial. Combined these criteria increase the UGSP's likelihood of selecting a high performing student that will complete their undergraduate studies and successfully pursue a career that involves some aspect of

social, behavioral or biomedical research. This specific pool of academically successful junior and senior undergraduate candidates also frequently meets the exceptional financial need criteria and qualifies as being from a disadvantaged background. Therefore, the eligibility criteria in § 68b.2 and the selection criteria in § 68b.5 are not in conflict, and placing priority on selecting junior and senior undergraduates allow the UGSP to accomplish the objectives of both sets of criteria.

Consequently, we did not make any changes to what we proposed in the previous NPRM in response to the two public comments that we received. The final rule is the same as what we proposed in the previous NPRM.

The following is provided as public information.

Regulatory Impact Analysis

We have examined the impacts of this final rule as required by Executive Order 12866, Regulatory Planning and Review (September 30, 1993); Executive Order 13563, Improving Regulation and Regulatory Review (January 18, 2011); the Regulatory Flexibility Act (September 19, 1980, 5 U.S.C. chapter 6); section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4); and Executive Order 13132, Federalism (August 4, 1999).

Executive Order 12866

Executive Order 12866, 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 must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Based on our analysis, we believe that the final rule is not a major rule and it will not constitute an economically significant regulatory action. Therefore, a regulatory assessment is not required.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C., chapter 6) requires agencies to analyze 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, usually businesses with fewer than 500 employees. Applicants who are eligible to apply for the UGSP are individuals and not small entities. It is certified that this final rule will not have a significant impact on a significant number of small entities. Therefore, a Regulatory Flexibility Analysis is not required.

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

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires agencies to 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 inflation-adjusted threshold for 2014 is approximately \$141 million. Participation in the UGSP is voluntary and not mandated. Therefore, it is certified that this final rule does not mandate any spending by state, local, or tribal government in the aggregate or by the private sector.

Executive Order 13132

Executive Order 13132, Federalism, requires that federal agencies consult with state and local government officials in the development of regulatory policies with federalism implications. This final rule has been reviewed as required under the Executive Order and it has been determined that the proposed rulemaking does not have any federalism implications. It is certified that this final rule will not have an effect on the States or on the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act

This final 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. chapter 35). The application and contract forms used

by the NIH Undergraduate Scholarship Program have been approved by OMB under OMB No. 0925-0299 (expires August 31, 2016).

Catalog of Federal Domestic Assistance

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

93.187 - NIH Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds

List of Subjects in 42 CFR Part 68b

Education of disadvantaged, Health--medical research, Student aid--education

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

PART 68b--NATIONAL INSTITUTES OF HEALTH (NIH) UNDERGRADUATE SCHOLARSHIP PROGRAM REGARDING PROFESSIONS NEEDED BY NATIONAL RESEARCH INSTITUTES (UGSP)

Sec.

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Authority: 42 U.S.C. 288-4.

§ 68b.1 What is the scope and purpose of the National Institutes of Health Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes?

This part applies to the award of scholarships under the National Institutes of Health Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes, authorized by section 487D of the Public Health Service Act (42 U.S.C. 288-4), to undergraduate students attending schools, as the term is defined in this part. The purpose of this program is to help ensure an adequate supply of trained health professionals for the National Institutes of Health, which has the mission to uncover new knowledge that will lead to better health.

§ 68b.2 Definitions.

As used in this part:

Academic year means all or part of a 9-month period during which an applicant is enrolled in an undergraduate school as a full-time student.

Acceptable level of academic standing means the level at which a full-time student retains eligibility to continue in attendance under the school's standards and practices.

Act means the Public Health Service Act, as amended.

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

Application means forms that have been completed in such manner, and containing such agreements, assurances, and information, as determined to be necessary by the Director.

Approved graduate training means graduate programs leading to a doctoral-level degree (e.g., Ph.D., M.D., D.O., D.D.S., D.V.M., M.D./Ph.D., and equivalent degrees) in a profession needed by the National Institutes of Health.

Director means the Director of the National Institutes of Health or his/her designee.

Full-time student means an individual registered for a sufficient number of credit hours to be classified as full-time, as defined by the school attended.

Individual from Disadvantaged Background means:

(1) An individual who—

(i) Comes from an environment that inhibited (but did not prevent) him or her from obtaining the knowledge, skills, and abilities required to enroll in an undergraduate institution; or

(ii) Comes from a family with an annual income below established low-income thresholds.

(2) These low-income thresholds are based on 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 of Health and Human Services for use in the U.S. Department of Health and Human Services' health professions programs. The Secretary periodically publishes these income levels in the [Federal Register](#).

Scholarship Program means the National Institutes of Health Undergraduate Scholarship Program Regarding Professions Needed by National Research Institutes authorized by section 487D of the Act (42 U.S.C. 288-4).

Scholarship Program participant or participant means an individual whose application to the Scholarship Program has been approved and whose contract has been signed by the Director.

Scholarship Program Review Committee means the committee that reviews, ranks, and accepts or declines applications for Program participation. This committee also

ascertains whether a participant will be awarded continued scholarship support after his or her initial acceptance.

School means a 4-year college or university that:

- (1) Is accredited by an agency recognized by the Commission on Recognition of Post-Secondary Accreditation; and
- (2) Is located in a State.

State means one of the several U.S. States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, Guam, American Samoa, Palau, Marshall Islands, and the Federated States of Micronesia.

§ 68b.3 Who is eligible to apply for a Scholarship Program award?

(a) To be eligible for a scholarship under this part, applicants must meet the following requirements:

- (1) Applicants must be accepted for enrollment, or be enrolled, as full-time undergraduate students in a school;
 - (2) Applicants must have an overall grade point average of at least 3.5 or a 3.5 average in their major field of study (on a 4.0 scale) or be ranked within the top five percent of their current class (or those students entering, if applying in their freshman year);
 - (3) Applicants must come from a disadvantaged background as defined by § 68b.2;
 - (4) Applicants must meet the citizenship requirements for federal employment;
- and

(5) Applicants must submit an application to participate in the Scholarship Program together with a signed contract as outlined in sections 487D(a) and (f) of the Act.

(b) Any applicant who owes an obligation for service to a State or other entity under an agreement entered into before filing an application under this part is ineligible for an award unless a written statement satisfactory to the Director is submitted from the State or entity that:

(1) There is no potential conflict in fulfilling the service obligation to the State or entity and the Scholarship Program, and

(2) The Scholarship Program service obligation will be served before the service obligation for professional practice owed to the State or entity.

§ 68b.4 How is an application made for a Scholarship Program award?

Each individual desiring a scholarship under this part must submit an application (including a signed contract as required under section 487D(a) of the Act) in such form and manner as the Director may prescribe.

§ 68b.5 How will applicants be selected to participate in the Scholarship Program?

(a) General. In deciding which applications for participation in the Scholarship Program will be approved, the Director will place the applications into categories based upon the selection priorities described in paragraph (b) of this section. Except for renewal awards (see paragraph (e) of this section), the Director will then evaluate each applicant under paragraph (c) of this section.

(b) Priorities. (1) First priority will be given to applicants who have completed at least 2 years of undergraduate course work, including four core science courses, and are classified by their educational institutions as juniors or seniors as of the beginning of the academic year of scholarship. (Core science courses include, but are not limited to, biology, chemistry, physics, and calculus.)

(2) Second priority will be given to applicants who have completed four core science courses, as defined above.

(3) Third priority will be given to applicants who are matriculated freshmen or sophomores.

(c) Selection. In selecting participants and determining continuation of program support, the Director will take into consideration those factors determined necessary to ensure effective participation in the Scholarship Program. These factors may include, but are not limited to:

(1) Biomedical research experience and performance,

(2) Academic performance,

(3) Career goals, and

(4) Recommendations.

(d) Duration of Scholarship award. Subject to the availability of funds appropriated for the Scholarship Program, the Director may, at his/her discretion, award scholarships under this part for a period of one, two, or three academic years.

(e) Continuation of scholarship support. Subject to the availability of funds for the Scholarship Program, the Director may continue scholarship support if :

- (1) The participant requests a continuation of scholarship support;
- (2) The scholarship will not extend the total period of Scholarship Program support beyond 4 years; and
- (3) The participant is eligible for continued participation in the Scholarship Program, as determined by the Scholarship Program Review Committee.

§ 68b.6 What will an individual be awarded for participating in the Scholarship Program?

(a) Amount of scholarship. (1) Subject to a maximum annual award of \$20,000, a scholarship award for each school year will consist of:

- (i) Tuition;
- (ii) Reasonable educational expenses, including required fees, books, supplies, and required educational equipment;
- (iii) Reasonable living expenses for the academic year as documented in the school's financial aid budget; and
- (iv) For purposes of this section, "required fees" means those fees that are charged by the school to all students pursuing a similar curriculum, and "required educational equipment" means educational equipment that must be purchased by all students pursuing a similar curriculum at that school.

(2) The Director may enter into an agreement with the school in which the participant is enrolled for the direct payment of tuition and reasonable educational expenses on the participant's behalf.

(b) Payment of scholarship: Leave-of-absence; repeated course work. The Director will suspend scholarship payments to or on behalf of a participant if the school:

(1) Approves a leave-of-absence for the participant for health, personal, or other reasons; or

(2) Requires the participant to repeat course work for which the Director has previously made scholarship payments under § 68b.6. However, if the repeated course work does not delay the participant's graduation date, scholarship payments will continue except for any additional costs relating to the repeated course work. Any scholarship payments suspended under this paragraph will be resumed by the Director upon notification by the school that the participant has returned from the leave-of-absence or has completed the repeated course work and is pursuing as a full-time student the course of study for which the scholarship was awarded.

§ 68b.7 What does an individual have to do in return for the Scholarship Program award?

(a) General. For each academic year of scholarship support received, participants must serve as full-time employees of the National Institutes of Health:

(1) For not less than 10 consecutive weeks of each year during which the participant receives the scholarship; and

(2) For 12 months for each academic year for which the scholarship has been provided.

(b) Beginning of service. The period of obligated service under paragraph (a)(2) of this section must begin within 60 days of obtaining the undergraduate degree, except for participants who receive a deferment under § 68b.8.

§ 68b.8 Under what circumstances can the period of obligated service be deferred to complete approved graduate training?

(a) Requested deferment. Upon the request of any participant receiving an undergraduate degree, the Director may defer the beginning date of the obligated service to allow the participant to complete an approved graduate training program. Individuals desiring a deferment under this part must submit a request in such form and manner as the Director may prescribe.

(b) Altering deferment. Before altering the length or type of approved graduate training for which the period of obligated service was deferred under paragraph (a) of this section, the participant must request and obtain the Director's approval of the alteration.

(c) Additional terms of deferment. The Director may prescribe additional terms and conditions for deferment under paragraphs (a) and (b) of this section as necessary to carry out the purposes of the Scholarship Program.

(d) Beginning of service after deferment. Any participant whose period of obligated service has been deferred under paragraph (a) of this section must begin the obligated service within 30 days of the expiration of their deferment.

§ 68b.9 What will happen if an individual does not comply with the terms and conditions of participating in the Scholarship Program?

(a) When a participant fails to maintain an acceptable level of academic standing, is dismissed from the school for disciplinary reasons, or voluntarily terminates the course of study or program for which the scholarship was awarded before completing the course of study or program, the participant must, instead of performing any service obligation, pay to the United States an amount equal to all scholarship funds awarded under § 68b.6. Payment of this amount must be made within 3 years of the date the participant becomes liable to make payment under this paragraph (a).

(b) If, for any reason not specified in § 68b.11(b), a participant fails to begin or complete the period of obligated service incurred under § 68b.7, including failing to comply with the applicable terms and conditions of a deferment granted by the Director, the participant must pay to the United States an amount determined by the penalties set forth in section 487D(e) of the Act. Payment of this amount shall be made within one year of the date that the participant failed to begin or complete the period of obligated service, as determined by the Director.

§ 68b.10 When can a Scholarship Program payment obligation be discharged in bankruptcy?

Any payment obligation incurred under § 68b.9 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 nondischarge of the obligation would be unconscionable.

§ 68b.11 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 Director may waive or suspend any service or payment obligation incurred by the participant upon request whenever compliance by the participant:

(1) Is impossible, or

(2)(i) Would involve extreme hardship, and

(ii) If enforcement of the service or payment obligation would be unconscionable, as required by section 487 D(e) of the Act, 42 U.S.C. 288-4(e).

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

(d) Compliance by a participant with a service or payment obligation will be considered impossible if the Director determines, on the basis of 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 that would be necessary to comply with the obligation.

(e) 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 Director, on the basis of 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 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 begin or complete the obligation incurred.

§ 68b.12 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 et seq.);
- (b) Debt Collection Improvement Act of 1996 (31 U.S.C. 3701 note);
- (c) Fair Credit Reporting Act (15 U.S.C. 1681 et seq.);
- (d) Federal Debt Collection Procedures Act of 1990 (28 U.S.C. 176); and
- (e) Privacy Act of 1974 (5 U.S.C 552a).

Dated: March 27, 2015.

Francis S. Collins,

Director

National Institutes of Health

Approved: July 29, 2015.

Sylvia M. Burwell

Secretary

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