

Order 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in Executive Order 13132 to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of Executive Order 13132 do not apply to this rule.

#### C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

#### D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

#### E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule will not have a significant impact on a substantial number of small entities because disapprovals of SIP revisions under section 110 and subchapter I, part D of the Clean Air Act do not affect any existing requirements applicable to small entities. Any existing Federal requirements will remain in place. Federal disapproval of the State SIP submittal will not affect State-enforceability. Moreover, EPA's disapproval of the submittal would not impose any new Federal requirements. Therefore, I certify that this action will not have a significant economic impact

on a substantial number of small entities.

#### F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed disapproval action does not include a Federal mandate that may result in estimated annual costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. The proposed disapproval will not change existing requirements and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this proposed action.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

**Note:** Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: November 24, 1999.

**Laura Yoshii,**

*Deputy Regional Administrator, Region IX.*

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**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 68c

**RIN 0925-AA19**

### National Institutes of Health Contraception and Infertility Research Loan Repayment Program

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The National Institutes of Health (NIH) through the Center for Population Research of the National Institute of Child Health and Human Development (NICHD) proposes to issue regulations to implement provisions of the Public Health Service (PHS) Act authorizing the NICHD Contraception and Infertility Research Loan Repayment Program (CIR-LRP). The purpose of the CIR-LRP is the recruitment and retention of highly qualified health professionals conducting contraception and/or infertility research.

**DATES:** Comments must be received on or before February 8, 2000 in order to assure that NIH will be able to consider the comments in preparing the final rule.

**ADDRESSES:** Comments should be sent to Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Blvd., Room 601, MSC 7669, Rockville, MD 20852. Comments may also be sent electronically by FAX (301-402-0169) or email (jm40z@nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Jerry Moore at the address above, or telephone (301) 496-4607 (not a toll-free number). For program information contact: Dr. Louis V. DePaolo, Contraception and Infertility Research Loan Repayment Program, Center for Population Research, National Institute of Child Health and Human Development, NIH, Building 61E, Room 8B01, Bethesda, Maryland 20892-7510; telephone (301) 496-6515 (not a toll-free number); FAX (301) 496-0962; e-mail (ld38p@nih.gov).

**SUPPLEMENTARY INFORMATION:** The NIH Revitalization Act of 1993 (Public Law 103-43) was enacted on June 10, 1993, adding section 487B of the Public Health Service (PHS) Act, 42 U.S.C. 288-2. Section 410(b) of Public Law 105-392, the Health Professions Education Partnership Act of 1998, amended section 487B of the PHS Act to increase the maximum annual loan repayment from \$20,000 to \$35,000. Section 487B, as amended, authorizes the Secretary of Health and Human Services to establish a program of entering into contracts with qualified health professionals under which such professionals agree to conduct contraception and/or infertility 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 their outstanding graduate and/or undergraduate educational loans.

The Secretary, in consultation with the Director of NICHD, has established

the NICHD Contraception and Infertility Research Loan Repayment Program (CIR-LRP) to implement this statutory authority. In return for loan repayments, applicants must agree to participate in contraception and/or infertility research for a period of obligated service of not less than two years. Selected applicants become participants in the CIR-LRP only upon the signing of a written contract by the Director, NICHD. The NIH is proposing to amend title 42 of the Code of Federal Regulations by adding a new Part 68c to govern the administration of this loan repayment program.

The proposed 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 purpose of this notice is to invite public comment on the proposed regulation. 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 proposed rule was reviewed under Executive Order 12866 by OIRA and was deemed to be significant. Therefore it has been reviewed by OMB prior to publication.

#### **Regulatory Flexibility Act**

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that regulatory proposals be analyzed to determine whether they create a significant impact on a substantial number of small entities. The Secretary certifies that any final rule resulting from this proposal will not have any such impact.

#### **Paperwork Reduction Act**

The application forms for use by the NICHD Contraception and Infertility Loan Repayment Program have been approved by OMB under OMB Approval No. 0925-0040 (expires December 31, 1999). This proposed rule does not contain any other 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).

#### **Catalog of Federal Domestic Assistance**

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

93.209—NICHD Contraception and Infertility Research Loan Repayment Program.

#### **List of Subjects in 42 CFR Part 68c**

Health professions, Loan programs—health, Medical research, Reporting and recordkeeping requirements.

Dated: June 29, 1999.

**Harold Varmus,**

*Director, National Institutes of Health.*

Approved: August 26, 1999.

**Donna E. Shalala,**

*Secretary.*

For the reasons presented in the preamble, it is proposed to amend chapter I of title 42 of the Code of Federal Regulations by adding a new Part 68c to read as follows:

#### **PART 68c—NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT CONTRACEPTION AND INFERTILITY RESEARCH LOAN REPAYMENT PROGRAM**

Sec.

68c.1 What is the scope and purpose of the National Institute of Child Health and Human Development (NICHD) Contraception and Infertility Research Loan Repayment Program (CIR-LRP)?

68c.2 Definitions.

68c.3 Who is eligible to apply?

68c.4 Who is eligible to participate?

68c.5 Who is ineligible to participate?

68c.6 How do individuals apply to participate in the CIR-LRP?

68c.7 How are applicants selected to participate in the CIR-LRP?

68c.8 What does the CIR-LRP provide to participants?

68c.9 What loans qualify for repayment?

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

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

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

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

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

68c.15 Additional conditions.

68c.16 What other regulations and statutes apply?

**Authority:** 42 U.S.C. 288-2.

**§ 68c.1 What is the scope and purpose of the National Institute of Child Health and Human Development (NICHD) Contraception and Infertility Research Loan Repayment Program (CIR-LRP)?**

This part applies to the award of educational loan payments under the NICHD Contraception and Infertility Research Loan Repayment Program (CIR-LRP) authorized by section 487B of the Public Health Service Act (42 U.S.C. 288-2). The purpose of this CIR-LRP is the recruitment and retention of highly qualified health professionals conducting contraception and/or infertility research.

**§ 68c.2 Definitions.**

As used in this part:

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

*Allied health professional* means:

- (1) A physician assistant; or
- (2) A research assistant with at least a bachelor's degree and applicable career goals.

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

*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.

*Contraception and Infertility Research Loan Repayment Program (CIR-LRP or Program)* means the NICHD Contraception and Infertility Research Loan Repayment Program authorized by section 487B of the Act.

*Contraception and Infertility Research Loan Repayment Program (CIR-LRP or Program) contract* refers to the agreement, which is signed by an applicant and the Secretary, wherein the applicant agrees to participate in research on infertility or contraceptive development and the Secretary agrees to repay qualified educational loans for a prescribed period as specified in this part.

*Contraception and Infertility Research Loan Repayment Program (CIR-LRP or Program) Panel* means a board assembled to review, rank, and approve or disapprove CIR-LRP applications. The Panel is composed of the Deputy Director, NICHD, representatives of NICHD's Office of Administrative Management, respective Program Officers of the Center for Population Research, and other special consultants as required.

*Contraceptive development* means research whose ultimate goal is to provide new or improved means of preventing pregnancy.

*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.

*Eligible NICHD-supported extramural site* means a site funded by NICHD that can be identified as one of the following:

- (1) A Cooperative Specialized Contraception and Infertility Research Center;
- (2) A Cooperative Specialized Research Center in Reproduction Research;
- (3) A Women's Reproductive Health Research Career Development Center; or
- (4) A Reproductive Medicine Unit identified as a clinical site for the National Cooperative Reproductive Medicine Network.

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

*Health professional* means an individual who is a physician, Ph.D.-level scientist, nurse, or a graduate student or postgraduate research fellow working toward a degree that will enable them to practice in one of those professions.

*Infertility research* means research whose long-range objective is to evaluate, treat or ameliorate conditions which result in the failure of couples to either conceive or bear young.

*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.

*NICHD intramural laboratory* means a laboratory that is supported by the NICHD intramural research program.

*Panel* means the NICHD Contraception and Infertility Research Loan Repayment Program Panel.

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

*Qualified educational loans* include Government and commercial educational loans, interest and related expenses 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.

*Research on infertility or contraceptive development* means activities which qualify for participation in the CIR-LRP as determined by the Program Panel.

*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.

*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 an individual's cessation of participation in the Program pursuant to a request by that participant that is implemented by the Secretary prior to the Program making payments on the participant's behalf. A withdrawal is without penalty to the participant and without obligation to the Program.

**§ 68c.3 Who is eligible to apply?**

To be eligible to apply to the CIR-LRP, an individual must be a qualified health or allied health professional who is at the time of application, or will be at the time of inception into the CIR-LRP, engaged in employment/training at

an NICHD intramural laboratory or an eligible NICHD-supported extramural site.

**§ 68c.4 Who is eligible to participate?**

To be eligible to participate in the CIR-LRP, the applicant must have institutional assurance of employment/affiliation with the NICHD intramural laboratory or eligible NICHD-supported extramural site and approval of the CIR-LRP Panel, must meet the criteria specified in § 68c.3, and not be ineligible to participate under § 68c.5

**§ 68c.5 Who is ineligible to participate?**

The following individuals are ineligible for CIR-LRP participation:

- (a) Persons who are not eligible applicants as specified under § 68c.3;
- (b) Persons who owe an obligation of health professional service to the Federal Government, a State, or other entity. 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, National Health Service Corp. Loan Repayment Program, and the NIH AIDS Research Loan Repayment Program.

**§ 68c.6 How do individuals apply to participate in the CIR-LRP?**

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

**§ 68c.7 How are applicants selected to participate in the CIR-LRP?**

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

- (a) Applicants must meet the eligibility requirements specified in § 68c.3 and § 68c.4.
- (b) Applicants must not be ineligible for participation as specified in § 68c.5.
- (c) Applicants must propose repayment of a loan that meets the requirements of § 68c.9.
- (d) Applicants must be selected for approval by the CIR-LRP Panel based upon a review of their applications.

**§ 68c.8 What does the CIR-LRP provide to participants?**

- (a) *Loan repayments.* Upon receipt of an individual's written commitment to serve a minimum initial period of two

years of obligated service in accordance with this part, the Secretary may pay up to \$35,000 per year of a participant's repayable debt for each year the individual serves.

(b) Under paragraph (a) of this section, the Secretary will make payments in the discharge of debt to the extent appropriated funds are available for that purpose. When a shortage of funds exists, participants may be funded partially, as determined by the Secretary. However, once a CIR-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 otherwise specified by mutual written agreement between the Secretary and the applicant. Benefits will be paid on a quarterly basis after each service period unless otherwise specified by mutual written agreement between the Secretary and the applicant.

**§ 68c.9 What loans qualify for repayment?**

(a) The CIR-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 CIR-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 for payment prior to inception into the CIR-LRP; and
- (7) Loans for which promissory notes have been signed after the individual's acceptance into the CIR-LRP.

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

Individuals must make a written commitment in accordance with this part to conduct, and must actually conduct research with respect to contraception and/or infertility at an NICHD intramural laboratory or an eligible NICHD-supported extramural site for a minimum initial period of two years.

**§ 68c.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 research on infertility or contraceptive development at an NICHD intramural laboratory or eligible NICHD-supported extramural site.

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

(a) Absent withdrawal (see § 68c.2) or termination under paragraph (d) of this section, any participant who fails to begin or 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 CIR-LRP on behalf of the participant plus an amount equal to \$1,000 multiplied by the number of months of the original two-year service obligation.
- (2) Participants who leave during the second year of the contract are liable for amounts already paid by the NICHD on

behalf of the participant plus \$1,000 for each unserved month.

(b) 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 rate amount of any benefits advanced beyond the period of completed service plus an amount equal to the number of months of obligated service that were not completed by the participant multiplied by \$1,000.

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

(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 that are not based upon a breach or default of the participant will not be considered a breach of contract and monetary damages will not be assessed.

(2) The participant transfers to another NICHD intramural laboratory or eligible NICHD-supported extramural site, in which case the participant remains bound to any and all obligations of the contract.

(3) The participant transfer to a site other than an NICHD intramural laboratory or eligible NICHD-supported extramural site, in which case the participant may not be assessed monetary penalties if, in the judgment of the CIR-LRP Panel, the participant continues to engage in contraception and/or infertility research for any remaining period of obligated service as set forth in the contract.

**§ 68c.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)(1) The Secretary 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 against equity and good conscience.

(2) 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 information and documentation as may be required, that the participant suffers from a physical or mental disability result 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 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;

(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 or future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

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

Any payment obligation incurred under § 68c.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.

**§ 68c.15 Additional conditions.**

In order to protect or conserve Federal funds or to carry out the purposes of section 487B of the Act, or of this part, the Secretary may impose additional conditions as a condition of any approval, waiver or suspension authorized by this part.

**§ 68c.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, Public Law 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, Public Law 101-647(28 U.S.C. 1).

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Inspector General**

**42 CFR Part 1001**

**Solicitation of New Safe Harbors and Special Fraud Alerts**

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual document solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the Federal and State health care programs' anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

**DATES:** To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 8, 2000.

**ADDRESSES:** Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-41-N, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG-41-N. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** Joel Schaer, (202) 619-0089, OIG Regulations Officer.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. The OIG Safe Harbor Provisions*

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Federal or State health care programs. The offense is classified as a felony, and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. The OIG may also impose administrative