

SUBCHAPTER D—GRANTS

PART 50—POLICIES OF GENERAL APPLICABILITY

Subpart A [Reserved]

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

Sec.

50.201 Applicability.

50.202 Definitions.

50.203 Sterilization of a mentally competent individual aged 21 or older.

50.204 Informed consent requirement.

50.205 Consent form requirements.

50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

50.207 Sterilization by hysterectomy.

50.208 Program or project requirements.

50.209 Use of Federal financial assistance.

50.210 Review of regulation.

APPENDIX TO SUBPART B OF PART 50—REQUIRED CONSENT FORM

Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

50.301 Applicability.

50.302 Definitions.

50.303 General rule.

50.304 Life of the mother would be endangered.

50.305 [Reserved]

50.306 Rape and incest.

50.307 Documentation needed by programs or projects.

50.308 Drugs and devices and termination of ectopic pregnancies.

50.309 Recordkeeping requirements.

50.310 Confidentiality.

Subpart D—Public Health Service Grant Appeals Procedure

50.401 What is the purpose of this subpart?

50.402 To what program do these regulations apply?

50.403 What is the policy basis for these procedures?

50.404 What disputes are covered by these procedures?

50.405 What is the structure of review committees?

50.406 What are the steps in the process?

Subpart E—Maximum Allowable Cost for Drugs

50.501 Applicability.

50.502 Definitions.

50.503 Policy.

50.504 Allowable cost of drugs.

Subpart F—Promoting Objectivity in Research

50.601 Purpose.

50.602 Applicability.

50.603 Definitions.

50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

50.605 Management and reporting of financial conflicts of interest.

50.606 Remedies.

50.607 Other HHS regulations that apply.

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); Sec. 1006, Public Health Service Act, 84 Stat. 1507 (42 U.S.C. 300a-4), unless otherwise noted.

SOURCE: 43 FR 52165, Nov. 8, 1978, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

Arrange for means to make arrangements (other than mere referral of an individual to, or the mere making of an appointment for him or her with, another health care provider) for the performance of a medical procedure on an individual by a health care provider other than the program or project.

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (1) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for

Public Health Service, HHS

§ 50.204

the care and treatment of mental illness, or (2) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose unless he or she has been declared competent for purposes which include the ability to consent to sterilization.

Public Health Service means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

The *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.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

[43 FR 52165, Nov. 8, 1978, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.203 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of an individual only if the following requirements have been met:

(a) The individual is at least 21 years old at the time consent is obtained.

(b) The individual is not a mentally incompetent individual.

(c) The individual has voluntarily given his or her informed consent in accordance with the procedures of § 50.204 of this subpart.

(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours

have passed after he or she gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 50.204 Informed consent requirement.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this section and § 50.205 of this subpart.

(a) A person who obtains informed consent for a sterilization procedure must offer to answer any questions the individual to be sterilized may have concerning the procedure, provide a copy of the consent form, and provide orally all of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw consent to the procedure any time before the sterilization without affecting his or her right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) Advice that the sterilization procedure is considered to be irreversible;

(4) A thorough explanation of the specific sterilization procedure to be performed;

(5) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(6) A full description of the benefits or advantages that may be expected as a result of the sterilization; and

(7) Advice that the sterilization will not be performed for at least 30 days except under the circumstances specified in § 50.203(d) of this subpart.

(b) An interpreter must be provided to assist the individual to be sterilized if he or she does not understand the language used on the consent form or the language used by the person obtaining the consent.

§ 50.205

42 CFR Ch. I (10–1–11 Edition)

(c) Suitable arrangements must be made to insure that the information specified in paragraph (a) of this section is effectively communicated to any individual to be sterilized who is blind, deaf or otherwise handicapped.

(d) A witness chosen by the individual to be sterilized may be present when consent is obtained.

(e) Informed consent may not be obtained while the individual to be sterilized is:

- (1) In labor or childbirth;
- (2) Seeking to obtain or obtaining an abortion; or
- (3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

(f) Any requirement of State and local law for obtaining consent, except one of spousal consent, must be followed.

§ 50.205 Consent form requirements.

(a) *Required consent form.* The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) *Required signatures.* The consent form must be signed and dated by:

- (1) The individual to be sterilized; and
- (2) The interpreter, if one is provided; and
- (3) The person who obtains the consent; and
- (4) The physician who will perform the sterilization procedure.

(c) *Required certifications.* (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized. Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed. If premature delivery occurs or emergency abdominal surgery is required within the 30-day period, the physician must certify that the sterilization was performed less than 30 days but not less than 72 hours after the date of the individual's signature on the consent form because of premature delivery or emergency abdominal surgery, as applicable. In the case of premature delivery, the physician must also state the expected date of delivery. In the case of emergency abdominal surgery, the physician must describe the emergency.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter's knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any

hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

(i) The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

(i) That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure

or hysterectomy it performs or arranges, meet all requirements of this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.

[43 FR 52165, Nov. 8, 1978, as amended at 47 FR 33701, Aug. 4, 1982]

§ 50.210 Review of regulation.

The Secretary will request public comment on the operation of the provisions of this subpart not later than 3 years after their effective date.

APPENDIX TO SUBPART B OF PART 50— REQUIRED CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from _____ (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits

Pt. 50, Subpt. B, App.

42 CFR Ch. I (10–1–11 Edition)

from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on ____ (day), ____ (month), ____ (year).

I, _____, hereby consent of my own free will to be sterilized by _____ by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature _____
Date: _____

(Month, day, year)

You are requested to supply the following information, but it is not required:

Ethnicity and Race Designation

Ethnicity:

- ☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (mark one or more):

- ☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter _____
Date _____

STATE OF PERSON OBTAINING CONSENT

Before _____ (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent _____
Date _____
Facility _____
Address _____

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon _____ (name of individual to be sterilized), on _____ (date of sterilization), _____ (operation), I explained to him/her the nature of the sterilization operation _____ (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

Public Health Service, HHS

§ 50.302

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

☐ Premature delivery

Individual's expected date of delivery: _____

☐ Emergency abdominal surgery:

(Describe circumstances): _____

Physician _____

Date _____

Paperwork Reduction Act Statement

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays the currently valid OMB control number. Public reporting burden for this collection of information will vary; however, we estimate an average of one hour per response, including for reviewing instructions, gathering and maintaining the necessary data, and disclosing the information. Send any comment regarding the burden estimate or any other aspect of this collection of information to the OS Reports Clearance Officer, ASBTF/Budget Room 503 HHH Building, 200 Independence Avenue, SW., Washington, DC 20201.

Respondents should be informed that the collection of information requested on this form is authorized by 42 CFR part 50, subpart B, relating to the sterilization of persons in federally assisted public health programs. The purpose of requesting this information is to ensure that individuals requesting sterilization receive information regarding the risks, benefits and consequences, and to assure the voluntary and informed consent of all persons undergoing sterilization procedures in federally assisted public health programs. Although not required, respondents are requested to supply information on their race and ethnicity. Failure to provide the other information requested on this consent form, and to sign this consent form, may re-

sult in an inability to receive sterilization procedures funded through federally assisted public health programs.

All information as to personal facts and circumstances obtained through this form will be held confidential, and not disclosed without the individual's consent, pursuant to any applicable confidentiality regulations.

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993; 68 FR 12308, Mar. 14, 2003]

Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

AUTHORITY: Sec. 118, Pub. L. 96-86, Oct. 12, 1979, unless otherwise noted.

SOURCE: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

§ 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

§ 50.302 Definitions.

As used in this subpart: (a) *Law enforcement agency* means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) *Medical procedures performed upon a victim of rape or incest* means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) *Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) *Public health service* means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A *rural health clinic*, as defined under section 1(d)(aa)(2) of Pub. L. 95-

§ 50.303

210, 91 Stat. 1485; except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§ 50.303 General rule.

Federal financial participation is not available for the performance of an abortion in programs or projects to which this subpart applies except under circumstances described in § 50.304 or § 50.306.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.304 Life of the mother would be endangered.

Federal financial participation is available in expenditures for an abortion when a physician has found, and so certified in writing to the program or project, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978]

§ 50.305 [Reserved]

§ 50.306 Rape and incest.

Federal financial participation is available in expenditures for medical procedures performed upon a victim of rape or incest if the program or project has received signed documentation from a law enforcement agency or public health service stating:

(a) That the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(b) The date on which the incident occurred;

(c) The date on which the report was made, which must have been within 60 days of the date on which the incident occurred;

(d) The name and address of the victim and the name and address of the person making the report (if different from the victim); and

(e) That the report included the signature of the person who reported the incident.

42 CFR Ch. I (10-1-11 Edition)

Federal financial participation is also available in expenditures for abortions for victims of rape or incest under the circumstances described in § 50.304 without regard to the requirements of the preceding sentence.

(Sec. 101, Pub. L. 95-205, 91 Stat. 1461, Dec. 9, 1977)

[43 FR 13868, July 21, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.307 Documentation needed by programs or projects.

Federal financial participation is unavailable for the performance of abortions or other medical procedures otherwise provided for under §§ 50.304 and 50.306 if the program or project has paid without first having received the certifications and documentation specified in those sections.

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.308 Drugs and devices and termination of ectopic pregnancies.

Federal financial participation is available with respect to the cost of drugs or devices to prevent implantation of the fertilized ovum, and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 50.309 Recordkeeping requirements.

Programs or projects to which this subpart applies must maintain copies of the certifications and documentation specified in §§ 50.304 and 50.306 for three years pursuant to the retention and custodial requirements for records at 45 CFR 74.20 *et seq.*

[43 FR 4570, Feb. 2, 1978, as amended at 44 FR 61598, Oct. 26, 1979]

§ 50.310 Confidentiality.

Information in the records or in the possession of programs or projects which is acquired in connection with the requirements of this subpart may not be disclosed in a form which permits the identification of an individual without the individual's consent except as may be necessary for the health of the individual or as may be necessary for the Secretary to monitor the activities of those programs or projects. In any event, any disclosure shall be subject to appropriate safeguards

Public Health Service, HHS

§ 50.404

which will minimize the likelihood of disclosures of personal information in identifiable form.

Subpart D—Public Health Service Grant Appeals Procedure

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); 45 CFR 16.3(c).

SOURCE: 54 FR 34770, Aug. 22, 1989, unless otherwise noted.

§ 50.401 What is the purpose of this subpart?

This subpart establishes an informal procedure for the resolution of certain postaward grant and cooperative agreement disputes within the agencies and offices identified in § 50.402.

[63 FR 66062, Dec. 1, 1998]

§ 50.402 To what program do these regulations apply?

This subpart applies to all grant and cooperative agreement programs, except block grants, which are administered by the National Institutes of Health; The Centers for Disease Control and Prevention; the Agency for Toxic Substances and Disease Registry; the Food and Drug Administration; and the Office of Public Health and Science. For purposes of this subpart, these entities are hereinafter referred to as “agencies.”

[70 FR 76175, Dec. 23, 2005]

§ 50.403 What is the policy basis for these procedures?

The Secretary of Health and Human Services has established a Departmental Appeals Board for the purpose of providing a fair and flexible process for the appeal of written final decisions involving certain grant and cooperative agreement programs administered by constituent agencies of the Department. The regulatory provision which establishes the circumstances under which the Board will accept an appeal (45 CFR 16.3) provides, among other things, that the appellant must have exhausted any preliminary appeal process required by regulation before a formal appeal to the Departmental Board will be allowed. This subpart provides such an informal preliminary

procedure for resolution of disputes in order to preclude submission of cases to the Departmental Appeals Board before an agency identified in § 50.402 has had an opportunity to review decisions of its officials and to settle disputes with grantees.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]

§ 50.404 What disputes are covered by these procedures?

(a) These procedures are applicable to the following adverse determinations under discretionary project grants and cooperative agreements (both referred to in this subpart as grants) issued by the agencies identified at § 50.402:

(1) Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.

(2) A determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.

(3) A determination that a grant is void.

(4) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.

(b) A determination subject to this subpart may not be reviewed by the review committee described in § 50.405 unless an officer or employee of the agency has notified the grantee in writing of the adverse determination. The notification must set forth the reasons for the determination in sufficient detail to enable the grantee to respond and must inform the grantee of the opportunity for review under this subpart.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]

§ 50.405 What is the structure of review committees?

The head of the agency, or his or her designee, shall appoint review committees to review adverse determinations made by officials for programs under their jurisdiction. A minimum of three employees shall be appointed (one of whom shall be designated as chairperson) either on an ad hoc, case-by-case basis, or as regular members of review committees for such terms as may be designated. None of the members of the review committee reviewing any given appeal may be from the office of the responsible official whose adverse determination is being appealed (e.g., project officer, grants specialist, program manager, grants management officer).

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]

§ 50.406 What are the steps in the process?

(a) A grantee with respect to whom an adverse determination described in § 50.404(a) above has been made and who desires a review of that determination must submit a request for such review to the head of the appropriate agency or his or her designee no later than 30 days after the written notification of the determination is received, except that if the grantee shows good cause why an extension of time should be granted, the head of the appropriate agency or his or her designee may grant an extension of time.

(b) The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the grantee's position with respect to such issue(s) and the pertinent facts and reasons in support of the grantee's position. In addition to the required written statement, the grantee shall provide copies of any documents supporting its claim.

(c) When a request for review has been filed under this subpart with respect to an adverse determination, no action may be taken by the awarding agency pursuant to such determination until the request has been disposed of, except that the filing of the request shall not affect any authority which the agency may have to suspend assist-

ance or otherwise to withhold or defer payments under the grant during proceedings under this subpart. This paragraph does not require the awarding agency to provide continuation funding during the appeal process to a grantee whose noncompeting continuation award has been denied.

(d) Upon receipt of a request for review, the head of the agency or his or her designee will make a decision as to whether the dispute is reviewable under this subpart and will promptly notify the grantee and the office responsible for the adverse determination of this decision. If the head of the agency or his or her designee determines that the dispute is reviewable, he or she will forward the matter to the review committee appointed under § 50.405.

(e) The agency involved will provide the review committee appointed under § 50.405 with copies of all relevant background materials (including applications(s), award(s), summary statement(s), and correspondence) and any additional pertinent information available. These materials must be tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(f) The grantee shall be given an opportunity to provide the review committee with additional statements and documentation not provided in the request for review described in paragraph (b) of this section. This additional submission, which must be organized and indexed as indicated under paragraph (e) of this section, should provide only material that is relevant to the review committee's deliberation of the issues in the case.

(g) The review committee may, at its discretion, invite the grantee and/or the agency staff to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

(h) Based on its review, the review committee will prepare a written decision to be signed by the chairperson and each of the other committee members. The review committee shall send the written decision with a transmittal letter to the grantee and shall send a copy of both to the official responsible for the adverse determination. If the

Public Health Service, HHS

§ 50.504

decision is adverse to the grantee's position, the transmittal letter must state the grantee's right to appeal to the Departmental Appeals Board under 45 CFR part 16.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66063, Dec. 1, 1998]

Subpart E—Maximum Allowable Cost for Drugs

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216).

SOURCE: 40 FR 34514, Aug. 15, 1975, unless otherwise noted.

§ 50.501 Applicability.

This subpart is applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service. It applies to Federal funds and to non-Federal funds which are required to be expended as a condition to receiving Federal funds under such programs or projects.

§ 50.502 Definitions.

As used in this subpart:

(a) *Public Health Service* means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, Food and Drug Administration, and all of their constituent agencies.

(b) *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.

(c) *Program funds* means (1) Federal funds provided through grant or contract to support a program or project covered by § 50.501, and (2) any non-Federal funds that are required as a condition of such grant or contract to be expended to carry out such program or project.

(d) *Provider* means one who furnishes medical or pharmaceutical services or supplies for which program funds may

be expended under any of the programs or projects described in § 50.501.

(e) *Acquisition cost* means the price generally and currently paid by providers for a drug marketed or sold by a particular formulator or labeler in the package size of drug most frequently purchased by providers, as determined by the Secretary on the basis of drug price information furnished by the Department.

[40 FR 34514, Aug. 15, 1975, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.503 Policy.

It is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible. In furtherance of this policy, the Secretary has established, in 45 CFR part 19, a procedure for determining the Maximum Allowable Cost for drugs which are purchased with program funds.

§ 50.504 Allowable cost of drugs.

(a) The maximum amount which may be expended from program funds for the acquisition of any drug shall be the lowest of

(1) The maximum allowable cost (MAC) of the drug, if any, established in accordance with 45 CFR part 19, plus a dispensing fee determined by the Secretary in accordance with paragraph (b) of this section, to be reasonable;

(2) The acquisition cost of the drug plus a dispensing fee determined by the Secretary, in accordance with paragraph (b) of this section, to be reasonable; or

(3) The provider's usual and customary charge to the public for the drug; *Provided*, That the MAC established for any drug shall not apply to a brand of that drug prescribed for a patient which the prescriber has certified, in accordance with paragraph (c) of this section, is medically necessary for that patient; *And Provided further*, That where compensation for drug dispensing is included in other costs allowable under the applicable program statute and regulations, the terms and conditions of the grant or contract, and the applicable cost principles prescribed in 45 CFR part 74, no separate dispensing fee will be recognized.

(b) In determining whether a dispensing fee is reasonable, the Secretary will take into account:

(1) Cost components such as overhead, professional services, and profits,

(2) Payment practices of third-party payment organizations, including other Federal programs such as titles XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in the particular area.

(c) A certification by a prescriber, pursuant to paragraph (a) of this section, that a brand of drug is medically necessary for a particular patient shall be in the prescriber's own handwriting, in such form and manner as the Secretary may prescribe. An example of an acceptable certification is the notation "brand necessary". A procedure for checking a box on a form will not constitute an acceptable certification.

Subpart F—Promoting Objectivity in Research

AUTHORITY: 42 U.S.C. 216, 289b–1, 299c–4; Sec. 219, Tit. II, Div. D, Pub. L. 111–117, 123 Stat. 3034.

SOURCE: 76 FR 53283, August 25, 2011, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

§ 50.602 Applicability.

This subpart is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications. In those

few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or *PHS Act* means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the In-

vestigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy

will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology

Transfer (STTR) Program, which was established by Public Law 102–564.

§ 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

Each Institution shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this subpart, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this subpart (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this subpart.

(b) Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to an Institution; or

(3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent

with this subpart, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(f) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that

the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to § 50.605(a).

(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to § 50.605(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

(j) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k) Certify, in each application for funding to which this subpart applies, that the Institution:

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this subpart.

§ 50.605 Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii)(A) In addition, whenever a financial conflict of interest is not identi-

fied or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken

to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

(4) Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)(i) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial

interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this subpart that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the PHS Awarding

Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- (viii) A description of the key elements of the Institution's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan;
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

(5) In addition to the types of financial conflicts of interest as defined in this subpart that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

(b) The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any

Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interest. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

§ 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

- 2 CFR part 376—Nonprocurement debarment and suspension (HHS)
- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure

Public Health Service, HHS

§ 51.2

- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other non-profit organizations, and commercial organizations
- 45 CFR part 79—Program fraud civil remedies
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments

PART 51—REQUIREMENTS APPLICABLE TO THE PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS PROGRAM

Sec.

51.1 Scope.

51.2 Definitions.

Subpart A—Basic Requirements

- 51.3 Formula for determining allotments.
- 51.4 Grants administration requirements.
- 51.5 Eligibility for allotment.
- 51.6 Use of allotments.
- 51.7 Eligibility for protection and advocacy services.
- 51.8 Annual reports.
- 51.9 [Reserved]
- 51.10 Remedial actions.
- 51.11–51.20 [Reserved]

Subpart B—Program Administration and Priorities

- 51.21 Contracts for program operations.
- 51.22 Governing authority.
- 51.23 Advisory council.
- 51.24 Program priorities.
- 51.25 Grievance procedure.
- 51.26 Conflicts of interest.
- 51.27 Training.
- 51.28–51.30 [Reserved]

Subpart C—Protection and Advocacy Services

- 51.31 Conduct of protection and advocacy activities.
- 51.32 Resolving disputes.
- 51.33–51.40 [Reserved]

Subpart D—Access to Records, Facilities and Individuals

- 51.41 Access to records.
- 51.42 Access to facilities and residents.
- 51.43 Denial of delay or access.

51.44 [Reserved]

51.45 Confidentiality of protection and advocacy system records.

51.46 Disclosing information obtained under a provider of mental health services.

AUTHORITY: 42 U.S.C. 10801, *et seq.*

SOURCE: 62 FR 53564, Oct. 15, 1997, unless otherwise noted.

§ 51.1 Scope.

The provisions of this part apply to recipients of Federal assistance under the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended.

§ 51.2 Definitions.

In addition to the definitions in section 102 of the Act, as amended, the following definitions apply:

Abuse means any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to an individual with mental illness, and includes but is not limited to acts such as: rape or sexual assault; striking; the use of excessive force when placing an individual with mental illness in bodily restraints; the use of bodily or chemical restraints which is not in compliance with Federal and State laws and regulations; verbal, nonverbal, mental and emotional harassment; and any other practice which is likely to cause immediate physical or psychological harm or result in long-term harm if such practices continue.

Act means the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended, also referred to as Protection and Advocacy for Individuals with Mental Illness Act.

ADD means the Administration on Developmental Disabilities within the Administration for Children and Families, Department of Health and Human Services.

Care or Treatment means services provided to prevent, identify, reduce or stabilize mental illness or emotional impairment such as mental health screening, evaluation, counseling, biomedical, behavioral and psychotherapies, supportive or other

adjunctive therapies, medication supervision, special education and rehabilitation, even if only “as needed” or under a contractual arrangement.

Center or *CMHS* means the Center for Mental Health Services, a component of the Substance Abuse and Mental Health Services Administration.

Complaint includes, but is not limited to any report or communication, whether formal or informal, written or oral, received by the P&A system, including media accounts, newspaper articles, telephone calls (including anonymous calls) from any source alleging abuse or neglect of an individual with mental illness.

Department or *HHS* means the U.S. Department of Health and Human Services.

Designated Official is the State official or public or private entity empowered by the Governor or State legislature to be accountable for the proper use of funds by the P&A system.

Director means the Director of the Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, or his or her designee.

Facility includes any public or private residential setting that provides overnight care accompanied by treatment services. Facilities include, but are not limited to the following: general and psychiatric hospitals, nursing homes, board and care homes, community housing, juvenile detention facilities, homeless shelters, and jails and prisons, including all general areas as well as special mental health or forensic units.

Fiscal Year or *FY* means the Federal fiscal year (October 1–September 30) unless otherwise specified.

Full Investigation is based upon a complaint or a determination of probable cause and means the access to facilities, clients and records authorized under this part that is necessary for a P&A system to make a determination about whether an allegation of abuse or neglect is taking place or has taken place. Full investigations may be conducted independently or in cooperation with other agencies authorized to conduct similar investigations.

Governor means the chief executive officer of the State, Territory or the

District of Columbia, or his or her designee, who has been formally designated to act for the Governor in carrying out the requirements of the Act and this part.

Individual with Mental Illness means an individual who has a significant mental illness or emotional impairment, as determined by a mental health professional qualified under the laws and regulations of the State and

(1) Who is an inpatient or resident in a facility rendering care or treatment, even if the whereabouts of such inpatient or resident is unknown;

(2) Who is in the process of being admitted to a facility rendering care or treatment, including persons being transported to such a facility, or

(3) Who is involuntarily confined in a detention facility, jail or prison.

Legal Guardian, Conservator, and Legal Representative all mean an individual whose appointment is made and regularly reviewed by a State court or agency empowered under State law to appoint and review such officers, and having authority to consent to health/mental health care or treatment of an individual with mental illness. It does not include persons acting only as a representative payee, persons acting only to handle financial payments, attorneys or persons acting on behalf of an individual with mental illness only in individual legal matters, or officials responsible for the provision of health or mental health services to an individual with mental illness, or their designees.

Neglect means a negligent act or omission by an individual responsible for providing services in a facility rendering care or treatment which caused or may have caused injury or death to an individual with mental illness or which placed an individual with mental illness at risk of injury or death, and includes, but is not limited to, acts or omissions such as failure to: establish or carry out an appropriate individual program or treatment plan (including a discharge plan); provide adequate nutrition, clothing, or health care; and the failure to provide a safe environment which also includes failure to maintain adequate numbers of appropriately trained staff.

Private Entity means a nonprofit or for-profit corporation, partnership or other nongovernmental organization.

Probable cause means reasonable grounds for belief that an individual with mental illness has been, or may be at significant risk of being subject to abuse or neglect. The individual making such determination may base the decision on reasonable inferences drawn from his or her experience or training regarding similar incidents, conditions or problems that are usually associated with abuse or neglect.

Program means activities carried out by the P&A system and operating as part of a P&A system to meet the requirements of the Act.

Public Entity means an organizational unit of a State or local government or a quasi-governmental entity with one or more governmental powers.

System means the organization or agency designated in a State to administer and operate a protection and advocacy program under Part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041, 6042) and thereby eligible to administer a program for individuals with mental illness.

Subpart A—Basic Requirements

§51.3 Formula for determining allotments.

The Secretary shall make allotments to eligible Systems from amounts apportioned each year under the Act on the basis of a formula prescribed by the Secretary in accordance with the requirements of sections 112 and 113 of the Act (42 U.S.C. 10822 and 10823).

§51.4 Grants administration requirements.

The following parts of titles 42 and 45 CFR apply to grants funded under this part.

42 CFR Part 50, Subpart D.

45 CFR Part 16—Procedures of the Departmental Grant Appeal Board.

45 CFR Part 74—Administration of Grants.

45 CFR Part 75—Informal Grant Appeals Procedures.

45 CFR Part 76—Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace.

45 CFR Part 80—Nondiscrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.

45 CFR Part 81—Practice and Procedure for Hearings under Part 80 of This Title.

45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.

45 CFR Part 86—Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving Federal Financial Assistance.

45 CFR Part 91—Nondiscrimination on the Basis of Age in Education Programs and Activities Receiving Federal Financial Assistance from HHS.

45 CFR Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

45 CFR Part 93—New Restrictions on Lobbying.

45 CFR Part 1386, subpart A.

§51.5 Eligibility for allotment.

(a) Federal financial assistance for protection and advocacy activities for individuals with mental illness will be given only to a System that has been established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041, *et seq.*) and designated in accordance with 45 CFR part 1386, subpart B.

(b) The P&A system must meet the requirements of sections 105 and 111 of the Act (42 U.S.C. 10805 and 10821) and that P&A system must be operational. Each system shall submit an application at the beginning of each PAIMI authorization period. This application shall contain at a minimum the program priorities and budget for the first year of the authorization period and the required assurances and certifications. Thereafter, the system shall submit yearly updates of the budget and program priorities for the upcoming fiscal year through its annual report.

(c) Written assurances of compliance with sections 105 and 111 of the Act (42 U.S.C. 10805 and 10821) and other requirements of the Act and this part shall be submitted by the P&A system in the format designated by the Director. These assurances will remain in effect for the period specified in the application for funds unless changes

§51.6

42 CFR Ch. I (10–1–11 Edition)

occur within the State which affect the functioning of the P&A system, in which case an amendment will be required 30 days prior to the effective date of the change. The P&A system shall also provide the Department the name of the designated official.

(d) The Governor's written assurance that the allotments made available under the Act will be used to supplement and not to supplant the level of non-Federal funds available in the State to protect and advocate the rights of individuals with mental illness shall be submitted by the P&A system. The Governor may provide this assurance along with the assurances provided to ADD under 45 CFR part 1386, as long as it can reasonably be construed as applying to the PAIMI program. Any future "supplement and not supplant" assurance shall explicitly refer to the PAIMI program.

§51.6 Use of allotments.

(a) Allotments must be used to supplement and not to supplant the level of non-Federal funds available in the State to protect and advocate the rights of individuals with mental illness.

(b) Allotments may not be used to support lobbying activities to influence proposed or pending Federal legislation or appropriations. This restriction does not affect the right of any P&A system, organization or individual to petition Congress or any other government body or official using other resources.

(c) Allotments may not be used to produce or distribute written, audio or visual materials or publicity intended or designed to support or defeat any candidate for public office.

(d) If an eligible P&A system is a public entity, that P&A system shall not be required by the State to obligate more than five percent of its annual allotment for State oversight administrative expenses under this grant such as costs of internal or external evaluations, monitoring or auditing. This restriction does not include:

(1) Salaries, wages and benefits of program staff;

(2) Costs associated with attending governing board or advisory council meetings; or

(3) Expenses associated with the provision of training or technical assistance for staff, contractors, members of the governing board or advisory council.

(e) No more than ten percent of each annual allotment may be used for providing technical assistance and training, including travel expenses for staff, contractors, or members of the governing board or advisory council as defined in §51.27.

(f) Allotments may be used to pay the otherwise allowable costs incurred by a P&A system in bringing lawsuits in its own right to redress incidents of abuse or neglect, discrimination, and other rights violations impacting on individuals with mental illness and when it appears on behalf of named plaintiffs or a class of plaintiffs for such purposes.

§51.7 Eligibility for protection and advocacy services.

In accordance with section 105(a)(1)(C) of the Act (42 U.S.C. 10805(a)(1)(C)) and the priorities established by the P&A system governing authority, together with the advisory council, pursuant to section 105(c)(2)(B) of the Act (42 U.S.C. 10805(c)(2)(B)), allotments may be used:

(a) To provide protection and advocacy services for:

(1) Individuals with mental illness as defined in 42 U.S.C. 10802(4) and 10805(a), including persons who report matters which occurred while they were individuals with mental illness;

(2) Persons who were individuals with mental illness who are residents of the State, but only with respect to matters which occur within 90 days after the date of the discharge of such individuals from a facility providing care or treatment; and

(3) Individuals with mental illness in Federal facilities rendering care or treatment who request representation by the eligible P&A system. Representation may be requested by an individual with mental illness, or by a legal guardian, conservator or legal representative.

(b) To provide representation of clients in civil commitment proceedings if the P&A system is acting on behalf

of an eligible individual to obtain judicial review of his or her commitment in order to appeal or otherwise challenge acts or omissions which have subjected the individual to abuse or neglect or otherwise violated his or her rights. This restriction does not prevent a P&A system from representing clients in commitment or recommitment proceedings using other resources so long as this representation does not conflict with responsibilities under the Act.

§ 51.8 Annual reports.

By January 1 of each year, a report shall be submitted, pursuant to section 105(a)(7) of the Act (42 U.S.C. 10805(a)(7)), to the Secretary which is in the format designated by the Secretary.

EFFECTIVE DATE NOTE: At 62 FR 53564, Oct. 15, 1997, § 51.8 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 51.9 [Reserved]

§ 51.10 Remedial actions.

Failure to submit an annual report in the designated format on time or to submit requested information and documentation, corrective action plans and ongoing implementation status reports in response to Federal review and monitoring activities or to satisfy any other requirement of the Act, this part, or other requirements, may be considered a breach of the terms and conditions of the grant award and may require remedial action, such as the suspension or termination of an active grant, withholding of payments or converting to a reimbursement method of payment. Any remedial actions shall be taken consistent with 45 CFR Part 74 and 42 CFR Part 50, as appropriate.

EFFECTIVE DATE NOTE: At 62 FR 53564, Oct. 15, 1997, § 51.10 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§§ 51.11–51.20 [Reserved]

Subpart B—Program Administration and Priorities

§ 51.21 Contracts for program operations.

(a) An eligible P&A system should work cooperatively with existing advocacy agencies and groups and, where appropriate, consider entering into contracts for protection and advocacy services with organizations already working on behalf of individuals with mental illness. Special consideration should be given to contracting for the services of groups run by individuals who have received or are receiving mental health services or by family members of such individuals.

(b) An eligible P&A system may contract for the operation of all or part of its program with another public or private nonprofit organization with demonstrated experience in working with individuals with mental illness provided that:

(1) Any organization that will operate the full program meets the requirements of section 104(a)(1), 105 and 111 of the Act (42 U.S.C. 10804(a)(1), 10805 and 10821) and has the capacity to perform protection and advocacy activities throughout the State;

(2) The eligible P&A system institutes oversight and monitoring procedures which ensure that this system will be able to meet all applicable terms, conditions and obligations of the Federal grant;

(3) The eligible P&A system and the contractor organization enter into a written agreement that includes at least the following:

(i) A description of the protection and advocacy services to be provided;

(ii) The type of personnel, their qualifications and training;

(iii) The methods to be used;

(iv) A timetable for performance;

(v) A budget;

(vi) Assurances that the contractor will meet all applicable terms and conditions of the grant;

(vii) Assurances that the contractor has adequate management and fiscal systems in place, including insurance coverage, if appropriate;

§ 51.22

(viii) Assurances that the contractor's staff is trained to provide advocacy services to and conduct full investigations on behalf of individuals with mental illness; and

(ix) Assurances that the contractor staff is trained to work with family members of clients served by the P&A system where the clients are:

(A) Minors;

(B) Legally competent and choose to involve the family member; or,

(C) Legally incompetent and the legal guardians, conservators or other legal representatives are family members.

§ 51.22 Governing authority.

(a) Each P&A system shall have a governing authority responsible for its planning, designing, implementing and functioning. It shall, jointly with the advisory council, annually establish program priorities and policies.

(b) If the P&A system is organized with a multi-member governing board:

(1) Each P&A system shall establish policies and procedures for the selection of its governing board members and for the board evaluation of the P&A system director. The terms of board members shall be staggered and for 4 years except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. A member who has been appointed for a term of 4 years may not be reappointed to the governing board during the 2-year period beginning on the date on which such 4-year term expired.

(2) The board shall be composed of members who broadly represent or are knowledgeable about the needs of the clients served by the P&A system and shall include a significant representation of individuals with mental illness who are, or have been eligible for services, or have received or are receiving mental health services, and family members, guardians, advocates, or authorized representatives of such individuals.

(3) If the governing authority is organized as a private nonprofit entity, the chairperson of the advisory council shall be a member of the governing board.

42 CFR Ch. I (10-1-11 Edition)

(c) Continuing efforts shall be made to include members of racial and ethnic minority groups as board members.

(d) Any member of the advisory council may also serve on the governing board.

§ 51.23 Advisory council.

(a) Each P&A system shall establish an advisory council to:

(1) Provide independent advice and recommendations to the system.

(2) Work jointly with the governing authority in the development of policies and priorities.

(3) Submit a section of the system's annual report as required under § 51.8.

(b) Members of the council shall include attorneys, mental health professionals, individuals from the public who are knowledgeable about mental illness, the advocacy needs of persons with mental illness and have demonstrated a substantial commitment to improving mental health services, a provider of mental health services, individuals who have received or are receiving mental health services and family members of such individuals. Continuing efforts shall be made to include members of racial and ethnic minority groups on the advisory council.

(1) At least 60 percent of the membership of the advisory council shall be comprised of individuals who have received or are receiving mental health services or who are family members of such individuals. At least one family member shall be a primary care giver for an individual who is currently a minor child or youth who is receiving or has received mental health services;

(2) The council shall be chaired by an individual who has received or is receiving mental health services or who is a family member of such an individual;

(3) The advisory council shall meet no less than three times annually. The terms of council members shall be staggered and for 4 years except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. A member who has been appointed for a term of 4 years may not be reappointed to the council during the 2-year period beginning on the date on which such 4-year term expired.

(c) Each P&A system shall provide its advisory council with reports, materials and fiscal data to enable review of existing program policies, priorities and performance outcomes. Such submissions shall be made at least annually and shall report expenditures for the past two fiscal years, as well as projected expenses for the next fiscal year, identified by budget category (e.g., salary and wages, contract for services, administrative expenses) including the amount allotted for training of each the advisory council, governing board and staff.

(d) Reimbursement of expenses. (1) Allotments may be used to pay for all or a part of the expenses incurred by members of the advisory council in order to participate in its activities. Expenses may include transportation costs, parking, meals, hotel costs, per diem expenses, stipends or subsistence allowances, and the cost of day care or child care (or its equivalent for the child's travel and subsistence expenses) for their dependents with mental illness or developmental disabilities.

(2) Each P&A system shall establish its own policies and procedures for reimbursement of expenses of council members, taking into account the needs of individual council members, available resources, and applicable restrictions on use of grant funds, including the restrictions in §§ 51.31(e) and 51.6(e).

EFFECTIVE DATE NOTE: At 62 FR 53564, Oct. 15, 1997, § 51.23 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 51.24 Program priorities.

(a) Program priorities and policies shall be established annually by the governing authority, jointly with the advisory council. Priorities shall specify short-term program goals and objectives, with measurable outcomes, to implement the established priorities. In developing priorities, consideration shall be given to, at a minimum, case selection criteria, the availability of staff and monetary resources, and special problems and cultural barriers faced by individuals with mental illness who are multiply handicapped or

who are members of racial or ethnic minorities in obtaining protection of their rights. Systemic and legislative activities shall also be addressed in the development and implementation of program priorities.

(b) Members of the public shall be given an opportunity, on an annual basis, to comment on the priorities established by, and the activities of, the P&A system. Procedures for public comment must provide for notice in a format accessible to individuals with mental illness, including such individuals who are in residential facilities, to family members and representatives of such individuals and to other individuals with disabilities. Procedures for public comment must provide for receipt of comments in writing or in person.

§ 51.25 Grievance procedure.

(a) The P&A system shall establish procedures to address grievances from:

(1) Clients or prospective clients of the P&A system to assure that individuals with mental illness have full access to the services of the program; and

(2) Individuals who have received or are receiving mental health services in the State, family members of such individuals, or representatives of such individuals or family members to assure that the eligible P&A system is operating in compliance with the Act.

(b) At a minimum, the grievance procedures shall provide for:

(1) An appeal to the governing authority from any final staff review and/or determination; in cases where the governing authority is the director of the P&A system, the final review and/or determination shall be made by a superior of the governing authority, e.g., a supervisor, or by an independent entity, e.g., an appointed board or committee.

(2) Reports, at least annually, to the governing authority and the advisory council describing the grievances received and processed and their resolution;

(3) Identification of individuals responsible for review;

(4) A timetable to ensure prompt notification concerning the grievance

§ 51.26

procedure to clients, prospective clients or persons denied representation, and to ensure prompt resolution;

(5) A written response to the grievant; and

(6) Protection of client confidentiality.

EFFECTIVE DATE NOTE: At 62 FR 53564, Oct. 15, 1997, § 51.25 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 51.26 Conflicts of interest.

The P&A system must develop appropriate policies and procedures to avoid actual or apparent conflict of interest involving clients, employees, contractors and subcontractors, and members of the governing authority and advisory council, particularly with respect to matters affecting client services, particular contracts and subcontracts, grievance review procedures, reimbursements and expenses, and the employment or termination of staff.

§ 51.27 Training.

A P&A system shall provide training for program staff, and may also provide training for contractors, governing board and advisory council members to enhance the development and implementation of effective protection and advocacy services for individuals with mental illness, including at a minimum:

(a)(1) Training of program staff to work with family members of clients served by the program where the individual with mental illness is:

(i) A minor,

(ii) Legally competent and chooses to involve the family member; or

(iii) Legally incompetent and the legal guardian, conservator or other legal representative is a family member.

(2) This training may be provided by individuals who have received or are receiving mental health services and family members of such individuals.

(b) Training to enhance sensitivity to and understanding of individuals with mental illness who are members of racial or ethnic minorities and to develop strategies for outreach to those populations.

42 CFR Ch. I (10–1–11 Edition)

(c) Training to conduct full investigations of abuse or neglect.

§§ 51.28–51.30 [Reserved]

Subpart C—Protection and Advocacy Services

§ 51.31 Conduct of protection and advocacy activities.

(a) Consistent with State and Federal law and the canons of professional ethics, a P&A system may use any appropriate technique and pursue administrative, legal or other appropriate remedies to protect and advocate on behalf of individuals with mental illness to address abuse, neglect or other violations of rights.

(b) A P&A system shall establish policies and procedures to guide and coordinate advocacy activities. The P&A system shall not implement a policy or practice restricting the remedies which may be sought on behalf of individuals with mental illness or compromising the authority of the P&A system to pursue such remedies through litigation, legal action or other forms of advocacy. However, this requirement does not prevent the P&A system from placing limitations on case or client acceptance criteria developed as part of the annual priorities. Prospective clients must be informed of any such limitations at the time they request service.

(c) Wherever possible, the program should establish an ongoing presence in residential mental health care or treatment facilities, and relevant hospital units.

(d) Program activities should be carried out in a manner which allows program staff to:

(1) Interact regularly with those individuals who are current or potential recipients of protection and advocacy services;

(2) Interact regularly with staff providing care or treatment;

(3) Obtain information and review records; and

(4) Communicate with family members, social and community service workers and others involved in providing care or treatment.

(e) A P&A system may support or provide training, including related

travel expenses, for individuals with mental illness, family members of such individuals, and other persons who are not program staff, contractors, or board or council members, to increase knowledge about protection and advocacy issues, to enhance leadership capabilities, or to promote Federal-State and intra-State cooperation on matter related to mental health system improvement. Decisions concerning the selection of individuals to receive such training shall be made in accordance with established policies, procedures and priorities of the P&A system.

(f) A P&A system may monitor, evaluate and comment on the development and implementation of Federal, State and local laws, regulations, plans, budgets, levies, projects, policies and hearings affecting individuals with mental illness as a part of federally funded advocacy activities. A P&A system shall carry out systemic advocacy—those efforts to implement changes in policies and practices of systems that impact persons with mental illness.

(g) Determination of “probable cause” may result from P&A system monitoring or other activities, including observation by P&A system personnel, and reviews of monitoring and other reports prepared by others whether pertaining to individuals with mental illness or to general conditions affecting their health or safety.

(h) A P&A which is a public P&A system shall be free from hiring freezes, reductions in force, prohibitions on staff travel, or other policies imposed by the State to the extent that such policies would impact program staff or activities funded with Federal dollars and would prevent the P&A system from carrying out its mandates under the Act.

(i) A P&A system may exercise its authority under State law where the authority exceeds the authority required by the Act. However, State law must not diminish the required authority of the Act.

§ 51.32 Resolving disputes.

(a) Each P&A system is encouraged to develop and employ techniques such as those involving negotiation, conciliation and mediation to resolve dis-

putes early in the protection and advocacy process.

(b) Disputes should be resolved whenever possible through nonadversarial process involving negotiation, mediation and conciliation. Consistent with State and Federal laws and canons of professional responsibility, family members should be involved in this process, as appropriate, where the individual with mental illness is:

(1) A minor,

(2) Legally competent and chooses to involve the family member, or

(3) Legally incompetent and the legal guardian, conservator or other legal representative is a family member or the legal guardian, conservator or other legal representative chose to involve the family member.

(c) A P&A system must exhaust in a timely manner all administrative remedies, where appropriate, prior to initiating legal action in a Federal or State court.

(d) Paragraph (c) of this section does not apply to any legal action instituted to prevent or eliminate imminent serious harm to an individual with mental illness nor does it apply in circumstances where administrative procedures do not exist. If in pursuing administrative remedies, the P&A system determines that any matter with respect to an individual with mental illness with mental illness with not be resolved within a reasonable time, the P&A system may pursue alternative remedies, including initiating legal action.

(e) A P&A system shall be held to the standard of exhaustion of remedies provided under State and Federal law. The Act imposes no additional burden respecting exhaustion of remedies.

§§ 51.33–51.40 [Reserved]

Subpart D—Access to Records, Facilities and Individuals

§ 51.41 Access to records.

(a) Access to records shall be extended promptly to all authorized agents of a P&A system.

(b) A P&A system shall have access to the records of any of the following individuals with mental illness:

(1) An individual who is a client of the P&A system if authorized by that individual or the legal guardian, conservator or other legal representative.

(2) An individual, including an individual who has died or whose whereabouts is unknown to whom all of the following conditions apply:

(i) The individual, due to his or her mental or physical condition, is unable to authorize the P&A system to have access.

(ii) The individual does not have a legal guardian, conservator or other legal representative, or the individual's guardian is the State or one of its political subdivisions; and

(iii) A complaint or report has been received and the P&A system has determined that there is probable cause to believe that the individual has been or may be subject to abuse or neglect.

(3) An individual who has a legal guardian, conservator, or other legal representative, with respect to whom a complaint or report has been received by the P&A system and with respect to whom the P&A system has determined that there is probable cause to believe that the health or safety of the individual is in serious and immediate jeopardy, whenever all of the following conditions exists:

(i) The P&A system has made a good faith effort to contact the representative upon prompt receipt of the representative's name and address;

(ii) The P&A system has made a good faith effort to offer assistance to the representative to resolve the situation; and

(iii) The representative has failed or refused to act on behalf of the individual.

(c) Information and individual records, whether written or in another medium, draft or final, including handwritten notes, electronic files, photographs or video or audio tape records, which shall be available to the P&A system under the Act shall include, but not be limited to:

(1) Information and individual records, obtained in the course of providing intake, assessment, evaluation, supportive and other services, including medical records, financial records, and reports prepared or received by a member of the staff of a facility or pro-

gram rendering care or treatment. This includes records stored or maintained in locations other than the facility or program as long as the system has obtained appropriate consent consistent with section 105(a)(4) of the Act. The system shall request of facilities that in requesting records from service providers or other facilities on residents that they indicate in the release form the records may be subject to review by a system.

(2) Reports prepared by an agency charged with investigating abuse neglect, or injury occurring at a facility rendering care or treatment, or by or for the facility itself, that describe any or all of the following:

(i) Abuse, neglect, or injury occurring at the facility;

(ii) The steps taken to investigate the incidents;

(iii) Reports and records, including personnel records, prepared or maintained by the facility, in connection with such reports of incidents; or

(iv) Supporting information that was relied upon in creating a report, including all information and records used or reviewed in preparing reports of abuse, neglect or injury such as records which describe persons who were interviewed, physical and documentary evidence that was reviewed, and the related investigative findings.

(3) Discharge planning records.

(4) Reports prepared by individuals and entities performing certification or licensure reviews, or by professional accreditation organizations, as well as related assessments prepared for the facility by its staff, contractors or related entities, except that nothing in this section is intended to preempt State law protecting records produced by medical care evaluation or peer review committees.

(5) Professional, performance, building or other safety standards, demographic and statistical information relating to the facility.

(d) A P&A system shall have reasonable access and authority to interview and examine all relevant records of any facility service recipient (consistent with the provisions of section 105(a)(4) of the Act) or employee.

(e) A P&A system shall be permitted to inspect and copy records, subject to

Public Health Service, HHS

§ 51.43

a reasonable charge to offset duplicating costs.

§ 51.42 Access to facilities and residents.

(a) Access to facilities and residents shall be extended to all authorized agents of a P&A system.

(b) A P&A system shall have reasonable unaccompanied access to public and private facilities and programs in the State which render care or treatment for individuals with mental illness, and to all areas of the facility which are used by residents or are accessible to residents. The P&A system shall have reasonable unaccompanied access to residents at all times necessary to conduct a full investigation of an incident of abuse or neglect. This authority shall include the opportunity to interview any facility service recipient, employee, or other persons, including the person thought to be the victim of such abuse, who might be reasonably believed by the system to have knowledge of the incident under investigation. Such access shall be afforded, upon request, by the P&A system when:

(1) An incident is reported or a complaint is made to the P&A system;

(2) The P&A system determines there is probable cause to believe that an incident has or may have occurred; or

(3) The P&A system determines that there is or may be imminent danger of serious abuse or neglect of an individual with mental illness.

(c) In addition to access as prescribed in paragraph (b) of this section, a P&A system shall have reasonable unaccompanied access to facilities including all area which are used by residents, are accessible to residents, and to programs and their residents at reasonable times, which at a minimum shall include normal working hours and visiting hours. Residents include adults or minors who have legal guardians or conservators. P&A activities shall be conducted so as to minimize interference with facility programs, respect residents' privacy interests, and honor a resident's request to terminate an interview. This access is for the purpose of:

(1) Providing information and training on, and referral to programs ad-

ressing the needs of individuals with mental illness, and information and training about individual rights and the protection and advocacy services available from the P&A system, including the name, address, and telephone number of the P&A system.

(2) Monitoring compliance with respect to the rights and safety of residents; and

(3) Inspecting, viewing and photographing all areas of the facility which are used by residents or are accessible to residents.

(d) Unaccompanied access to residents shall include the opportunity to meet and communicate privately with individuals regularly, both formally and informally, by telephone, mail and in person. Residents include minors or adults who have legal guardians or conservators.

(e) The right of access specified in paragraph (c) of this section shall apply despite the existence of any State or local laws or regulations which restrict informal access to minors and adults with legal guardians or conservators. The system shall make every effort to ensure that the parents of minors or guardians of individuals in the care of a facility are informed that the system will be monitoring activities at the facility and may in the course of such monitoring have access to the minor or adult with a legal guardian. The system shall take no formal action on behalf of individuals with legal guardians or conservators, or initiate a formal attorney/client or advocate/client relationship without appropriate consent, except in emergency situations as described in § 51.41(b)(3).

(f) A P&A system providing representation to individuals with mental illness in Federal facilities shall have all the rights and authority accorded other representatives of residents of such facilities pursuant to State and Federal laws.

§ 51.43 Denial or delay of access.

If a P&A system's access to facilities, programs, residents or records covered by the Act or this part is delayed or denied, the P&A system shall be provided promptly with a written statement of

reasons, including, in the case of a denial for alleged lack of authorization, the name, address and telephone number of the legal guardian, conservator, or other legal representative of an individual with mental illness. Access to facilities, records or residents shall not be delayed or denied without the prompt provision of written statements of the reasons for the denial.

§ 51.44 [Reserved]

§ 51.45 Confidentiality of protection and advocacy system records.

(a) Records maintained by the P&A system are the property of the P&A system which must protect them from loss, damage, tampering or use by unauthorized individuals. The P&A system must:

(1) Except as provided elsewhere in this section, keep confidential all records and information, including information contained in any automated electronic database pertaining to:

(i) Clients to the same extent as is required under Federal or State laws for a provider of mental health services;

(ii) Individuals who have been provided general information or technical assistance on a particular matter;

(iii) Identity of individuals who report incidents of abuse or neglect or furnish information that forms the basis for a determination that probable cause exists; and

(iv) Names of individuals who are residents and provide information for the record.

(2) Have written policies governing access to, storage of, duplication and release of information from client records; and

(3) Obtain written consent from the client, if competent, or from his or her legal representative, from individuals who have been provided general information or technical assistance on a particular matter and from individuals who furnish reports or information that forms the basis for a determination of probable cause, before releasing information to individuals not otherwise authorized to receive it.

(b) Nothing in this subpart shall prevent the P&A system from: (1) Issuing a public report of the results of an investigation which maintains the con-

fidentiality of the individuals listed in paragraph (a)(1) of this section or,

(2) Reporting the results of an investigation which maintains the confidentiality of individual service recipients to responsible investigative or enforcement agencies should an investigation reveal information concerning the facility, its staff, or employees warranting possible sanctions or corrective action. This information may be reported to agencies responsible for facility licensing or accreditation, employee discipline, employee licensing or certification, or criminal prosecution.

(c) For purposes of any periodic audit, report, or evaluation of the performance of the P&A system, the Secretary shall not require the P&A system to disclose the identity, or any other personally identifiable information, of any individual requesting assistance under a program. This requirement does not restrict access by the Department or other authorized Federal or State officials to client records or other records of the P&A system when deemed necessary for audit purposes and for monitoring P&A system compliance with applicable Federal or State laws and regulations. The purpose of obtaining such information is solely to determine that P&A systems are spending their grant funds awarded under the Act on serving individuals with mental illness. Officials that have access to such information must keep it confidential to the maximum extent permitted by law and regulations. If photostatic copies of materials are provided, then the destruction of such evidence is required once such reviews have been completed.

(d) Subject to the restrictions and procedures set out in this section, implementing section 106 (a) and (b) of the Act (42 U.S.C. 10806 (a) and (b)), this part does not limit access by a legal guardian, conservator, or other legal representative of an individual with mental illness, unless prohibited by State or Federal law, court order or the attorney-client privilege.

§ 51.46 Disclosing information obtained from a provider of mental health services.

(a) Except as provided in paragraph (b) of this section, if a P&A system has access to records pursuant to section 105(a)(4) of the Act (42 U.S.C. 10805(a)(4)) which, under Federal or State law, are required to be maintained in a confidential manner by a provider of mental health services, it may not disclose information from such records to the individual who is the subject of the information if the mental health professional responsible for supervising the provision of mental health services to that individual has given the P&A system a written determination that disclosure of such information to the individual would be detrimental to the individual's health. The provider shall be responsible for giving any such written determination to the P&A system at the same time as access to the records containing the information is granted.

(b)(1) If the disclosure of information has been denied under paragraph (a) of this section to an individual, the following individuals or the P&A system may select another mental health professional to review the information and to determine if disclosure of the information would be detrimental to the individual's health:

- (i) Such individual;
- (ii) The legal guardian, conservator or other legal representative of the individual; or
- (iii) An eligible P&A system, acting on behalf of an individual:

(A) Whose legal guardian is the State; or

(B) Whose legal guardian, conservator, or other legal representative has not, within a reasonable time after the denial of access to information under paragraph (a), selected a mental health professional to review the information.

(2) If such mental health professional determines, based on professional judgment, that disclosure of the information would not be detrimental to the health of the individual, the P&A system may disclose such information to the individual.

(c) The restriction in paragraph (b) of this section does not affect the P&A system's access to the records.

PART 51a—PROJECT GRANTS FOR MATERNAL AND CHILD HEALTH

Sec.

51a.1 To which programs does this regulation apply?

51a.2 Definitions.

51a.3 Who is eligible to apply for Federal funding?

51a.4 How is application made for Federal funding?

51a.5 What criteria will DHHS use to decide which projects to fund?

51a.6 What confidentiality requirements must be met?

51a.7 What other DHHS regulations apply?

51a.8 What other conditions apply to these grants?

AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302); sec. 502(a), 502(b)(1)(A), and 506(a)(3) of the Social Security Act, 95 Stat. 819-20 (42 U.S.C. 702(a), 702(b)(1)(A) and 706(a)(3)).

SOURCE: 51 FR 7727, Mar. 5, 1986, unless otherwise noted.

§ 51a.1 To which programs does this regulation apply?

The regulation in this part applies to grants, contracts, and other arrangements under section 502(a) and 502(b)(1)(A) of the Social Security Act, as amended (42 U.S.C. 702(a) and 702(b)(1)(A)), the Maternal and Child Health (MCH) Federal Set-Aside project grant programs. Section 502(a) authorizes funding for special projects of regional and national significance (SPRANS), research and training projects with respect to maternal and child health and children with special health care needs (including early intervention training and services development); genetic disease testing, counseling and information programs; comprehensive hemophilia diagnostic and treatment centers; projects for screening and follow-up of newborns for sickle cell anemia and other genetic disorders; and special maternal and child health improvement projects. Section 502(b)(1)(A) authorizes funding for projects termed community integrated service system (CISS) projects for the development and expansion of: maternal and infant health home visiting; projects to increase the participation of obstetricians and pediatricians in title V and title XIX programs; integrated maternal and child health

§51a.2

service systems; maternal and child health centers operating under the direction of not-for-profit hospitals; rural maternal and child health programs; and outpatient and community-based services programs for children with special health care needs.

[59 FR 36706, July 19, 1994]

§51a.2 Definitions.

Act means the Social Security Act, as amended.

Genetic diseases means inherited disorders caused by the transmission of certain aberrant genes from one generation to another.

Hemophilia means a genetically transmitted bleeding disorder resulting from a deficiency of a plasma clotting factor.

Institution of higher learning means any college or university accredited by a regionalized body or bodies approved for such purpose by the Secretary of Education, and any teaching hospital which has higher learning among its purposes and functions and which has a formal affiliation with an accredited school of medicine and a full-time academic medical staff holding faculty status in such school of medicine.

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

§51a.3 Who is eligible to apply for Federal funding?

(a) With the exception of training and research, as described in paragraph (b) of this section, any public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 450b) is eligible to apply for federal funding under this Part.

(b) Only public or nonprofit private institutions of higher learning may apply for training grants. Only public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs may apply for grants contracts or cooperative agreements for research in maternal and child health services or

42 CFR Ch. I (10–1–11 Edition)

in services for children with special health care needs.

[59 FR 36706, July 19, 1994]

§51a.4 How is application made for Federal funding?

An application for funding under the MCH Federal Set-Aside project grant programs must be submitted to the Secretary at such time and in such manner as the Secretary may prescribe. It must include a budget and narrative plan of the manner in which the project will meet each of the requirements prescribed by the Secretary. The plan must describe the project in sufficient detail to identify clearly the nature, need, and specific objectives of, and methodology for carrying out, the project.

(Approved by the Office of Management and Budget under control number 0915–0050)

[59 FR 36706, July 19, 1994]

§51a.5 What criteria will DHHS use to decide which projects to fund?

(a) The Secretary will determine the allocation of funds available under sections 502(a) and 502(b)(1)(A) of the Act for each of the activities described in §51a.1.

(b) Within the limit of funds determined by the Secretary to be available for each of the activities described in §51a.1, the Secretary may award Federal funding for projects under this part to applicants which will, in his or her judgment, best promote the purpose of title V of the Social Security Act and address achievement of Healthy Children 2000 objectives,¹ taking, the following factors into account:

¹Healthy Children 2000: National Health Promotion and Disease Prevention Objectives Related to Mothers, Infants, Children, Adolescents, and Youth is a special compendium of health status goals and national health objectives affecting mothers, infants, children, adolescents, and youth originally published in Healthy People 2000 in September 1990. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0 or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office Washington, DC 20402–9325, (telephone: 202 512–1800).

Public Health Service, HHS

§51a.7

(1) The extent to which the project will contribute to the advancement of maternal and child health and/or improvement of the health of children with special health care needs;

(2) The extent to which the project is responsive to policy concerns applicable to MCH grants and to program objectives, requirements, priorities and/or review criteria for specific project categories, as published in program announcements or guidance materials.

(3) The extent to which the estimated cost to the Government of the project is reasonable, considering the anticipated results;

(4) The extent to which the project personnel are well qualified by training and/or experience for their roles in the project and the applicant organization has adequate facilities and personnel; and

(5) The extent to which, insofar as practicable, the proposed activities, if well executed, are capable of attaining project objectives.

(c) For the following types of CISS projects, preference for funding will be given to qualified applicants in areas with a high infant mortality rate (relative to the latest average infant mortality rate in the United States or in the State in which the area is located):

(1) Projects for the development and expansion of maternal and infant health home visiting;

(2) Projects to increase the participation of obstetricians and pediatricians in title V and title XIX programs;

(3) Integrated maternal and child health service systems;

(4) Maternal and child health centers operating under the direction of not-for-profit hospitals;

(5) Rural maternal and child health programs; and

(6) Outpatient and community based services for children with special health care needs.

[59 FR 36706, July 19, 1994]

§51a.6 What confidentiality requirements must be met?

All information as to personal facts and circumstances obtained by the project's staff about recipients of services shall be held confidential, and shall not be disclosed without the individual's consent except as may be oth-

erwise required by applicable law or as may be necessary to provide for medical audits by the Secretary with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§51a.7 What other DHHS regulations apply?

(a) Several other DHHS regulations apply to awards under this part. These include, but are not limited to:

42 CFR part 50—Policies of general applicability:

subpart B—Sterilization of persons in federally assisted family planning projects.

subpart C—Abortions and related medical services in federally assisted programs of the Public Health Service.

subpart E—Maximum allowable cost for drugs.

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants).

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Service—Effectuation of title VI of the Civil Rights Act of 1964.

45 CFR part 81—Practice and procedure for hearings under Part 80 of this title.

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance.

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

45 CFR part 93—New restrictions on lobbying.

(b) In addition to the above regulations, the following apply to projects funded through grants:

42 CFR part 50—Policies of general applicability:

subpart D—Public Health Service grant appeals procedure.

45 CFR part 16—Procedures of the Departmental Grant Appeals Board.

45 CFR part 74—Administration of grants to nonprofit organizations.

45 CFR part 75—Informal grant appeals procedures.

§51a.8

45 CFR part 92—Administration of grants to State and local governments.

[59 FR 36707, July 19, 1994]

§51a.8 What other conditions apply to these grants?

(a) Recipients of project grants will be required to submit such additional information to the Secretary on an annual basis as the Secretary determines, including:

(1) the number of individuals served or trained, as appropriate under the project;

(2) a copy of any evaluation conducted by the recipient; and

(3) a list of Healthy Children 2000 objectives addressed by the project and data on how the project contributed toward meeting the objectives.

(b) The Secretary may at the time of award of project grants under this Part impose additional conditions, including conditions governing the use of information or consent forms, when, in the Secretary's judgment, they are necessary to advance the approved program, the interest of public health, or the conservation of grant funds.

(c) Grant recipients of Healthy Tomorrows Partnership for Children Program, a Community Integrated Service System-funded initiative, must contribute non-Federal matching funds in years 2 through 5 of the project period equal to two times the amount of the Federal Grant Award or such lesser amount determined by the Secretary for good cause shown. Reimbursement for services provided to an individual under a State plan under Title XIX will not be deemed "non-Federal matching funds" for the purposes of this provision.

[59 FR 36707, July 19, 1994, as amended at 72 FR 3080, Jan. 24, 2007]

PART 51b—PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

Subpart A—General Provisions

Sec.

51b.101 To which programs do these regulations apply?

51b.102 Definitions.

51b.103 What are the general application requirements?

51b.104 Can personnel, supplies, and related items be provided in lieu of cash?

42 CFR Ch. I (10–1–11 Edition)

51b.105 Which other HHS regulations apply to these grants?

51b.106 What other conditions apply to these grants?

51b.107 Is participation in preventive health service programs required by these regulations?

Subpart B—Grants for Childhood Immunization Programs

51b.201 To which programs does this subpart apply?

51b.202 Definitions.

51b.203 Who is eligible for a grant under this subpart?

51b.204 What information is required in the application?

51b.205 How will grant applications be evaluated and the grants awarded?

51b.206 How can grant funds be used?

Subpart C [Reserved]

Subpart D—Grants for Venereal Disease Control Programs

51b.401 To which programs does this subpart apply?

51b.402 Definitions.

51b.403 Who is eligible for a grant under this subpart?

51b.404 What are the confidentiality requirements?

51b.405 What information is required in the application?

51b.406 How will grant applications be evaluated and the grants awarded?

51b.407 How can grant funds be used?

Subpart E [Reserved]

Subpart F—Grants for Research, Demonstrations, and Public Information and Education for the Prevention and Control of Venereal Disease

51b.601 To which programs does this subpart apply?

51b.602 Who is eligible for a grant under this subpart?

51b.603 What are the confidentiality requirements?

51b.604 What information is required in the application?

51b.605 How will grant applications be evaluated and the grants awarded?

51b.606 How can grant funds be used?

AUTHORITY: Secs. 317 and 318, Public Health Service Act, 92 Stat. 3574 and 3582 (42 U.S.C. 247b, 247c); sec. 1743 Pub. L. 97–35, 95 Stat. 763 (31 U.S.C. 1243 note).

Subpart A—General Provisions

SOURCE: 48 FR 4473, Feb. 1, 1983, unless otherwise noted.

§ 51b.101 To which programs do these regulations apply?

The regulations in this part apply to grants for preventive health service programs authorized under section 317 (42 U.S.C. 247b) and for venereal disease prevention and control programs authorized under section 318 (42 U.S.C. 247c) of the Act.

§ 51b.102 Definitions.

As used in these regulations:

Act means the Public Health Service Act, as amended.

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

State means one of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

§ 51b.103 What are the general application requirements?

(a) The project application shall contain a full description of the program objectives, plans, and activities. With respect to programs authorized by section 317 of the Act only, the application shall also provide, as the Secretary may require:

(1) The amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program.

(2) A description of the services provided by the applicant for this accounting period covered under paragraph (a)(1) of this section.

(3) The amount of Federal funds needed by the applicant to continue providing these services.

(4) A description of any proposed changes in the provision of the services, reasons and priorities, and the amount of Federal funds needed by the applicant to make the changes.

(b) The application shall contain evidence satisfactory to the Secretary that it has been submitted, as appro-

priate, for action to the planning agency designated by the Secretary under title XV of the Act (42 CFR parts 122 and 123). These grants are subject to the intergovernmental review of Federal programs of Executive Order 12372.

(c) The application shall contain assurances that no one will be denied services because of inability to pay, and that the services are provided in a manner which preserves human dignity and maximizes acceptance.

§ 51b.104 Can personnel, supplies, and related items be provided in lieu of cash?

The Secretary may reduce a grant by the amount of the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished a grant recipient when furnished at the request of the recipient. The Secretary also may reduce a grant by the amount of the pay, allowances, travel expenses, and any other costs in connection with the detail of any officer or employee of the Government to the recipient when the detail is at the request of the recipient. The amount the grant is reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing personnel and shall be deemed to have been paid to the recipient.

§ 51b.105 Which other HHS regulations apply to these grants?

Several other HHS regulations apply to grants under this part. These include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Administration of grants

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Debarment and suspension from eligibility for financial assistance

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

§51b.106

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

[49 FR 38109, Sept. 27, 1984]

§51b.106 What other conditions apply to these grants?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 2 to 5 years.

(b) For budgetary and funding purposes, the project period is generally divided into 12-month intervals called budget periods. A grantee must submit a separate application to have the support continued for each subsequent budget period after the initial award. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) Any funds granted pursuant to this subpart shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(e) The Secretary may, at the time of award, impose additional conditions, including conditions governing the use of information or consent forms, when, in the Secretary's judgment, they are

42 CFR Ch. I (10–1–11 Edition)

necessary to advance the approved program, the interest of the public health, or the conservation of grant funds.

§51b.107 Is participation in preventive health service programs required by these regulations?

Nothing in these regulations shall be construed to require any State or political subdivision to have a preventive health service program which would require any person who objects to treatment to be treated under the program.

Subpart B—Grants for Childhood Immunization Programs

SOURCE: 44 FR 40501, July 11, 1979, unless otherwise noted.

§51b.201 To which programs does this subpart apply?

The regulations in this subpart apply to the award of grants under section 317 of the Act for programs to immunize children against vaccine preventable diseases.

§51b.202 Definitions.

As used in this subpart:

Childhood immunization program means a preventive health service program to immunize children against vaccine preventable diseases including poliomyelitis, measles, mumps, rubella, diphtheria, pertussis, and tetanus.

§51b.203 Who is eligible for a grant under this subpart?

An applicant must be a State agency or an agency of a political subdivision of a State which has legal responsibility for disease control under the laws of a State.

§51b.204 What information is required in the application?

(a) The initial application must cover the project period, and must include a description of the following:

(1) The need for grant support.

(2) The immediate (1 year budget period) and long-range (2–5 year project period) objectives of the project in specific and measurable terms.

(3) Current immunization programs and the additional or intensified activities to be carried out to meet the objectives and priorities.

(4) The following program elements should be included and described:

(i) A plan to assure that children begin and complete their immunizations on schedule, including the use of a standard immunization record card, a provider-based tickler system (public and private) for the recall of children, and a hospital-based immunization education program for new mothers.

(ii) Assessment of immunization status of school enterers, children attending licensed day-care centers, and children under 2 years of age and new enrollees under age 5 served in public clinics.

(iii) A plan for surveillance of vaccine-preventable diseases that includes morbidity and mortality reporting as well as field and laboratory investigations.

(iv) Procedures for prompt review of the data collected from the morbidity surveillance system to allow for immediate response to all occurrence of suspected diphtheria and polio cases upon notification and response to suspected measles cases within 48 hours.

(v) A system for monitoring vaccine-associated reactions including a mechanism for responding to persons with vaccine-related complaints.

(vi) A plan to systematically immunize susceptible children at school entry through vigorous enforcement of school immunization laws.

(5) The manner in which the applicant intends to evaluate the project.

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

(1) A budget and justification for the grant funds requested.

(2) A summary of the progress achieved during the previous budget period.

(3) A description of any changes in the information shown in the project application.

[48 FR 4474, Feb. 1, 1983]

§51b.205 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting part of the cost of a childhood immunization program.

Grants will be awarded to those applicants whose projects he determines will best promote the purposes of section 317 of the Act. Before awarding a grant to a local public entity of a State, the Secretary will consult with the State health authority.

(b) Priorities for funding will be based on the following factors:

(1) The relative extent of the problems which are caused by one or more of the vaccine preventable diseases in the area served by the applicant.

(2) The extent to which the proposed program is designed to eliminate or reduce the problems.

(3) The extent to which the proposed program will increase the immunization rates in population groups identified as having the lowest immunity levels.

(4) The extent to which the grantee will cooperate with and use public and nonprofit private entities and volunteers.

(5) The extent to which a strong commitment to the objectives of the program is reflected in the commitment of grantee resources to the program.

[44 FR 40501, July 11, 1979, as amended at 48 FR 4475, Feb. 1, 1983]

§51b.206 How can grant funds be used?

Grant funds awarded under this subpart may be used to purchase supplies, materials, and equipment for childhood immunization programs. Grant funds also may be used to pay for salaries or wages and related expenses for personnel directly involved in the planning, organization, promotion, epidemiology, surveillance, and other program activities.

Subpart C [Reserved]

Subpart D—Grants for Venereal Disease Control Programs

SOURCE: 48 FR 4475, Feb. 1, 1983, unless otherwise noted.

§51b.401 To which programs does this subpart apply?

The regulations in this subpart apply to the award of project grants under section 318(c) of the Act for venereal

§ 51b.402

disease prevention and control programs, and under section 318(b) of the Act with respect to public information and education activities which are integral to a balanced, comprehensive venereal disease control program.

§ 51b.402 Definitions.

As used in this subpart:

Venereal disease means gonorrhea, syphilis, or any other disease which can be sexually transmitted and which the Secretary determines is or may be amenable to control with assistance provided under this authority and which is of national significance.

Venereal disease control program means a program designed to carry out activities or to provide services to systematically detect and prevent venereal disease as distinguished from those activities or services which are designed to diagnose or treat venereal disease patients or suspects.

§ 51b.403 Who is eligible for a grant under this subpart?

An applicant must be a State agency or a political subdivision of a State which has legal responsibility for disease control under the laws of the State.

§ 51b.404 What are the confidentiality requirements?

All information obtained by program personnel in connection with the examination, care, and treatment of an individual in this program shall be held confidential. It shall not be disclosed without the individual's consent except as may be required by the law of a State or political subdivision of a State or as may be necessary to provide services to the individual. Information may be disclosed in summary, statistical, or other form, or for clinical or research purposes, but only if the disclosure does not identify particular individuals.

§ 51b.405 What information is required in the application?

(a) The initial application must include a description of the following:

- (1) The nature and extent of the venereal disease problem in the area.
- (2) The need for project grant support.

42 CFR Ch. I (10–1–11 Edition)

(3) The immediate (1-year budget period) and long-range (2–5 year project period) objectives of the project in specific and measurable terms.

(4) The activities to be carried out to meet the objectives. The following program elements must be included and described:

- (i) Venereal disease surveillance.
- (ii) Casefinding and case followup.
- (iii) Interstate epidemiologic referral and followup.
- (iv) Public venereal disease information and education.
- (v) Professional (including appropriate allied health personnel) venereal disease education, training, and clinical skills improvement activities, including efforts to assure high quality clinical services in public venereal disease clinics.

(5) At the option of the applicant, special studies or demonstrations to evaluate or test venereal disease prevention and control strategies and activities.

(6) The manner in which the applicant intends to conduct and evaluate the project, including a system for analysis of morbidity data so that control activities can be efficiently evaluated and targeted.

(7) The diagnostic and treatment services that will be provided.

(8) A budget and justification for the grant funds requested. Since public information and education activities are authorized separately from other control program activities, funds requested for this purpose must be itemized and justified separately in the narrative part of the application.

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

- (1) A budget and justification for the grant funds requested.
- (2) A summary of the progress achieved during the previous budget period.
- (3) A description of any changes in the information shown in the project application.

§ 51b.406 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting the cost of a venereal disease control program. Before awarding a grant to a political subdivision of a State, the Secretary will consult with the State health authority.

(b) Priorities for funding will be based on the following factors:

(1) The relative extent of the venereal disease problem in the area served by the applicant.

(2) The design of the venereal disease prevention and control program.

(3) The general quality of the applicant's plan of operation and objectives in accordance with the requirements in these regulations. Emphasis will be placed on determining the extent to which services are coordinated among health care providers in the area served and integrated into a cohesive plan for delivery of service to groups having the highest incidence of venereal disease.

(4) The capacity of the applicant to make effective use of Federal funds.

(5) The commitment of the applicant to the control of venereal disease as reflected in the commitment of applicant resources to the program.

§ 51b.407 How can grant funds be used?

Grant funds awarded under this subpart may be used only for programs approved under section 318(c), and with respect to public information and education, those programs approved under section 318(b) of the Act. Unless specifically approved, grant funds shall not be used for performing diagnostic tests (other than gonorrhea screening tests), maintaining central registries, purchasing data processing equipment, or providing diagnostic and treatment facilities and services. The applicant must provide assurances, however, that these services will be available as needed as an adjunct to control program activities supported with grant funds. To obtain special approval for grant support of such activities, the grantee shall justify the exception to the satisfaction of the Secretary that funds for this purpose are necessary for the proper conduct of the program and are otherwise

unavailable. Support of these services will generally be approved only in the following situations:

(a) Special studies or demonstrations, (b) the support of developmental or start-up activity, or (c) the support of an essential service which will result in a savings to a detection or prevention activity supported by the grant. Unless otherwise approved, exceptions based on paragraphs (b) and (c) of this section are only allowed during one funding period. The grantee is expected to support these activities in subsequent funding periods.

Subpart E [Reserved]**Subpart F—Grants for Research, Demonstrations, and Public Information and Education for the Prevention and Control of Venereal Disease**

SOURCE: 48 FR 4476, Feb. 1, 1983, unless otherwise noted.

§ 51b.601 To which programs does this subpart apply?

The regulations in this subpart apply to the award of venereal disease control project grants for research, demonstrations, public information, and education activities which can be applied to achieve improvements in venereal disease prevention and control under section 318(b) of the Act.

§ 51b.602 Who is eligible for a grant under this subpart?

An applicant must be a State, political subdivision of any State, or any other public or nonprofit private entity.

§ 51b.603 What are the confidentiality requirements?

All information obtained by program personnel in connection with the examination, care, and treatment of an individual in this program shall be held confidential. It shall not be disclosed without the individual's consent except as may be required by the law of a State, or political subdivision of a State, or as may be necessary to provide services to the individual. Information may be disclosed in summary,

§ 51b.604

statistical, or other form, or for clinical or research purposes, but only if the disclosure does not identify particular individuals.

§ 51b.604 What information is required in the application?

(a) The initial application must include a description of the following:

(1) The setting and circumstances for which project grant support is being requested, including:

(i) The immediate and long-range objectives of the project in specific and measurable terms.

(ii) The activities which will be undertaken to accomplish the objectives, including the timing of these activities.

(iii) The anticipated application of findings to the national venereal disease control effort.

(iv) Any other information which will support the request for grant assistance.

(2) The relationship between the planned activities and the project objectives. The application must describe in detail how the applicant intends to proceed, particularly if the project is unusually complex and several activities are interdependent or unprecedented.

(3) A comprehensive and realistic plan which the applicant will use to evaluate the project. The plan must include periodic assessment of any possible impact, both positive and negative, that the proposed project might have upon the established venereal disease control program in the locality or localities in which the project will be undertaken.

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

(1) A budget and justification for the grant funds requested.

(2) A summary of the progress achieved during the previous budget period.

(3) A description of any changes in the information shown in the project application.

42 CFR Ch. I (10–1–11 Edition)

§ 51b.605 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting the costs of special activities authorized under section 318(b) of the Act.

(b) Grant applications will be reviewed and evaluated according to the following criteria:

(1) Is there adequate evidence that the proposed project is needed and that the outcome has potential to directly benefit the national venereal disease control effort?

(2) Are the project objectives specific, measurable, realistic, time phased, and related to promoting the purposes of section 318?

(3) Is the method of operation logical and clearly related to project objectives, and does it describe how the applicant intends to proceed particularly with activities which are complex, interrelated, or unprecedented?

(4) Does the method of operation include an assessment of any possible impact, both positive and negative, that the conduct of the proposed initiative might have upon the established venereal disease control program in the locality or localities in which the project will be undertaken?

(5) Does the proposal include a comprehensive and realistic plan for the evaluation of the project, and specify the measures and instruments of measurement to be used?

(6) Is the budget request reasonable and consistent with the intended use of grant funds?

(7) If the applicant intends only to evaluate an existing disease prevention and control approach, are the objectives substantially different from those which could be met by routine program evaluation?

§ 51b.606 How can grant funds be used?

(a) Grant funds may be used for the costs associated with planning, organizing, and conducting applied research, demonstrations, and public information and education programs.

(b) Grant funds may also be used to reimburse individuals who agree to be participants in the applied research

Public Health Service, HHS

§ 51c.102

projects. This reimbursement, however, must be justified as necessary and reasonable. A schedule of reimbursements must be submitted with the application and approved as part of the program plan.

(c) Grant funds may not be used to supplant funds supporting existing venereal disease control services provided by a State or locality.

PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES

Subpart A—General Provisions

Sec.	
51c.101	Applicability.
51c.102	Definitions.
51c.103	Eligibility.
51c.104	Application.
51c.105	Accord with health planning.
51c.106	Amount of grant.
51c.107	Use of project funds.
51c.108	Grant payments.
51c.109	Nondiscrimination.
51c.110	Confidentiality.
51c.111	Publications and copyright.
51c.112	Grantee accountability.
51c.113	Applicability of 45 CFR part 74.

Subpart B—Grants for Planning and Developing Community Health Centers

51c.201	Applicability.
51c.202	Application.
51c.203	Project elements.
51c.204	Grant evaluation and award.

Subpart C—Grants for Operating Community Health Centers

51c.301	Applicability.
51c.302	Application.
51c.303	Project elements.
51c.304	Governing board.
51c.305	Grant evaluation and award.

Subpart D—Grants for Operating Community Health Projects

51c.401	Applicability.
51c.402	Application.
51c.403	Project elements.
51c.404	Grant evaluation and award.

Subpart E—Acquisition and Modernization of Existing Buildings

51c.501	Applicability.
51c.502	Definitions.
51c.503	Application.
51c.504	Project elements.
51c.505	Determination of cost.
51c.506	Use of grant funds.

51c.507 Facility which has previously received Federal grant.

AUTHORITY: Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254c); sec. 215, Public Health Service Act, 58 Stat. 690, (42 U.S.C. 216).

SOURCE: 41 FR 53205, Dec. 3, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 51c.101 Applicability.

The regulations of this subpart are applicable to all project grants authorized by section 330 of the Public Health Service Act (42 U.S.C. 254c).

§ 51c.102 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act.

(b) *Catchment area* means the area served by a project funded under section 330 of the Act.

(c)(1) *Community health center* or *center* means an entity which, through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities, provides for all residents of its catchment area:

(i) Primary health services;

(ii) As determined by the Secretary to be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services;

(iii) Referral to providers of supplemental health services and payment, as determined by the Secretary to be appropriate and feasible, for their provision of such services;

(iv) Environmental health services, as determined by the Secretary to be appropriate for particular centers; and

(v) Information on the availability and proper use of health services.

(2) For purposes of paragraph (c)(1) of this section, the provision of a given service by a center will be determined by the Secretary to be appropriate where:

(i) There is a need, as determined by the Secretary, for the provision of such service in the catchment area; and

(ii) The provision of such service by the center is feasible, taking into consideration the center's projected revenues, other resources, and grant support under this part.

(d) *Environmental health services* means the detection and alleviation of unhealthful conditions of the environment of the catchment area, such as problems associated with water supply, sewage treatment, solid waste disposal, rodent and parasite infestation, and housing conditions. For the purposes of this part, the detection and alleviation of unhealthful conditions of the environment includes the notification of and making of arrangements with appropriate Federal, State, or local authorities responsible for correcting such conditions.

(e) *Medically underserved population* means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Medically underserved areas will be designated by the Secretary and a list of those designated will be published in the FEDERAL REGISTER from time to time, taking into consideration the following factors, among others:

(1) Available health resources in relation to size of the area and its population, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pediatrics, or obstetrics and gynecology to population;

(2) Health indices for the population of the area, such as infant mortality rate;

(3) Economic factors affecting the population's access to health services, such as percentage of the population with incomes below the poverty level; and

(4) Demographic factors affecting the population's need and demand for health services, such as percentage of the population age 65 and over.

(f) *Nonprofit*, as applied to any private agency, institution, or organization, means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure,

to the benefit of any private shareholder or individual.

(g) *Physician* means a licensed doctor of medicine or doctor of osteopathy.

(h) *Primary health services* means:

(1) Diagnostic, treatment, consultative, referral, and other services rendered by physicians, and, where feasible, by physician's extenders, such as physicians' assistants, nurse clinicians, and nurse practitioners;

(2) Diagnostic laboratory services and diagnostic radiologic services;

(3) Preventive health services, including medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, prenatal services, well child care (including periodic screening), immunizations, and voluntary family planning services;

(4) Emergency medical services, including provision, through clearly defined arrangements, for access of users of the center to health care for medical emergencies during and after the center's regularly scheduled hours;

(5) Transportation services as needed for adequate patient care, sufficient so that residents of the catchment area served by the center with special difficulties of access to services provided by the center receive such services; and

(6) Preventive dental services provided by a licensed dentist or other qualified personnel, including (i) oral hygiene instruction; (ii) oral prophylaxis, as necessary; and (iii) topical application of fluorides, and the prescription of fluorides for systemic use when not available in the community water supply.

(i) *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.

(j) *Supplemental health services* means health services which are not included as primary health services and which are:

(1) Inpatient and outpatient hospital services;

(2) Home health services;

(3) Extended care facility services;

(4) Rehabilitative services (including physical and occupational therapy) and long-term physical medicine;

(5) Mental health services, including services of psychiatrists, psychologists, and other appropriate mental health professionals;

(6) Dental services other than those provided as primary health services;

(7) Vision services, including routine eye and vision examinations and provision of eyeglasses, as appropriate and feasible;

(8) Allied health services;

(9) Pharmaceutical services, including the provision of prescription drugs;

(10) Therapeutic radiologic services;

(11) Public health services (including nutrition education and social services);

(12) Ambulatory surgical services;

(13) Health education services; and

(14) Services, including the services of outreach workers, which promote and facilitate optimal use of primary health services and services referred to in the preceding subparagraphs of this paragraph and, if a substantial number of individuals in the population served by the center are of limited English-speaking ability, the services of outreach workers and other personnel fluent in the language or languages spoken by such individuals.

§51c.103 Eligibility.

Any public or nonprofit private entity is eligible to apply for a grant under this part.

§51c.104 Application.

(a) An application for a grant under this part shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.

(b) The application shall contain a budget and narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this part. The application must describe how and the extent to which the project has met, or plans to meet, each of the requirements in subpart B (relating to grants for planning and developing community health centers), subpart C (relating to grants for the operation of community health centers), or subpart D (relating to

grants for the operation of community health projects), as applicable. In addition, applications must include:

(1) A statement of specific, measurable objectives and the methods to be used to assess the achievement of the objectives in specified time periods and at least on an annual basis.

(2) The precise boundaries of the catchment area to be served by the applicant, including an identification of the medically underserved population or populations within the catchment area. In addition, the application shall include information sufficient to enable the Secretary to determine that the applicant's catchment area meets the following criteria:

(i) The size of such area is such that the services to be provided by the applicant are available and accessible to the residents of the area promptly and as appropriate;

(ii) The boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by Federal and State health and social service programs; and

(iii) The boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

(3) The results of an assessment of the need that the population served or proposed to be served has for the services to be provided by the project (or in the case of applications for planning and development projects, the methods to be used in assessing such need), utilizing, but not limited to, the factors set forth in §51c.102(e)(1)–(4).

(4) Position descriptions for key personnel who will be utilized in carrying out the activities of the project and a statement indicating the need for the positions to be supported with grant funds to accomplish the objectives of the project.

(5) Letters and other forms of evidence showing that efforts have been made to secure financial and professional assistance and support for the project within the proposed catchment area and the continuing involvement of

the community in the development and operation of the project.

(6) An assurance that an independent certified public accountant, or a public accountant licensed before December 31, 1970, will be engaged to certify that the system for the management and control of its financial assets will be in accord with sound financial management practices, including applicable Federal requirements.

(7) A list of all services proposed to be provided by the project.

(8) A list of services which are to be provided directly by the project through its own staff and resources and a description of any contractual or other arrangements (including copies of documents, where available) entered into, or planned for the provision of services.

(9) The schedule of fees and/or payments and schedule of discounts for services provided by the project.

(10) Evidence that all applicable requirements for review and/or approval of the application under title XV of the Act have been met.

(11) An assurance that the project will be conducted in accordance with the applicable requirements of this part.

(c) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the applicable regulations of this part, and any additional conditions of the grant.

(Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254c); sec. 215, Public Health Service Act, 58 Stat. 690, 67 Stat. 63 (42 U.S.C. 216))

[41 FR 53205, Dec. 3, 1976, as amended at 48 FR 29201, June 24, 1983; 48 FR 45558, Oct. 6, 1983]

§51c.105 Accord with health planning.

A grant may be made under this part only if the applicable requirements of title XV of the Act relating to review and approval by the appropriate health planning agencies have been met.

§51c.106 Amount of grant.

(a) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated

portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary: *Provided, however,* That no grant shall be made for an amount in excess of the total cost found necessary by the Secretary to carry out the project.

(i) In determining the percentage of project costs to be borne by the grantee, factors which the Secretary will take into consideration will include the following:

(A) The ability of the grantee to finance its share of project costs from non-Federal sources;

(B) The need in the area served by the project for the services to be provided; and

(C) The extent to which the project will provide services in an innovative manner which the Secretary desires to stimulate in the interest of developing more effective health service delivery systems on a regional or national basis.

(ii) At any time after approval of an application under this part, the Secretary may retroactively agree to a percentage of project costs to be borne by the grantee lower than that determined pursuant to paragraph (a)(2)(i) of this section where he finds that changed circumstances justify a smaller contribution.

(iii) In determining the grantee's share of project costs, costs borne by Federal grant funds, or costs used to match other Federal grants, may not

be included except as otherwise provided by law or regulations.

(b) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is recommended.

(c) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application.

§51c.107 Use of project funds.

(a) Any funds granted pursuant to this part, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 330 of the Act, the applicable regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) Project funds awarded under this part may be used for, but need not be limited to, the following:

(1) The costs of acquiring and modernizing existing buildings (including the costs of amortizing the principal of, and paying interest on, loans), but only in accordance with subpart E of this part and as approved in the grant award;

(2) The costs of obtaining technical assistance to develop and improve the management capability of the project, but only as approved by the Secretary;

(3) The reimbursement of members of the grantee's governing board, if any, for reasonable expenses actually incurred by reason of their participation in board activities;

(4) The reimbursement of governing board members for wages lost by reason of participation in the activities of such board if the member is from a family with an annual family income below \$10,000 or if the member is a single person with an annual income below \$7,000;

(5) The cost of delivering health services, including services rendered on a prepaid capitation basis, to residents of the project's catchment area within the following limitations: grant funds

may be used to pay the full cost of project services to individuals and families with annual incomes at or below those set forth in the most recent "CSA Income Poverty Guidelines" (45 CFR 1060.2) issued by the Community Services Administration; and to pay the portion of the cost of services provided in accordance with the schedule of discounts which, under such schedule, is uncompensated; *Provided*, That (i) charges will be made to such individuals and families in accordance with §51c.303(f) of subpart C; (ii) reasonable effort shall be made to collect such charges under a billing and collections system; and (iii) the charge to grant funds shall exclude any amounts collected pursuant to paragraph (b)(5)(ii) of this section;

(6) The cost of insurance for medical emergency and out-of-area coverage;

(7) The cost of providing to the staff of the project training related to the provision of health services provided or to be provided by the project, and, to the staff and governing board, if any, training related to the management of an ambulatory care facility, consistent with the applicable requirements of 45 CFR part 74; and

(8) The cost of developing and maintaining a reserve fund where required by State law for prepaid health care plans.

(c) Prior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

§51c.108 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§51c.109 Nondiscrimination.

(a) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, (42 U.S.C. 2000d *et seq.*)) and in particular section 601 of such Act which provides that no person in the United States shall on the

§51c.110

grounds of race, color, or national origin be excluded from participation, in be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal Financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80). In addition, no person shall, on the grounds of age, sex, creed, or marital status (unless otherwise medically indicated), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity so receiving Federal financial assistance.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§51c.110 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about recipients of services shall be held confidential, and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary or his designee with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§51c.111 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, non-exclusive, and irrevocable license or

42 CFR Ch. I (10-1-11 Edition)

right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§51c.112 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid as well as other funds and in-kind contributions by presenting or otherwise making available evidence satisfactory to the Secretary of expenditure for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the government of the political subdivisions of the State. All grantees other than a State, as defined, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout—(1) Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as

Public Health Service, HHS

§ 51c.203

final settlement with respect to each approved project the total sum of:

- (i) Any amount not accounted for pursuant to paragraph (a) of this section;
- (ii) Any credits for earned interest pursuant to paragraph (b) of this section;
- (iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

§ 51c.113 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this part:

45 CFR PART 74

Subpart

- A General.
- B Cash depositories.
- C Bonding and insurance.
- D Retention and custodial requirements for records.
- F Grant-related income.
- G Matching and cost sharing.
- K Grant payment requirements.
- L Budget revision procedures.
- M Grant closeout, suspension, and termination.
- O Property.
- Q Cost principles.

Subpart B—Grants for Planning and Developing Community Health Centers

§ 51c.201 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 330(c) of the Act for projects for planning and developing community health centers which will serve medically underserved populations.

§ 51c.202 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of subpart A,

contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of § 51c.203.

§ 51c.203 Project elements.

A project for the planning and developing of a community health center supported under this subpart must:

(a) Prepare an assessment of the need of the population proposed to be served by the community health center for the services set forth in § 51c.102(c)(1) of subpart A, with special attention to the need of the medically underserved population for such services. Such assessment of need shall, at a minimum, consider the factors listed in § 51c.102(e)(1)–(4).

(b) Design a community health center program for such population, based on such assessment, which indicates in detail how the proposed community health center will fulfill the needs identified in the assessment prepared pursuant to paragraph (a) of this section and how it will meet the requirements contained in subpart C of this part.

(c) Develop a plan for the implementation of the program designed pursuant to paragraph (b) of this section. Such implementation plan shall provide for the time-phased recruitment and training of the personnel essential for the operation of a community health center and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements contained in subpart C of this part as of the end of the project period.

(d) Implement the plan developed pursuant to paragraph (c) of this section in accordance with such paragraph.

(e) Make efforts to secure, within the proposed catchment area of such center to the extent possible, financial and professional assistance and support for the project.

(f) Initiate and encourage continuing community involvement in the development and operation of the project.

(g) Establish standards and qualifications for personnel (including the project director).

§ 51c.204

(h) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

§ 51c.204 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(c) of the Act and the applicable regulations of this part, taking into account:

(1) The degree to which the proposed project satisfactorily provides for the elements set forth in § 51c.203;

(2) The relative need of the population to be served for the services to be provided;

(3) The administrative and management capability of the applicant;

(4) The potential of the project for development of new and effective methods for health services delivery and management;

(5) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(6) The extent to which community resources will be utilized in the project;

(7) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking into consideration the following factors;

(i) The urban-rural area to be served;

(ii) The nature of the organization applying; and

(iii) The organizational structure for delivery of services;

(8) Whether the project's catchment area is exclusive of the area served by a community health center;

(9) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects.

(b) The Secretary may:

(1) Make no more than two grants under this subpart for the same project.

42 CFR Ch. I (10–1–11 Edition)

(2) Make a grant under this subpart to an entity which has been awarded one or more grants under section 330(d)(1)(A) and/or section 330(d)(1)(B) of the Act only if the grant under this subpart is for a new project.

Subpart C—Grants for Operating Community Health Centers

§ 51c.301 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A, are applicable to grants awarded pursuant to section 330(d)(1)(A) of the Act for the costs of operation of community health centers which serve medically underserved populations.

§ 51c.302 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of subpart A,

(a) Be submitted by an entity which may be a co-applicant which the Secretary determines is a community health center, and

(b) Contain information sufficient to enable the Secretary to determine that the center will meet the requirements of § 51c.103.

[41 FR 53205, Dec. 3, 1976, as amended at 42 FR 60418, Nov. 25, 1977]

§ 51c.303 Project elements.

A community health center supported under this subpart must:

(a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center's catchment area.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirements of § 51c.110 of subpart A.

(c) Have an ongoing quality assurance program which provides for the following:

(1) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care;

(2) Periodic assessment of the appropriateness of the utilization of services

and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments shall:

(i) Be conducted by physicians or by other licensed health professionals under the supervision of physicians;

(ii) Be based on the systematic collection and evaluation of patient records; and

(iii) Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

(d) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit on an annual basis (unless waived for cause by the Secretary) by an independent certified public accountant or a public accountant licensed prior to December 31, 1970, to determine, at a minimum, the fiscal integrity of grant financial transactions and reports, and compliance with the regulations of this part and the terms and conditions of the grant.

(e) Where the cost of care and services furnished by or through the project is to be reimbursed under title XIX or title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the title XIX or title XX State agency for such reimbursement.

(f) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. *Provided*, That such schedule of discounts shall provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (45 CFR 1060.2) and for no discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines, except that nominal fees for services may be collected from individuals with annual incomes at or below such levels where imposition of such fees is consistent with project goals.

(g) Make every reasonable effort, including the establishment of systems

for eligibility determination, billing, and collection, to:

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, to social services and family planning under title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (f) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (f) of this section.

(h) Have a governing board which meets the requirements of §51c.304.

(i) Have developed an overall plan and budget for the center that:

(1) Provides for an annual operating budget and a three-year financial management plan which include all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items;

(2) Provides for a capital expenditures plan for at least a three-year period (including the year to which the operating budget described in paragraph (i)(1) of this section is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objective of, each anticipated expenditure in excess of \$100,000 related to the acquisition of land, the improvement of land, buildings, and equipment and the replacement, modernization and expansion of buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(3) Provides for plan review and updating at least annually; and

(4) Is prepared under the direction of the governing board, by a committee consisting of representatives of the governing board, and administrative staff, and the medical staff, if any, of the center.

§51c.304

42 CFR Ch. I (10–1–11 Edition)

(j) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which shall enable the center to provide such statistics and other information as the Secretary may reasonably require relating to the center's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(k) Review its catchment area annually to insure that the criteria set out in §51c.104(b)(2) of subpart A are met and, where such criteria are not met, revise its catchment area, with the approval of the Secretary, to conform to such criteria to the extent feasible.

(l) In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English shall be so identified.

(m) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(n) To the extent possible, coordinate and integrate project activities with the activities of other Federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(o) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(p) Provide sufficient staff, qualified by training and experience, to carry out the activities of the center.

(q) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(r) Utilize, to the maximum extent feasible, other Federal, State, and local, and private resources available for support of the project, prior to use of project funds under this part.

(s) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities.

(t) Where the center will provide services through contract or other cooperative arrangements with other providers of services, establish rates and methods of payment for health care. Such payments must be made pursuant to agreements, with a schedule of rates and payment procedures maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary.

(u) Operate in a manner such that no person shall be denied service by reason of his inability to pay therefor: *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

(v) In addition to the above, projects which are supported with grant funds for the operation of a prepaid health care plan also must provide:

(1) A marketing and enrollment plan, including market analysis, marketing strategy, and enrollment growth projections.

(2) A plan that provides for funding on a capitation basis of such portion of the residents of the catchment area of the center, as the Secretary shall determine.

(3) An assurance that services shall be available to all residents of the catchment area without regard to method of payment or health status.

§51c.304 Governing board.

A governing board for the center shall be established by an applicant as follows:

(a) *Size.* The board shall consist of at least 9 but not more than 25 members, except that this requirement may be

waived by the Secretary for good cause shown.

(b) *Composition.* (1) A majority of the board members shall be individuals who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, sex.

(2) No more than one-half of the remaining members of the board may be individuals who derive more than 10 percent of their annual income from the health care industry.

(3) The remaining members of the board shall be representative of the community in which the center's catchment area is located and shall be selected for their expertise in community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community.

(4) No member of the board shall be an employee of the center, or spouse or child, parent, brother or sister by blood or marriage of such an employee. The project director may be a non-voting, ex-officio member of the board.

(c) *Selection of members.* The method of selection of all governing board members shall be prescribed in the by-laws or other internal governing rules of the center. Such by-laws or other rules must specify a process of selection of individuals on the governing board who represent the population served or to be served by the center so that such individuals, as a group, are representative of such population. Such process of selection in the by-laws or other rules is subject to approval by the Secretary.

(d) *Functions and responsibilities.* (1) The governing board for the center shall have authority for the establishment of policy in the conduct of the center.

(2) The governing board shall hold regularly scheduled meetings, at least once each month, for which minutes shall be kept.

(3) The governing board shall have specific responsibility for:

(i) Approval for the selection and dismissal of a project director or chief executive officer of the center;

(ii) Establishing personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales, employee grievance procedures, and equal opportunity practices;

(iii) Adopting policy for financial management practices, including a system to assure accountability for center resources, approval of the annual project budget, center priorities, eligibility for services including criteria for partial payment schedules, and long-range financial planning;

(iv) Evaluating center activities including services utilization patterns, productivity of the center, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances;

(v) Assuring that the center is operated in compliance with applicable Federal, State, and local laws and regulations; and

(vi) Adopting health care policies including scope and availability of services, location and hours of services, and quality-of-care audit procedures.

§ 51c.305 Grant evaluation and award.

Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(A) of the Act and the applicable regulations of this part, taking into consideration;

(a) The extent to which the project would provide for the elements set forth in § 51c.303;

(b) The relative need of the population to be served for the services to be provided;

(c) The potential of the center for the development of new and effective methods for health services delivery and management;

(d) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(e) The administrative and management capability of the applicant;

(f) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking

§51c.401

42 CFR Ch. I (10–1–11 Edition)

into consideration the following factors:

- (1) The urban-rural area to be served;
- (2) The nature of the organization applying;
- (3) The organizational structure for delivery of services;
- (g) The number of users of the center and the level of utilization of services in previous operational periods, if any;
- (h) Whether the center's catchment area is exclusive of the area served by another center;
- (i) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects;
- (j) The extent to which community resources will be utilized by the project;
- (k) The extent to which the center will provide preventive health services so as to maintain and improve the health status of the population served; and
- (l) The extent to which center operations will emphasize direct health services, efficiency of operations and sound financial management.

Subpart D—Grants for Operating Community Health Projects

§51c.401 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A are applicable to grants awarded pursuant to section 330(d)(1)(B) of the Act for the costs of operation of projects which provide health services to medically underserved populations.

§51c.402 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of §51c.104 of subpart A, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of §51c.403 of this subpart.

§51c.403 Project elements.

A project for the operation of a community health project supported under this subpart must:

(a) Meet all of the requirements of §51c.303 of this part except for paragraph (h).

(b) Provide those services enumerated in §51c.102(c)(1) of this part which the Secretary determines to be feasible and desirable and which are specified in the grant award.

(c) Establish a governing board meeting the requirements of §51c.304 by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart.

§51c.404 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(B) of the Act and the applicable regulations of this part,

(1) Where the project meets the requirements of §51c.403(a); and

(2) Taking into consideration the following:

(i) The degree to which the project would provide the services enumerated in §51c.102(c)(1) and the feasibility of its providing all of such enumerated services by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart;

(ii) Whether the project will have a governing board meeting the requirements of §51c.304 by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart;

(iii) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health service or reimbursement programs or projects;

(iv) The need of the population to be served for the services to be provided;

(v) The potential of the project for the development of new and effective methods for health services delivery and management;

(vi) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(vii) The administrative and management capacity of the applicant; and

(viii) The extent to which community resources will be utilized in the project.

(b) The Secretary may:

(1) Make no more than two grants for the same entity under section 330(d)(1)(B) of the Act;

(2) Not make any grant under section 330(d)(1)(B) to an entity which, for the same project, has been awarded more than one grant under section 330(c) of the Act;

(3) Not make a grant under section 330(d)(1)(B) to an entity which has been awarded a grant under section 330(d)(1)(A) of the Act.

Subpart E—Acquisition and Modernization of Existing Buildings

§ 51c.501 Applicability.

The regulations of this subpart, in addition to the regulations of the other applicable subparts of this part, are applicable to grants under section 330 of the Act for project costs which include the cost of acquisition and/or modernization of existing buildings (including the cost of amortizing the principal of, and paying the interest on, loans), except that, these regulations are not applicable to grants for project costs which include the costs of modernization of existing buildings if those costs can otherwise be supported under subparts B, C, or D of this part.

[43 FR 5352, Feb. 7, 1978]

§ 51c.502 Definitions.

(a) *Equipment* means nonexpendable personal property as defined in 45 CFR 74.132.

(b) *Existing building* means a completed or substantially completed structure, and may include the realty on which it is or is to be located.

(c) *Modernization* means the alteration, repair, remodeling and/or renovation of a building (including the initial equipment thereof and improvements to the building's site) which, when completed, will render the building suitable for use by the project for which the grant is made.

[43 FR 5352, Feb. 7, 1978]

§ 51c.503 Application.

(a) *General requirements.* An application for a grant under this part for a project under subparts B, C, or D which includes the acquisition and/or modernization of an existing building must include the following:

(1) A legal description of the site and a drawing showing the location of the building;

(2) A description of the architectural, structural, and other pertinent characteristics of the building sufficient to show that it is or that it will be, after alteration and renovation or after modernization, suitable for use by the project;

(3) A detailed estimate of the cost of the proposed acquisition and/or modernization;

(4) A description of, and copies of any relevant documents concerning, any existing or proposed financing arrangements for the acquisition and/or modernization;

(5) The proposed schedule for acquisition and/or modernization and occupancy;

(6) An assessment of the environmental impact of the proposed acquisition and/or modernization as called for by section 102(2)(c) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(c)) and such information as may be necessary to comply with the National Historic Preservation Act of 1966 (16 U.S.C. 470(f));

(7) Reasonable assurances that—

(i) The applicant has or will obtain a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way, sufficient to assure for a period of not less than 20 years (in the case of interim facilities, for the period constituting the estimated useful life of such facilities) undisturbed use and possession for the purpose of the operation of the project;

(ii) The building will be used for the purposes for which the grant is made;

(iii) The building complies, or after alteration and renovation or after modernization will comply, with applicable State and local codes and with:

(A) "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped" Number ANSI A117.1-1961 (R 1971), as

modified by other standards prescribed by the Secretary or the Administrator of the General Services Administration. The applicant shall be responsible for conducting inspections to insure compliance with the specifications;

(B) The applicable standards set forth in Life Safety Code 1973, NFPA No. 101, which is hereby incorporated by reference and made a part hereof. Copies of such document are available for examination at the Department's and Regional Offices' Information Centers listed in 45 CFR 5.31 and may also be obtained from the National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210 for \$3.00 per copy.

(iv) In the case of a public applicant with an approved project which involves the displacement of persons or businesses on or after January 2, 1971, whose real property has or will be taken, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646) and the applicable regulations issued thereunder (45 CFR part 15);

(v) Sufficient funds will be available to meet any portion of the cost of acquiring and/or modernizing the building not borne by the grant under this part;

(vi) Sufficient funds will be available after acquisition and/or modernization of the building for effective use of the building for the purposes of the project;

(vii) The applicable requirements of the Flood Disaster Protection Act of 1973 have been met;

(8) Such other information as the Secretary may reasonably require.

(b) *Requirement for acquisition grants.* Except for a grant solely for amortization of principal and payment of interest on an existing loan, an application for a grant for a project which includes the acquisition of an existing building must include, in addition to the requirements of paragraph (a) of this section, evidence satisfactory to the Secretary that the applicant has explored other alternatives to the proposed acquisition (such as leasing facilities or acquiring other facilities in the project's catchment area) and that the proposed acquisition constitutes the

soundest alternative from a financial and program standpoint.

(c) *Requirements for modernization grants.* In addition to the requirements of paragraph (a) of this section, an application for a grant for a project which includes modernization of an existing building must include the following:

(1) Plans and specifications for the proposed modernization which conform to the standards specified in §51c.503(a)(7)(iii);

(2) Reasonable assurance that any laborer or mechanic employed by any contractor or subcontractor in the performance of work on the modernization project will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor under the Davis-Bacon Act (40 U.S.C. 276a *et seq.*) and will receive compensation at a rate not less than one and one-half times his basic rate of pay for all hours worked in any workweek in excess of 8 hours in any calendar day; and

(3) Copies of any construction and materials contracts already entered into for the proposed modernization.

[41 FR 57000, Dec. 30, 1976, as amended at 43 FR 5352, Feb. 7, 1978]

§51c.504 Project elements.

(a) *General requirements.* A grantee which has received a grant under section 330 of the Act for a project which includes the acquisition and/or modernization of an existing building must:

(1) *Assurances.* Comply with the assurances provided pursuant to this subpart.

(2) *Approval of estimated cost.* Not enter into any contract for the acquisition and/or modernization funded under this subpart where the cost of such acquisition and/or modernization exceeds the estimates in the application, without the prior approval of the Secretary.

(3) *Non-default.* Make every effort to prevent any default on any loan secured by the building and, in the event of a default, promptly notify the Secretary of the default and make every effort on a timely basis to cure the default.

(b) *Requirements for acquisition grants.* In addition to the requirements of paragraph (a) of this section, a grantee

which has received a grant under section 330 of the Act for a project which includes the acquisition of an existing building must:

(1) *Bona-fide sale.* Acquire or, in the case of a grant solely for amortization of principal and payment of interest on an existing loan, have acquired the existing building pursuant to a bona-fide sale involving an actual cost to the applicant and resulting in additional or improved facilities for the purposes of the project.

(2) *Standards of construction and equipment.* Except in the case of a grant solely for amortization of principal and payment of interest on an existing loan, obtain a determination by the Secretary that the facility conforms (or upon completion of any necessary alteration and renovation or modernization will conform) to the standards set forth in §51c.503(a)(7)(iii) of this subpart before entering into a final or unconditional contract for the acquisition. Where the Secretary finds that exceptions to or modifications of any such standards would be consistent with the purposes of the Act and of the program, he may authorize such exceptions or modifications.

(3) *Financing.* Where the grantee will obtain a loan secured by the building in order to acquire the building, obtain such financing at the lowest current rate prevailing in the area for comparable loans on comparable facilities.

(c) *Requirements for modernization grants.* In addition to the requirements of paragraph (a) of this section, a grantee which has received a grant under section 330 of the Act for a project which includes the modernization of an existing building must:

(1) *Costs in excess of approved costs.* Finance all costs in excess of the estimated costs approved in the application and submit to the Secretary for prior approval any changes that substantially alter the scope of the function, utilities, or safety of the facility.

(2) *Competitive bids.* (i) Obtain the approval of the Secretary before the project is advertised or placed on the market for bidding; such approval must include a determination by the Secretary that the final plans and specifications conform to the standards set

forth in §51c.503(a)(7)(iii) of these regulations.

(ii) Except as otherwise provided by State or local law, contract for construction (including the purchase and installation of built-in equipment) on a lump sum fixed-price basis, and award contracts on the basis of competitive bidding obtained by public advertising with award of the contracts to the lowest responsive and responsible bidders. The provision for exceptions based on State and local law shall not be invoked to give local contractors or suppliers a percentage preference over non-local contractors bidding for the same contract. Such practices are precluded by this paragraph.

(3) *Construction contracts.* (i) Include the following conditions and provisions in all construction contracts for the modernization project:

(A) The provisions set forth in "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunities," Form DHHS 514 (rev. 7/76) (issued by the Office of Grants Administration Policy, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) Regulations, except in the case of contracts in the amount of \$2,000 or less; and pertaining to Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, relating to nondiscrimination in construction contract employment, except in the case of contracts in the amount of \$10,000 or less;

(B) That the contractor shall furnish performance and payment bonds each of which shall be in the full amount of the contract price, and shall maintain, during the life of the contract, adequate fire, workmen's compensation, public liability, and property damage insurance; *Provided, however,* That in the case of a State or local unit of government which enters into a construction contract of less than \$100,000, State or local provisions with respect to performance and payment bonds shall be deemed to meet the requirements of this paragraph; and

(C) That the Secretary shall have access at all reasonable times to work

§51c.505

wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

(ii) *Executive Order 11246*. Comply with the applicable requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965) as amended, relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(4) *Modernization supervision*. Provide and maintain competent and adequate architectural or engineering supervision and inspection at the modernization site to insure that the completed work conforms with the plans and specifications.

(5) *Completion responsibility*. Complete the modernization in accordance with the grant application and the approved plans and specifications.

(6) *Progress reports*. Furnish progress reports and such other information concerning the modernization as the Secretary may require.

(d) The Secretary may at any time approve exceptions to the provisions of this section where he finds that such exceptions are not inconsistent with section 330 of the Act, other requirements of law, or the purposes of the program.

[41 FR 57000, Dec. 30, 1976, as amended at 43 FR 5352, Feb. 7, 1978]

§51c.505 Determination of cost.

The cost of acquisition and/or modernization of existing buildings for which funds may be granted under this part will be determined by the Secretary, utilizing such documentation submitted by the applicant as the Secretary may prescribe (including the reports of such real estate appraisers as the Secretary may approve) and other relevant factors, taking into consideration only that portion of the existing building necessary for the operation of the approved project.

[41 FR 5700, Dec. 30, 1976]

§51c.506 Use of grant funds.

Grant funds may be used to amortize the principal of or pay interest on a loan or mortgage on an existing building acquired under this part, including

42 CFR Ch. I (10–1–11 Edition)

a building purchased by a grantee prior to the promulgation of this part, but only if the building is being used for the purposes of section 330 and complies with the applicable provisions of this subpart and only to the extent the Secretary finds such principal amounts and interest rates to be reasonable.

[41 FR 5700, Dec. 30, 1976]

§51c.507 Facility which has previously received Federal grant.

No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

[41 FR 5700, Dec. 30, 1976]

PART 51d—MENTAL HEALTH AND SUBSTANCE ABUSE EMERGENCY RESPONSE PROCEDURES

Sec.

51d.1 To what does this subpart apply?

51d.2 Definitions.

51d.3 Who is eligible for an award under this subpart?

51d.4 What information is required in the application?

51d.5 How is an emergency determined to exist?

51d.6 How will applications be evaluated and awarded?

51d.7 What are the limitations on how award funds may be used?

51d.8 Which other HHS regulations apply to these awards?

51d.9 What other conditions apply to these awards?

51d.10 What are the reporting requirements?

AUTHORITY: 42 U.S.C. 290aa(m).

SOURCE: 66 FR 51877, Oct. 11, 2001, unless otherwise noted.

§51d.1 To what does this subpart apply?

The regulations in this subpart apply to grants that enable public entities to respond to needs in local communities created by mental health or substance abuse emergencies, as authorized under section 501(m) of the Public Health Service Act (42 U.S.C. 290aa(m)).

Public Health Service, HHS

§ 51d.4

§ 51d.2 Definitions.

As used in this part:

Federally recognized Indian Tribal government means the governing body of any Indian tribe, band, nation, or other organized group or community, including any Native village as defined in, or established pursuant to, the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians;

Immediate award means a short term award of up to \$50,000, or such greater amount as determined by the Secretary on a case-by-case basis, to address the immediate needs resulting from a mental health or substance abuse emergency. Such funding may be provided for a period of up to 90 days.

Intermediate award means an award intended to meet the more ongoing needs resulting from a mental health or substance abuse emergency than is possible under an Immediate award. Intermediate awards may fund up to one year of services, although in some exceptional circumstances, and to the extent that funding is available, such funding may be continued for an additional period of up to one year.

Public entity means any State, any political subdivision of a State, any Federally recognized Indian tribal government or tribal organization.

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

State means one of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

Tribal organization means the recognized governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the

maximum participation of Indians in all phases of its activities.

[66 FR 51877, Oct. 11, 2001, as amended at 67 FR 56931, Sept. 6, 2002]

§ 51d.3 Who is eligible for an award under this subpart?

An applicant must be a public entity as defined by this subpart. Applicants are eligible for either or both Immediate and Intermediate awards.

§ 51d.4 What information is required in the application?

(a) *Application for Immediate awards:* The application is to contain the following information:

(1) A certification by the State's chief executive officer, or, for the purposes of a Federally recognized Indian tribal government, the principal elected official, or such officer's or official's designee, that a mental health or substance abuse emergency exists, as well as a written statement setting out the basis for the certification;

(2) A brief program plan describing needs;

(3) An estimate of the number of people to be served and the geographical area to be served;

(4) A description of the types of services to be provided;

(5) A budget justifying the amount of the request;

(6) Required certifications; and

(7) Such other pertinent information as the Secretary may require.

(b) *Application for Intermediate awards:* The application is to be submitted on an OMB-approved application form and contain the following:

(1) If the applicant has not applied previously for an Immediate award, a certification by the State's chief executive officer, or, for the purposes of a Federally recognized Indian tribal government, the principal elected official, or such officer's or official's designee, that a mental health or substance abuse emergency exists, as well as a written statement setting out the basis for the certification;

(2) An application submission date within three months of the date of the event that precipitated the mental health or substance abuse emergency, as certified in accordance with 51d.4(a)(1) or (b)(1), except that upon

§51d.5

42 CFR Ch. I (10–1–11 Edition)

the request of a State, the Secretary may provide a waiver of this application submission deadline if the Secretary determines there is good cause to justify the waiver;

(3) A detailed and comprehensive assessment of need;

(4) Demographics specific to the estimated number of people to be served;

(5) A description of the services that were provided up to the date of the submission of the Intermediate award application;

(6) The geographical area to be served;

(7) A detailed implementation program plan and related time line, including a description of outreach to special population groups affected by the crisis;

(8) A budget justifying the amount of the request for personnel, equipment, supplies, travel, training, data collection and any technical assistance required; the budget shall include an identification of the resources the applicant is able to commit to the project, if any, including any in-kind contributions;

(9) Any information that has changed since an Immediate application was submitted, if one was submitted; and

(10) such other pertinent information as the Secretary may require.

(c) *Signature on Award Applications.* The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, all applicable regulations, and any additional conditions of the grant.

§51d.5 How is an emergency determined to exist?

(a) In making a decision as to whether a mental health or substance abuse emergency exists for purposes of section 501(m) of the PHS Act, the Secretary, using discretion, will consider all relevant factors, but at a minimum the following must exist:

(1) Existing State, Tribal and local systems for mental health and/or substance abuse services are overwhelmed or unable to meet the existing mental health or substance abuse needs of the local community at issue; and

(2) This inability to meet the mental health and/or substance abuse service needs of a local community is the direct consequence of a clear precipitating event. This precipitating event must:

(i) Have a sudden, rapid onset and a definite conclusion, such as:

(A) A natural disaster (including, but not limited to, a hurricane, tornado, storm, flood, earthquake, fire, drought, or other natural catastrophe); or

(B) A technological disaster (including, but not limited to, a chemical spill, a major industrial accident, or a transportation accident); or

(C) A criminal act with significant casualties (including, but not limited to, a domestic act of terrorism, a hostage situation, or an incident of mass violence including school shootings and riots); and

(ii) Result in significant:

(A) Death,

(B) Injury,

(C) Exposure to life-threatening circumstances,

(D) Hardship,

(E) Suffering,

(F) Loss of property, or

(G) Loss of community infrastructure (e.g., loss of treatment facilities, staff, public transportation and/or utilities, or isolation from services); and

(3) No other local, State, Tribal or Federal funding is available to adequately address the specific level of need resulting from the precipitating event and resulting emergency mental health and/or substance abuse service needs of the impacted community.

(b) In making a determination that a mental health or substance abuse emergency exists, the Secretary will consider the certification and written statements provided in accordance with §51d.4(a)(1) or (b)(1), and other information independently available to the Secretary.

(c) Once the Secretary determines that a mental health or substance abuse emergency exists, the Secretary may exercise discretion to make awards to enable public entities to respond to the emergency, within the limits of funds available.

§51d.6 How will applications be evaluated and awarded?

(a) In assessing applications for funding, the Secretary will utilize the following criteria.

(1) *Documentation of Need.* Applicant has demonstrated mental health and/or substance abuse needs directly resulting from the precipitating event. The precipitating event is clearly identified along with information regarding its impact. Applicant has identified any high risk groups or populations with special concerns that may impact the delivery of services (e.g., children, adolescents, older adults, ethnic and cultural groups, lower income populations). This documentation of need shall include the extent of physical, psychological and social problems observed, and a description of how the estimate of the number of people to be served was made. Applicant has clearly documented that no other local, State, Tribal or Federal funding sources are available to address the need.

(2) *Plan of Services.* Applicant has a clear plan of services to address documented needs within a defined geographic area and in a specified time period. The plan of services is appropriate to the type of grant requested (e.g., Immediate or Intermediate) and specifically addresses the needs of any high risk groups or populations with special concerns identified in the assessment of need. The plan of services clearly identifies the following:

(a) The types of services to be provided (e.g., outreach, crisis counseling, public education on stress management and crisis mental health, public education on substance abuse prevention, information and referral services, short term substance abuse or mental health prevention and/or treatment services);

(b) Strategies for targeting those identified as needing services, including high risk groups or populations with special concerns identified in the needs assessment;

(c) Appropriate training to be provided to staff to assure that services are appropriate to the crisis situation and the plans for community recovery;

(d) Quality control methods in place to assure appropriate services to the target population;

(e) Staff support mechanisms that are available;

(f) Plans for coordination of services with key local, State, Tribal and Federal partners involved in addressing the precipitating event (e.g., emergency management agencies, law enforcement, education agencies, public health agencies, and other agencies active in crisis response); and

(g) An estimate of the length of time for which said services requiring Federal funding will be needed, and the manner in which long-term cases will be referred for continued assistance after Federal funds have ended.

(3) *Organizational Capability.* Applicant is a public entity with demonstrated organizational capacity to deliver services as described in the plan of services. The applicant should also have a demonstrated history of service delivery to the target population within the defined service area for the program. The budget submitted shall provide sufficient justification and demonstrate that it is consistent with the documentation of need and plan of services. This shall include a description of the facilities to be utilized, including plans for securing office space if necessary to the project.

(b) In determining the appropriateness and necessity of funding, the Secretary may consult with other Federal agencies responsible for responding to crisis incidents, including the Readiness, Response and Recovery Directorate within the Federal Emergency Management Agency (FEMA), the Safe and Drug Free Schools Program within the U.S. Department of Education, the Office for Victims of Crime (OVC) within the U.S. Department of Justice, the National Transportation Safety Board (NTSB) within the U.S. Department of Transportation, the Emergency Response Program within the Environmental Protection Agency (EPA), the Bureau of Indian Affairs (BIA) within the U.S. Department of the Interior, the Animal and Plant Health Inspection Service within the U.S. Department of Agriculture, the Indian Health Service (IHS) within the U.S. Department of Health and Human Services, and other Federal agencies with jurisdiction over specific types of crisis response.

§51d.7

§51d.7 What are the limitations on how award funds may be used?

Unallowable Expenses: The following expenses will not be reimbursed under section 501(m) of the PHS Act:

- (1) Major construction costs;
- (2) Childcare services, unless provided by the institution or entity providing mental health or substance abuse treatment and integral to the treatment program;
- (3) Services outside of the geographic area specified in the application, except to the extent that the precipitating event requires physical relocation of either affected parties or facilities;
- (4) Any mental health or substance abuse services not directly related to the mental health or substance abuse emergency;
- (5) Any expenses that supplant ongoing local, State, Tribal or Federal expenditures; and
- (6) Any other costs unallowable by Federal law or regulation.

§51d.8 Which other HHS regulations apply to these awards?

Several other HHS regulations apply to grants under this part. These include, but are not limited to:

- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 76—Debarment and suspension from eligibility for financial assistance
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or

42 CFR Ch. I (10–1–11 Edition)

benefitting from Federal financial assistance

- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

[66 FR 51877, Oct. 11, 2001, as amended at 67 FR 56931, Sept. 6, 2002]

§51d.9 What other conditions apply to these awards?

Award funding made under this authority is to be supplemental in nature. Consistent with the criteria in §51d.5 and the certification in §51d.4(a)(1), such funds will only be made available if no other local, State, Tribal or Federal source is available to adequately address the emergency mental health and/or substance abuse service needs of the impacted community.

§51d.10 What are the reporting requirements?

(a) For immediate awards:

(1) A mid-program report only if an Intermediate award application is being prepared and submitted. This report shall be included as part of the Intermediate award application,

(2) Quarterly financial status reports of expenditures to date, due 30 days following the end of the reporting period, as permitted by 45 CFR 92.41(b),

(3) A final program report, a financial status report, and a final voucher 90 days after the last day of Immediate award services, in accordance with 45 CFR 92.50(b).

(b) For intermediate awards:

(1) Quarterly progress reports, due 30 days following the end of the reporting period, as permitted by 45 CFR 92.40(b),

(2) Quarterly financial status reports of expenditures to date, due 30 days following the end of the reporting period, as permitted by 45 CFR 92.41(b),

(3) A final program report, to be submitted within 90 days after the end of the program services period, in accordance with 45 CFR 92.50(b),

(4) A financial status report, to be submitted within 90 days after the end

Public Health Service, HHS

§ 52.2

of the program services period, in accordance with 45 CFR 92.50(b),

(5) Such additional reports as the Secretary may require.

(c) The following shall be specifically addressed in final program reports:

- (1) Description of services provided,
- (2) Number of individuals assisted,
- (3) Amount of funding expended and for what purposes,
- (4) Personnel costs,
- (5) Training costs,
- (6) Technical consultation costs,
- (7) Equipment costs,
- (8) Travel and transportation costs, and
- (9) A narrative describing lessons learned and exemplary practices, and a description of the transition plan, for how services will be funded or provided when Federal funds have been exhausted.

PARTS 51e–51g [RESERVED]

PART 52—GRANTS FOR RESEARCH PROJECTS

Sec.

52.1 To which programs do these regulations apply?

52.2 Definitions.

52.3 Who is eligible to apply for a grant?

52.4 How to apply for a grant.

52.5 Evaluation and disposition of applications.

52.6 Grant awards.

52.7 Use of funds; changes.

52.8 Other HHS policies and regulations that apply.

52.9 Additional conditions.

AUTHORITY: 42 U.S.C. 216.

§ 52.1 To which programs do these regulations apply?

(a) *General.* The regulations of this part apply to all health-related research project grants administered by the PHS or its components, except for grants for health services research, demonstration, and evaluation projects administered by the Agency for Health Care Policy and Research. These regulations do not apply to research grants that are not for the support of an identified research project (sometimes referred to as general research support grants), grants for the construction or operation of research facilities, grants for prevention or educational pro-

grams, demonstration grants, traineeships, training grants, or to the support of research training under the National Research Service Awards program.

(b) *Specific programs covered.* From time to time the Secretary will publish a list of the research project grant programs covered by this part. The list is for informational purposes only and is not intended to restrict the statement of applicability in paragraph (a) of this section. In addition, information on particular research project grant programs, including applications and instructions, may be obtained from the component of the PHS that administers the program.

[61 FR 55105, Oct. 24, 1996.]

§ 52.2 Definitions.

As used in this part:

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

Grantee means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part. The term shall also mean the recipient of a cooperative agreement awarded under this part.

HHS means the Department of Health and Human Services.

Principal investigator means the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project.

Project means the particular activity for which funding is sought under this part as described in the application for grant award.

Public Health Service and *PHS* means the operating division of the Department that consists of the Agency for Health Care Policy and Research, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Office of the Assistant Secretary for Health, the Substance

§ 52.3

Abuse and Mental Health Administration, and the Agency for Toxic Substances and Disease Registry.

Research means a systematic investigation, study or experiment designed to contribute to general knowledge relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanisms relating to, the biological functions, diseases, or related matters to be studied.

Secretary means the Secretary of HHS and any other officer or employee of the HHS to whom the authority involved may be delegated.

[61 FR 55105, Oct. 24, 1996, as amended at 74 FR 57921, Nov. 10, 2009]

§ 52.3 Who is eligible to apply for a grant?

(a) *Persons eligible.* Any individual, corporation, public or private institution or agency, or other legal entity shall be eligible for a grant award, except:

(1) An individual or entity which is otherwise ineligible for an award under applicable law or regulation;

(2) Federal agencies or institutions, unless specifically authorized by law to receive the grant; or

(3) Individuals, corporations, institutions, agencies, and other entities during the period they are debarred or suspended from eligibility for Federal financial assistance (see 45 CFR part 76).

(b) *Permissible activities within research projects.* Any project found by the Secretary to be a research project within the meaning of this part shall be eligible for a grant award. Eligible projects may consist of laboratory, clinical, population, field, statistical, basic, applied or other types of investigations, studies or experiments, or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple disciplines, facilities and resources.

(c) *Preferences.* In the award of grants for international research relating to the development and evaluation of vaccines and treatments for AIDS under

42 CFR Ch. I (10–1–11 Edition)

section 2315 of the Act, preference shall be given to:

(1) Activities conducted by, or in cooperation with, the World Health Organization, and

(2) With respect to activities in the Western Hemisphere, activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

[61 FR 55105, Oct. 24, 1996]

§ 52.4 How to apply for a grant.

Each institution interested in applying for a grant under this part must submit an application at such time and in such form and manner as the Secretary may prescribe.

[61 FR 55105, Oct. 24, 1996]

§ 52.5 Evaluation and disposition of applications.

(a) *Evaluation.* All applications filed in accordance with § 52.4 shall be evaluated by the Secretary through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council or other body as may be required by law. The Secretary's evaluation shall take into account among other pertinent factors the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, and the adequacy of the applicant's resources available for the project and the amount of grant funds necessary for completion, and in the case of applications for support of research in emergency medical services, special consideration shall be given to applications for grants for research relating to the delivery of emergency medical services in rural areas.

(b) *Disposition.* On the basis of the Secretary's evaluation of an application in accordance with paragraph (a) of this section and subject to approvals, recommendations or consultations by the appropriate National Advisory

Council or other body as may be required by law, the Secretary will (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part. With respect to approved projects, the Secretary will determine the project period (subject to extension as provided in § 52.7(c)) during which the project may be supported. Any deferral and disapproval of an application will not preclude its reconsideration or a re-application.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.6 Grant awards.

(a) Within the limits of funds available for that purpose, the Secretary will award a grant to those applicants whose approved projects will in the Secretary's judgment best promote the purposes of the statute authorizing the grant and the regulations of this part. The date specified by the Secretary as the beginning of the project period shall be no later than 9 months following the date of any initial or new award statement unless the Secretary finds that because of the nature of a project or the grantee's particular circumstances earlier assurance of grant support is required to initiate the project. Any funds granted under this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) *Evaluation of unapproved drug treatments for AIDS.* Grants under section 2314 of the Act to support research relating to the evaluation of drug treatments for AIDS not approved by the Commissioner of Food and Drugs, shall be subject to appropriate scientific and ethical guidelines established by the Secretary for each project, pursuant to section 2314(c) of the Act. In order to receive a grant, the applicant must agree to comply with those guidelines.

(c) *Notice of grant award.* (1) The notice of grant award specifies how long HHS intends to support the project

without requiring the project to compete for funds. This period, called the project period, will usually be for 1-5 years.

(2) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit an application at the time and in the form and manner as the Secretary may prescribe to have support continued for each subsequent year.

(3) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) *Multiple or concurrent awards.* Whenever a research project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate, approve, and make one or more awards pursuant to one or more applications. When making more than one award in response to a single application, the Secretary shall consult with the applicant organization(s), as appropriate.

(e) *Unobligated balances.* The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained.

(f) *Award for continuation of project under new grantee.* The Secretary, upon application in accordance with the provisions of § 52.4 and without further action by a Council or other body, may make a grant to any institution or other person eligible under § 52.3 for continuation of a currently supported project for which a grant was previously made to another institution or person, provided the Secretary finds that the change in the conduct of the project is consonant with the previous

§ 52.7

evaluation and approval of the project under § 52.5.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 61 FR 55105, Oct. 24, 1996; 74 FR 57921, Nov. 10, 2009]

§ 52.7 Use of funds; changes.

(a) *Delegation of fiscal responsibility.* The grantee may not in whole or in part delegate or transfer to another person responsibility for the use or expenditure of grant funds.

(b) *Changes in project.* The permissible changes by the principal investigator in the approved project shall be limited to changes in methodology, approach or other aspects of the project to expedite achievement of the project's research objectives, including changes that grow out of the approved project and serve the best scientific strategy. If the grantee and the principal investigator are uncertain whether a change complies with this provision, the question must be referred to the Secretary for a final determination.

(c) *Changes in project period.* The project period determined pursuant to § 52.5(b) may be extended by the Secretary, with or without additional grant support, for such an additional period as the Secretary determines may be required to complete, or fulfill the purposes of, the approved project.

[45 FR 12240, Feb. 25, 1980]

§ 52.8 Other HHS regulations and policies that apply.

Several other HHS policies and regulations apply to grants under this part. These include, but are not necessarily limited to:

37 CFR part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Administration of grants

42 CFR Ch. I (10–1–11 Edition)

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR part 93—New restrictions on lobbying
59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

NOTE: This policy is subject to changes, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, BETHESDA, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to changes, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

“PHS Grants Policy Statement,” DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994.

NOTE: This policy is subject to changes, and interested persons should contact the Grants Policy Branch, OASH, Room 17A45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301-443-1874; not a toll-free number) to obtain references to the current version and any amendments.]

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986).

Public Health Service, HHS

§ 52a.1

NOTE: This policy is subject to changes, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain references to the current version and any amendments.]

[61 FR 55106 Oct. 24, 1996]

§ 52.9 Additional conditions.

The Secretary may with respect to any grant award or class of awards impose additional conditions prior to or at the time of any award when in the Secretary's judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

PART 52a—NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

Sec.

52a.1 To which programs do these regulations apply?

52a.2 Definitions.

52a.3 Who is eligible to apply?

52a.4 What information must each application contain?

52a.5 How will NIH evaluate applications?

52a.6 Information about grant awards.

52a.7 For what purposes may a grantee spend grant funds?

52a.8 Other HHS regulations and policies that apply.

52a.9 Additional conditions.

AUTHORITY: 42 U.S.C. 216, 284g, 285a-6(c)(1)(E), 285a-7(c)(1)(G), 285b-4, 285c-5, 285c-8, 285d-6, 285e-2, 285e-3, 285e-10a, 285f-1, 285g-5, 285g-7, 285g-9, 285m-3, 285o-2, 286a-7(c)(1)(G), 287c-32(c), 300cc-16.

SOURCE: 57 FR 61006, Dec. 23, 1992, unless otherwise noted.

§ 52a.1 To which programs do these regulations apply?

(a) The regulations of this part apply to grants by the National Institutes of Health and its organizational components to support the planning, establishment, expansion, and operation of research and demonstration and/or multipurpose centers in health fields described in this paragraph. Specifically, these regulations apply to:

(1) National Institute of Mental Health centers of excellence with respect to research on autism, as authorized by section 409C of the Act (42 U.S.C. 284g);

(2) National cancer research and demonstration centers (including payments for construction), as authorized by section 414 of the Act (42 U.S.C. 285a-3);

(3) National cancer research and demonstration centers with respect to breast cancer, as authorized by section 417 of the Act (42 U.S.C. 285a-6);

(4) National cancer and demonstration centers with respect to prostate cancer, as authorized by section 417A of the Act (42 U.S.C. 285a-7);

(5) National research and demonstration centers for heart, blood vessel, lung, and blood diseases, sickle cell anemia, blood resources, and pediatric cardiovascular diseases (including payments for construction), as authorized by section 422 of the Act (42 U.S.C. 485b-4);

(6) Research and training centers (including diabetes mellitus, and digestive, endocrine, metabolic, kidney and urologic diseases), as authorized by section 431 of the Act (42 U.S.C. 285c-5);

(7) Research and training centers regarding nutritional disorders, as authorized by section 434 of the Act (42 U.S.C. 285c-8);

(8) Multipurpose arthritis and musculoskeletal diseases centers (including payments for alteration, but not construction), as authorized by section 441 of the Act (42 U.S.C. 285d-6);

(9) Alzheimer's disease centers, as authorized by section 445 of the Act (42 U.S.C. 285e-2);

(10) Claude D. Peppers Older Americans Independence Centers, as authorized by section 445A of the Act (42 U.S.C. 285e-3);

(11) Centers of excellence in Alzheimer's disease research and treatment, as authorized by section 445I of the Act (42 U.S.C. 285e-10a);

(12) Research centers regarding chronic fatigue syndrome, as authorized by section 447 of the Act (42 U.S.C. 285f-1);

(13) Research centers with respect to contraception and infertility, as authorized by section 452A of the Act (42 U.S.C. 285g-5);

§ 52a.2

42 CFR Ch. I (10–1–11 Edition)

(14) Child health research centers, as authorized by section 452C of the Act (42 U.S.C. 285g–7);

(15) Fragile X research centers, as authorized by 452E of the Act (42 U.S.C. 285g–9);

(16) Multipurpose deafness and other communication disorders centers, as authorized by section 464C of the Act (42 U.S.C. 285m–3);

(17) National drug abuse research centers, as authorized by section 464N of the Act (42 U.S.C. 285o–2);

(18) Centers of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations, as authorized by section 485F of the Act (42 U.S.C. 287c–32); and

(19) Centers for acquired immunodeficiency syndrome (AIDS) research, as authorized by section 2316 of the Act (42 U.S.C. 300cc–16).

(b) This part does not apply to:

(1) Grants for construction (see 42 CFR part 52b), except as noted in paragraph (a) of this section;

(2) Grants covered by 42 CFR part 52 (grants for research projects); or

(3) Grants for general research support under section 301(a)(3) of the Act (42 U.S.C. 241(a)(3)).

(c) This part also applies to cooperative agreements made to support the centers specified in paragraph (a) of this section. When a reference is made in this part to “grants,” the reference shall include “cooperative agreements.”

[61 FR 55108, Oct. 24, 1996, as amended at 68 FR 69621, Dec. 15, 2003]

§ 52a.2 Definitions.

As used in this part:

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

Center means:

(a) For purposes of grants authorized by section 409C of the Act, a public or nonprofit private entity which provides for planning and conducting basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of autism, including the fields of developmental neurobiology, genetics, and psychopharmacology;

(b) For purposes of grants authorized by section 414 of the Act, an agency or institution which provides for planning and conducting basic and clinical research into, training in, and demonstration of advanced diagnostic, control, prevention and treatment methods for cancer;

(c) For purposes of grants authorized by section 417 of the Act, an agency or institution which provides for planning and conducting basic, clinical, epidemiological, psychological, prevention and treatment research and related activities on breast cancer;

(d) For purposes of grants authorized by section 417A of the Act, an agency or institution which provides for planning and conducting basic, clinical, and epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer;

(e) For purposes of grants authorized by section 422 of the Act, an agency or institution which provides for planning and basic and clinical research into, training in, and demonstration of, management of blood resources and advanced diagnostic, prevention, and treatment methods (including emergency services) for heart, blood vessel, lung, or blood diseases including sickle cell anemia;

(f) For purposes of grants authorized by section 431 of the Act, a single institution or a consortium of cooperating institutions, which conducts research, training, information programs, epidemiological studies, data collection activities and development of model programs in diabetes mellitus and related endocrine and metabolic diseases;

(g) For purposes of grants authorized by section 434 of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research, training, and information programs in nutritional disorders, including obesity;

(h) For purposes of grants authorized by section 441 of the Act, a facility which conducts basic and clinical research into arthritis and musculoskeletal diseases; and orthopedic procedures, training, and information programs for the health community and the general public;

(i) For purposes of grants authorized by section 445 of the Act, a public or private nonprofit entity (including university medical centers) which conducts basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease;

(j) For purposes of grants authorized by section 445A of the Act, a single public or private nonprofit institution or entity or a consortium of cooperating institutions or entities which conducts research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals.

(k) For the purposes of section 445I of the Act, a single institution or consortium of cooperating institutions which conducts basic and clinical research on Alzheimer's disease.

(l) For purposes of grants authorized by section 447 of the Act, a single institution or consortium of cooperating institutions which conducts basic and clinical research on chronic fatigue syndrome;

(m) For purposes of grants authorized by section 452A of the Act, a single institution or consortium of cooperating institutions which conducts clinical and other applied research, training programs, continuing education programs, and information programs with respect to methods of contraception, and infertility;

(n) For purposes of grants authorized by section 452C of the Act, an agency or institution which conducts research with respect to child health, and gives priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children;

(o) For purposes of grants authorized by section 452E of the Act, a single in-

stitution or a consortium of cooperating institutions which conducts research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X;

(p) For purposes of grants authorized by section 464C of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research into, training in, information and continuing education programs for the health community and the general public about, and demonstration of, advanced diagnostic, prevention, and treatment methods for disorders of hearing and other communication processes and complications resulting from these disorders;

(q) For purposes of grants authorized by section 464N of the Act, institutions designated as National Drug Abuse Research Centers for interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse;

(r) For purposes of grants authorized by section 485F of the Act, a biomedical or behavioral research institution or consortia that:

(1) Have a significant number of members of minority health disparity populations or other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution);

(2) Have been effective in assisting such students of the institution to complete the program of education or training and receive the degree involved;

(3) Have made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate; and

(4) Have made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution; or

(s) For the purposes of grants authorized in section 2316 of the Act, an entity for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for

§ 52a.3

acquired immunodeficiency syndrome (AIDS).

Director means the Director of NIH or the organizational component authorized to award grants to support centers under this part.

Grant(s) means, unless the context otherwise requires, an award of funds to support a center authorized under § 52a.1. The term includes cooperative agreement(s).

NIH means the National Institutes of Health and its organizational components that award grants.

Nonprofit as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Project period means the period of time, from one to five years, specified in the notice of grant award that the NIH or the awarding component intends to support a proposed center without requiring the center to compete for funds.

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55108, Oct. 24, 1996; 68 FR 69621, Dec. 15, 2003]

§ 52a.3 Who is eligible to apply?

(a) Any public or private nonprofit agency, institution, or consortium of agencies is eligible to apply for a grant under sections 409C, 414, 417, 417A, 422, 445, 445A, 445I, 447, 452A, and 2316 of the Act.

(b) Any public or private nonprofit or for-profit agency, institution, or consortium of agencies is eligible to apply for a grant under sections 428, 431, 434, 441, 452C, 452E, 464C, 464J, 464N, and 485F of the Act.

(c) Any applicant under this part must be located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the successor States of the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55109, Oct. 24, 1996; 68 FR 69622, Dec. 15, 2003]

42 CFR Ch. I (10–1–11 Edition)

§ 52a.4 What information must each application contain?

Each application under this part must include detailed information as to the following:

(a) The personnel, facilities, and other resources available to the applicant with which to initiate and maintain the proposed center grants program;

(b) Any research, training, demonstration, or information dissemination activities in which the applicant is currently engaged; the sources of funding for these activities; and the relevance of these activities to the proposed center grants program;

(c) Proposed research, training, demonstration, and information dissemination activities;

(d) The proposed organizational structure of the center and the relationship of the proposed center to the applicant organization(s);

(e) The names and qualifications of the center director and key staff members who would be responsible for conducting the proposed activities;

(f) Proposed methods for monitoring and evaluating individual activities and the overall center program;

(g) Proposed methods for coordinating the center's activities, where appropriate, with similar efforts by other public and private organizations;

(h) The availability of any community resources necessary to carry out proposed activities; and

(i) Efforts to be made to generate and collect income from sources other than NIH to be used to further the purposes of the center program. NIH encourages these efforts. Income may include, but is not limited to, that generated from the sale or rental of products or services produced by grant-supported activities, such as laboratory tests, computer time, and payments received from patients or third parties, where appropriate (the disposition of grant-related income is governed by 45 CFR 74.40 through 74.47 and 45 CFR 92.25);

(j) The proposed budget for the center and a justification for the amount of the grant funds requested; and

(k) Any other information that the Director of the awarding institute may request.

(Approved under OMB Control Number 0925-0001)

§ 52a.5 How will NIH evaluate applications?

(a) NIH considers the following in evaluating Center grant applications:

(1) The scientific and technical merit of the proposed program;

(2) The qualifications and experience of the center director and other key personnel;

(3) The statutory and program purposes to be accomplished;

(4) The extent to which the various components of the proposed program would be coordinated into one multidisciplinary effort within the center;

(5) The extent to which the center's activities would be coordinated with similar efforts by other organizations;

(6) The administrative and managerial capability of the applicant;

(7) The reasonableness of the proposed budget in relation to the proposed program; and

(8) Other factors which the awarding institute, center, or division considers appropriate in light of its particular statutory mission.

(b) Where required by statute or NIH policy, applications are reviewed by appropriate national advisory councils or boards before awards are made. NIH grants may be awarded generally only after approval recommendations from both appropriate scientific peer review groups and national advisory councils or boards.

§ 52a.6 Information about grant awards.

(a) The notice of grant award specifies how long NIH intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(b) Generally, the grant will initially be for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such

awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the NIH that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application, nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(Approved under OMB Control Number 0925-0001)

§ 52a.7 For what purposes may a grantee spend grant funds?

A grantee shall spend funds it receives under this part solely in accordance with the approved application and budget, the authorizing legislation, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR 74.27.

[61 FR 55109, Oct. 24, 1996]

§ 52a.8 Other HHS regulations and policies that apply.

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

42 CFR part 50, Subpart A—Responsibilities of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, Subpart D—Public Health Service grant appeals procedures

42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR part 75—Informal grant appeals procedures

§ 52a.9

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR part 93—New restrictions on lobbying
59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

[NOTE: This policy is subject to change, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, MSC 0161, BETHESDA, MD 20892-0601 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

[NOTE: This policy is subject to change, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSA 7010, BETHESDA, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, Office of Extramural Research, NIH (Revised September 1986).

NOTE: This policy is subject to change, and interested persons should contact the Office of Laboratory Animal Welfare, Office of Extramural Research, NIH, Rockledge 1, 6705 Rockledge Drive, Bethesda, Maryland 20817, telephone 301-594-2382 (not a toll-free number) to obtain references to the current version and any amendments.

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55109, Oct. 24, 1996; 68 FR 69622, Dec. 15, 2003]

42 CFR Ch. I (10–1–11 Edition)

§ 52a.9 Additional conditions.

The Director may, with respect to any grant award, impose additional conditions prior to or at the time of any award when in the Director's judgment the conditions are necessary to assure the carrying out of the purposes of the award, the interests of the public health, or the conservation of grant funds.

[61 FR 55110, Oct. 24, 1996]

PART 52b—NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS

Sec.

52b.1 To what programs do these regulations apply?

52b.2 Definitions.

52b.3 Who is eligible to apply?

52b.4 How to apply.

52b.5 How will NIH evaluate applications?

52b.6 What is the rate of federal financial participation?

52b.7 How is the grantee obligated to use the facility?

52b.8 How will NIH monitor the use of facilities constructed with federal funds?

52b.9 What is the right of the United States to recover federal funds when facilities are not used for research or are transferred?

52b.10 What are the terms and conditions of awards?

52b.11 What are the requirements for acquisition and modernization of existing facilities?

52b.12 What are the minimum requirements of construction and equipment?

52b.13 Additional conditions.

52b.14 Other federal laws, regulations, executive orders, and policies that apply.

AUTHORITY: 42 U.S.C. 216, 285a-2, 285a-3, 285b-3, 285b-4, 285d-6, 285i, 285m-3, 285o-4, 287a-2, 287a-3, 300cc-41.

SOURCE: 64 FR 63722, Nov. 22, 1999, unless otherwise noted.

§ 52b.1 To what programs do these regulations apply?

(a) *General.* Except as provided in paragraph (c) of this section, this part applies to all grants awarded by NIH and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the building (or applicable part of the building)

Public Health Service, HHS

§ 52b.5

suitable for the purpose for which it was constructed.

(b) *Specific programs covered.* From time to time the Director may publish a list of the construction grant programs covered by this part. The list is for informational purposes only and is not intended to restrict the statement of applicability in paragraph (a) of this section. In addition, information on particular construction grant programs, including applications and instructions, may be obtained from the component of NIH that administers the program.

(c) *Specific programs excluded.* The regulations of this part do not apply to minor alterations, renovations, or repairs funded under a research project grant (see part 52 of this chapter) or alterations or renovations funded under an NIH center grant (see part 52a of this chapter).

§ 52b.2 Definitions.

As used in this part:

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

Construction means the construction of new buildings or the modernization of, or the completion of shell space in, existing buildings (including the installation of fixed equipment), but excluding the cost of land acquisition and off-site improvements.

Construction grant means funds awarded for construction in accordance with the applicable provisions of the Act and this part.

Director means the Director of NIH or the director of an NIH national research institute, center, or other component of NIH, authorized to award grants for construction under the applicable provisions of the Act, and any official to whom the authority involved is delegated.

Federal share with respect to any construction project means the proportion, expressed as a percentage, of the cost of a project to be paid by a grant award under the Act.

HHS, DHHS, and Department mean the Department of Health and Human Services.

Institute means any national research institute, center, or other agency of the National Institutes of Health.

Modernization means the alteration, renovation, remodeling, improvement, expansion, and/or repair of existing buildings and the provision of equipment necessary to make the building suitable for use for the purposes of the particular program.

NIH means the National Institutes of Health and its organizational components that award construction grants.

Nonprofit as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Project means the particular construction activity which is supported by a grant under this part.

Secretary means the Secretary of Health and Human Services and any official to whom the authority involved is delegated.

§ 52b.3 Who is eligible to apply?

In order to be eligible for a construction grant under this part, the applicant must:

(a) Be a public or private nonprofit agency or institution;

(b) Be located in a state, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the successor states of the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau); and

(c) Meet any additional eligibility criteria specified in the applicable provisions of the Act.

§ 52b.4 How to apply.

Applications for construction grants under this part shall be made at the times and in the form and manner as the Secretary may prescribe.

§ 52b.5 How will NIH evaluate applications?

(a) In evaluating and approving applications for construction grants under this part, the Director shall take into account, among other pertinent factors, the following:

(1) The priority score assigned to the application by an NIH peer review

§ 52b.6

group as described in paragraph (b) of this section;

(2) The relevance of the project for which construction is proposed to the objectives and priorities of the particular program authorized by the Act;

(3) The scientific merit of the research activities that will be carried out in the proposed facility;

(4) The scientific or professional standing or reputation of the applicant and of its existing or proposed officers and research staff;

(5) The availability, by affiliation or other association, of other scientific or health personnel and facilities to the extent necessary to carry out effectively the program proposed for the facility, including the adequacy of an acceptable biohazard control and containment program when warranted;

(6) The need for the facility and its total effects on similar or related facilities in the locale, and the need for appropriate geographic distribution of similar facilities; and

(7) The financial need of the applicant.

(b) The priority score of the application shall be based, among other pertinent factors, on the following criteria:

(1) The scientific merit of the total program and its component parts to be carried out in the facility;

(2) The administrative and leadership capabilities of the applicant's officers and staff;

(3) The organization of the applicant's research program and its relationship with the applicant's overall research programs;

(4) The anticipated effect of the project on other relevant research programs and facilities in the geographic area, and nationwide;

(5) The need for the project or additional space; and

(6) The project cost and design.

§ 52b.6 What is the rate of federal financial participation?

(a) Unless otherwise specified by statute, the rate of federal financial participation in a construction project supported by a grant under this part shall not be more than 50 percent of the necessary allowable costs of construction as determined by the Director, except that when the Director

42 CFR Ch. I (10–1–11 Edition)

finds good cause for waiving this limitation, the amount of the construction grant may be more than 50 percent of the necessary allowable costs of construction.

(b) Subject to paragraph (a) of this section, the Director shall set the actual rate of federal financial participation in the necessary allowable costs of construction, taking into consideration the most effective use of available federal funds to further the purposes of the applicable provisions of the Act.

§ 52b.7 How is the grantee obligated to use the facility?

(a) The grantee shall use the facility (or that portion of the facility supported by a grant under this part) for its originally authorized purpose so long as needed for that purpose, or other period prescribed by statute, unless the grantee obtains advance approval from the Director, in the form and manner as the Director may prescribe, to use the facility for another purpose. Use for other purposes shall be limited as prescribed in § 52b.9(c)(2).

(b) The Director, in determining whether to approve an alternative use of the facility, shall take into consideration the extent to which:

(1) The facility will be used by the grantee or other owner for a purpose described in § 52b.9(c)(2); or

(2) There are reasonable assurances that alternative facilities not previously used for NIH supported research will be utilized to carry out the original purpose as prescribed in § 52b.9(c)(1).

(c) *Sale or transfer.* In the form and manner as the Director may prescribe, the grantee may request the Director's approval to sell the facility or transfer title to a third party eligible under § 52b.3 for continued use of the facility for an authorized purpose in accordance with paragraphs (a) and (b) of this section. If approval is permissible under the Act or other federal statute and is granted, the terms of the transfer shall provide that the transferee shall assume all the rights and obligations of the transferor set forth in 45 CFR part 74, the regulations of this part, and the other terms and conditions of the grant.

§ 52b.8 How will NIH monitor the use of facilities constructed with federal funds?

NIH may monitor the use of each facility constructed with funds awarded under this part to ensure its continued use for the originally authorized research purpose, by means of reviewing periodic facility use certifications or reports, site visits, and other appropriate means.

§ 52b.9 What is the right of the United States to recover Federal funds when facilities are not used for research or are transferred?

(a) If the grantee plans to cease using the facility for the particular biomedical research or training purposes for which it was constructed as required by § 52b.7 (or alternate use authorized under § 52b.7(a) or paragraph (c) of this section), or the grantee decides to sell or transfer title to an entity ineligible for a grant under § 52b.3, the grantee shall request disposition instructions from NIH in the form and manner as the Director may prescribe. Those instructions shall provide for one of the following alternatives:

(1) The facility may be sold and the grantee or transferee shall pay to the United States an amount computed by multiplying the federal share of the facility times the proceeds from the sale (after deducting the actual and reasonable selling and fix-up expenses, if any, from the sales proceeds). The sales procedures must provide for competition to the extent practicable, and be designed to provide the highest possible return;

(2) The grantee may retain title and shall pay to the United States an amount computed by multiplying the current fair market value of the facility by the federal share of the facility; or

(3) The grantee shall transfer the title to either the United States or to an eligible non-federal party approved by the Director. The grantee shall be entitled to be paid an amount computed by multiplying the current fair market value of the facility by the nonfederal share of the facility.

(b) The grantee or transferor of a facility which is sold or transferred, or the owner of a facility the use of which

has changed, as described in paragraph (a) of this section, shall report that action in writing to the Director not later than 10 days from the date on which the sale, transfer, or change occurs, in the form and manner as the Director may prescribe.

(c) In lieu of disposition of a facility pursuant to the provisions of paragraph (a) of this section, the Director may, for good cause, supported by assurances provided by the grantee or transferee, approve one of the following alternatives:

(1) Transfer of the remaining usage obligation to facilities of substantially comparable or greater value or utility, to carry out the biomedical research or training purpose for which the grant was awarded. In this event, the remaining usage obligation shall be released from the original facility constructed with grant funds and transferred to the new facility, and the grantee shall remain subject to all other requirements imposed under this part with respect to the new facility; or

(2) Use the facility for as long as needed, in order of priority, for one of the following purposes:

(i) For other health related activities consistent with the purposes of one or more of the activities of the awarding institute as authorized under title IV or other provisions of the Act;

(ii) To provide training and instruction in the health fields for health professionals or health related information programs for the public; or

(iii) Other health related purposes consistent with one or more of the purposes authorized under the Act.

(d) The right of recovery of the United States set forth in paragraph (a) of this section shall not, prior to judgment, constitute a lien on any facility supported in whole or in part by a federal grant, including a construction grant under this part.

(e) Any amount required to be paid to the United States under this section will be paid to the awarding institute for disposition as required by law.

(Approved by the Office of Management and Budget under Control Number 0925-0424; expires November 30, 2001)

§ 52b.10 What are the terms and conditions of awards?

In addition to any other requirement imposed by law or determined by the Director to be reasonably necessary to fulfill the purposes of the grant, each construction grant shall be subject to the terms and conditions and the grantee assurances required by this section, supported by such documentation as the Director may reasonably require. The Director may, by general policy or for good cause shown by an applicant, approve exceptions to these terms and conditions or assurances where the Director finds that the exceptions are consistent with the applicable provisions of the Act and the purposes of the particular program:

(a) *Title.* The applicant must have a fee simple or other estate or interest in the site, including necessary easements and rights-of-way, sufficient to assure for the estimated useful life of the facility, as determined by the Director, undisturbed use and possession for the purpose of the construction and operation of the facility.

(b) *Plans and specifications.* Approval by the Director of the final working drawings, specifications, and cost estimates must be obtained before the project is advertised or placed on the market for bidding. The approval must include a determination by the Director that the final plans and specifications conform to the minimum standards of construction and equipment as set forth in § 52b.12.

(c) *Relocation assistance.* An applicant with an approved project which involves the displacement of persons or businesses shall comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (42 U.S.C. 4601 *et seq.*) and the applicable regulations issued under that Act (45 CFR part 15; 49 CFR part 24).

(d) *Approval of changes in estimated cost.* Unless approved by the Director, the applicant shall not enter into any construction contracts for the project or a part of the project, the cost of which exceeds the estimated cost approved in the terms of an award for that portion of the work covered by the plans and specifications. Exceptions

shall be requested in the form and manner as the Director may prescribe.

(e) *Completion responsibility.* The applicant must construct the project, or cause it to be constructed, to final completion in accordance with the grant application, the terms and conditions of the award, and the approved plans and specifications.

(f) *Construction schedule inspection.* Prior to the start of construction, the grantee shall submit an approved copy of the construction schedule (critical path method) to the Director in the form and manner as the Director may prescribe.

(g) *Construction management.* The applicant must provide and maintain competent and adequate construction management services for inspection at the construction site to ensure that the completed work conforms with the approved plans and specifications. Construction management services shall include daily construction logs and monthly status reports which shall be maintained at the job site and shall be submitted to the Director at the times and in the form and manner as the Director may prescribe.

(h) *Nonfederal share.* Sufficient funds must be available to meet the nonfederal share of the costs of constructing the facility.

(i) *Funds for operation.* Sufficient funds must be available when construction is completed for effective use of the facility for the purposes for which it is being constructed.

(j) *Inspection.* The Director and the Director's representatives shall have access at all reasonable times to all work areas and documents during any stage of construction and the contractor shall provide proper facilities for this access and inspection.

(k) *Accessibility to handicapped persons.* The facility must be designed to comply with the Uniform Federal Accessibility Standards (41 CFR part 101–19, subpart 101–19.6, Appendix A), as modified by other standards prescribed by the Director or the Administrator of General Services. The applicant shall conduct inspections to ensure compliance with these specifications by the contractor.

(l) *Notice of Federal Interest.* The grantee shall record a Notice of Federal Interest in the appropriate official land records of the jurisdiction in which the property is located.

(m) *Title insurance.* The grantee shall purchase a title insurance policy unless a legal opinion has been provided which certifies that the grantee institution has fee simple title to the site free and clear of all liens, easements, rights-of-way, and any other adverse interests which would encumber the project. The Director may waive this requirement upon a request from the grantee adequately documenting self-insurance against the risks involved and containing such other information as the Director may prescribe.

(n) *Physical destruction insurance.* At the time construction is completed or at the time of beneficial occupancy, whichever comes first, the grantee shall purchase an insurance policy which insures the facility for the full appraised value of the property using state certified appraisers. The insurance policy must protect the property from total and partial physical destruction. The insurance policy must be maintained throughout the period of federal interest. The Director may waive this requirement upon a written request from the grantee adequately documenting self-insurance against the risks involved and containing such other information as the Director may prescribe.

(Approved by the Office of Management and Budget under Control Number 0925-0424; expires November 30, 2001)

§ 52b.11 What are the requirements for acquisition and modernization of existing facilities?

Grant awards for the acquisition and modernization of existing facilities are permitted if authorized by the statutes authorizing the construction grant program and shall be subject to the requirements of this section.

(a) *Minimum standards of construction and equipment.* A determination by the Director that the facility conforms (or upon completion of any necessary construction will conform) to the minimum standards of construction and equipment as set forth in § 52b.12 shall be obtained before entering into a final

or unconditional contract for the acquisition and/or modernization of facilities. Where the Director finds that exceptions to or modifications of these minimum standards would be consistent with the purposes of the applicable section of the Act under which the acquisition or modernization is supported, the Director may authorize the exceptions or modifications.

(b) *Estimated cost of acquisition and remodeling: suitability of facility.* Each application for a project involving the acquisition of existing facilities shall include in the detailed estimates of the costs of the project, the cost of acquiring the facilities, and any cost of remodeling, renovating or altering the facilities to serve the purposes for which they are acquired. The application shall demonstrate to the satisfaction of the Director that the architectural, mechanical, electrical, plumbing, structural, and other pertinent features of the facility, as modified by any proposed expansion, remodeling, renovation, or alteration, will be suitable for the purposes of the applicable sections of the Act.

(c) *Bona fide sale.* Grant awards for the acquisition of existing facilities shall be subject to the condition that the acquisition constitutes a bona fide sale involving an actual cost to the applicant and will result in additional or improved facilities for purposes of the applicable provisions of the Act.

(d) *Facility previously funded by a federal grant.* No grant for the acquisition or modernization of a facility which has previously been funded in whole or in part by a federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of the prior grant.

(Approved by the Office of Management and Budget under Control Number 0925-0424; expires November 30, 2001)

§ 52b.12 What are the minimum requirements of construction and equipment?

(a) *General.* In addition to being subject to other laws, regulations, executive orders, and policies referred to in

§ 52b.14, the standards set forth in this section have been determined by the Director to constitute minimum requirements of construction and equipment, including the expansion, remodeling, renovation, or alteration of existing buildings, and these standards, as may be amended, or any revisions or successors of these standards, shall apply to all projects for which federal assistance is requested under this part. The publications referenced in this section are hereby incorporated by reference and made a part of the regulations in this part.

(b) *Incorporation by reference.* The Director of the Federal Register approves the incorporations by reference in paragraph (c) of this section in accordance with 5 U.S.C. 552(a)(1) and 1 CFR part 51. Copies may also be obtained from the organizations at the addresses listed in paragraph (c) of this section. Copies may be inspected at the National Cancer Institute, Executive Plaza North, Room 539, 6130 Executive Boulevard, Rockville, MD 20852 (telephone 301-496-8534; not a toll-free number); the National Center for Research Services, Building 31, Room 3B11, 9000 Rockville Pike, Bethesda, MD 20892 (telephone 301-496-5793; not a toll-free number); and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. The Director may for good cause shown, approve plans and specifications which contain deviations from the requirements prescribed in paragraph (c) of this section, if the Director is satisfied that the purposes of the requirements have been fulfilled. In addition to these requirements, each project shall meet the requirements of the applicable state and local codes and ordinances relating to construction.

(c) *Design and construction standards.* The facility shall comply with the following mandatory design and construction standards:

(1) “Guidelines for Design and Construction of Hospital and Health Care Facilities” (1996–97). American Institute of Architects Academy of Archi-

tecture for Health (AIA); available from AIA Rizzoli Catalogue Sales, 117 Post Street, San Francisco, CA 94108 (telephone 1-800-522-6657, fax 415-984-0024).

(2) 1995 ASHRAE Handbook: Heating, Ventilating, and Air Conditioning Applications (1995), Chapter 13, “Laboratory Systems.” American Society of Heating, Refrigerating and Air Conditioning Engineers, Inc., 1791 Tullie Circle, NE, Atlanta, GA 30329 (telephone 404-636-8400).

(3) ICBO “Uniform Building Code,” Volumes 1–3 (1997). International Conference of Building Officials (ICBO), 5360 South Workman Mill Road, Whittier, CA 90601-2298 (telephone 562-699-0541 or 800-284-4406).

(4) BOCA National Building Code (1996) 1998 Supplement, Building Officials and Code Administrators International, Inc. (BOCA), 4051 West Fossmoor Road, Country Club Hills, IL 60478-5795 (telephone 708-799-4981; fax 708-799-4981).

(5) “Recommended Lateral Force Requirements and Commentary” (1996). Structural Engineers Association of California; available from International Conference of Building Officials, 5360 South Workman Mill Road, Whittier, CA 90601-2298 (telephone 562-699-0541).

(6) “Prudent Practices in the Laboratory: Handling and Disposal of Chemicals” (1995). National Research Council; available from National Academy Press, 8700 Spectrum Drive, Landover, MD 20785 (telephone 1-800-624-6242).

(7) The following material is available for purchase from the National Fire Protection Association (NFPA), 11 Tracy Drive, Avon, MA 02322-9908 (telephone 617-770-3000 or 1-800-735-0100):

(i) NFPA 45, “Standard on Protection for Laboratories Using Chemicals” (1996).

(ii) NFPA 70, “National Electric Code” (1996).

(iii) NFPA 99, Chapter 4, “Gas and Vacuum Systems” (1996).

(iv) NFPA 101, “Life Safety Code” (1997).

(v) NFPA “Health Care Facilities Handbook” (1996).

(8) NSF Standard No. 49 for Class II (Laminar Flow) Biohazard Cabinetry (1992). National Sanitation Foundation

Public Health Service, HHS

§ 52b.14

(NSF), 3475 Plymouth Road, Box 1468, Ann Arbor, MI 48106 (telephone 734-769-9010).

(9) ACGIH “Industrial Ventilation: A Manual of Recommended Practice” (1998). American Conference of Governmental Industrial Hygienists (ACGIH), 1330 Kemper Meadow Drive, Cincinnati, OH 45240-1634 (telephone 513-742-2020).

(10) AIHA “Laboratory Ventilation Workbook” (1994). American Industrial Hygiene Association (AIHA), 2700 Prosperity Avenue, Suite 250, Fairfax, VA 22031 (telephone 703-849-8888).

(11) The following material is available for purchase from the Southern Building Code Congress (SBCC), 900 Montclair Road, Birmingham, AL 35213-1206 (telephone 205-591-1853; fax 202-591-0075:

(i) SBCC “International Standard Plumbing Code” (1997).

(ii) SBCC “Standard Building Code” (1997).

[64 FR 63722, Nov. 22, 1999, as amended at 69 FR 18803, Apr. 9, 2004]

§ 52b.13 Additional conditions.

The Director may with respect to any grant award impose additional conditions consistent with the regulations of this part prior to or at the time of any award when in the Director’s judgment the conditions are necessary to assure or protect advancement of the approved project, the purposes of the applicable provisions of the Act, or the conservation of grant funds.

§ 52b.14 Other federal laws, regulations, executive orders, and policies that apply.

Other federal laws, regulations, executive orders, and policies apply to grants under this part. These include, but are not necessarily limited to:

(a) Laws.

An Act to Provide for the Preservation of Historical and Archeological Data (and other purposes), as amended (16 U.S.C. 469 *et seq.*).

Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151 *et seq.*).

Earthquake Hazards Reduction Act of 1977, as amended (42 U.S.C. 7701 *et seq.*).

Flood Disaster Protection Act of 1973, section 202, as amended (42 U.S.C. 4106).

National Historic Preservation Act, section 106, as amended (16 U.S.C. 470f).

Safe Drinking Water Act, as amended (42 U.S.C. 300f *et seq.*).

(b) Regulations.

9 CFR part 3—Standards (Animal Welfare).

29 CFR 1910.1450—Occupational exposure to hazardous chemicals in laboratories.

36 CFR part 1190—Minimum guidelines and requirements for accessible design.

41 CFR part 101-19, subpart 101-19.6—Accommodations for the physically handicapped.

41 CFR part 101-19, subpart 101-19.6, Appendix A—Uniform Federal accessibility standards.

42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science.

42 CFR part 50, subpart D—Public Health Service grant appeals procedure.

45 CFR part 15—Uniform relocation assistance and real property acquisition for Federal and federally assisted programs.

45 CFR part 16—Procedures of the Departmental Grant Appeals Board.

45 CFR part 46—Protection of human subjects.

45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments.

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants).

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964.

45 CFR part 81—Practice and procedure for hearings under part 80 of this chapter.

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance.

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefitting from Federal financial assistance.

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments.

45 CFR part 93—New restrictions on lobbying.

49 CFR part 24—Uniform relocation assistance and real property acquisition for Federal and federally assisted programs.

(c) *Executive orders.*

Executive Order 11988, Floodplain Management (May 24, 1977)(3 CFR, 1977 Comp., p. 117).

Executive Order 11990, Protection of Wetlands (May 24, 1977)(3 CFR, 1977 Comp., p. 121).

Executive Order 12699, Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (January 5, 1990)(3 CFR, 1990 Comp., p. 269).

(d) *Policies.* (1) Design Policy and Guidelines (1996). Division of Engineering Services, National Institutes of Health (NOTE: To obtain copies of the policy, interested persons should contact the Division of Engineering Services, 9000 Rockville Pike, Building 13, Room 2E43, Bethesda, MD 20892 (telephone 301-496-6186; not a toll-free number) or visit the following site on the World Wide Web (<http://des.od.nih.gov/nihpol.html>)).

(2) NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (1994) (NOTE: To obtain copies of the policy, interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161 (telephone 301-402-1770; not a toll-free number)).

(3) NIH Guidelines for Research Involving Recombinant DNA Molecules (1994) (NOTE: To obtain copies of the policy, interested persons should contact the Office of Recombinant DNA Activities, NIH, 6000 Executive Boulevard, Suite 323, MSC 7010, Bethesda, MD 20892-7010 (telephone 301-496-9838; not a toll-free number)).

(4) "NIH Grants Policy Statement," NIH Pub. No. 99-80 (Oct. 1998) (Note: To obtain copies of the policy, interested persons should contact the Extramural Outreach and Information Resources Office (EOIRO), Office of Extramural Research, NIH, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20892-7910 (telephone 301-435-0714; not a toll-free number). Information may also be obtained by contacting the EOIRO via its e-mail address (asknih@odrockml.od.nih.gov) and by browsing the NIH Home Page site on the World Wide Web (<http://www.nih.gov>)).

(5) "Guide for the Care and Use of Laboratory Animals (1996). Institute of

Laboratory Animal Resources, Commission on Life Sciences, National Research Council (NOTE: To obtain copies of the policy, interested persons should contact the Office for Protection from Research Risks, NIH, 6100 Executive Boulevard, Suite 3B01, MSC 7507, Rockville, MD 20852-7507 (telephone 301-496-7005; not a toll-free number)).

(6) "Public Health Service Policy on Humane Care and Use of Laboratory Animals." (Rev. Sept. 1986). Office for Protection from Research Risks, NIH (Note: To obtain copies of the policy, interested persons should contact the Office for Protection from Research Risks, NIH, 6100 Executive Boulevard, Suite 3B01, MSC 7507, Rockville, MD 20852-7507 (telephone 301-496-7005; not a toll-free number)).

(7) "Biosafety in Microbiological and Biomedical Laboratories." DHHS Publication No. (CDC) 88-8395 (1993). Centers for Disease Control and Prevention (CDC) (NOTE: To obtain copies of the policy, interested persons should contact the Division of Safety, Occupational Safety and Health Branch, NIH, 13 South Drive, Room 3K04, MSC 5760, Bethesda, MD 20892-5760 (telephone 301-496-2960; not a toll-free number)).

(8) "NIH Guidelines for the Laboratory Use of Chemical Carcinogens," DHHS Publication No. (NIH) 81-2385 (May 1981) (NOTE: To obtain copies of the policy, interested persons should contact the Division of Safety, Occupational Safety and Health Branch, NIH, 13 South Drive, Room 3K04, MSC 5760, Bethesda, MD 20892-5760 (telephone 301-496-2960; not a toll-free number)).

(9) "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects (March 6, 1998)." NIH Guide for Grants and Contracts (NOTE: To obtain copies of the policy, interested persons should contact the Office of Extramural Research, NIH, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20817-7910 (telephone 301-435-0714; not a toll-free number). Information may also be obtained by browsing the NIH Home Page site on the World Wide Web (<http://www.nih.gov>)).

PART 52c—MINORITY BIOMEDICAL RESEARCH SUPPORT PROGRAM

Sec.

- 52c.1 Applicability.
- 52c.2 Definitions.
- 52c.3 Eligibility.
- 52c.4 Application.
- 52c.5 Grant awards.
- 52c.6 Expenditure of grant funds.
- 52c.7 Other HHS regulations that apply.
- 52c.8 Additional conditions.

AUTHORITY: 42 U.S.C. 216, 241(a)(3).

SOURCE: 45 FR 12246, Feb. 25, 1980, unless otherwise noted.

§ 52c.1 Applicability.

The regulations in this part apply to grants (under the Minority Biomedical Research Support Program) awarded in accordance with section 301(a)(3) of the Public Health Service (PHS) Act (42 U.S.C. 241(a)(3)) to increase the numbers of ethnic minority faculty, students, and investigators engaged in biomedical research, and to broaden the opportunities for participation in biomedical research of ethnic minority faculty, students, and investigators, by providing general support for biomedical research programs at eligible institutions.

[58 FR 61030, Nov. 19, 1993]

§ 52c.2 Definitions.

As used in this part:

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

Ethnic minorities includes but is not limited to such groups as Black Americans, Hispanic Americans, Asian/Pacific Islanders, and American Indians/Native Alaskans (Native Americans).

HHS means the Department of Health and Human Services.

Nonprofit as applied to any institution means an institution which is a corporation or association no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Program director means a single individual, designated in the grant application, who is scientifically trained and has research experience and who is responsible for the overall execution of the program supported under this part at the grantee institution.

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.

[58 FR 61030, Nov. 19, 1993]

§ 52c.3 Eligibility.

To be eligible for a grant under this Program, an applicant must be:

(a) One of the following:

(1) A public or private nonprofit university, four year college, or other institution offering undergraduate, graduate, or health professional degrees, with a traditionally high (more than 50 percent) minority student enrollment;

(2) A public or private nonprofit two year college with a traditionally high (more than 50 percent) minority student enrollment;

(3) A public or private nonprofit university, four year college, or other institution offering undergraduate, graduate, or health professional degrees, with a student enrollment a significant proportion (but not necessarily more than 50 percent) of which is derived from ethnic minorities, provided the Secretary determines that said institution has a demonstrated commitment to the special encouragement of and assistance to ethnic minority faculty, students, and investigators; or

(4) An Indian tribe which has a recognized governing body which performs substantial governmental functions, or an Alaska Regional Corporation as defined in the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*), and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the successor States of the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 58 FR 61030, Nov. 19, 1993]

§ 52c.4 Application.

An institution interested in applying for a grant under this part must submit an application at the time and in the

§ 52c.5

form and manner that the Secretary may prescribe.

[58 FR 61030, Nov. 19, 1993]

§ 52c.5 Grant awards.

(a) Within the limits of funds available, and upon such recommendation as may be required by law, the Secretary shall award grants to those applications with proposed biomedical research programs which will, in the Secretary's judgment, best promote the purposes of this part, taking into consideration among other pertinent factors:

(1) The benefits that can be expected to accrue to the national effort in biomedical research and in increasing the pool of biomedical researchers;

(2) The institution's capability, from a scientific and technical standpoint, to engage in biomedical research;

(3) The benefits that can be expected to accrue to the institution and its students;

(4) The administrative and managerial capability and competence of the applicant;

(5) The availability of the facilities and resources (including where necessary collaborative arrangements with other institutions) to engage in biomedical research;

(6) The applicant's relative need for funding; and

(7) The overall significance of the proposal in terms of numbers of ethnic minority persons benefited thereby.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 1-5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued

42 CFR Ch. I (10-1-11 Edition)

funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 58 FR 61030, Nov. 19, 1993]

§ 52c.6 Expenditure of grant funds.

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) The Secretary may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the Secretary's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

[45 FR 12246, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 45 FR 68392, Oct. 15, 1980]

§ 52c.7 Other HHS regulations that apply.

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

37 CFR part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR part 50, subpart A—Responsibilities of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, subpart D—Public Health Service grant appeals procedures

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Administration of grants

Public Health Service, HHS

§ 52d.3

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs and activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR part 93—New restrictions on lobbying
51 FR 16958, or successor—NIH Guidelines for Research Involving Recombinant DNA Molecules

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986), or successor

[58 FR 61030, Nov. 19, 1993]

§ 52c.8 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Secretary's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 52d—NATIONAL CANCER INSTITUTE CLINICAL CANCER EDUCATION PROGRAM

Sec.

52d.1 Applicability.

52d.2 Definitions.

52d.3 Eligibility.

52d.4 Application.

52d.5 Program requirements.

52d.6 Grant awards.

52d.7 Expenditure of grant funds.

52d.8 Other HHS regulations that apply.

52d.9 Additional conditions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 835 (42 U.S.C. 216); sec. 404(a)(4), 92 Stat. 3426 (42 U.S.C. 285).

SOURCE: 45 FR 12247, Feb. 25, 1980, unless otherwise noted.

§ 52d.1 Applicability.

The regulations in this part apply to grants under the Clinical Cancer Education Program authorized by section 404(a)(4) of the Public Health Service Act, to encourage planning and development of multidisciplinary educational programs aimed at achieving optimal care of cancer patients and to enable students in the health professions to acquire basic knowledge of neoplastic disease and the preventive measures and diagnostic and therapeutic skills necessary to the provision of such care.

§ 52d.2 Definitions.

(a) *Act* means the Public Health Service Act, as amended.

(b) *Director, NCI*, means the Director of the National Cancer Institute and any other officer or employee of said Institute to whom the authority involved has been delegated.

(c) [Reserved]

(d) *Board* means the National Cancer Advisory Board established by section 407 of the Act (42 U.S.C. 286b).

(e) *Affiliated teaching hospital* means a hospital which, although not owned by such school, has a written agreement with a school of medicine, osteopathy, dentistry, or public health eligible for assistance under this part, providing for effective control by the school of the teaching in the hospital.

(f) *Specialized cancer institute* means an institution which has as its primary mission the diagnosis, prevention, or treatment of cancer.

[45 FR 12247, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980, as amended at 47 FR 53012, Nov. 24, 1982]

§ 52d.3 Eligibility.

To be eligible for a grant under this part, an applicant must be:

(a) A public or private school of medicine, osteopathy, dentistry, or public health, affiliated teaching hospital, or specialized cancer institute; and

§ 52d.4

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

[45 FR 12247, Feb. 25, 1980, as amended at 47 FR 53012, Nov. 24, 1982]

§ 52d.4 Application.

(a) Application for a grant under this subpart shall be made on an authorized form.¹ Applicants shall submit completed forms, on or before the dates the Director, NCI, may prescribe.

(b) [Reserved]

(c) In addition to any other pertinent information that the Director, NCI, may require, each application shall set forth in detail:

(1) A program plan defining the objectives of the proposed program and the means by which these objectives would be achieved, including descriptions of:

(i) The general educational level (e.g., pre-doctoral, post-doctoral) of the students to be involved in the program;

(ii) The proposed course of study and its relation to the diagnosis, prevention, control, and treatment of cancer;

(iii) The clinical experiences to be provided to the students;

(iv) Multidisciplinary aspects of the program;

(v) The particular schools or branches within the institution which would have responsibility for individual aspects of the program; and

(vi) The teaching mechanisms to be employed, including specific discussion of those techniques which would be innovative.

(2) The availability of personnel, facilities, and resources needed to carry out the program;

(3) The names, qualifications, and proposed duties of the program director and any staff members who would be responsible for the program, including a description of those duties which would actually be carried out by the program director and those which

¹Applications and instructions are available from the Division of Cancer Research Resources and Centers, Education Branch, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20205.

42 CFR Ch. I (10-1-11 Edition)

would be shared with or assigned to others;

(4) The names and qualifications of proposed members of a cancer education committee which would be established by the applicant to advise it on the planning, organization, operation and evaluation of the program and the specific duties which would be assigned to said committee;

(5) Insofar as necessary, cooperative arrangements with other schools, hospitals, and institutions which would participate in the program;

(6) The proposed project period, a detailed budget for the first budget period including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested project period, and a justification for the amount of grant funds requested;

(7) Proposed methods for monitoring and evaluating the program; and

(8) A description of how the education and training effort will be sustained upon expiration of the award.

[45 FR 12247, Feb. 25, 1980, as amended at 47 FR 53012, Nov. 24, 1982]

§ 52d.5 Program requirements.

(a) If the program is to be offered at the graduate level, it must be multidisciplinary in scope involving at least two or more clinical or preclinical sciences relating to cancer;

(b) The cancer education committee provided for in the approved application must meet at least four times per year, and must be chaired by the program director.

§ 52d.6 Grant awards.

(a) Within the limits of funds available, after consultation with the Board, the Director, NCI, may award grants to applicants with proposed programs which in the NCI Director's judgment best promote the purposes of this part, taking into consideration among other pertinent factors:

(1) The relevance of the proposed program to the objectives of this part;

(2) The extent to which the program would involve innovative teaching techniques;

(3) The availability of adequate staff, facilities, and resources (including

where necessary cooperative arrangements with other institutions or hospitals) to carry out the program;

(4) The qualifications and experience of the program director;

(5) The authority of the program director to ensure that the program is planned with multidisciplinary input and that multidisciplinary aspects of the program are carried out;

(6) The extent to which the cancer education committee is broadly representative of the disciplines concerned with cancer care and teaching and is allowed to participate in the planning, organization, operation, and evaluation of the program;

(7) If the program is to be offered at the pre-doctoral level, the extent to which its objectives are designed to aid students:

(i) To acquire a basic understanding of fundamental principles of cancer biology, epidemiology, detection, diagnosis, prevention, treatment and control;

(ii) To interest students in learning more about cancer; and

(iii) To develop an appreciation of the need for a comprehensive multidisciplinary approach to the care of cancer patients;

(8) The administrative and managerial capability of the applicant;

(9) The reasonableness of the proposed budget in relation to the proposed program;

(10) The adequacy of the methods for monitoring and evaluating the program on a continuing basis; and

(11) The degree to which the application adequately provides for the requirements set forth in § 52d.5.

(b) The notice of grant award specifies how long HHS intends to support the program without requiring the program to recompete for funds. This period, called the project period, will usually be for 1–5 years.

(c) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's

progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 52d.7 Expenditure of grant funds.

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the awards, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74, except that grant funds may not be used for costs incurred in connection with activities which, prior to the grant, were part of the grantee's standard curriculum.

(b) The Director, NCI, may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the NCI Director's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

§ 52d.8 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not limited to:

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 74—Administration of grants

45 CFR part 75—Informal grant appeals procedures

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

§ 52d.9

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

[49 FR 38111, Sept. 27, 1984]

§ 52d.9 Additional conditions.

The Director, NCI, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the NCI Director's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 52e—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS FOR PREVENTION AND CONTROL PROJECTS

Sec.

52e.1 To what programs do these regulations apply?

52e.2 Definitions.

52e.3 Who is eligible to apply?

52e.4 How to apply.

52e.5 What are the project requirements?

52e.6 How will NIH evaluate applications?

52e.7 What are the terms and conditions of awards?

52e.8 Other HHS regulations and policies that apply.

52e.9 Additional conditions.

AUTHORITY: 42 U.S.C. 216, 285b-1.

SOURCE: 45 FR 12249, Feb. 25, 1980, unless otherwise noted.

§ 52e.1 To what programs do these regulations apply?

(a) This part applies to grants under section 419 of the Act (42 U.S.C. 285b-1) for projects to:

(1) Demonstrate and evaluate the effectiveness of new techniques or procedures for the prevention and control of heart, blood vessel, lung, and blood diseases, with special consideration given to the prevention and control of these diseases in children, and in populations

42 CFR Ch. I (10-1-11 Edition)

that are at increased risk with respect to such diseases;

(2) Develop and evaluate methods of educating health practitioners concerning the prevention and control of these diseases; and

(3) Develop and evaluate methods of educating the public concerning the prevention and control of these diseases.

(b) For purposes of this part, prevention and control projects shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

[45 FR 12249, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980, as amended at 58 FR 54298, Oct. 21, 1993; 59 FR 59372, Nov. 17, 1994]

§ 52e.2 Definitions.

As used in this part:

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

Council means the National Heart, Lung, and Blood Advisory Council, established under section 406 of the Act (42 U.S.C. 284a).

Director means the Director of the National Heart, Lung, and Blood Institute and any official to whom the authority involved may be delegated.

Emergency medical services means the services utilized in responding to the perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

HHS means the Department of Health and Human Services.

National program means the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program referred to in section 421 of the Act (42 U.S.C. 285b-3).

Nonprofit as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Public Health Service, HHS

§ 52e.5

PHS means the Public Health Service.

[58 FR 54298, Oct. 21, 1993]

§ 52e.3 Who is eligible to apply?

To be eligible for a grant under this part, an applicant must be a public or nonprofit private agency or institution.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

§ 52e.4 How to apply.

(a) Application for a grant under this subpart shall be made on an authorized form.² Applicants shall submit completed forms on or before the dates the Director may prescribe.

(b) Each private institution which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) In addition to any other pertinent information that the Director may require each application shall set forth in detail:

(1) The nature and purpose of the proposed project and the methods to be employed in carrying it out;

(2) The relevance of the proposed project to the National Program;

(3) The defined population to participate in the proposed project and the rationale for its selection;

(4) With respect to applications relating to projects covered by § 52e.1(a)(1), prior research findings on which the proposed project is based;

(5) The personnel, facilities, and other resources, including community resources, available to carry out the proposed project;

(6) Current activities of the applicant involving prevention or control of heart, blood vessel, lung, and blood diseases, the sources of funding for such activities, and the anticipated relationship of these activities to the proposed project;

(7) The names and qualifications of the project director and key staff mem-

bers who would be responsible for conducting the proposed project;

(8) Proposed methods for monitoring and evaluating the project; and

(9) The proposed project period; a detailed budget for the first budget period, including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested project period; and a justification for the amount of grant funds requested.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

§ 52e.5 What are the project requirements?

(a) An approvable application must demonstrate to the satisfaction of the Director that:

(1) With respect to applications relating to projects covered by § 52e.1(a)(1), the techniques or procedures to be demonstrated and evaluated have been found safe and effective in the research setting and, based upon research findings, appear to have the potential for general applicability to the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases;

(2) With respect to applications relating to projects covered by § 52e.1(a)(2) and § 52e.1(a)(3), the project will include development and evaluation of one or more methods for educating health practitioners or the public concerning advances in the prevention, diagnosis, or treatment of such diseases; and

(3) The nature of the project is such that its completion may be anticipated within the project period, or such other period as may be specified in the application.

(b) The project must, in the judgment of the Director, be necessary for cooperation by the National Heart, Lung, and Blood Institute with one or more other Federal Health agencies, State, local or regional public health agencies, or nonprofit private health agencies in the diagnosis, prevention, or treatment of heart, blood vessel, lung or blood diseases.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298 and 54299, Oct. 21, 1993]

²Applications and instructions are available from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20205.

§ 52e.6

42 CFR Ch. I (10–1–11 Edition)

§ 52e.6 How will NIH evaluate applications?

(a) Within the limits of funds available, after consultation with the Council, the Director may award grants to applicants with proposed projects which in the Director's judgment will best promote the purposes of section 419 of the Act, taking into consideration among other pertinent factors:

(1) The scientific and technical merit of the proposed project;

(2) The significance of the project in relation to the goals of the National Program;

(3) Whether the project appropriately emphasizes the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases of children;

(4) The qualifications and experience of the project director and other key personnel;

(5) The administrative and managerial capability and fiscal responsibility of the applicant;

(6) The reasonableness of the proposed budget in relation to the proposed project;

(7) The adequacy of the methods proposed for monitoring and evaluating the proposed project; and

(8) The degree to which the application adequately provides for the requirements set forth in §§ 52e.5(a) and 52e.5(b).

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re compete for funds. This period, called the project period, will usually be for 1–5 years.

(c) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant com-

mits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(e) Any funds granted under this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms, and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

§ 52e.7 What are the terms and conditions of awards?

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) The Director may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the NHLBI Director's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298 and 54299, Oct. 21, 1993]

§ 52e.8 Other HHS regulations and policies that apply.

Several other regulations apply to grants under this part. These include but are not necessarily limited to:

42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

Public Health Service, HHS

§ 52h.2

- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments
- 45 CFR part 93—New restrictions on lobbying
- 51 FR 16958 or successor—NIH Guidelines for Research Involving Recombinant DNA Molecules
- “Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986), or successor
- 59 FR 14508 (as republished March 28, 1994), as may be amended, or its successor—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

[58 FR 54298, Oct. 21, 1993, as amended at 59 FR 59372, Nov. 17, 1994]

§ 52e.9 Additional conditions.

The Director, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Director's judgment those conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54299, Oct. 21, 1993]

PART 52h—SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS

Sec.

- 52h.1 Applicability.
- 52h.2 Definitions.
- 52h.3 Establishment and operation of peer review groups.
- 52h.4 Composition of peer review groups.
- 52h.5 Conflict of interest.
- 52h.6 Availability of information.
- 52h.7 What matters must be reviewed for grants?
- 52h.8 What are the review criteria for grants?
- 52h.9 What matters must be reviewed for unsolicited contract proposals?
- 52h.10 What matters must be reviewed for solicited contract proposals?
- 52h.11 What are the review criteria for contract projects and proposals?
- 52h.12 Other regulations that apply.

AUTHORITY: 42 U.S.C. 216; 42 U.S.C. 282 (b)(6); 42 U.S.C. 284 (c)(3); 42 U.S.C. 289a.

SOURCE: 69 FR 275, Jan. 5, 2004, unless otherwise noted.

§ 52h.1 Applicability.

(a) This part applies to:

(1) Applications of the National Institutes of Health for grants or cooperative agreements (a reference in this part to grants includes cooperative agreements) for biomedical and behavioral research; and

(2) Biomedical and behavioral research and development contract project concepts and proposals for contract projects administered by the National Institutes of Health.

(b) This part does not apply to applications for:

(1) Continuation funding for budget periods within an approved project period;

(2) Supplemental funding to meet increased administrative costs within a project period; or

(3) Construction grants.

§ 52h.2 Definitions.

As used in this part:

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

(b) *Appearance of a conflict of interest* means that a reviewer or close relative

or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer or the government official managing the review and would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review; the government official managing the review (the Scientific Review Administrator or equivalent) will evaluate the appearance of a conflict of interest and determine, in accordance with this subpart, whether or not the interest would likely bias the reviewer's evaluation of the application or proposal.

(c) *Awarding official* 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; except that, where the Act specifically authorizes another official to make awards in connection with a particular program, the awarding official shall mean that official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(d) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(e) *Close relative* means a parent, spouse, domestic partner, or son or daughter.

(f) *Contract proposal* means a written offer to enter into a contract that is submitted to the appropriate agency official by an individual or nonfederal organization which includes, at a minimum, a description of the nature, purpose, duration, and cost of the project, and the methods, personnel, and facilities to be utilized in carrying it out. A contract proposal may be unsolicited by the federal government or submitted in response to a request for proposals.

(g) *Development* means the systematic use of knowledge gained from research to create useful materials, devices, systems, or methods.

(h) *DHHS* means the Department of Health and Human Services.

(i) *Director* means the Director of the National Institutes of Health and any

other official or employee of the National Institutes of Health to whom the authority involved has been delegated.

(j) *Grant* as used in this part, includes cooperative agreements.

(k) *Peer review group* means a group of primarily nongovernment experts qualified by training and experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, to give expert advice on the scientific and technical merit of grant applications or contract proposals, or the concept of contract projects, in accordance with this part.

(l) *Principal investigator* has the same meaning as in 42 CFR part 52.

(m) *Professional associate* means any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities within three years of the date of the review.

(n) *Project approach* means the methodology to be followed and the resources needed in carrying out the project.

(o) *Project concept* means the basic purpose, scope, and objectives of the project.

(p) *Project period* has the same meaning as in 42 CFR part 52.

(q) *Real conflict of interest* means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as determined by the government official managing the review (the Scientific Review Administrator, or equivalent), as acknowledged by the reviewer, or as prescribed by this part. A reviewer shall have a real conflict of interest if he/she or a close relative or professional associate of the reviewer:

(1) Has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review;

(2) Apart from any direct financial benefit deriving from an application or proposal under review, has received or could receive a financial benefit from

the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year; this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the reviewer's already existing stock holdings. The Director, NIH, may amend the dollar threshold periodically, as appropriate, after public notice and comment; or

(3) Has any other interest in the application or proposal that is likely to bias the reviewer's evaluation of that application or proposal. Regardless of the level of financial involvement or other interest, if the reviewer feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue. The peer review system relies on the professionalism of each reviewer to identify to the designated government official any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

(r) *Request for proposals* means a Government solicitation to prospective offerors, under procedures for negotiated contracts, to submit a proposal to fulfill specific agency requirements based on terms and conditions defined in the request for proposals. The request for proposals contains information sufficient to enable all offerors to prepare proposals, and is as complete as possible with respect to: nature of work to be performed; descriptions and specifications of items to be delivered; performance schedule; special requirements clauses, or other circumstances affecting the contract; format for cost proposals; and evaluation criteria by which the proposals will be evaluated.

(s) *Research* has the same meaning as in 42 CFR part 52.

(t) *Research and development contract project* means an identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts, intended and designed to acquire new or fuller knowledge and understanding in the areas of biomedical or behavioral research and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods.

(u) *Scientific review group* has the same meaning as peer review group, which is defined in paragraph (k) of this section.

(v) *Solicited contract proposal* has the same meaning as the definition of offer in 48 CFR 2.101.

(w) *Unsolicited contract proposal* has the same meaning as unsolicited proposal in 48 CFR 15.601.

§ 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2) and chapter 9 of the DHHS General Administration Manual¹ shall govern the establishment and operation of peer review groups.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9, and 52h.10.

§ 52h.4 Composition of peer review groups.

(a) To the extent applicable, the selection and appointment of members of peer review groups and their terms of service shall be governed by chapter 9 of the DHHS General Administration Manual.

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, or upon their qualifications as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, taking into account, among other factors:

(1) The level of formal scientific or technical education completed or experience acquired by the individual;

(2) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigator, assistant) in which the

¹The DHHS General Administration Manual is available for public inspection and copying at the Department's information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

§ 52h.5

42 CFR Ch. I (10–1–11 Edition)

individual has done so, and the quality of the research;

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations; and

(4) The need for the group to have included within its membership experts from various areas of specialization within relevant scientific or technical fields, or authorities knowledgeable in the various disciplines and fields related to the scientific areas under review.

(c) Except as otherwise provided by law, not more than one-fourth of the members of any peer review group to which this part applies may be officers or employees of the United States. Being a member of a scientific peer review group does not make an individual an officer or employee of the United States.

§ 52h.5 Conflict of interest.

(a) This section applies only to conflicts of interest involving members of peer review groups. This section does not cover individuals serving on National Advisory Councils or Boards, Boards of Scientific Counselors, or Program Advisory Committees who, if not already officers or employees of the United States, are special Government employees and covered by title 18 of the United States Code, the Office of Government Ethics Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 11222, as amended. For those federal employees serving on peer review groups, in accordance with § 52h.4, the requirements of title 18 of the United States Code, 5 CFR part 2635 and Executive Order 12674, as modified by Executive Order 12731, apply.

(b) A reviewer with a real conflict of interest must recuse him/herself from the review of the application or proposal, except as otherwise provided in this section.

(1) A reviewer who is a salaried employee, whether full-time or part-time, of the applicant institution, offeror, or principal investigator, or is negotiating for employment, shall be considered to have a real conflict of interest with regard to an application/proposal from that organization or principal in-

vestigator, except that the Director may determine there is no real conflict of interest or an appearance of a conflict of interest where the components of a large or multicomponent organization are sufficiently independent to constitute, in effect, separate organizations, provided that the reviewer has no responsibilities at the institution that would significantly affect the other component.

(2) Where a reviewer's real conflict of interest is based upon the financial or other interest of a close relative or professional associate of the reviewer, that reviewer must recuse him/herself, unless the Director provides a waiver in accordance with paragraph (b)(4) of this section.

(3) For contract proposal reviews, an individual with a real conflict of interest in a particular proposal(s) is generally not permitted to participate in the review of any proposals responding to the same request for proposals. However, if there is no other qualified reviewer available having that individual's expertise and that expertise is essential to ensure a competent and fair review, a waiver may be granted by the Director to permit that individual to serve as a reviewer of those proposals with which the reviewer has no conflict, while recusing him/herself from the review of any particular proposal(s) in which there is a conflict of interest.

(4) The Director may waive any of the requirements in paragraph (b) of this section relating to a real conflict of interest if the Director determines that there are no other practical means for securing appropriate expert advice on a particular grant or cooperative agreement application, contract project, or contract proposal, and that the real conflict of interest is not so substantial as to be likely to affect the integrity of the advice to be provided by the reviewer.

(c) Any appearance of a conflict of interest will result in recusal of the reviewer, unless the Director provides a waiver, determining that it would be difficult or impractical to carry out the review otherwise, and the integrity of the review process would not be impaired by the reviewer's participation.

(d) When a peer review group meets regularly it is assumed that a relationship among individual reviewers in the group exists and that the group as a whole may not be objective about evaluating the work of one of its members. In such a case, a member's application or proposal shall be reviewed by another qualified review group to ensure that a competent and objective review is obtained.

(e) When a member of a peer review group participates in or is present during the concept review of a contract proposal that occurs after release of the solicitation, as described under § 52h.10(b), but before receipt of proposals, the member is not considered to have a real conflict of interest as described in paragraph (b) of this section, but is subject to paragraph (c) of this section concerning appearance of conflict of interest if the member is planning to respond to the solicitation. When the concept review occurs after receipt of proposals, paragraph (b) applies.

(f) No member of a peer review group may participate in any review of a specific grant application or contract project for which the member has had or is expected to have any other responsibility or involvement (whether pre-award or post-award) as an officer or employee of the United States.

(g) The Director may periodically issue guidance to the government officials responsible for managing reviews and reviewers on what interests would constitute a real conflict of interest or an appearance of a conflict of interest.

§ 52h.6 Availability of information.

(a) Transcripts, minutes, and other documents made available to or prepared for or by a peer review group will be available for public inspection and copying to the extent provided by the Freedom of Information Act, as amended (5 U.S.C. 552), the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the Privacy Act of 1974, as amended (5 U.S.C. 552a), and implementing DHHS regulations (45 CFR parts 5, 5b).

(b) Meetings of peer review groups reviewing grant applications or contract proposals are closed to the public in accordance with sections 552b(c)(4) and

552b(c)(6) of the Government in the Sunshine Act, as amended (5 U.S.C. 552b(c)(4) and 552b(c)(6)) and section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2). Documents made available to, or prepared for or by peer review groups that contain trade secrets or commercial or financial information obtained from a person that is privileged or confidential, and personal information concerning individuals associated with applications or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, are exempt from disclosure in accordance with the Freedom of Information Act, as amended (5 U.S.C. 552(b)(4) and 552(b)(6)).

(c) Meetings of peer review groups reviewing contract project concepts are open to the public in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2) and the Government in the Sunshine Act, as amended (5 U.S.C. 552b).

§ 52h.7 What matters must be reviewed for grants?

(a) Except as otherwise provided by law, no awarding official shall award a grant based upon an application covered by this part unless the application has been reviewed by a peer review group in accordance with the provisions of this part and the group has made recommendations concerning the scientific merit of that application. In addition, where under applicable law an awarding official is required to secure the approval or advice of a national council or board concerning an application, the application may not be considered by the council or board unless it has been reviewed by the appropriate peer review group, in accordance with the provisions of this part, and the group has made recommendations concerning the scientific merit of the application, except where the council or board is the peer review group.

(b) Except to the extent otherwise provided by law, recommendations by peer review groups are advisory only and not binding on the awarding official or the national advisory council or board.

§ 52h.8 What are the review criteria for grants?

In carrying out its review under § 52h.7, the scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account, among other pertinent factors:

- (a) The significance of the goals of the proposed research, from a scientific or technical standpoint;
- (b) The adequacy of the approach and methodology proposed to carry out the research;
- (c) The innovativeness and originality of the proposed research;
- (d) The qualifications and experience of the principal investigator and proposed staff;
- (e) The scientific environment and reasonable availability of resources necessary to the research;
- (f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;
- (g) The reasonableness of the proposed budget and duration in relation to the proposed research; and
- (h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

§ 52h.9 What matters must be reviewed for unsolicited contract proposals?

(a) Except as otherwise provided by law, no awarding official shall award a contract based upon an unsolicited contract proposal covered by this part unless the proposal has been reviewed by a peer review group in accordance with the provisions of this part and the group has made recommendations concerning the scientific merit of that proposal.

(b) Except to the extent otherwise provided by law, peer review group recommendations are advisory only and not binding on the awarding official.

§ 52h.10 What matters must be reviewed for solicited contract proposals?

(a) Subject to paragraphs (b) and (c) of this section, no awarding official shall issue a request for contract proposals with respect to a contract

project involving solicited contract proposals, unless the project concept has been reviewed by a peer review group or advisory council in accordance with this part and the group has made recommendations concerning the scientific merit of the concept.

(b) The awarding official may delay carrying out the requirements for peer review of paragraph (a) of this section until after issuing a request for proposals if the official determines that the accomplishment of essential program objectives would otherwise be placed in jeopardy and any further delay clearly would not be in the best interest of the Government. The awarding official shall specify in writing the grounds on which this determination is based. Under these circumstances, the awarding official will not award a contract until peer review of the project concept and the proposals has been completed. The request for proposals shall state that the project concept will be reviewed by a peer review group and that no award will be made until the review is conducted and recommendations made based on that review.

(c) The awarding official may determine that peer review of the project concept for behavioral or biomedical research and development contracts is not needed if one of the following circumstances applies: the solicitation is to re-compete or extend a project that is within the scope of a current project that has been peer reviewed, or there is a Congressional authorization or mandate to conduct specific contract projects. If a substantial amount of time has passed since the concept review, the awarding official shall determine whether peer review is required to ensure the continued scientific merit of the concept.

(d) Except to the extent otherwise provided by law, the recommendations referred to in this section are advisory only and not binding on the awarding official.

§ 52h.11 What are the review criteria for contract projects and proposals?

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group shall

Public Health Service, HHS

§ 53.111

take into account, among other pertinent factors:

(1) The significance from a scientific or technical standpoint of the goals of the proposed research or development activity;

(2) The availability of the technology and other resources necessary to achieve those goals;

(3) The extent to which there are identified, practical uses for the anticipated results of the activity; and

(4) Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity.

(b) In carrying out its review of unsolicited contract proposals under § 52h.9, the peer review group shall take into account, among other pertinent factors, the criteria in § 52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited proposals under § 52h.10(a) or (b), the peer review group shall evaluate each proposal in accordance with the criteria set forth in the request for proposals.

§ 52h.12 Other regulations that apply.

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals set forth elsewhere in this title, title 45, or title 48 of the Code of Federal Regulations.

PART 53—GRANTS, LOANS AND LOAN GUARANTEES FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND MEDICAL FACILITIES

Subparts A–K [Reserved]

Subpart L—Services for Persons Unable To Pay; Community Service; Nondiscrimination

Sec.

53.111 Services for persons unable to pay.

53.112 Nondiscrimination.

53.113 Community service.

Subpart M [Reserved]

Subpart N—Loan Guarantees and Direct Loans

53.154 Waiver of right of recovery.

53.155 Modification of loans.

53.156 Fees for modification requests.

AUTHORITY: Secs. 215, 603, 609, 621, 623, Public Health Service Act as amended, 58 Stat. 690, 78 Stat. 451 and 456, 84 Stat. 344 and 346 (42 U.S.C. 216, 291c, 291i, 291j–1 and 291j–3; 31 U.S.C. 9701).

Subparts A–K [Reserved]

Subpart L—Services for Persons Unable To Pay; Community Service; Nondiscrimination.

§ 53.111 Services for persons unable to pay.

(a) *Applicability.* The provisions of this section apply to every applicant which heretofore has given or hereafter will give an assurance that it will make available a reasonable volume of services to persons unable to pay therefor but shall not apply to an applicant (1) for more than 20 years after the completion of construction of any facility with respect to which funds have been paid under section 606 of the Act or (2) beyond the period during which any amount of a direct loan made under sections 610 or 623 of the Act, or any amount of a loan with respect to which a loan guarantee and interest subsidy has been provided under sections 623 and 624 of the Act remains unpaid.

(b) *Definitions.* As used in this section:

(1) The term *facility* includes hospitals, facilities for long-term care, outpatient facilities, rehabilitation facilities, and public health centers;

(2) The term *applicant* means an applicant for, or recipient of, a grant, a loan guarantee or a loan under the Act;

(3) *Fiscal year* means the fiscal year of the applicant;

(4) The term *operating costs* means the actual operating costs of the applicant for a fiscal year as determined in accordance with cost determination principles and requirements under title XVIII of the Social Security Act (42 U.S.C. 1395): *Provided*, That such “operating costs” shall be determined for the applicant’s entire facility and for

all patients regardless of the source of payment for such care: *And provided further*, That in determining such operating costs there shall be deducted the amount of all actual or estimated reimbursements, as applicable, for services received or to be received pursuant to title XVIII and XIX of the Social Security Act (42 U.S.C. 1395 and 1936);

(5) The term *reasonable cost* means the cost of providing services to a specific patient determined in accordance with the cost determination principles and requirements under title XVIII of the Social Security Act (42 U.S.C. 1395) and subpart D of the regulations thereunder (20 CFR part 405,¹ part 401 *et seq.*);

(6) The term *uncompensated services* means services which are made available to persons unable to pay therefor without charge or at a charge which is less than the reasonable cost of such services. The level of such services is measured by the difference between the amount charged such persons for such services and the reasonable cost thereof;

(7) *Reasonable volume of services to persons unable to pay therefor* means a level of uncompensated services which meets a need for such services in the area served by an applicant and which is within the financial ability of such applicant to provide.

(c) *Assurance*. (1) Before an application under this part is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor. The requirement of an assurance from an applicant shall be waived if the applicant demonstrates to the satisfaction of the State agency, subject to subsequent approval by the Secretary, that such a requirement is not feasible from a financial viewpoint.

(2) Prior to recommending that such requirement be waived, the State agency shall publish in a newspaper of general circulation in the area served by the applicant a notice of the request

for such waiver and invite public comment thereon, allowing not less than 30 days therefor. All comments received shall be available for public inspection, and shall be considered by the State agency in arriving at its recommendation. Notice of the determination on the request for waiver shall be given to all interested persons and to the public before the approval of the Secretary is sought.

(d) *Presumptive compliance guideline*. An applicant which, for a fiscal year, (1) budgets for the support of, and makes available on request, uncompensated services at a level not less than the lesser of 3 percent of operating costs or 10 percent of all Federal assistance provided to or on behalf of the applicant under the Act, or (2) certifies that it will not exclude any person from admission on the ground that such person is unable to pay for needed services and that it will make available to each person so admitted services provided by the facility without charge or at a charge below reasonable cost which does not exceed any such person's ability to pay therefor as determined in accordance with criteria established pursuant to paragraph (g), shall be deemed in presumptive compliance with its assurance. In the case of a loan guarantee with interest subsidy or a direct loan guarantee be sold by the Secretary with an interest subsidy, the amount of Federal assistance shall include the total amount of the interest subsidy which the Secretary is, or will be, obligated to pay over the full life of the loan, as well as any other payments which the Secretary makes on behalf of the applicant in connection with the loan guarantee or the direct loan which has been sold.

(e) *Compliance reports*. (1) Each applicant shall, not later than 120 days after the end of a fiscal year, unless a longer period is approved by the State agency for good cause shown, file with the State agency a copy of its annual statement for such year as required by section 646 of the Act and § 53.128(q), which shall set forth its operating costs.

(2) With respect to each fiscal year for which a level of uncompensated services has been established in accordance with this section, the annual

¹Redesignated as 42 CFR part 405 at 42 FR 52826, Sept. 30, 1977.

statement shall also set forth the amount of uncompensated services provided in such year.

(i) The provision of a level of uncompensated services in such year which equals or exceeds the level established pursuant to paragraph (h) of this section for such year shall constitute compliance with the assurance.

(ii) If the level of services provided was less than the level of uncompensated services established pursuant to paragraph (h) of this section, the applicant shall submit with such statement: A justification therefor, showing that the provision of such lower level of uncompensated services was reasonable under the circumstances; and a description of the steps it proposes to take to assure the availability and utilization of the level of uncompensated services to be established for the current fiscal year, which shall include an affirmative action plan, utilizing press releases or other appropriate means as the facility may desire to bring to the attention of the public the availability of such uncompensated services and the conditions of eligibility therefor.

(3) Each applicant shall file with its annual statement a copy of that portion of its adopted budget for the current fiscal year relating to the support of uncompensated services in such year. Such budget for uncompensated services shall be based on the operating costs of the applicant for the preceding fiscal year and shall give due cognizance to probable increases in operating costs. Except in the case of a certification pursuant to paragraph (d)(2) of this section, if the budget statement does not conform to the presumptive compliance guideline, the applicant shall submit with its statement.

(i) A justification therefor, showing that such lower level of uncompensated services is reasonable under the circumstances, and

(ii) A plan to increase such uncompensated services to meet the presumptive compliance guideline or such other level of uncompensated services as may have been established or as it requests the State agency to establish in accordance with paragraph (h) of this section.

(4) The applicant shall also submit such additional reports related to com-

pliance with its assurance as the State agency may reasonably require.

(5) Pending the establishment of a level of uncompensated services for any fiscal year pursuant to paragraph (h) of this section, the applicant shall, in such fiscal year, provide a level of services which is the higher of

(i) The level established for the preceding fiscal year (or if no such level has been established for such prior year, the level of services provided in such year) or

(ii) The level proposed in its adopted budget for the current fiscal year.

(f) *Qualifying services.* (1) In determining the amount of uncompensated services provided by an applicant, there shall be included only those services provided to an individual with respect to whom the applicant has made a written determination prior to the provision of such services that such individual is unable to pay therefor under the criteria established pursuant to 42 CFR 53.111(g), except that:

(i) Such determination may be made after the provision of such services in the case of services provided on an emergency basis: *Provided*, That when billing is made for such service, such billing must be accompanied by substantially the information required in the posted notice under paragraph (i) of this section; and

(ii) Such determination may be made after the provision of such services in the case of a change in circumstances as a result of the illness or injury occasioning such services (e.g., the patient's financial condition has changed due to a loss of wages resulting from the illness) or in case of insurance coverage or other resources being less than anticipated or the costs of services being greater than anticipated. *Further*, in all cases where such determination was not made prior to the provision of services, such services may not be included as uncompensated services if any collection effort has been made other than the rendering of bills permissible in the above exceptions: *Provided*, That such a determination may be made at any time if the determination was hindered or delayed by reason of erroneous or incomplete information furnished by or in behalf of the patient.

(2) There shall be excluded from the computation of uncompensated services:

(i) Any amount which the applicant has received, or is entitled to receive, from a third party insurer or under a governmental program; and

(ii) The reasonable cost of any services for which payment in whole or in part would be available under a governmental program (e.g., Medicare and Medicaid) in which the applicant, although eligible to do so, does not participate, but only to the extent of such otherwise available payment.

(g) *Persons unable to pay for services.*

(1) The State agency shall set forth in its State plan, subject to approval by the Secretary, criteria for identifying persons unable to pay for services, which shall include persons who are otherwise self-supporting but unable to pay the full charge for needed services. Such criteria shall be based on the following or similar factors:

(i) The health and medical care insurance coverage, personal or family income, the size of the patient's family, and other financial obligations and resources of the patient or the family in relation to the reasonable cost of the services;

(ii) Generally recognized standards of need such as:

(a) The State standard for the medically needy as determined for the purposes of the Aid for Families with Dependent Children program;

(b) The current Social Security Administration poverty income level;

(c) The current Office of Economic Opportunity Income Poverty Guidelines applicable in the area; or

(iii) Any other equivalent measures which are found by the Secretary to provide a reasonable basis for determining an individual's ability to pay for medical and hospital services.

(2) A copy of such criteria shall be provided by the applicant, upon request, to any patient or former patient of the applicant and to any person seeking services from the applicant.

(3) The State agency shall provide a copy of such criteria to any person requesting it.

(h) *Level of uncompensated services.* (1) The State agency shall set forth in its State plan procedures for the deter-

mination for each applicant of the level of uncompensated services which constitutes a reasonable volume of services to persons unable to pay therefor provided that in no event shall the level of uncompensated services established under this section exceed the presumptive compliance guideline.

(2) The State agency shall for the purpose of making such determination, review, and evaluate the annual statement, the budget and the related documents submitted by each applicant pursuant to paragraph (e) of this section, by applying the following criteria:

(i) The financial status of the applicant, taking account of income from all sources, and its financial ability to provide uncompensated services;

(ii) The nature and quantity of services provided by the applicant;

(iii) The need within the area served by the applicant for the provision, without charge or at charge which is less than reasonable cost, for services of the nature provided or to be provided by the applicant; and

(iv) The extent and nature of joint or cooperative programs with other facilities for the provision of uncompensated services, and the extent and nature of outreach services directed to the needs of underserved areas.

(3) In accordance with its findings made after such review and evaluation, the State agency shall, within 60 days after receipt of the annual statement and related documents required by paragraph (e) of this section, for each fiscal year of an applicant which begins following the expiration of 90 days after the effective date of this regulation:

(i) Establish a level of uncompensated services for each applicant which may be equal to or less than the presumptive compliance guideline: *Provided*, That if the State agency determines, in accordance with paragraph (h)(2) of this section, that (a) there is a need in the area served by an applicant for a level of uncompensated services greater than the level proposed in the applicant's budget statement, and (b) the applicant is financially able to provide such greater level of uncompensated services, the State agency shall

establish such greater level as the level applicable to the applicant; and

(ii) Accept or modify a plan submitted pursuant to paragraph (e) of this section.

(4) The State agency shall notify the applicant in writing of the level of uncompensated services which it has established for the applicant for the fiscal year. At the time of notifying the applicant, the State agency shall also publish as a public notice in a newspaper of general circulation within the community served by the applicant the rate that has been established and a statement that the documents upon which the agency based its determination are available for public inspection at a location and time prescribed. In the case of the establishment by the State agency of a rate which is less than the presumptive compliance guideline, such notice shall also include a statement that persons wishing to object to the rate established may do so by writing to the State agency within 20 days after publication of the notice: *Provided*, That the applicant may object to any level established which is greater than the level proposed in the applicant's budget statement.

(5) In accordance with the provisions of paragraph (h)(4) of this section, the applicant or any person or persons residing or located within the area served by the applicant, or any organization on behalf of such person or persons, may submit to the State agency within 20 days of the publication and sending of the notice objections to the rate established by the State agency for the applicant. Such objections may be supported in writing by factual information and argument. The State agency shall give public notice of receipt of the objections and shall make the objections and their supporting documents available for public inspection and comment. It may, if it believes that determination of the objections will be assisted by oral evidence or by oral argument, set a public hearing on the objections and shall give notice of such hearing to all interested parties and to the public. The State agency shall within 60 days of the expiration of the period within which objections may be filed, rule upon the objections in

writing, stating its reason for sustaining or overruling them, in whole or in part, and establishing finally the rate of uncompensated services either the same as, above, or below the rate previously established, as may best accord with all of the evidence on file with or heard by the State agency. Notice of the final determination shall be mailed to all parties who filed objections or who participated in the proceedings leading to the redetermination.

(6) Within 20 days of receipt of written notice of the final determination of a State agency after ruling on objections to the rate established by the State agency, the applicant or any other interested person or organization may submit to the Secretary a written request for review of the State agency determination. Such review shall be made upon the record of the State agency determination which shall be sustained if supported by substantial evidence and is not otherwise arbitrary or capricious. If the Secretary or his designee determines that the rate established by the State agency is unsupported by the evidence in the record or is otherwise arbitrary or capricious, the Secretary or his designee shall, upon the basis of the record or upon other evidence or information which is before him or which he may obtain, establish a level of uncompensated services which he determines, in accordance with the criteria set out in paragraph (h)(2) of this section, is appropriate.

(7) The level of uncompensated services established for an applicant under this section for any fiscal year shall constitute a reasonable volume of services to persons unable to pay therefor with respect to such applicant for such fiscal year.

(i) *Posted notice.* The applicant shall post notice (which shall be multilingual where the applicant serves a multilingual community), in substantially the following form, in appropriate areas within the facility (admissions, office, emergency department and business office) for the purpose of informing patients or potential patients that criteria for eligibility and applications are available upon request:

NOTICE OF HILL-BURTON OBLIGATION

This hospital (or other facility) is required by law to give a reasonable amount of service at no cost or less than full cost to people who cannot pay. If you think that you are eligible for these services, please contact our business office (give office location) and ask for assistance. If you are not satisfied with the results, you may contact (the State Hill-Burton agency with address).

Provided, That an applicant which has selected a presumptive compliance guideline under paragraph (d)(1) of this section may, at its option, either (1) add to such notice language stating that the facility's obligation is limited to a specified dollar volume of uncompensated services and that if the facility has, during a specified period (e.g., year, quarter, month), already provided a volume of uncompensated services sufficient to satisfy such obligation, any person inquiring about such services will be given a written statement to that effect which shall also state when additional uncompensated services will be available; or (2) post an additional notice stating that the facility's obligation has been satisfied for the current period and stating when additional uncompensated services will be available.

(j) *Evaluation and enforcement.* The State plan shall provide for evaluation and enforcement of the assurance in accordance with the following requirements:

(1) The State agency shall,

(i) At least annually, perform evaluations of the amount of the various services provided in each facility with respect to which Federal assistance has been provided under the Act, to determine whether such assurance is being complied with; and

(ii) Establish procedures for the investigation of complaints that such assurance is not being complied with.

(2) Evaluation pursuant to paragraph (j)(1) of this section shall be based on the annual budget of each facility for uncompensated services and on financial statements of such facilities filed pursuant to section 646 of the Act and § 53.128(q), and on such other information, including reports of investigations and hearing decisions, as the State agency deems relevant and material.

(3) The State plan shall provide for adequate methods of enforcement of the assurance, including effective sanctions to be applied against any facility which fails to comply with such assur-

ance. Such sanctions may include, but need not be limited to, license revocation, termination of State assistance, and court action.

(k) *Reports.* (1) The State agency shall, not less often than annually, report in writing to the Secretary its evaluation of each facility's compliance with the assurance, the disposition of each complaint received by the State agency, proposed remedial action with respect to each facility found by the State agency to be not in compliance with the assurance, and the status of such remedial action.

(2) In addition, the State agency shall promptly report to the Regional Attorney and Regional Health Director of the Department of Health and Human Services the institution of any legal action against a facility or the State agency involving compliance with the assurance.

[37 FR 14721, July 22, 1972, as amended at 38 FR 16354, June 22, 1973; 40 FR 46203, Oct. 6, 1975]

§ 53.112 Nondiscrimination.

(a) Before an application is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that all portions and services of the entire facility for the construction or modernization of which, or in connection with which, aid under the Act is sought will be made available without discrimination on account of creed and no professionally qualified person will be discriminated against on account of creed with respect to the privilege of professional practice in the facility.

(b) Each construction contract is subject to the condition that the applicant shall comply with the requirements of Executive Order 11246, September 24, 1965 (30 FR 12319), relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(c) Attention is called to the requirement of title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d; 78 Stat. 252) which provides that no person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied

the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, applicable to assistance under this part for construction and modernization of hospitals and medical facilities, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

[37 FR 182, Jan. 6, 1972, as amended at 39 FR 31767, Aug. 30, 1974]

§ 53.113 Community service.

(a) *Applicability.* The provisions of this section apply to every applicant which heretofore has given or hereafter will give a community service assurance.

(b) *Definitions.* As used in this section:

(1) The term *community service assurance* means an assurance required by regulations promulgated pursuant to section 603(e)(1) of the Act or the predecessor of that section (section 622(f), Public Health Service Act, enacted by Pub. L. 79-725, 60 Stat. 1041).

(2) The term *facility* has the same meaning as is given it in § 53.111(b)(1).

(3) The term *applicant* has the same meaning as is given it in § 53.111(b)(2).

(4) The term *fiscal year* has the same meaning as is given it in § 53.111(b)(3).

(c) *Assurance.* Before an application under this part is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that the facility will furnish a community service.

(d) *Compliance.* In order to comply with its community service assurance an applicant must:

(1)(i) Make the services it furnishes available to the general public, or

(ii) Limit the availability of such services only on the basis of age, medical indigency, or type or kind of medical or mental disability, or

(iii) If the facility constitutes a medical or nursing care unit of a home or other institution, make such home or other institution available in accordance with paragraph (d)(1) (i) or (ii) of this section; and

(2)(i) Make arrangements, if eligible to do so, for reimbursement for services with:

(A) Those principal State and local governmental third-party payors which provide reimbursement for services that is not less than the actual cost of such services as determined in accordance with accepted cost accounting principles; and

(B) Those Federal governmental third-party programs, such as Medicare and Medicaid, to the extent that the applicant is entitled to reimbursement at reasonable cost under a formula established in accordance with applicable Federal law.

(ii) Take such additional steps as may be necessary to ensure that admission to and services of the facility will be available to beneficiaries of the governmental programs specified in paragraph (d)(2)(i) of this section without discrimination (or preference) on account of their being such beneficiaries.

(e) *Reports.* The annual statement required by section 646 of the Act and § 53.128(q), a copy of which must be submitted to the State agency in accordance with the requirements of § 53.111(e)(1), shall set forth the amount of the reimbursement received pursuant to each arrangement with a principal governmental third-party payor.

(f) *Evaluation and enforcement.* The State plan shall provide for evaluation and enforcement of the community service assurance in accordance with the following requirements:

(1) The State agency shall,

(i) At least annually, evaluate the compliance of facilities with such assurance; and

(ii) Establish procedures for the investigation of complaints that such assurance is not being complied with.

(2) The State plan shall provide for adequate methods of enforcement of the assurance, including effective sanctions to be applied against any facility which fails to comply with such assurance. Such sanctions may include, but need not be limited to, license revocation, termination of State assistance and court action.

(g) *Reports.* (1) The State agency shall, not less often than annually, report in writing to the Secretary its

general evaluation of facilities' compliance with the assurance, the disposition of each complaint received by the State agency, proposed remedial action with respect to each facility found by the State agency to be not in compliance with the assurance, and the status of such remedial action.

(2) In addition, the State agency shall promptly report to the Regional Attorney and Regional Health Director of the Department of Health and Human Services the institution of any legal action against a facility or the State agency involving compliance with the assurance.

[39 FR 31767, Aug. 30, 1974, as amended at 42 FR 16780, Mar. 30, 1977]

Subpart M [Reserved]

Subpart N—Loan Guarantees and Direct Loans

§ 53.154 Waiver of right of recovery.

In determining whether there is good cause for waiver of any right of recovery which he may have against a non-profit private agency by reason of any payments made pursuant to a loan guarantee, or against a public agency by reason of the failure of such agency to make payments of principal and interest on a direct loan to such agency, the Secretary shall take into consideration the extent to which:

(a) The facility with respect to which the loan guarantee or direct loan was made will continue to be devoted by the applicant or other owner to use for the purpose for which it was constructed or another public or nonprofit purpose which will promote the purposes of the Act;

(b) There are reasonable assurances that for the remainder of the repayment period of the loan other public or non-profit facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and extent for such purposes; and

(c) Such recovery would seriously curtail the provision of medical services to persons in need of such services in the area.

[37 FR 182, Jan. 6, 1972]

§ 53.155 Modification of loans.

No official of the Department of Health and Human Services will approve any proposal to modify the terms of a loan guaranteed under title VI of the Public Health Service Act (42 U.S.C. 291 *et seq.*) and this subpart which would permit the use of the guaranteed loan (or the guarantee) as collateral for an issue of tax-exempt securities.

[48 FR 42984, Sept. 21, 1983]

§ 53.156 Fees for modification requests.

(a) Fees will be charged for the processing of requests for parity, and for major and minor modifications of the terms of documents evidencing and securing direct and guaranteed loans. In accordance with the requirements of the User Charge Statute, 31 U.S.C. 9701(b), the Secretary determines the amount of the application fee that must be submitted with each type of modification.

(1) As used in this section, a *request for parity* allows new debt to share lien position (*i.e.*, collateral) with an existing Hill-Burton loan.

(2) As used in this section, a *major modification* is any modification involving the release of \$100,000 or more of collateral; a corporate restructuring that involves a transfer of assets; master indenture requests; modifications to a sinking fund; defeasance requests and requests for additional secured indebtedness; and any, other modification that involves a comparably significant use of Department resources.

(3) As used in this section, a *minor modification* is any modification involving the release of less than \$100,000 of collateral; an easement; and any other modification that involves a comparable use of Department resources.

(b) A request for modification is to be accompanied by a certified check or money order in the amount of the appropriate fee, payable to the U.S. Treasury. The fees for modification requests submitted on or after October 28, 1986 are as follows:

- (1) \$1,500 for a minor modification,
- (2) \$4,500 for a major modification,
- and
- (3) \$5,500 for a request for parity.

(c) A submitter may withdraw its request for modification within 10 business days following its receipt and receive a refund of the fee.

(d) If the Secretary determines that a change in the amount of a fee is appropriate, the Department will issue a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed amount.

[51 FR 39376, Oct. 28, 1986]

PART 54—CHARITABLE CHOICE REGULATIONS APPLICABLE TO STATES RECEIVING SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANTS AND/OR PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS GRANTS

Sec.

54.1 Scope.

54.2 Definitions.

54.3 Nondiscrimination against religious organizations.

54.4 Religious activities.

54.5 Religious character and independence.

54.6 Employment practices.

54.7 Nondiscrimination requirement.

54.8 Right to services from an alternative provider.

54.9 Assurances and State oversight of the Charitable Choice requirements.

54.10 Fiscal accountability.

54.11 Effects on State and local funds.

54.12 Treatment of intermediate organizations.

54.13 Educational requirements for personnel in drug treatment programs.

AUTHORITY: 42 U.S.C. 300x-65, *et seq.*, 42 U.S.C. 290kk, *et seq.*, 42 U.S.C. 300x-21, *et seq.*, 42 U.S.C. 290cc-21, *et seq.*, and 42 U.S.C. 2000bb, *et seq.*

SOURCE: 68 FR 56444, Sept. 30, 2003, unless otherwise noted.

§ 54.1 Scope.

These provisions apply only to funds provided directly to pay for substance abuse prevention and treatment services under 42 U.S.C. 300x-21 *et seq.*, and 42 U.S.C. 290cc-21 to 290cc-35. This part does not apply to direct funding under any such authorities for activities that do not involve the provision of substance abuse services, such as for infrastructure activities authorized under Section 1971 of the PHS Act, 42 U.S.C. 300y, and for technical assistance ac-

tivities. This part implements the SAMHSA Charitable Choice provisions, 42 U.S.C. 300x-65 and 42 U.S.C. 290kk, *et seq.*

§ 54.2 Definitions.

(a) *Applicable program* means the programs authorized under:

(1) The Substance Abuse Prevention and Treatment (SAPT) Block Grant, 42 U.S.C. 300x to 300x-66, and

(2) The Projects for Assistance in Transition from Homelessness (PATH) Formula Grants, 42 U.S.C. 290cc-21 to 290cc-35 insofar as they fund substance abuse prevention and/or treatment services.

(b) *Religious organization* means a nonprofit religious organization.

(c) *Program beneficiary* means an individual who receives substance abuse services under a program funded in whole or in part by applicable programs.

(d) *Program participant* means a public or private entity that has received financial assistance, under an applicable program.

(e) *SAMHSA* means the U.S. Substance Abuse and Mental Health Services Administration.

(f) *SAMHSA Charitable Choice provisions* means the provisions of 42 U.S.C. 300x-65 and 42 U.S.C. 290kk, *et seq.*

(g) *Direct funding or Funds provided directly* means funding that is provided to an organization directly by a governmental entity or intermediate organization that has the same duties under this part as a governmental entity, as opposed to funding that an organization receives as the result of the genuine and independent private choice of a beneficiary through a voucher, certificate, coupon, or other similar mechanism.

§ 54.3 Nondiscrimination against religious organizations.

(a) Religious organizations are eligible, on the same basis as any other organization, to participate in applicable programs, as long as their services are provided consistent with the Establishment Clause and the Free Exercise Clause of the First Amendment to the United States Constitution. Except as provided herein or in the SAMHSA Charitable Choice provisions, nothing

§ 54.4

in these regulations shall restrict the ability of the Federal government, or a State or local government, from applying to religious organizations the same eligibility conditions in applicable programs as are applied to any other non-profit private organization.

(b) Neither the Federal government nor a State or local government receiving funds under these programs shall discriminate against an organization that is, or applies to be, a program participant on the basis of religion or the organization's religious character or affiliation.

§ 54.4 Religious activities.

No funds provided directly from SAMHSA or the relevant State or local government to organizations participating in applicable programs may be expended for inherently religious activities, such as worship, religious instruction, or proselytization. If an organization conducts such activities, it must offer them separately, in time or location, from the programs or services for which it receives funds directly from SAMHSA or the relevant State or local government under any applicable program, and participation must be voluntary for the program beneficiaries.

§ 54.5 Religious character and independence.

A religious organization that participates in an applicable program will retain its independence from Federal, State, and local governments and may continue to carry out its mission, including the definition, practice and expression of its religious beliefs. The organization may not expend funds that it receives directly from SAMHSA or the relevant State or local government to support any inherently religious activities, such as worship, religious instruction, or proselytization. Among other things, faith-based organizations may use space in their facilities to provide services supported by applicable programs, without removing religious art, icons, scriptures, or other symbols. In addition, a SAMHSA-funded religious organization retains the authority over its internal governance, and it may retain religious terms in its organization's name, select its board mem-

42 CFR Ch. I (10–1–11 Edition)

bers on a religious basis, and include religious references in its organization's mission statements and other governing documents.

§ 54.6 Employment practices.

(a) The participation of a religious organization in, or its receipt of funds from, an applicable program does not affect that organization's exemption provided under 42 U.S.C. 2000e–1 regarding employment practices.

(b) To the extent that 42 U.S.C. 300x–57(a)(2) or 42 U.S.C. 290cc–33(a)(2) precludes a program participant from employing individuals of a particular religion to perform work connected with the carrying on of its activities, those provisions do not apply if such program participant is a religious corporation, association, educational institution, or society and can demonstrate that its religious exercise would be substantially burdened by application of these religious nondiscrimination requirements to its employment practices in the program or activity at issue. In order to make this demonstration, the program participant must certify: that it sincerely believes that employing individuals of a particular religion is important to the definition and maintenance of its religious identity, autonomy, and/or communal religious exercise; that it makes employment decisions on a religious basis in analogous programs; that the grant would materially affect its ability to provide the type of services in question; and that providing the services in question is expressive of its values or mission. The organization must maintain documentation to support these determinations and must make such documentation available to SAMHSA upon request.

(c) Nothing in this section shall be construed to modify or affect any State law or regulation that relates to discrimination in employment.

(d) The phrases “with respect to the employment,” “individuals of a particular religion,” and “religious corporation, association, educational institution, or society” shall have the same meaning as those terms have under section 702 of the Civil Rights Act of 1964, 42 U.S.C. 2000e–1(a).

§ 54.7 Nondiscrimination requirement.

A religious organization that is a program participant shall not, in providing program services or engaging in outreach activities under applicable programs, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

§ 54.8 Right to services from an alternative provider.

(a) *General requirements.* If an otherwise eligible program beneficiary or prospective program beneficiary objects to the religious character of a program participant, within a reasonable period of time after the date of such objection, such program beneficiary shall have rights to notice, referral, and alternative services, as outlined in paragraphs (b) through (d) of this section.

(b) *Notice.* Program participants that refer an individual to alternative service providers, and the State government that administers the applicable programs, shall ensure that notice of the individual's right to services from an alternative provider is provided to all program beneficiaries or prospective beneficiaries. The notice must clearly articulate the program beneficiary's right to a referral and to services that reasonably meet the requirements of timeliness, capacity, accessibility, and equivalency as discussed in this section. A model notice is set out in appendix A to part 54a.

(c) *Referral to an alternative provider.* If a program beneficiary or prospective program beneficiary objects to the religious character of a program participant that is a religious organization, that participating religious organization shall, within a reasonable time after the date of such objection, refer such individual to an alternative provider. The State shall have a system in place to ensure that referrals are made to an alternative provider. That system shall ensure that the following occurs:

(1) The religious organization that is a program participant shall, within a reasonable time after the date of such

objection, refer the beneficiary to an alternative provider;

(2) In making such referral, the program participant shall consider any list that the State or local government makes available to entities in the geographic area that provide program services, which may include utilizing any treatment locator system developed by SAMHSA;

(3) All referrals shall be made in a manner consistent with all applicable confidentiality laws, including, but not limited to, 42 CFR Part 2 ("Confidentiality of Alcohol and Drug Abuse Patient Records");

(4) Upon referring a program beneficiary to an alternative provider, the program participant shall notify the State or responsible unit of government of such referral; and

(5) The program participant shall ensure that the program beneficiary makes contact with the alternative provider to which he or she is referred.

(d) *Provision and funding of alternative services.* If an otherwise eligible applicant or recipient objects to the religious character of a SAMHSA-funded service provider, the recipient is entitled to receive services from an alternative provider. In such cases, the State or local agency must provide the individual with alternative services within a reasonable period of time, as defined by the State agency. That alternative provider must be reasonably accessible and have the capacity to provide comparable services to the individual. Such services shall have a value that is not less than the value of the services that the individual would have received from the program participant to which the individual had such objection, as defined by the State agency. The alternative provider need not be a secular organization. It must simply be a provider to which the recipient has no religious objection. States may define and apply the terms "reasonably accessible," "a reasonable period of time," "comparable," "capacity," and "value that is not less than." The appropriate State or local governments that administer SAMHSA-funded programs shall ensure that notice of their right to alternative services is provided to applicants or recipients. The notice must clearly articulate the recipient's

right to a referral and to services that reasonably meet the timeliness, capacity, accessibility, and equivalency requirements discussed above.

(e) *PATH annual report.* As part of the annual report to SAMHSA, PATH grantees shall include a description of the activities the grantee has taken to comply with 42 CFR part 54.

§ 54.9 Assurances and State oversight of the Charitable Choice requirements.

In order to ensure that States receiving grant funding under the SAPT block grant and PATH formula grant programs comply with the SAMHSA Charitable Choice provisions and provide oversight of religious organizations that provide substance abuse services under such programs, States are required as part of their applications for funding to certify that they will comply with all of the requirements of such provisions and the implementing regulations under this part, and that they will provide such oversight of religious organizations.

§ 54.10 Fiscal accountability.

(a) Religious organizations that receive applicable program funds for substance abuse services are subject to the same regulations as other nongovernmental organizations to account, in accordance with generally accepted auditing and accounting principles, for the use of such funds.

(b) Religious organizations shall segregate Federal funds they receive under an applicable program into a separate account from non-Federal funds. Only the Federal funds shall be subject to audit by government under the SAMHSA program.

§ 54.11 Effects on State and local funds.

If a State or local government contributes its own funds to supplement activities carried out under the applicable programs, the State or local government has the option to separate out the Federal funds or commingle them. If the funds are commingled, the provisions of this part shall apply to all of the commingled funds in the same manner, and to the same extent, as the provisions apply to the Federal funds.

§ 54.12 Treatment of intermediate organizations.

If a nongovernmental organization (referred to here as an “intermediate organization”), acting under a contract or other agreement with the Federal Government or a State or local government, is given the authority under the contract or agreement to select nongovernmental organizations to provide services under any applicable program, the intermediate organization shall have the same duties under this part as the government. The intermediate organization retains all other rights of a nongovernmental organization under this part and the SAMHSA Charitable Choice provisions.

§ 54.13 Educational requirements for personnel in drug treatment programs.

In determining whether personnel of a program participant that has a record of successful drug treatment for the preceding three years have satisfied State or local requirements for education and training, a State or local government shall not discriminate against education and training provided to such personnel by a religious organization, so long as such education and training is comparable to that provided by nonreligious organizations, or is comparable to education and training that the State or local government would otherwise credit for purposes of determining whether the relevant requirements have been satisfied.

PART 54a—CHARITABLE CHOICE REGULATIONS APPLICABLE TO STATES, LOCAL GOVERNMENTS AND RELIGIOUS ORGANIZATIONS RECEIVING DISCRETIONARY FUNDING UNDER TITLE V OF THE PUBLIC HEALTH SERVICE ACT, 42 U.S.C. 290aa, ET SEQ., FOR SUBSTANCE ABUSE PREVENTION AND TREATMENT SERVICES

Sec.

54a.1 Scope.

54a.2 Definitions.

54a.3 Nondiscrimination against religious organizations.

54a.4 Religious activities.

Public Health Service, HHS

§ 54a.4

- 54a.5 Religious character and independence.
- 54a.6 Employment practices.
- 54a.7 Nondiscrimination requirement.
- 54a.8 Right to services from an alternative provider.
- 54a.9 Oversight of the Charitable Choice requirements.
- 54a.10 Fiscal accountability.
- 54a.11 Effect on State and local funds.
- 54a.12 Treatment of intermediate organizations.
- 54a.13 Educational requirements for personnel in drug treatment programs.
- 54a.14 Determination of nonprofit status.

APPENDIX TO PART 54A—MODEL NOTICE TO INDIVIDUALS RECEIVING SUBSTANCE ABUSE SERVICES.

AUTHORITY: 42 U.S.C. 300x-65, and 42 U.S.C. 290kk, *et seq.*, 42 U.S.C. 290aa, *et seq.*

SOURCE: 68 FR 56446, Sept. 30, 2003, unless otherwise noted.

§ 54a.1 Scope.

These provisions apply only to funds provided directly to pay for substance abuse prevention and treatment services under Title V of the Public Health Service Act, 42 U.S.C. 290aa, *et seq.*, which are administered by the Substance Abuse and Mental Health Services Administration. This part does not apply to direct funding under any such authorities for only mental health services or for certain infrastructure and technical assistance activities, such as cooperative agreements for technical assistance centers, that do not provide substance abuse services to clients. This part implements the provisions of 42 U.S.C. 300x-65 and 42 U.S.C. 290kk, *et seq.*

§ 54a.2 Definitions.

(a) *Applicable program* means the programs authorized under Title V of the PHS Act, 42 U.S.C. 290aa, *et seq.*, for the provision of substance abuse prevention and or treatment services.

(b) *Religious organization* means a nonprofit religious organization.

(c) *Program beneficiary* means an individual who receives substance abuse services under a program funded in whole or in part by applicable programs.

(d) *Program participant* means a public or private entity that has received financial assistance under an applicable program.

(e) *SAMHSA* means the Substance Abuse and Mental Health Services Administration.

(f) *SAMHSA Charitable Choice* provisions means the provisions of 42 U.S.C. 300x-65 and 42 U.S.C. 290kk, *et seq.*

(g) *Direct funding* or *Funds provided directly* means funding that is provided to an organization directly by a governmental entity or intermediate organization that has the same duties under this part as a governmental entity, as opposed to funding that an organization receives as the result of the genuine and independent private choice of a beneficiary through a voucher, certificate, coupon, or other similar mechanism.

§ 54a.3 Nondiscrimination against religious organizations.

(a) Religious organizations are eligible, on the same basis as any other organization, to participate in applicable programs as long as their services are provided consistent with the Establishment Clause and the Free Exercise Clause of the First Amendment to the United States Constitution. Except as provided herein or in the SAMHSA Charitable Choice provisions, nothing in these regulations shall restrict the ability of the Federal government, or a State or local government, from applying to religious organizations the same eligibility conditions in applicable programs as are applied to any other nonprofit private organization.

(b) Neither the Federal government nor a State or local government receiving funds under these programs shall discriminate against an organization that is, or applies to be, a program participant on the basis of the organization's religious character or affiliation.

§ 54a.4 Religious activities.

No funds provided directly from SAMHSA or the relevant State or local government to organizations participating in applicable programs may be expended for inherently religious activities, such as worship, religious instruction, or proselytization. If an organization conducts such activities, it must offer them separately, in time or location, from the programs or services for which it receives funds directly from SAMHSA or the relevant State or

§ 54a.5

local government under any applicable program, and participation must be voluntary for the program beneficiaries.

§ 54a.5 Religious character and independence.

A religious organization that participates in an applicable program will retain its independence from Federal, State, and local governments and may continue to carry out its mission, including the definition, practice and expression of its religious beliefs. The organization may not expend funds that it receives directly from SAMHSA or the relevant State or local government to support any inherently religious activities, such as worship, religious instruction, or proselytization. Among other things, faith-based organizations may use space in their facilities to provide services supported by applicable programs, without removing religious art, icons, scriptures, or other symbols. In addition, a SAMHSA-funded religious organization retains the authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.

§ 54a.6 Employment practices.

(a) The participation of a religious organization in or its receipt of funds from an applicable program does not affect that organization's exemption provided under 42 U.S.C. 2000e-1 regarding employment practices.

(b) Nothing in this section shall be construed to modify or affect any State law or regulation that relates to discrimination in employment.

§ 54a.7 Nondiscrimination requirement.

A religious organization that is a program participant shall not, in providing program services or engaging in outreach activities under applicable programs, discriminate against a program beneficiary or prospective program on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

42 CFR Ch. I (10-1-11 Edition)

§ 54a.8 Right to services from an alternative provider.

(a) *General requirements.* If an otherwise eligible program beneficiary or prospective program beneficiary objects to the religious character of a program participant, within a reasonable period of time after the date of such objection, such program beneficiary shall have rights to notice, referral, and alternative services, as outlined in paragraphs (b) through (d) of this section. With respect to SAMHSA discretionary programs, for purposes of determining what is the appropriate Federal, State, or local government, the following principle shall apply: When SAMHSA provides funding directly to another unit of government, such as a State or local government, that unit of government is responsible for providing the alternative services. When SAMHSA provides discretionary grant funding directly to a nongovernmental organization, SAMHSA is the responsible unit of government.

(b) *Notice.* Program participants that refer an individual to alternative providers, and the appropriate Federal, State, or local governments that administer the applicable programs, shall ensure that notice of the individual's rights to services from an alternative provider is provided to all program beneficiaries or prospective beneficiaries. The notice must clearly articulate the program beneficiary's right to a referral and to services that reasonably meet the requirements of timeliness, capacity, accessibility, and equivalency as discussed in this section. A model notice is set out in appendix A to this part.

(c) *Referral to services from an alternative provider.* If a program beneficiary or a prospective program beneficiary objects to the religious character of a program participant that is a religious organization, that participating religious organization shall, within a reasonable time after the date of such objection, refer such individual to an alternative provider.

(1) When the State or local government is the responsible unit of government, the State shall have a system in place to ensure that such referrals are made. That system shall ensure that the following occurs:

(i) The religious organization that is a program participant shall, within a reasonable time after the date of such objection, refer the beneficiary to an alternative provider;

(ii) In making such referral, the religious organization shall consider any list that the State or local government makes available to entities in the geographic area that provide program services, which may include utilizing any treatment locator system developed by SAMHSA;

(iii) All referrals are to be made in a manner consistent with all applicable confidentiality laws, including, but not limited to, 42 CFR part 2 (“Confidentiality of Alcohol and Drug Abuse Patient Records”);

(iv) Upon referring a program beneficiary to an alternative provider, the religious organization shall notify the responsible unit of government of such referral; and

(v) The religious organization shall ensure that the program beneficiary makes contact with the alternative provider to which he or she is referred.

(2) When SAMHSA is the responsible unit of government, the referral process is as follows:

(i) When a program beneficiary requests alternative services, the religious organization will seek to make such a referral.

(ii) If the religious organization cannot locate an appropriate provider of alternative services, the religious organization will contact SAMHSA. They will work together to identify additional alternative providers, utilizing the SAMHSA Treatment Locator system, if appropriate.

(iii) The religious organization will contact these alternative providers and seek to make the referral, in a manner consistent with all applicable confidentiality laws, including, but not limited to, 42 CFR part 2 (“Confidentiality of Alcohol and Drug Abuse Patient Records”).

(iv) In the event the religious organization is still unable to locate an alternative provider, it may again contact SAMHSA for assistance.

(d) *Referral reporting procedures.* The program participant shall notify the appropriate Federal, State or local government agency that administers

the program of such referral. If a State or local government is the responsible unit of government, it may determine its own reporting procedures. When SAMHSA is the responsible unit of government, this notification will occur during the course of the regular reports that may be required under the terms of the funding award.

(e) *Provision and funding of alternative services.* The responsible unit of government, as defined in paragraph (a) of this section, shall provide to an otherwise eligible program beneficiary or prospective program beneficiary who objects to the religious character of a program participant, services and fund services from an alternative provider that is reasonably accessible to, and has the capacity to provide such services to the individual. Such services shall have a value that is not less than the value of the services that the individual would have received from the program participant to which the individual had such objection. The appropriate State or local governments that administer SAMHSA-funded programs shall ensure that notice of their right to alternative services is provided to applicants or recipients. The alternative provider need not be a secular organization. It must simply be a provider to which the program beneficiary has no religious objection.

(1) When the State receives a discretionary grant from SAMHSA, it shall utilize its own implementation procedures for these provisions and shall use funds from the SAMHSA discretionary grant to finance such alternative services, as needed;

(2) When the local government receives a discretionary grant from SAMHSA, it shall utilize State implementation procedures for these provisions and shall use funds from the SAMHSA discretionary grant to finance such alternative services, as needed;

(3) When a religious organization receives a discretionary grant from SAMHSA, if a publicly funded alternative provider is available that is reasonably accessible and can provide equivalent services, the religious organization shall refer the beneficiary to

§ 54a.9

that provider. However, if such a provider is not available, the religious organization shall contract with an alternative provider to provide such services and may finance such services with funds from the SAMHSA discretionary grant.

§ 54a.9 Oversight of the Charitable Choice requirements.

In order to ensure that program funds are used in compliance with the SAMHSA Charitable Choice provisions, applicants for funds under applicable programs are required, as part of their applications for funding, to certify that they will comply with all of the requirements of the SAMHSA Charitable Choice provisions and the implementing regulations under this part.

§ 54a.10 Fiscal accountability.

(a) Religious organizations that receive applicable program funds for substance abuse services are subject to the same regulations as other nongovernmental organizations to account, in accordance with generally accepted auditing and accounting principles, for the use of such funds.

(b) Religious organizations shall segregate Federal funds they receive under applicable programs into a separate account from non-Federal funds. Only the Federal funds shall be subject to audit by the government under the SAMHSA program.

§ 54a.11 Effect on State and local funds.

If a State or local government contributes its own funds to supplement activities carried out under the applicable programs, the State or local government has the option to separate out the Federal funds or commingle them. If the funds are commingled, the provisions of this part shall apply to all of the commingled funds, in the same manner, and to the same extent, as the provisions apply to the Federal funds.

§ 54a.12 Treatment of intermediate organizations.

If a nongovernmental organization (referred to here as an “intermediate organization”), acting under a contract or other agreement with the Federal Government or a State or local govern-

42 CFR Ch. I (10–1–11 Edition)

ment, is given the authority under the contract or agreement to select nongovernmental organizations to provide services under any applicable program, the intermediate organization shall have the same duties under this part as the government. The intermediate organization retains all other rights of a nongovernmental organization under this part and the SAMHSA Charitable Choice provisions.

§ 54a.13 Educational requirements for personnel in drug treatment programs.

In determining whether personnel of a program participant that has a record of successful drug treatment for the preceding three years have satisfied State or local requirements for education and training, a State or local government shall not discriminate against education and training provided to such personnel by a religious organization, so long as such education and training is comparable to that provided by nonreligious organizations, or is comparable to education and training that the State or local government would otherwise credit for purposes of determining whether the relevant requirements have been satisfied.

§ 54a.14 Determination of nonprofit status.

The nonprofit status of any SAMHSA applicant can be determined by any of the following:

(a) Reference to the organization’s listing in the Internal Revenue Service’s (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS code.

(b) A copy of a currently valid IRS Tax exemption certificate.

(c) A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of its net earnings accrue to any private shareholder or individuals.

(d) A certified copy of the organization’s certificate of incorporation or similar document if it clearly establishes the nonprofit status of the organization.

(e) Any of the above proof for a State or national parent organization and a

Public Health Service, HHS

§ 55a.104

statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

APPENDIX TO PART 54A—MODEL NOTICE OF INDIVIDUALS RECEIVING SUBSTANCE ABUSE SERVICES

MODEL NOTICE TO INDIVIDUALS RECEIVING SUBSTANCE ABUSE SERVICES

No provider of substance abuse services receiving Federal funds from the U.S. Substance Abuse and Mental Health Services Administration, including this organization, may discriminate against you on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

If you object to the religious character of this organization, Federal law gives you the right to a referral to another provider of substance abuse services. The referral, and your receipt of alternative services, must occur within a reasonable period of time after you request them. The alternative provider must be accessible to you and have the capacity to provide substance abuse services. The services provided to you by the alternative provider must be of a value not less than the value of the services you would have received from this organization.

PART 55a—PROGRAM GRANTS FOR BLACK LUNG CLINICS

Subpart A—General Provisions

Sec.

55a.101 Definitions.

55a.102 Who is eligible to apply for a Black Lung clinics grant?

55a.103 What criteria has HHS established for deciding which grant application to fund?

55a.104 What confidentiality requirements must be met?

55a.105 How must grantees carry out their projects?

55a.106 Provision for waiver by the Secretary.

55a.107 What other regulations apply?

Subpart B—Grants to States

55a.201 What is required for a State application?

Subpart C—Grants to Entities Other Than States

55a.301 What is required for an application from an entity other than a State?

AUTHORITY: Sec. 427(a), Federal Mine Safety and Health Act of 1977, 92 Stat. 100 (30 U.S.C. 937(a)).

SOURCE: 50 FR 7913, Feb. 27, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 55a.101 Definitions.

Act, as used in this part, means the Federal Mine Safety and Health Act of 1977, as amended (30 U.S.C. 801 *et seq.*).

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.

Miner or *coal miner* means any individual who works or has worked in or around a coal mine or coal preparation facility in the extraction or preparation of coal. The term also includes an individual who works or has worked in coal mine construction or transportation in or around a coal mine, to the extent that the individual was exposed to coal dust as a result of employment.

§ 55a.102 Who is eligible to apply for a Black Lung clinics grant?

Any State or public or private entity may apply for a grant under this part.

§ 55a.103 What criteria has HHS established for deciding which grant application to fund?

(a) The Secretary will give preference to a State, which meets the requirements of this part and applies for a grant under this part, over other applicants in that State.

(b) Within the limits of funds available for these purposes the Secretary may award grants to assist in the carrying out of those programs which will in the Secretary's judgment best promote the purposes of section 427(a) of the Act, taking into account;

(1) The number of miners to be served and their needs; and

(2) The quality and breadth of services to be provided.

§ 55a.104 What confidentiality requirements must be met?

All information as to personal facts and circumstances obtained by the grantee's staff about recipients of services shall be held confidential and shall not be disclosed without the individual's consent except as may be required

§ 55a.105

by law or as may be necessary to provide service to the individual or to provide for audits with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 55a.105 How must grantees carry out their projects?

Grantees must carry out their projects in accordance with their applications and the provisions of this part.

§ 55a.106 Provision for waiver by the Secretary.

The Secretary may, for good cause shown, waive provisions of these regulations.

§ 55a.107 What other regulations apply?

Other regulations which apply to the Black Lung Clinics Program include, but are not limited to, the following:

- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure;
- 42 CFR part 50, subpart E—Maximum allowable cost for drugs;
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board;
- 45 CFR part 19—Limitations on payment or reimbursement for drugs;
- 45 CFR part 74—Administration of grants;
- 45 CFR part 75—Informal grant appeals procedures;
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964;
- 45 CFR part 81—Practice and procedure for hearings under part 80;
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance; and
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

Subpart B—Grants to States

§ 55a.201 What is required for a State application?

An approvable State application must contain assurances that the State will:

42 CFR Ch. I (10–1–11 Edition)

(a) Provide the following services for active and inactive miners in the State:

- (1) Primary care;
 - (2) Patient and family education and counseling;
 - (3) Outreach;
 - (4) Patient care coordination, including individual patient care plans for all patients;
 - (5) Antismoking advice; and
 - (6) Other symptomatic treatments.
- (b) Provide medical services in consultation with a physician with special training or experience in the diagnosis and treatment of respiratory diseases.
- (c) Meet all criteria for approval and designation by the Department of Labor under 20 CFR part 725 to perform disability examination and provide treatment under the Act.

(d) Use grant funds under this part to supplement and not supplant existing services of the State.

(e) Provide the services described above for those miners previously served by a Black Lung Clinic in the State for which grant support expires during the funding period of the State's grant.

(f) Provide services described above regardless of a person's ability to pay.

(g) Audit its expenditures from amounts received under this part in accordance with the provisions of Attachment P, Audit Requirements, of Office of Management and Budget Circular A-102, Uniform Requirements for Assistance to State and Local Governments, as adopted for the Department of Health and Human Services by 45 CFR part 74.

(Approved by the Office of Management and Budget under control number 0915-0081)

[50 FR 7913, Feb. 27, 1985, as amended at 50 FR 53156, Dec. 30, 1985]

Subpart C—Grants to Entities Other Than States

§ 55a.301 What is required for an application from an entity other than a State?

An approvable application must contain the following:

- (a) A plan for the provision of the services required by § 55a.201(a), consistent with the requirements of § 55a.201 (b) and (c). The plan must also

contain at least the following elements:

(1) A description of the target population to whom services are to be provided, including a statement of the need for services;

(2) An assurance that charges shall be made for services rendered as follows:

(i) A schedule shall be maintained listing fees or payments for the provision of services, designed to cover reasonable costs of operations;

(ii) A schedule of discounts adjusted on the basis of a patient's ability to pay shall be maintained. The schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below the poverty line established in accordance with section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), (except that nominal fees for service may be requested, but not required, from individuals and families with annual incomes at or below the poverty line). No discounts shall be provided to individuals and families with annual incomes greater than twice the poverty line; and

(iii) Where third-party payors (including Government Agencies) are authorized or under a legal obligation to pay all or a portion of such charges, all services covered by that reimbursement plan will be billed and every reasonable effort will be made to obtain payment.

(b) An assurance that no person will be denied services because of inability to pay.

(c) An assurance that grant funds received under this part will be used to supplement and not supplant existing services of the grantee.

(Approved by the Office of Management and Budget under control number 0915-0081)

[50 FR 7913, Feb. 27, 1985, as amended at 50 FR 53156, Dec. 30, 1985]

PART 56—GRANTS FOR MIGRANT HEALTH SERVICES

Subpart A—General Provisions

Sec.

- 56.101 Applicability.
- 56.102 Definitions.
- 56.103 Eligibility.

- 56.104 Application.
- 56.105 Accord with health planning.
- 56.106 Amount of grant.
- 56.107 Priorities for grants.
- 56.108 Use of grant funds.
- 56.109 Grant payments.
- 56.110 Nondiscrimination.
- 56.111 Confidentiality.
- 56.112 Publications and copyright.
- 56.113 Grantee accountability.
- 56.114 Applicability of 45 CFR part 74.

Subpart B—Grants for Planning and Developing Migrant Health Centers

- 56.201 Applicability.
- 56.202 Application.
- 56.203 Project elements.
- 56.204 Grant evaluation and award.

Subpart C—Grants for Operating Migrant Health Centers

- 56.301 Applicability.
- 56.302 Application.
- 56.303 Project elements.
- 56.304 Governing board.
- 56.305 Grant evaluation and award.

Subpart D—Grants for Operating Migrant Health Entities

- 56.401 Applicability.
- 56.402 Application.
- 56.403 Project elements.
- 56.404 Grant evaluation and award.

Subpart E—Grants for Planning and Developing Migrant Health Programs

- 56.501 Applicability.
- 56.502 Application.
- 56.503 Project elements.
- 56.504 Grant evaluation and award.

Subpart F—Grants for Operating Migrant Health Programs

- 56.601 Applicability.
- 56.602 Application.
- 56.603 Project elements.
- 56.604 Grant evaluation and award.

Subpart G—Grants for Technical Assistance

- 56.701 Applicability.
- 56.702 Application.
- 56.703 Project elements.
- 56.704 Grant evaluation and award.

Subpart H—Acquisition and Modernization of Existing Buildings

- 56.801 Applicability of 42 CFR part 51c, subpart E.

AUTHORITY: Secs. 215, 319, Public Health Service Act (42 U.S.C. 216, 247d).

SOURCE: 42 FR 60406, Nov. 25, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 56.101 Applicability.

The regulations of this subpart are applicable to all grants authorized by section 319 of the Public Health Service Act (42 U.S.C. 247d).

§ 56.102 Definitions.

As used in this part:

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

(b)(1) *Agriculture* means farming in all its branches, including—

(i) Cultivation and tillage of the soil;

(ii) The production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in, or on, the land; and

(iii) Any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in subsection (ii).

(c) *Catchment area* means the geographic area served by a project funded under section 319 of the Act.

(d) *Environmental health services* means the detection and alleviation of unhealthful conditions of the environment of the persons served by the project, such as problems associated with water supply, sewage treatment, solid waste disposal, rodent and parasite infestation, field sanitation, and housing conditions and the treatment of medical conditions arising therefrom. For the purposes of this part, the detection and alleviation of unhealthful conditions of the environment includes the notification of appropriate Federal, State, or local authorities responsible for correcting such conditions and the making of arrangements therefor with such authorities.

(e) *Health professionals* means professionals (such as physicians, dentists, nurses, podiatrists, optometrists, and physicians' extenders) who are engaged

in the delivery of health services and who meet all applicable Federal or State requirements to provide their professional services.

(f) *High impact area* means a catchment area which has not less than 6,000 migratory agricultural workers, seasonal agricultural workers, and members of the families of such workers residing within its boundaries for more than two months in the most recent calendar year for which statistical data acceptable to the Secretary is available.

(g)(1) *Migrant health center* means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides for migratory agricultural workers, seasonal agricultural workers, and the members of the families of such workers, within its catchment area:

(i) Primary health services;

(ii) As determined by the Secretary to be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services;

(iii) Referral to providers of supplemental health services and payment, as determined by the Secretary to be appropriate and feasible, for the provision of such services;

(iv) Environmental health services, as determined by the Secretary to be appropriate for particular centers;

(v) As determined by the Secretary to be appropriate for particular centers, infectious and parasitic disease screening and control services;

(vi) As determined by the Secretary to be appropriate for particular centers, accident prevention programs, including prevention of excessive exposure to pesticides through, but not limited to, notification of appropriate Federal, State or local authorities of hazardous conditions due to pesticide use; and

(vii) Information on the availability and proper use of health services.

(2) For purposes of paragraph (g)(1) of this section, the provision of a given service by a center will be determined by the Secretary to be appropriate where

(i) There is a need, as determined by the Secretary, for the provision of such service to individuals described in paragraph (g)(1) of this section in the catchment area; and

(ii) The provision of such service by the center is feasible, taking into consideration the center's projected revenues, other resources, and grant support under this part.

(h) *Migratory agricultural worker* means an individual whose principal employment is in agriculture on a seasonal basis, who has been so employed within the last 24 months, and who establishes for the purpose of such employment a temporary place of abode;

(i) *Nonprofit*, as applied to any private agency, institution, or organization, means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(j) *Physician* means a licensed doctor of medicine or doctor of osteopathy.

(k) *Primary care* means preventive, diagnostic, treatment, consultant, referral, and other services rendered by physicians (including, as appropriate, physicians' extenders), routine associated laboratory services and diagnostic radiologic services, and emergency health services.

(1) *Primary health services* means:

(1) Diagnostic, treatment, consultative referral, and other services rendered by physicians and, where feasible, by physicians' extenders, such as physicians' assistants, nurse clinicians, and nurse practitioners;

(2) Diagnostic laboratory services and diagnostic radiologic services;

(3) Preventive health services, including children's eye and ear examinations, prenatal and post-partum care, perinatal services, well child care (including periodic screening), immunizations, and voluntary family planning services;

(4) Emergency medical services, including provision, through clearly defined arrangements, for access of users of the center to health care for medical and dental emergencies during and after the center's regularly scheduled hours;

(5) Transportation services as needed for adequate patient care, sufficient so that residents of the catchment area served by the center with special difficulties of access to services provided by the center receive such services; and

(6) Preventive dental services provided by a licensed dentist or other qualified personnel, including—

(i) Oral hygiene instruction;

(ii) Oral prophylaxis, as necessary; and

(iii) Topical application of fluorides, and the prescription of fluorides for systemic use when not available in the community water supply.

(m) *Seasonal agricultural worker* means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(n) *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.

(o) *Supplemental health services* means health services which are not included as primary health services and which are:

(1) Inpatient and outpatient hospital services;

(2) Home health services;

(3) Extended care facility services;

(4) Rehabilitative services (including physical and occupational therapy) and long-term physical medicine;

(5) Mental health services, including services of psychiatrists, psychologists, and other appropriate mental health professionals;

(6) Dental services other than those provided as primary health services;

(7) Vision services, including routine eye and vision examinations and provision of eyeglasses, as appropriate and feasible;

(8) Allied health services;

(9) Pharmaceutical services, including the provision of prescription drugs;

(10) Therapeutic radiologic services;

(11) Ambulatory surgical services;

(12) Public health services (including nutrition education and social services);

(13) Health education services; and

(14) Services including the services of outreach workers, which promote and

facilitate optimal use of primary health services and services referred to in the preceding subparagraphs of this paragraph and, if a substantial number of individuals in the population served by the center are of limited English-speaking ability, the services of outreach workers and other personnel fluent in the language or languages spoken by such individuals.

§ 56.103 Eligibility.

Any public or nonprofit private entity is eligible to apply for a grant under this part.

§ 56.104 Application.

(a) An application for a grant under this part shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.

(b) The application shall contain a budget and narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this part. The application must describe how and the extent to which the project has met, or plans to meet, each of the requirements in subpart B (relating to grants for planning and development of migrant health centers), subpart C (relating to grants for the operation of migrant health centers), subpart D (relating to grants for the operation of migrant health entities), subpart E (relating to grants for planning and developing migrant health programs), subpart F (relating to grants for the operation of migrant health programs), or subpart G (relating to grants for technical assistance), as applicable. In addition, applications must include:

(1) A statement of specific, measurable objectives and the methods to be used to assess the achievement of the objectives in specified time periods and at least on an annual basis.

(2) The precise boundaries of the catchment area to be served by the applicant. In addition, the application shall include information sufficient to enable the Secretary to determine that the applicant's catchment area meets the following criteria:

(i) The size of such area is such that the services to be provided by the applicant are available and accessible to

the residents of the area promptly and as appropriate;

(ii) The boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by Federal and State health and social service programs; and

(iii) The boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

(3)(i) The number of migratory agricultural workers and members of their families, and seasonal agricultural workers and members of their families which resided in the project's catchment area in the most recent calendar year for which statistical data acceptable to the Secretary is available; and

(ii) The approximate period or periods of residence of all groups of migratory agricultural workers and their families counted under paragraph (b)(3)(i) of this section.

(4) The results of an assessment of the need that the population to be served has for the services to be provided by the project (or in the case of applications for planning and development projects, the methods to be used in assessing such need), taking into consideration the following factors:

(i) Available health resources in relation to size of the catchment area and population of migratory and seasonal agricultural workers and their families in such area, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pediatrics, or obstetrics and gynecology, to such population;

(ii) Health indices for such population, such as infant mortality rate;

(iii) Economic factors affecting such population's use of health services, such as percentage of such population with incomes below the poverty level;

(iv) Demographic factors affecting such population's need and demand for health services, such as percentage of such population age 65 and over; and

(v) Special factors of access resulting from the conditions of employment of

Public Health Service, HHS

§ 56.106

such workers (including working hours, housing, and sanitation).

(5) Position descriptions for personnel who will be utilized in carrying out the activities of the project and a statement indicating the need for the positions to be supported with grant funds to accomplish the objectives of the project.

(6) Letters and other forms of evidence showing that efforts have been made to secure financial and professional assistance and support for the project within the proposed catchment area and the continuing involvement of the community in the development and operation of the project.

(7) An assurance that an independent certified public accountant will be engaged to certify that the project's system for the management and control of its finances will be in accord with sound financial management practices, including applicable Federal requirements.

(8) A list of all services proposed to be provided by the project.

(9) A list of services which are to be provided directly by the project through its own staff and resources and a description of any contractual or other arrangements (including copies of documents, where available) entered into, or planned for the provision of services.

(10) The schedule of fees and/or payments and schedule of discounts for services provided by the project.

(11) If the applicant provides services to populations other than migratory and seasonal agricultural workers and their families, identification of such populations.

NOTE: Funds granted under this part and non-Federal funds required to be expended by the project as a condition of any such grant may not be used to provide services to individuals who are not migratory or seasonal agricultural workers or members of the families of such workers.

(12) Evidence that all applicable requirements for review and/or approval of the application under title XV of the Act have been met.

(13) An assurance that the project will be conducted in accordance with the applicable requirements of this part.

(c) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the applicable regulations of this part, and any additional conditions of the grant.

(Sec. 215, Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); sec. 329, Public Health Service Act, 95 Stat. 569 (42 U.S.C. 254b)).

[42 FR 60406, Nov. 25, 1977, as amended at 48 FR 29202, June 24, 1983; 48 FR 45559, Oct. 6, 1983]

§ 56.105 Accord with health planning.

A grant may be made under this part only if the applicable requirements of title XV of the Act relating to review and approval by the appropriate health planning agencies have been met.

§ 56.106 Amount of grant.

(a) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary: *Provided, however*, That no grant shall be made for an amount in excess of the total costs found necessary by the Secretary to carry out the project.

(i) In determining the percentage of project costs to be borne by the grantee, factors which the Secretary will take into consideration will include the following:

(A) The ability of the grantee to finance its share of project costs from non-Federal sources;

(B) The need in the area served by the project for the services to be provided; and

(C) The extent to which the project will provide services in an innovative manner which the Secretary desires to stimulate in the interest of developing more effective health service delivery systems on a regional or national basis.

(ii) At any time after approval of an application under this part, the Secretary may retroactively agree to a percentage of project costs to be borne by the grantee lower than that determined pursuant to paragraph (a)(2)(i) of this section where he finds that changed circumstances justify a smaller contribution.

(iii) In determining the grantee's share of project costs, costs borne by Federal grant funds, or costs used to match other Federal grants, may not be included except as otherwise provided by law or regulations.

(b) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is recommended.

(c) Neither the approval of any project nor any grant award, shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application.

§ 56.107 Priorities for grants.

(a) Grants under sections 319(c)(1)(A), 319(d)(1)(A), 319(d)(1)(B) of the Act and subparts B, C, and D of this part shall be made in accordance with the following priorities:

(1) Highest priority will be given to approvable applications which propose to serve catchment areas in which 6,000 or more migratory agricultural workers and members of their families reside for more than two months in the calendar year.

(2) Second priority will be given to approvable applications which propose to serve catchment areas in which fewer than 6,000 but more than 1,000 mi-

gratory agricultural workers and members of their families reside for more than two months in the applicable calendar year.

(3) Third priority will be given to approvable applications which propose to serve catchment areas in which migratory agricultural workers and members of their families reside but in which fewer than 1,000 such persons reside for more than two months in the applicable calendar year.

(4) Fourth priority will be given to approvable applications which propose to serve catchment areas in which migratory agricultural workers and members of their families reside in the applicable calendar year but in which no such persons reside for more than two months in such year.

(5) Fifth priority will be given to approvable applications which propose to serve catchment areas in which no migratory agricultural workers or members of their families reside for any period in the applicable calendar year but in which 6,000 or more seasonal agricultural workers and the members of their families reside.

(6) Lowest priority will be given to approvable applications which propose to serve catchment areas in which no migratory agricultural workers or members of their families reside for any period in the applicable calendar year and in which fewer than 6,000 seasonal agricultural workers and the members of their families reside.

(b) Grants under sections 319(c)(1)(B) and 319(d)(1)(C) of the Act and subparts E and F of this part will be made in accordance with priorities set forth in paragraphs (a)(2) through (a)(6) of this section, in the order set forth.

(c) For the purposes of this section, the applicable calendar year will be the calendar year for which data is provided in accordance with § 56.104(b)(3) of this subpart.

§ 56.108 Use of grant funds.

(a) Any funds granted pursuant to this part, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 319 of the Act, the applicable regulations of this part, the terms and conditions of the award,

Public Health Service, HHS

§ 56.110

and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) Project funds awarded under this part may be used for, but need not be limited to, the following:

(1) The costs of acquiring and modernizing existing buildings (including the costs of amortizing the principal of, and paying interest on, loans), but only in accordance with subpart H of this part and as approved in the grant award;

(2) The costs of obtaining technical assistance to develop and improve the management or service capability of the project but only as approved by the Secretary;

(3) To reimburse members of the grantee's governing board established pursuant to § 56.304 of subpart C, or advisory council established pursuant to § 56.603(q) of subpart F, if any, for reasonable expenses actually incurred by reason of their participation in the activities of such board or council;

(4) To reimburse such governing board or advisory council members who are individuals eligible to be served by the project for wages lost by reason of participation in the activities of such board or council;

(5) The cost of delivering health services to migratory agricultural workers, seasonal agricultural workers and the members of their families within the project's catchment area, within the following limitations: grant funds may be used to pay the full cost of project services to such individuals and families with annual incomes at or below those set forth in the most recent "CSA Income Poverty Guidelines" (45 CFR 1060.2) issued by the Community Services Administration, and to pay the portion of the cost of services provided in accordance with the schedule of discounts which, under such schedule, is uncompensated; *Provided, That*

(i) Charges will be made to such individuals and families in accordance with § 56.303(f) of subpart C or § 56.603(e) of subpart F, as applicable;

(ii) Reasonable effort shall be made to collect such charges under a billing and collections system; and

(iii) The charge to grant funds shall exclude any amounts collected pursuant to paragraph (b)(5)(ii) of this section;

(6) The cost of insurance for medical emergency and out-of-area coverage; and

(7) The cost of providing to the staff and governing board, if any, of the project training related to the management of an ambulatory care facility, and to the staff of a project funded under subpart C, D, or F of this part, training related to the provision of primary, supplemental and environmental health services provided or to be provided by the project, consistent with the applicable requirements of 45 CFR part 74.

(c) Prior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

§ 56.109 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 56.110 Nondiscrimination.

(a) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80). In addition, no person shall, on the grounds of age, sex, creed, or marital status (unless otherwise medically indicated), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity so receiving Federal financial assistance.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 56.111 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about recipients of services shall be held confidential and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary or his designee with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 56.112 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, non-exclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 56.113 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid as well as other funds and in-kind contributions by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the require-

ments of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the government of the political subdivisions of the State. All grantees other than a State, as so defined, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout—(1) Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project, the sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (b) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 56.114 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to States and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this part:

45 CFR PART 74

Subpart

- A General.
- B Cash depositories.
- C Bonding and insurance.
- D Retention and custodial requirements for records.
- F Grant-related income.
- G Matching and cost sharing.
- K Grant payment requirements.
- L Budget revision procedures.
- M Grant closeout, suspension, and termination.
- O Property.
- Q Cost principles.

Subpart B—Grants for Planning and Developing Migrant Health Centers**§ 56.201 Applicability.**

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 319(c)(1)(A) of the Act for projects for planning and developing migrant health centers in high impact areas.

§ 56.202 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of subpart A of this part, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part.

§ 56.203 Project elements.

A project for planning and developing a migrant health center supported under this subpart must:

- (a) Determine (by survey or other appropriate means) the approximate

number of (1) migratory agricultural workers and the members of their families, and (2) seasonal agricultural workers and the members of their families, within the proposed catchment area in the calendar year in which the grant is made and the period of time these workers and their families reside in the catchment area during such year.

- (b) Prepare an assessment of the need of the population proposed to be served by the migrant health center for the services set forth in § 56.102(g)(1) of subpart A of this part. This assessment of need must, at a minimum, include the factors listed in § 56.104(b)(3) (i)–(iv).

- (c) Design a migrant health center program for such population, based on the assessment prepared pursuant to paragraph (b) of this section which indicates in detail how the proposed center will fulfill the needs identified in that assessment and meet the requirements of subpart C of this part.

- (d) Develop a plan for the implementation of the program designed pursuant to paragraph (c) of this section. This implementation plan must provide for the time-phased recruitment and training of the personnel essential for the operation of a migrant health center and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements contained in subpart C of this part by the end of the project period.

- (e) Implement the plan developed pursuant to paragraph (d) of this section in accordance with such paragraph.

- (f) Make efforts to secure within the proposed catchment area of such center, to the extent possible, financial and professional assistance and support for the project.

- (g) Initiate and encourage continuing community involvement in the development and operation of the project through, for example, contributions or loans of cash, services, equipment, full- or part-time staff, space, materials, or facilities.

- (h) Provide for sufficient staff, qualified by training and experience, to carry out the project and establish standards and qualifications for personnel (including the project director).

§ 56.204

(i) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

(j) Provide the means for evaluating the project's progress in achievement of its specific objectives, and submit such progress reports on the project as the Secretary may from time to time request.

§ 56.204 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area which will not be served by another project funded under this part and meet the applicable requirements of section 319(c)(1)(A) of the Act and this part, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of subpart A of this part; *Provided*, That in the case of applicants which propose to serve substantially the same catchment areas or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107,

(1) Priority shall be given to applications submitted by community-based organizations which are representative of the population to be served by the project. For purposes of this paragraph, an applicant shall be deemed to be such an organization if it provides a formal mechanism (such as membership on the organization's governing body or membership on an advisory body) which gives migratory seasonal agricultural workers and their families significant involvement in the formulation of the organization's policies; and

(2) Where all such applicants are community-based organizations representative of the population to be served by the project, the Secretary shall award the grant to the applicants which will, in his judgment, best promote the purposes of section 319(c)(1)(A) of the Act and the applicable regulations of this part, taking into account with respect to each application:

42 CFR Ch. I (10–1–11 Edition)

(i) The degree to which the proposed project satisfactorily provides for the elements set forth in § 56.203;

(ii) The administrative and management capability of the applicant;

(iii) The extent to which community resources will be utilized in the project; and

(iv) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects.

(b) The Secretary shall award no more than two grants under this subpart for the same project.

Subpart C—Grants for Operating Migrant Health Centers

§ 56.301 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 319(d)(1)(A) of the Act for the costs of operation of migrant health centers in high impact areas.

§ 56.302 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of subpart A of this part,

(a) Be submitted by an entity (which may be a co-applicant) which the Secretary determines is a migrant health center, and

(b) Contain information sufficient to enable the Secretary to determine that the center will meet the requirements of this part.

§ 56.303 Project elements.

A migrant health center supported under this subpart must:

(a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the migratory and seasonal agricultural workers and their families within the center's catchment area.

(b) Implement a system for maintaining the confidentiality of patient

records in accordance with the requirements of § 56.111 of subpart A of this part.

(c) Have an ongoing quality assurance program which provides for the following:

(1) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care;

(2) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided by the center, and by other providers through contract or other cooperative arrangement with the center. Such assessments must:

(i) Be conducted by physicians or by other appropriate health professionals under the supervision of physicians or, as appropriate, by health professionals who are peers of the health professionals who provided the services;

(ii) Be based on the systematic collection and evaluation of patient records; and

(iii) Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

(d) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit (1) conducted in accordance with the "Guide for Audits of Migrant Health Grants" of the DHHS Audit Agency, and (2) conducted with reasonable frequency, usually annually but not less frequently than every two years (unless waived for cause by the Secretary), to be made by qualified individuals who are sufficiently independent of those who authorize the expenditure of Federal funds to produce unbiased opinions, conclusions, or judgments, and to determine, at a minimum, the fiscal integrity of grant financial transactions and reports, and compliance with the applicable regulations of this part and the terms and conditions of the grant.

(e) Where the cost of care and services furnished by or through the center is to be reimbursed under title XIX or title XX of the Social Security Act, ob-

tain or make every reasonable effort to obtain a written agreement with the title XIX or title XX State agency for such reimbursement.

(f) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. The schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (42 CFR 1060.2) (except that nominal fees for service may be collected from such individuals and families) and for no discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines.

(g) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, to social services and family planning under title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (f) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (f) of this section.

(h) Have a governing board which meets the requirements of § 56.304.

(i) Have developed an overall plan and budget for the center that:

(1) Provides for an annual operating budget and a three-year financial management plan which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items;

(2) Provides for a capital expenditure plan for at least a three-year period

(including the year to which the operating budget described in paragraph (h)(i)(1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objective of, each anticipated expenditure in excess of \$100,000 related to the acquisition of land, the improvement of land, buildings, and equipment and the replacement, modernization and expansion of buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(3) Provides for plan review and updating at least annually; and

(4) Is prepared under the direction of the governing board by a committee consisting of representatives of the governing board, the administrative staff, and the medical staff, if any, of the center.

(j) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which will enable the center to provide such statistics and other information as the Secretary may reasonably require relating to the center's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services, and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(k) Review its catchment area annually to insure that the criteria set out in § 56.104(b)(2) are met and, if criteria are not met, revise its catchment area, with the approval of the Secretary, to conform with such criteria to the extent feasible.

(l) In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and

bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English must be so identified.

(m) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(n) To the extent possible, coordinate and integrate project activities with the activities of other federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(o) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(p) Provide sufficient staff, qualified by training and experience, to carry out the activities of the center.

(q) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(r) Utilize, to the maximum extent feasible, other Federal, State and local, and private resources available for support of the project, prior to use of project funds under this part.

(s) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities.

(t) Where the center will provide services through contract or other cooperative arrangements with other providers of services, the center must:

(1) Enter into the contract or arrangement only if the provider of services will provide the services in a timely manner and make the services accessible and acceptable to the population to be served;

(2) Make payment for services so provided only pursuant to agreements with the providers in accordance with a schedule of rates and payment procedures established and maintained by the center. The center must be prepared to substantiate that such rates are reasonable and necessary;

(3) Directly provide at least primary care unless the center has made arrangements for the provision of primary care which include transfer of all medical and financial information relating to such care to the center; and

(4) Enter into contracts or arrangements for the provision of primary health services only if alternative resources are reasonably available to provide these services in the event of termination of such arrangements.

(u) Operate in a manner such that no migratory or seasonal agricultural worker or member of their family will be denied service by reason of his or her inability to pay therefor. *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

§ 56.304 Governing board.

The governing board of the center must meet the following requirements:

(a) *Size.* The board must consist of at least 9 but not more than 25 members except that this provision may be waived by the Secretary for good cause shown.

(b) *Composition.* (1) A majority of the board members must be migratory and seasonal agricultural workers and members of their families who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, and sex.

(2) No more than two-thirds of the remaining members of the board may be individuals who derive more than 10 percent of their annual income from the health care industry.

(3) The remaining members of the board must be representatives of the community in which the center's catchment area is located and shall be selected for their expertise in relevant subject areas, such as community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social services within the community.

(4) No member of the board shall be an employee of the center, or spouse or child, parent, brother or sister by blood of marriage of such an employee. The project director may be a nonvoting, ex-officio member of the board.

(c) *Selection of members.* The method of selection must be prescribed in the

by-laws or other internal governing rules of the center. Such by-laws or other rules must specify a process of selection of individuals on the governing board who represent the population served or to be served by the center so that such individuals, as a group, are representative of such population. Such process of selection in the by-laws or other rules is subject to approval by the Secretary.

(d) *Functions and responsibilities.* (1) The governing board shall have authority for the establishment of policy in the conduct of the center.

(2) The governing board shall hold regularly scheduled meetings, at least once each month, except for periods of the year, as specified in the bylaws, during which monthly meetings are not practical due to migration out of the catchment area.

(3) Minutes must be kept for all regularly scheduled meetings of the board.

(4) The governing board shall have specific responsibility for:

(i) Approval of the selection and dismissal of the project director or chief executive officer of the center;

(ii) Establishing personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales;

(iii) The development of bylaws which specify the responsibility of the board and principal operating officials of the centers;

(iv) Adopting policy for financial management practices, including a system to assure accountability for center resources, approval of the annual project budget, center priorities, eligibility for services, including criteria for partial payment schedules, and long-range financial planning;

(v) Evaluating center activities, including services utilization patterns, productivity of the center, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances;

(vi) Assuring that the center is operated in compliance with applicable Federal, State, and local laws and regulations; and

§ 56.305

42 CFR Ch. I (10–1–11 Edition)

(vii) Adopting health care policies including scope and availability of services, location and hours of services, and quality assurance procedures.

§ 56.305 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area which will not be served by another project funded under this part and meet the applicable requirements of section 319(d)(1)(A) of the Act and this part, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of subpart A of this part: *Provided*, That in the case of applicants which propose to serve substantially the same catchment area or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107, the Secretary will award grants to the applicants which, in his judgment, will best promote the purpose of section 319(d)(1)(A) of the Act and the applicable regulations of this part, taking into account with respect to each application:

(1) The extent to which the project would provide for the elements set forth in § 56.303;

(2) The capability of the applicant to provide quality health care services;

(3) The soundness of the financial management plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(4) The administrative and management capability of the applicant;

(5) The capability of the applicant to provide primary health services directly. In evaluating the relative capability of the applicant to provide such services directly, the Secretary shall take into consideration whether the direct provision of such services is inappropriate because:

(i) Provision of such services through contract or other arrangement would be more cost-effective;

(ii) Provision of such services directly would unnecessarily duplicate existing resources; or

(iii) Provision of such services other than directly would enhance the accessibility or acceptability of such services to the population to be served.

(6) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects;

(7) The extent that community resources will be utilized by the project; and

(8) Consistent with the other requirements of this part, the degree to which and the manner in which the applicant provides specific health services which the Secretary has, through publication of a notice in the FEDERAL REGISTER, established as services which should receive emphasis by applicants.

Subpart D—Grants for Operating Migrant Health Entities

§ 56.401 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 319(d)(1)(B) of the Act for the costs of operation of entities which intend to become migrant health centers and which provide health services to migratory agricultural workers, seasonal agricultural workers, and the members of their families in high impact areas.

§ 56.402 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of subpart A of this part,

(a) Be submitted by an entity which the Secretary determines intends to become a migrant health center but which will not, at the time of the grant award, meet one or more of the requirements of paragraphs (a) through (1) of § 56.303 of subpart C of this part; and

(b) Contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part. Such information must include a plan which identifies which requirements of § 56.303 will not be met at

the time of grant award and provides a timetable for and a detailed statement of the means to be employed in meeting those requirements.

§ 56.403 Project elements.

A project for the operation of a migrant health entity supported under this subpart must:

(a) Meet all of the requirements of § 56.303 of this part, *Provided*, That the project will not be required to meet the requirements of paragraphs (c), (h), (i), or (n) of such section if the Secretary finds that meeting any such requirement is not feasible or practical at the time of grant award.

(b) Provide those services enumerated in § 56.102(g)(1) of subpart A of this part which are specified in the grant award.

(c) Meet the requirements of § 56.303 of subpart C of this part by the end of the period of support under section 319(d)(1)(B) of the Act and this subpart, in accordance with the plan submitted under § 56.402(b) of this subpart.

§ 56.404 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purposes, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area not served by another project funded under this part and meet the applicable requirements of section 319(d)(1)(B) of the Act and this part, in accordance with the priorities established pursuant to section 319(b) of the Act and § 56.107 of subpart A of this part; *Provided*, That in the case of applicants which propose to serve substantially the same catchment area or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107, the Secretary will award the grant to the applicants which, in his judgment, will best promote the purposes of section 319(d)(1)(B) of the Act and the applicable regulations of this part, taking into account with respect to each application:

(1) The degree to which the project would provide the services enumerated in § 56.102(g)(1) and the feasibility of its

providing all of such enumerated services by the end of the period of support under section 319(d)(1)(B) of the Act and this subpart;

(2) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other federally assisted health service or reimbursement programs or projects;

(3) The capability of the project to provide quality health care services;

(4) The administrative and management capability of the applicant; and

(5) The capability of the applicant to provide primary health services directly. In evaluating the relative capability of the applicant to provide such services directly, the Secretary shall take into consideration whether the direct provision of services is inappropriate because:

(i) Provision of such services through contract or other arrangement would be more cost-effective;

(ii) Provision of such services directly would unnecessarily duplicate existing resources; or

(iii) Provision of the services other than directly would enhance the accessibility or acceptability of the services to the population served.

(6) The extent to which community resources will be utilized by the project; and

(7) Consistent with the other requirements of this part, the degree to which and the manner in which the applicant provides specific health services which the Secretary has, through publication of a notice in the FEDERAL REGISTER, established as services which should receive emphasis by applicants.

(b) The Secretary shall:

(1) Make no more than two grants for the same entity under section 319(d)(1)(B) of the Act;

(2) Not make any grant under section 319(d)(1)(B) to an entity which, for the same project, has been awarded more than one grant under section 319(c) of the Act;

(3) Not make a grant under section 319(d)(1)(B) to an entity which has been awarded a grant under section 319(d)(1)(A) of the Act.

Subpart E—Grants for Planning and Developing Migrant Health Programs

§ 56.501 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 319(c)(1)(B) of the Act for projects to plan and develop migrant health programs to provide health services to migratory agricultural workers, seasonal agricultural workers and the members of their families in areas in which no migrant health center exists and in which not more than 6,000 migratory agricultural workers and their families reside for more than two months.

§ 56.502 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of subpart A of this part,

(a) Be submitted for a project within a catchment area which

(1) Is not served, in whole or in part, by a migrant health center, and

(2) Has not more than 6,000 migratory agricultural workers and members of their families residing therein for more than 2 months per year; and

(b) Contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part.

§ 56.503 Project elements.

A project for the planning and development of a migrant health program supported under this subpart must:

(a) Determine (by survey or other appropriate means) the approximate number of

(1) Migratory agricultural workers and the members of their families, and

(2) Seasonal agricultural workers and the members of their families within the project's catchment area in the calendar year in which the grant is made and the period of time these workers and their families reside in the catchment area during such year.

(b) Prepare an assessment of need of the population proposed to be served by

the migrant health program for the services set forth in § 56.603(a) of subpart F of this part. This assessment of need must, at a minimum, consider the factors listed in § 56.104(b)(3) (i)–(iv).

(c) Design a migrant health program for such population, based on such assessment, which indicates in detail how the proposed program will fulfill the needs identified in that assessment and meet the requirements of subpart F of this part.

(d) Develop a plan for the implementation of the program designed pursuant to paragraph (c) of this section. The implementation plan must provide for the time-phased recruitment and training of the personnel essential for the operation of a migrant health program and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements of subpart F of this part as of the end of the project period.

(e) Implement the plan developed pursuant to paragraph (d) of this section in accordance with such paragraph.

(f) Make efforts to secure within the proposed catchment area of such project, to the extent possible, financial and professional assistance and support for the project.

(g) Initiate and encourage continuing community involvement in the development and operation of the project through, for example, contributions or loans of cash, services, equipment, full- or part-time staff, space, materials, or facilities.

(h) Provide for sufficient staff, qualified by training and experience, to carry out the project and establish standards and qualifications for personnel (including the project director).

(i) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

(j) Provide for the means of evaluating the project's progress in achievement of its specific objectives and submission of such progress reports on the project as the Secretary may from time to time request.

§ 56.504 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which, in his judgment, will provide needed health services in a catchment area not served by another project funded under this part and meet the applicable requirements of section 319(c)(1)(B) of the Act and this part, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of subpart A of this part; *Provided*, That in the case of applicants which propose to serve substantially the same catchment areas or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107,

(1) Priority shall be given to applications submitted by community-based organizations which are representative of the population to be served by the project. For purposes of this paragraph, an applicant shall be deemed to be such an organization if it provides a formal mechanism (such as membership on the organization's governing body or membership on an advisory body) which gives migratory and seasonal agricultural workers and their families significant involvement in the formulation of the organization's policies; and

(2) Where all such applicants are community-based organizations representative of the population to be served by the project, the Secretary shall award the grant to the applicants which will, in his judgment, best promote the purposes of section 319(c)(1)(B) of the Act and the applicable regulations of this part, taking into account with respect to each application:

- (i) The degree to which the proposed project satisfactorily provides for the elements set forth in § 56.203;
- (ii) The administrative and management capability of the applicant;
- (iii) The extent to which community resources will be utilized in the project; and
- (iv) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other

federally assisted health services or reimbursement programs or projects.

(b) The Secretary shall award no more than one grant under this subpart for the same project.

Subpart F—Grants for Operating Migrant Health Programs

§ 56.601 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part, are applicable to grants awarded pursuant to section 319(d)(1)(C) of the Act for projects for operating programs to provide health services to migratory agricultural workers, seasonal agricultural workers and the members of their families in areas in which no migrant health center exists and in which not more than 6,000 migratory agricultural workers and their families reside for more than two months.

§ 56.602 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 56.104 of subpart A of this part,

(a) Be submitted for a project with a catchment area which

(1) Is not served, in whole or in part, by a migrant health center, and

(2) Has not more than 6,000 migratory agricultural workers and the members of their families residing therein for more than two months per year; and

(b) Contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of this part.

§ 56.603 Project elements.

A project for operating a migrant health program supported under this subpart must:

(a) Provide to migratory and seasonal agricultural workers and the members of their families in its catchment area one or more of the following groups of services so that such services are available and accessible promptly as appropriate, and in a manner which will assure continuity of care, as approved by the Secretary and

set forth (including specific services to be provided) in the grant award:

(1) Emergency health care, including diagnostic and treatment services in an ambulatory health care setting or hospital and dental services for the alleviation of acute pain and suffering for medical emergencies, when provision of such services is necessary to avoid jeopardizing the patient's condition until appropriate services from other providers can reasonably be obtained;

(2) Primary care;

(3) Arrangements with existing health care facilities to furnish primary health services (other than primary care);

(4) Other services set forth in § 56.102(g)(1) which are needed to improve the health of such individuals.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirement of § 56.111 of subpart A of this part.

(c) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit conducted in accordance with the DHHS Audit Agency Guide for Audits of Migrant Health Grants, as amended, on at least an annual basis (unless waived for cause by the Secretary), by an independent certified public accountant or public accountant licensed before December 31, 1970, to determine, at a minimum, the fiscal integrity of grant financial transactions and reports and compliance with the regulations of this part and the terms and conditions of the grant.

(d) When the cost of care and services furnished by or through the project is to be reimbursed under title XIX or title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the title XIX or title XX State agency for such reimbursement.

(e) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. The schedule of discounts must provide for a full discount to individuals and families with annual

incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (42 CFR 1060.2) (except that nominal fees for service may be collected from individuals and families with annual incomes at or below such levels if imposition of such fees is consistent with project goals) and for no discount to individuals and families with annual incomes greater than twice those set forth in the Guidelines.

(f) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, to social services and family planning under title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (e) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (e) of this section.

(g) Develop an overall financial management plan and an operating budget for the project which include and identify, in accordance with generally accepted accounting principles, all anticipated current income and expense items and capital income and expense items, if any.

(h) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which will meet the project's management needs and shall enable the project to provide such statistics and other information as the Secretary may reasonably require relating to the project's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services, and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(i) Review its catchment area annually to insure that the criteria set out in § 56.104(b)(2) are met and, where such criteria are not met, revise its catchment area, with the approval of the Secretary, to conform with such criteria to the extent feasible.

(j) In the case of a project which serves a population including a substantial proportion of individuals of limited English-speaking ability, have a plan and made arrangements responsive to the needs of these populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English must be so identified.

(k) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(l) To the extent possible, coordinate and integrate project activities with the activities of other federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(m) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(n) Provide sufficient staff, qualified by training and experience, to carry out the activities of the project.

(o) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(p) Utilize, to the maximum extent feasible, other Federal, State and local, and private resources available for support of the project, prior to use of project funds under this part.

(q) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities, and, to the extent feasible, establishment of an advisory

council to advise with respect to the overall management of the project including services to be provided, the manner of their provision, and appointment of personnel. The membership of such advisory council shall be representative of the population to be served in terms of appropriate demographic characteristics, such as race, sex, and ethnicity.

(r) Where the project will provide services through contract or other co-operative arrangements with other providers of services, the project must

(1) Enter into any such contract or arrangement only if the provider of services will provide the services in a timely manner and make the services accessible and acceptable to the population to be served; and

(2) Make payment for services so provided in accordance with a schedule of rates and payment procedures established and maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary.

(s) Operate in a manner such that no migratory or seasonal agricultural worker or member of their families will be denied service by reason of his or her inability to pay therefor. *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

(t) Have an ongoing quality assurance program as described in § 56.303(c) except as the Secretary finds that such a program would not be feasible.

§ 56.604 Grant evaluation and award.

(a) Within the limit of funds determined by the Secretary to be available the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, provide needed health services in a catchment area which will not be served by another project funded under this part and meet the applicable requirements of section 319(d)(1)(C) of the Act and this subpart, in accordance with priorities established pursuant to section 319(b) of the Act and § 56.107 of subpart A of this part; *Provided,* That in the case of applicants which propose to

§ 56.701

serve substantially the same catchment areas or where available funds are insufficient to fund all approvable applications within a priority category specified in § 56.107.

(1) Priority shall be given to applications submitted by community-based organizations which are representative of the population to be served by the project. For purposes of this paragraph, an applicant shall be deemed to be such an organization if it provides a formal mechanism (such as membership on the organization's governing body or membership on an advisory body) which gives migratory seasonal agricultural workers and their families significant involvement in the formulation of the organization's policies; and

(2) Where all such applicants are community-based organizations representative of the population to be served by the project, the Secretary shall award the grant to the applicants which will, in his judgment, best promote the purposes of section 319(d)(1)(C) of the Act and the applicable regulations of this part, taking into account with respect to each application:

- (i) The degree to which the proposed project satisfactorily provides for the elements set forth in § 56.203;
- (ii) The administrative and management capability of the applicant;
- (iii) The extent to which community resources will be utilized in the project; and
- (iv) The degree to which the applicant intends to integrate services supported by a grant under this part with health services provided under other federally assisted health services or reimbursement programs or projects.

Subpart G—Grants for Technical Assistance

§ 56.701 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A of this part except as otherwise set forth herein, are applicable to grants awarded pursuant to section 319(g) of the Act for the provision of technical and other non-financial assistance to grantees under sections 319(c)(1)(A), 319(d)(1)(A) and 319(d)(1)(B) of the Act.

42 CFR Ch. I (10–1–11 Edition)

§ 56.702 Application.

To be approved by the Secretary under this subpart, an application for a grant must meet the requirements of §§ 56.104(a), 56.104(b) (1), (4), (7), (10), and (11), and 56.104(c) of subpart A of this part.

§ 56.703 Project elements.

A project for the provision of technical assistance to migrant health centers and entities which intend to become migrant health centers which is supported under this subpart must:

(a) Provide to such centers and entities as are specified in the grant award, such technical and other nonfinancial assistance (such as fiscal and program management assistance or training of the staff of such center or entity in such management) as may be specified in the grant award. Such technical or other nonfinancial assistance shall be designed to assist such centers and entities in:

(1) Developing plans for becoming migrant centers; and/or

(2) Meeting the requirements of sections 319(f)(2) of the Act.

(b) Provide such assistance through its own staff or resources.

(c) Where the project will provide training to the staff of a center or entity in management or the provision of health services, provide such training consistent, as applicable, with § 56.108(b)(7).

(d) Maintain such records and make such reports on the expenditure of funds under this subpart and provision of such assistance as the Secretary may require.

§ 56.704 Grant evaluation and award.

Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 319(g) of the Act and applicable regulations of this part, taking into consideration:

(a) The cost-effectiveness of the application; and

(b) The number of centers and entities to be served by the applicant.

Subpart H—Acquisition and Modernization of Existing Buildings

§ 56.801 Applicability of 42 CFR part 51c, subpart E.

The provisions of 42 CFR part 51c, subpart E, establishing requirements for the acquisition and modernization of existing buildings, shall apply to all grants under section 319 of the Act for project costs which include the cost of acquisition and/or modernization of existing buildings (including the cost of amortizing the principal of, and paying the interest on, loans); except that, for purposes of this subpart, references within subpart E to part 51c, or to subparts of part 51c, shall be deemed to be references to part 56, or to the appropriate subparts of part 56, and references to section 330 of the Act shall be deemed to be references to section 319 of the Act.

[43 FR 5353, Feb. 7, 1978]

PART 57—GRANTS FOR CONSTRUCTION OF TEACHING FACILITIES, EDUCATIONAL IMPROVEMENTS, SCHOLARSHIPS AND STUDENT LOANS

Subparts A–B [Reserved]

Subpart C—Health Professions Student Loans

Sec.

- 57.201 Applicability.
- 57.202 Definitions.
- 57.203 Application by school.
- 57.204 Payment of Federal capital contributions and reallocation of funds remitted to the Secretary.
- 57.205 Health professions student loan funds.
- 57.206 Eligibility and selection of health professions student loan applicants.
- 57.207 Maximum amount of health professions student loans.
- 57.208 Health professions student loan promissory note and disclosure requirements.
- 57.209 Payment of health professions student loans.
- 57.210 Repayment and collection of health professions student loans.
- 57.211 Cancellation of health professions student loans for disability or death.
- 57.212 [Reserved]

- 57.213 Continuation of provisions for cancellation of loans made prior to November 18, 1971.
- 57.213a Loan cancellation reimbursement.
- 57.214 Repayment of loans made after November 17, 1971, for failure to complete a program of study.
- 57.215 Records, reports, inspection, and audit.
- 57.216 What additional Department regulations apply to schools?
- 57.216a Performance standard.
- 57.217 Additional conditions.
- 57.218 Noncompliance.

Subpart D—Nursing Student Loans

- 57.301 Applicability.
- 57.302 Definitions.
- 57.303 Application by school.
- 57.304 Payment of Federal capital contributions and reallocation of funds remitted to the Secretary.
- 57.305 Nursing student loan funds.
- 57.306 Eligibility and selection of nursing student loan applicants.
- 57.307 Maximum amount of nursing student loans.
- 57.308 Nursing student loan promissory note.
- 57.309 Payment of nursing student loans.
- 57.310 Repayment and collection of nursing student loans.
- 57.311 Cancellation of nursing student loans for disability or death.
- 57.312 Repayment of loans for service in a shortage area.
- 57.313 Loan cancellation for full-time employment as a registered nurse.
- 57.313a Loan cancellation reimbursement.
- 57.314 Repayment of loans made after November 17, 1971, for failure to complete a program of study.
- 57.315 Records, reports, inspection, and audit.
- 57.316 What additional Department regulations apply to schools?
- 57.316a Performance standard.
- 57.317 Additional conditions.
- 57.318 Noncompliance.

Subpart E—Grants for Construction of Nurse Training Facilities

- 57.409 Good cause for other use of completed facility.

Subparts F–O [Reserved]

Subpart P—Loan Guarantees and Interest Subsidies to Assist in Construction of Teaching Facilities for Health Profession Personnel

- 57.1501 Applicability.
- 57.1502 Definitions.
- 57.1503 Eligibility.

§ 57.201

- 57.1504 Application.
- 57.1505 Approval of applications.
- 57.1506 Priority.
- 57.1507 Limitations applicable to loan guarantee.
- 57.1508 Amount of interest subsidy payments; limitations.
- 57.1509 Forms of credit and security instruments.
- 57.1510 Security for loans.
- 57.1511 Opinion of legal counsel.
- 57.1512 Length and maturity of loans.
- 57.1513 Repayment.
- 57.1514 Loan guarantee and interest subsidy agreements.
- 57.1515 Loan closing.
- 57.1516 Right of recovery-subordination.
- 57.1517 Waiver of right of recovery.
- 57.1518 Modification of loans.

Subparts Q–T [Reserved]

Subpart U—Armed Forces Health Professions Scholarship Program

- 57.2001 Applicability.
- 57.2002 Definitions.
- 57.2003 Determinations of increased enrollment solely for the program.

Subpart V [Reserved]

Subpart W—Physician Shortage Area Scholarship Grants

- 57.2201 Applicability.
- 57.2202 Definitions.
- 57.2203 Eligibility.
- 57.2204 Application.
- 57.2205 Priority for selection of scholarship recipients.
- 57.2206 Grant award.
- 57.2207 Amount of scholarship grant.
- 57.2208 Payment of scholarship grant.
- 57.2209 Conditions of scholarship grant.
- 57.2210 Failure to comply.
- 57.2211 Waiver or suspension.

Subparts X–FF [Reserved]

Subpart GG—Payment for Tuition and Other Educational Costs

- 57.3201 To which programs do these regulations apply?
- 57.3202 How will allowable increases be determined?

Subparts HH–PP [Reserved]

Subparts A–B [Reserved]

42 CFR Ch. I (10–1–11 Edition)

Subpart C—Health Professions Student Loans

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); secs. 740–747 of the Public Health Service Act, 77 Stat. 170–173, as amended by 90 Stat. 2266–2268, 91 Stat. 390–391, 95 Stat. 920, 99 Stat. 532–536, and 102 Stat. 3125 (42 U.S.C. 294m–q); renumbered as secs. 721–735, as amended by Pub. L. 102–408, 106 Stat. 2011–2022 (42 U.S.C. 292q–292y).

SOURCE: 44 FR 29055, May 18, 1979, unless otherwise noted.

§ 57.201 Applicability.

The regulations of this subpart apply to the federal capital contributions made by the Secretary to public or other nonprofit health professions schools for the establishment of health professions student loan funds and to loans made to students by schools from these funds.

§ 57.202 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Date upon which a student ceases to be a full-time student means the first day of the month which is nearest to the date upon which an individual ceases to be a full-time student as defined in this section.

Default means the failure of a borrower of a loan made under this subpart to make an installment payment when due, or comply with any other term of the promissory note for such loan, except that a loan made under this subpart shall not be considered to be in default if the loan is discharged in bankruptcy, the borrower's repayment schedule has been renegotiated and the borrower is complying with the renegotiated schedule, or the loan is in forbearance.

Federal capital loan means a loan made by the Secretary to a school under section 744(a) of the Act, as in effect prior to October 1, 1977, the proceeds of which are to be returned to the Secretary.

Full-time student means a student who is enrolled in a health professions school and pursuing a course of study

which is a full-time academic workload, as determined by the school, leading to a degree specified in section 722(b) of the Act.

Grace period means the period of 1 year beginning on the date upon which a student ceases to be a full-time student at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine.

Health professions school or school, for purposes of this subpart, means a public or private nonprofit school of medicine, school of dentistry, school of osteopathic medicine, school of pharmacy, school of podiatric medicine, school of optometry, or school of veterinary medicine as defined in section 799(1)(A) of the Act.

Health professions student loan means the amount of money advanced to a student by a school from a health professions student loan fund under a properly executed promissory note.

Institutional capital contribution means the money provided by a school, in an amount not less than one-ninth of the federal capital contribution, and deposited in a health professions student loan fund.

National of the United States means: (1) A citizen of the United States, or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States, as defined in the Immigration and Nationality Act, at 8 U.S.C. section 1101(a)(22).

School year means the traditional approximately 9-month September to June annual session. For the purpose of computing school year equivalents for students who, during a 12-month period, attend for a longer period than the traditional school year, the school year will be considered to be 9 months in length.

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, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam,

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

[44 FR 29055, May 18, 1979, as amended at 52 FR 20987, June 3, 1987; 53 FR 46549, Nov. 17, 1988; 56 FR 19293, Apr. 26, 1991; 56 FR 25446, June 4, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.203 Application by school.

(a) Each school seeking a Federal capital contribution must submit an application at the time and in the form and manner that the Secretary may require. The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the regulations of this subpart, and the terms and conditions of the award.

(b) Each application will be reviewed to determine eligibility and the reasonableness of the amount of Federal support requested. The Secretary may require the applicant to submit additional data for this purpose.

(c) An application will not be approved unless an agreement between the Secretary and the applicant school for a Federal capital contribution under section 721 of the Act is reached.

[44 FR 29055, May 18, 1979, as amended at 49 FR 38112, Sept. 27, 1984; 56 FR 19293, Apr. 26, 1991; 57 FR 45734, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§ 57.204 Payment of Federal capital contributions and reallocation of funds remitted to the Secretary.

(a) *Annual payment.* The Secretary will make payments to each school with which he or she has entered into an agreement under the Act at a time determined by him or her. If the total of the amounts requested for any fiscal year by all schools for Federal capital contributions exceeds the amount of Federal funds determined by the Secretary at the time of payment to be available for this purpose, the payment to each school will be reduced to whichever is smaller:

(1) The amount requested in the application, or

(2) An amount which bears the same ratio to the total amount of Federal funds determined by the Secretary at the time of payment to be available for

that fiscal year for the Health Professions Student Loan Program as the number of full-time students estimated by the Secretary to be enrolled in that school bears to the estimated total number of full-time students in all participating schools during that year. Amounts remaining after these payments are made will be distributed in accordance with this paragraph among schools whose applications requested more than the amount paid to them, but with whatever adjustments that may be necessary to prevent the total paid to any school from exceeding the total requested by it.

(b) *Method of payment.* The payment of Federal capital contributions to a school will be paid in a manner that avoids unnecessary accumulations of money in any health professions student loan fund.

(c) *Reallocation of funds remitted to the Secretary.* All funds from a student loan fund established under this subpart which are remitted to the Secretary in any fiscal year shall be available for allotment under this subpart, in the same fiscal year and the succeeding fiscal year, to schools which, during the period beginning on July 1, 1972, and ending on September 30, 1985, established student loan funds with Federal capital contributions under this subpart. The Secretary will from time to time set dates by which the schools must file applications to receive a portion of these funds. If the total of the amounts requested for any fiscal year by eligible schools exceeds the amount of funds determined by the Secretary at the time of payment to be available for this purpose, the payment to each school will be reduced to whichever is smaller:

(1) The amount requested in the application, or

(2) An amount which bears the same ratio to the total amount of returned funds determined by the Secretary at the time of payment to be available for that fiscal year for the Health Professions Student Loan program as the number of full-time students estimated by the Secretary to be enrolled in that school bears to the estimated total number of full-time students in all eligible schools during that year.

Amounts remaining after these payments are made will be distributed in accordance with this paragraph among schools whose applications requested more than the amount paid to them, with whatever adjustments may be necessary to prevent the total paid to any school from exceeding the total requested by it.

[44 FR 29055, May 18, 1979, as amended at 53 FR 46549, Nov. 17, 1988; 56 FR 19293, Apr. 26, 1991]

§ 57.205 Health professions student loan funds.

(a) *Funds established with Federal capital contributions.* Any fund established by a school with Federal capital contributions will be accounted for separately from other funds, providing a clear audit trail for all transactions. At all times the fund must contain monies representing the institutional capital contribution. The school must at all times maintain all monies relating to the fund in one or more interest-bearing accounts or investment instruments which meet OMB requirements established for Federal monies held by third parties. The school must place all earnings into the fund but may first deduct from total earnings any reasonable and customary charges incurred through the use of an interest-bearing account. An institution shall exercise the level of care required of a fiduciary with regard to these deposits and investments, and shall be responsible for reimbursing the fund for any losses that occur due to the use of investments that are not federally insured.

(1) The Federal capital contribution fund is to be used by the school only for:

(i) Health professions student loans to full-time students;

(ii) Capital distribution as provided in section 728 of the Act or as agreed to by the school and the Secretary; and

(iii) Costs of litigation, costs associated with membership in credit bureaus, and to the extent specifically approved by the Secretary, other collection costs that exceed the usual expenses incurred in the collection of health professions student loans.

(2) A school must review the balance in the fund on at least a semi-annual basis to determine whether the fund

balance compared with projected levels of expenditures and collections exceeds its needs. A school in closing status must review the balance in the fund on a quarterly basis. Monies identified as in excess of the school's needs must be reported, and the Federal share returned to the Federal Government, by the due date of the required report which identifies the excess monies. The school's determination is subject to the review and approval of the Secretary.

(b) *Funds established with Federal capital loans.* (1) Each Federal capital loan is subject to the terms of the promissory note executed by an authorized official on behalf of the borrowing school.

(2) The Federal capital loans must be carried in a special account of the school, to be used by the school only for (i) repayments of principal and interest on Federal capital loans; and (ii) costs of litigation; costs associated with membership in credit bureaus; and, to the extent specifically approved by the Secretary, other collection costs that exceed the usual expenses incurred in the collection of health professions student loans.

(c) Failure to comply with the requirements of this section will subject a school to the noncompliance provisions of § 57.218 and the Department's Claims Collections regulations (45 CFR part 30), as appropriate.

(Approved by the Office of Management and Budget under control number 0915-0047)

[44 FR 29055, May 18, 1979, as amended at 48 FR 25069, June 3, 1983; 56 FR 40725, Aug. 15, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.206 Eligibility and selection of health professions student loan applicants.

(a) *Determination of eligibility.* (1) Applicants are eligible for consideration for a health professions student loan if they are:

(i) Residents of the United States and either a citizen or national of the United States, an alien lawfully admitted for permanent residence in the United States, a citizen of the Commonwealth of the Northern Mariana Islands, a citizen of the Republic of Palau, a citizen of the Republic of the Marshall Islands, or a citizen of the Federated States of Micronesia;

(ii) Enrolled, or accepted for enrollment in the school as full-time students;

(iii) In need of the amount of the loan to pursue a full-time course of study at the school;

(iv) Of exceptional financial need in the case of students of medicine or osteopathic medicine. A student will be considered to demonstrate exceptional financial need if the school determines that his or her resources, as described in paragraph (b)(1) of this section, do not exceed the lesser of \$6,700 or one-half of the costs of attendance at the school. Summer earnings, educational loans, veterans (G.I.) benefits and earnings during the school year will not be considered as resources in determining whether an applicant meets the eligibility criteria for exceptional financial need, but will be considered in determining the amount of funds a student may receive; and

(v) In compliance with the requirement to register for the draft, if required to do so under section 3 of the Military Selective Service Act.

(2) An applicant who has previously attended an institution of higher education must submit a financial aid transcript which includes at least the following data:

(i) Applicant's name and social security number;

(ii) Amounts and sources of loans and grants previously received by the applicant for study at an institution of higher education;

(iii) Whether the applicant is in default on any of these loans, or owes a refund on any grants;

(iv) Certification from each institution previously attended by the applicant that the applicant has received no financial aid, if applicable; and

(v) From each institution previously attended, the signature of an official authorized by the institution to sign such transcripts on behalf of the institution.

(b) *Selection of applicants.* The school will select qualified applicants, including medical (M.D. and D.O.) applicants, and determine the amount of student loans by considering:

(1) The financial resources available to the student by using one of the national need analysis systems or any

other procedure approved by the Secretary of Education in combination with other information which the school has regarding the student's financial status. The school must take into account, regardless of the tax status of the student, the expected contribution from parents, spouse, self or other family members; and

(2) The costs reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's ability to attend the school on a full-time basis. The school must document the criteria used for determining these costs.

(c) *Selection of medical (M.D. and D.O.) student applicants.* In addition to the factors in § 57.206(b), the school must select medical (M.D. and D.O.) students graduating after June 30, 1979, based on the order of greatest need, taking into consideration the other resources available to the student through the school. For purposes of establishing priority for selecting medical (M.D. and D.O.) student applicants to receive health professions student loans, summer earnings, educational loans, veterans (G.I.) benefits, and earnings during the school year will be considered as financial resources.

(d) *Verification of loan information.* The school must verify, to the best of its ability, the information provided by the student on the loan application. To comply with this requirement, a school may require that a student provide, for example: Photocopies of the parents', student's, and spouse's Federal income tax forms with original signatures for the most recent tax year (or certification that no Federal income tax return was filed); tax returns that are certified as having been received by the Internal Revenue Service; or other documentation that the school considers necessary to help assure that information on the loan application is correct.

(Approved by the Office of Management and Budget under control number 0915-0047)

[44 FR 32698, June 7, 1979, as amended at 48 FR 25069, June 3, 1983; 49 FR 38112, Sept. 27, 1984; 52 FR 20987, June 3, 1987; 53 FR 46549, Nov. 17, 1988; 56 FR 19293, Apr. 26, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.207 Maximum amount of health professions student loans.

The total of the health professions student loans made from the fund to any student for a school year may not exceed \$2,500 and the cost of tuition. The maximum amount loaned during a 12-month period to any student enrolled in a school which provides a course of study longer than the 9-month school year may be proportionately increased.

§ 57.208 Health professions student loan promissory note and disclosure requirements.

(a) *Promissory note form.* Each health professions student loan must be evidenced by a properly executed promissory note in a form approved by the Secretary. The school must safeguard the promissory note against fire, theft, and tampering.

(1) Each promissory note must state that the loan will bear interest on the unpaid balance computed only for periods during which repayment of the loan is required, at the rate of 5 percent per year.

(2) Each promissory note must contain an acceleration clause provided by the Secretary, which will permit the acceleration of delinquent loans at the school's option.

(3) A copy of each executed note must be supplied by the school to the student borrower.

(b) *Security.* A school must require security or endorsement if the borrower is a minor and if, under the applicable State law, the note signed by him or her would not create a binding obligation. The school may not require security or endorsement in any other circumstances.

(c) *Disclosure requirements.* (1) For any loan made after June 30, 1986, the school shall, at the time the loan is made, provide the following loan information to the student:

(i) The yearly and cumulative maximum amounts that may be borrowed by the student;

(ii) The terms under which repayment of the loan will begin;

(iii) The maximum number of years in which the loan must be repaid;

(iv) The interest rate that will be paid by the borrower and the minimum

amount of the required monthly payment;

(v) The amount of any other fees charged to the borrower by the lender;

(vi) Any options the borrower may have for deferral, cancellation, prepayment, consolidation, or other refinancing of the loan;

(vii) A definition of default on the loan and a specification of the consequences which will result to the borrower if the borrower defaults, including a description of any arrangements which may be made with credit bureau organizations;

(viii) To the extent practicable, the effect of accepting the loan on the eligibility of the borrower for other forms of student assistance; and

(ix) A description of the actions that may be taken by the Federal Government to collect the loan, including a description of the type of information concerning the borrower that the Federal Government may disclose to:

(A) Officers, employees, or agents of the Department of Health and Human Services,

(B) Officers, employees, or agents of schools with which the Secretary has an agreement under this subpart, or

(C) Any other person involved in the collection of a loan under this subpart.

(2) For any loan made after June 30, 1986, the school shall, prior to the borrower's completion or termination of studies at the school, provide the following loan information to the student:

(i) Each amount borrowed by the student under this subpart;

(ii) The total amount borrowed by the student under this subpart; and

(iii) A schedule for the repayment of the amounts borrowed under this subpart, including the number, amount, and frequency of payments to be made.

(3) In addition to the requirements set forth in paragraphs (c)(1) and (c)(2) of this section, the school must comply with the applicable requirements of Truth in Lending Regulation Z (12 CFR part 226).

(Approved by the Office of Management and Budget under control number 0915-0047)

[44 FR 29055, May 18, 1979, as amended at 48 FR 25069, June 3, 1983; 50 FR 34420, Aug. 23, 1985; 52 FR 20987, June 3, 1987; 56 FR 19293, Apr. 26, 1991; 57 FR 45734, Oct. 5, 1992]

§ 57.209 Payment of health professions student loans.

(a) Health professions student loans from any fund may be paid to or on behalf of student borrowers in installments considered appropriate by the school except that a school may not pay to or on behalf of any borrower more during any given installment period (e.g., semester, term, or quarter) than the school determines the student needs for that period.

(b) No payment may be made from a fund to or on behalf of any student borrower if at the time of the payment the borrower is not a full-time student.

§ 57.210 Repayment and collection of health professions student loans.

(a) Each health professions student loan, including accrued interests, will be repayable in equal or graduated periodic installments in amounts calculated on the basis of a 10-year repayment period. Except as otherwise provided in this paragraph, repayment of a loan must begin one year after the student ceases to be a full-time student.

(1) If a borrower reenters the same or another school as a full-time student within the 1-year period, the date upon which interest will accrue and the repayment period will begin will be determined by the date on which the student last ceases to be a full-time student at that school.

(2) The following periods will be excluded from the 10-year repayment period:

(i) All periods for up to a total of 3 years of active duty performed by the borrower as a member of the Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanic and Atmospheric Administration Corps or the U.S. Public Health Service Corps;

(ii) All periods for up to a total of 3 years of service as a volunteer under the Peace Corps Act;

(iii) All periods of advanced professional training including internships and residencies, except as specified in paragraph (a)(2)(vi) of this section;

(iv) All periods during which the borrower is pursuing a full-time course of study at an eligible health professions school;

(v) A period not in excess of 2 years during which a borrower who is a full-

time student in a health professions school leaves the school, with the intent to return to such school as a full-time student, to engage in a full-time educational activity which is directly related to the health profession for which the individual is preparing. To qualify for such deferment, the full-time educational activity must be one which:

(A) Is part of a joint-degree program or a formal program of joint study in conjunction with the health profession for which the borrower is preparing at the school; or

(B) Is an activity which will enhance the borrower's knowledge and skills in the health profession for which the borrower is preparing at the school, as determined by the school.

The borrower must request such deferment from the school in which he or she is enrolled no later than 60 days prior to leaving such school to engage in the full-time educational activity. The school must then determine, no later than 30 days prior to the borrower's leaving such school, whether the borrower qualifies for such deferment. A borrower who qualifies for this type of deferment receives the grace period upon completion or termination of his or her studies leading to the first professional degree in the health discipline being pursued. If the borrower fails to return to school, the school retroactively must begin the borrower's grace period based on the date the borrower terminated his or her studies at the school, and must begin the repayment period immediately following the end of the grace period; and

(vi) A period not in excess of 2 years during which a borrower who is a graduate of a health professions school participates in:

(A) A fellowship training program which is directly related to the health profession for which the borrower prepared at the school, as determined by the school from which the borrower received his or her loan, and is engaged in by the borrower no later than 12 months after the completion of the borrower's participation in advanced professional training as described in paragraph (a)(2)(iii) of this section, or prior to the completion of such bor-

rower's participation in such training. To qualify for such deferment, the fellowship training program must be one which:

(1) Is a full-time activity in research or research training or in health care policy; and

(2) Is a formally established fellowship program which was not created for a specific individual; or

(B) A full-time educational activity which is directly related to the health profession for which the borrower prepared at the school, as determined by the school from which the borrower received his or her loan, and is engaged in by the borrower no later than 12 months after the completion of the borrower's participation in advanced professional training as described in paragraph (a)(2)(iii) of this section, or prior to the completion of the borrower's participation in such training. To qualify for such deferment, the full-time educational activity must be one which:

(1) Is part of a joint-degree program in conjunction with the health profession for which the borrower prepared at the school; or

(2) Is required for licensure, registration, or certification in the health profession for which the borrower received the HPSL loan; or

(3) Is a full-time educational program in public health, health administration, or a health care discipline directly related to the health profession for which the borrower received the loan.

(3) To receive a deferment, a borrower must, no later than 30 days prior to the onset of the activity (or no later than 30 days prior to the due date of the first payment if the borrower begins the activity during the grace period), and annually thereafter, provide the lending school with evidence of his or her status in the deferrable activity, and evidence that verifies deferment eligibility of the activity. This evidence must include certification by the Program Director or other authorized official that the borrower's activity meets the deferment requirements. The borrower must also notify the school upon completion or termination of the activity. It is the responsibility of the borrower to provide the lending school

with all required information or other information regarding the requested deferment. The school may deny a request for deferment if it is not filed in accordance with the requirements of this section.

(4) Subject to the provisions of paragraph (b)(3) of this section, a borrower must establish a repayment schedule with the school providing for payments not less often than quarterly. Any borrower whose repayment is delinquent more than 60 days must establish a monthly repayment schedule with the school. However, a borrower may at his or her option and without penalty, prepay all or part of the principal and accrued interest at any time.

(5) A school may grant forbearance whenever extraordinary circumstances such as unemployment, poor health or other personal problems temporarily affect the borrower's ability to make scheduled loan repayments.

(b)(1) Each school at which a fund is established must exercise due diligence in the collection of health professions student loans due the fund. In the exercise of due diligence, a school must follow procedures which are at least as extensive and effective as those used in the collection of other student loan accounts due the school, and must use the steps outlined below in accordance with collection practices which are generally accepted among institutions of higher education:

(i) Conduct and document an entrance interview (individually or in groups) with the borrower prior to disbursing HPSL funds in an academic year. During the entrance interview the school must obtain documentation which indicates that the borrower is aware of the rights and responsibilities associated with HPSL funds and personal information which would assist in locating the borrower if he or she fails to keep the school informed of his or her current address. The requirements of this subparagraph may be met by correspondence, if the school determines that a face-to-face meeting (individually or in groups) is impracticable.

(ii) Conduct and document an exit interview (individually or in groups) with the borrower. During the exit interview, the school must provide

each borrower with information necessary to carry out the terms of repayment, remind the borrower of the rights and responsibilities associated with HPSL funds, and update the personal information collected prior to disbursing HPSL funds which would assist in locating the borrower if he or she fails to keep the school informed of his or her current address. If the borrower terminates studies without advance notice, the school must document attempts to inform the borrower of the substance of the exit interview and to secure exit interview information from the borrower by mail.

(iii) Notify the borrower in writing of the impending repayment obligation at least twice during the grace period;

(iv) Notify a borrower who is in deferment status in writing of the impending repayment obligation 1 to 3 months prior to the expiration of the approved period of deferment;

(v) Perform regular billing;

(vi) Follow up past due payments with a series of at least four documented and reasonably spaced attempts to contact the borrower, at least three of which must be in writing at not more than 30-day intervals, prior to the loan becoming 120 days past due, provided that the school has a current address for the borrower;

(vii) Perform address searches when necessary;

(viii) Use collection agents, which may include the use of an internal collection agent;

(ix) Institute legal proceedings against borrowers after all other attempts at collection have failed, unless the school determines, subject to the approval of the Secretary, that such litigation would not be cost-effective; and

(x) Become a member of a credit bureau and notify the credit bureau of accounts past due by more than 120 days. In place of one or more of the procedures outlined above schools may substitute collection techniques that are equally or more effective, but only after they have demonstrated the effectiveness of the techniques and obtained written approval from the Secretary.

(2) *Late charge.* (i) For any health professions student loan made after June 30, 1969, but prior to October 22,

1985, the school may fix a charge for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment under section 722(c) of the Act for any failure to file timely and satisfactory evidence of the entitlement. The amount of the charge may not exceed \$1 for the first month or part of a month by which the installment or evidence is late and \$2 for each succeeding month or part of a month. The school may elect to add the amount of this charge to the principal amount of the loan as of the day after the day on which the installment or evidence was due, or to make the amount of the charge payable to the school no later than the due date of the next installment following receipt of the notice of the charge by the borrower.

(ii) For any health professions student loan made on or after October 22, 1985, the school shall assess a charge for failure of the borrower to pay all or any part of an installment when the loan is more than 60 days past due and, in the case of a borrower who is entitled to deferment under section 722(c) of the Act, for any failure to file satisfactory evidence of the entitlement within 60 days of the date payment would otherwise be due. No charge may be made if the loan is less than 61 days past due. The amount of this charge may not exceed an amount equal to 6 percent of the amount due at the time the charge is calculated. The school may elect to add the amount of this charge to the principal amount of the loan as of the day on which the charge is calculated, or to make the amount of the charge payable to the school no later than the due date of the next installment following receipt of the notice of the charge by the borrower.

(3) With respect to any health professions student loan made after June 30, 1969, the school may require the borrower to make payments of at least \$15 per month on all outstanding health professions student loans during the repayment period.

(4) A school must, on an annual basis, review and assess the collectibility of any loan more than 3 years past due. If the school determines that the prospects of future collection are promising

enough to justify periodic review of the debt, and neither the statute of limitations nor the 10-year repayment period has expired, the school may retain the account for continued collections, provided that it makes an attempt at least semi-annually to collect from the borrower. When the due diligence procedures required by paragraph (b)(1) of this section have been exhausted, the school is responsible for determining the collection methods it will use for the semi-annual collection effort required on these loans. If the school determines that the prospects of future collection are not promising, or when the statute of limitations or the 10-year repayment period has expired, the loan must be considered uncollectible. A school may determine a loan to be uncollectible sooner than 3 years past due when it has evidence that the loan cannot be collected, but in no case should a school consider a loan as uncollectible if it has not been in default for at least 120 days. A school is not subject to the requirements in paragraphs (b)(4) (i) and (iii) of this section for loans that became uncollectible, as determined by the school, before August 1, 1985.

(i) A school must request permission to write off an uncollectible loan within 30 days of the determination that it is uncollectible or reimburse the fund in the full amount of the loan, pursuant to § 57.210(b)(4)(iii). The 30-day period for submitting the loan for write-off review begins on the date that the determination of uncollectibility is made, in accordance with paragraph (b)(4) of this section. In any instance where the Secretary determines that a school has failed to exercise due diligence in the collection of a loan, in accordance with the applicable regulatory requirements, the school will be required to place in the fund the full amount of principal, interest, and penalty charges that remains uncollected on the loan. Reimbursement must be made by the following June 30 or December 31, whichever is sooner, except that in no case will a school be required to reimburse the fund in less than 30 days following the Secretary's disapproval of the request for write-off approval.

(ii) If the Secretary determines that a school has exercised due diligence in the collection of a loan, in accordance with the applicable regulatory requirements, or if the school determines that the loan was uncollectible prior to August 1, 1985, the school will be permitted to reduce its accounts receivable for the HPSSL fund by the full amount of principal, interest, and penalty charges that remains uncollected on that loan and will not be required to return the Federal share of the loss to the Secretary.

(iii) If a school does not request permission to write off an uncollectible loan within the required timeframe, it must reimburse the fund for the full amount of principal, interest, and penalty charges that remains uncollected on that loan. This reimbursement must be made by the following June 30 or December 31, whichever is sooner, except that in no case will a school be required to reimburse the fund in less than 30 days following its determination that a loan is uncollectible.

(iv) Failure to comply with the requirement of this section will subject a school to the noncompliance provisions of § 57.218 and the Department's Claims Collection regulations (45 CFR part 30), as appropriate.

(5) *Disclosure of taxpayer identity information.* Upon written request by the Secretary, the Secretary of the Internal Revenue Service (IRS) may disclose the address of any taxpayer who has defaulted on a health professions student loan, for use only by officers, employees, or agents of the Department, to locate the defaulted borrower to collect the loan. Any such mailing address may be disclosed by the Secretary to any school from which the defaulted borrower received a health professions student loan, for use only by officers, employees, or agents of the school whose duties relate to the collection of health professions student loan funds, to locate the defaulted borrower to collect the loan. Any school which requests and obtains this address information must comply with the requirements of the Secretary and the IRS re-

garding the safeguarding and proper handling of this information.

(Approved by the Office of Management and Budget under control number 0915-0047)

[44 FR 29055, May 18, 1979, as amended at 48 FR 25069, June 3, 1983; 49 FR 38112, Sept. 27, 1984; 50 FR 34420, Aug. 23, 1985; 52 FR 20988, June 3, 1987; 53 FR 6092, Feb. 29, 1988; 56 FR 19293, Apr. 26, 1991; 56 FR 40726, Aug. 15, 1991; 57 FR 45734, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§ 57.211 Cancellation of health professions students loans for disability or death.

(a) *Permanent and total disability.* The Secretary will cancel a student borrower's indebtedness in accordance with section 722(d) of the Act if the borrower is found to be permanently and totally disabled on recommendation of the school and as supported by whatever medical certification the Secretary may require. A borrower is totally and permanently disabled if he or she is unable to engage in any substantial gainful activity because of a medically determinable impairment, which the Secretary expects to continue for a long time or to result in death.

(b) *Death.* The Secretary will cancel a student borrower's indebtedness in accordance with section 722(d) of the Act upon the death of the borrower. The school to which the borrower was indebted must secure a certification of death or whatever official proof is conclusive under State law.

(Approved by the Office of Management and Budget under control number 0915-0047)

[44 FR 29055, May 18, 1979, as amended at 56 FR 19293, Apr. 26, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.212 [Reserved]

§ 57.213 Continuation of provisions for cancellation of loans made prior to November 18, 1971.

Individuals who received health professions student loans as students of medicine, osteopathic medicine, dentistry or optometry prior to November 18, 1971, may still receive cancellation of these loans for practicing in a shortage area or for practicing in a rural shortage area characterized by low family income. The regulations set forth in 42 CFR 57.215(b) (1976), as

§ 57.213a

adopted on February 7, 1974 remain applicable to cancellation on this basis. The provisions can be found at 39 FR 4774 (February 7, 1974) and a copy can be obtained by writing to the Division of Student Assistance, Bureau of Health Professions, Room 8-34, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

[49 FR 38112, Sept. 27, 1984, as amended at 56 FR 19294, Apr. 26, 1991]

§ 57.213a Loan cancellation reimbursement.

(a) For loans made prior to October 22, 1985, in the event that insufficient funds are available to the Secretary in any fiscal year to enable him or her to pay to all schools their proportionate shares of all loans and interest canceled under this subpart for practice in a shortage area, death, or disability:

(1) Each school will be paid an amount bearing the same ratio to the total of the funds available for that purpose as the principal of loans canceled by that school in that fiscal year bears to the total principal of loans canceled by all schools in that year; and

(2) Any additional amounts to which a school is entitled will be paid by the Secretary at the time of distribution of the assets of the school's Fund under section 728 of the Act.

(b) For loans made on or after October 22, 1985, a school may assess the borrower a charge to insure against the loss of the institutional share of a loan canceled due to the borrower's death or permanent and total disability. The school must develop annually a rate which reflects its cancellation experience. This charge shall not exceed .6 percent of the loan amount. Funds collected under this provision must be maintained by the school in an insured, interest-bearing account (with any earned interest credited to this insurance fund), and used only to reimburse the school for the institutional share of any HPSL loan made on or after October 22, 1985, that is canceled due to the borrower's death or permanent and total disability. A school is not required to establish a separate bank ac-

42 CFR Ch. I (10-1-11 Edition)

count, but is required to maintain separate accountability.

[53 FR 46549, Nov. 17, 1988, as amended at 56 FR 19294, Apr. 26, 1991; 57 FR 45734, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§ 57.214 Repayment of loans made after November 17, 1971, for failure to complete a program of study.

In the event that the Secretary undertakes to repay educational loans under section 722(k) of the Act, he or she will use the following criteria to make a determination as to each applicant's eligibility:

(a) An applicant will be considered to have failed to complete the course of study leading to the first professional degree for which an eligible education loan was made upon certification by a health professions school that the individual ceased to be enrolled in the school subsequent to November 17, 1971;

(b) An applicant will be considered to be in exceptionally needy circumstances if, upon comparison of the income and other financial resources of the applicant with his or her expenses and financial obligations, the Secretary determines that repayment of the loan would constitute a serious economic burden on the applicant. In making this determination, the Secretary will take into consideration the applicant's net financial assets, his or her potential earning capacity, and the relationship of the income available to the applicant to the low-income levels published annually by the Secretary under paragraph (c) of this section;

(c) An applicant will be considered to be from a low-income family if the applicant 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 this program, and the family has no substantial net financial assets. Income levels as adjusted will be published annually by the Secretary in the FEDERAL REGISTER.

(d) An applicant will be considered to be from a disadvantaged family if the individual comes from a family in which the annual income minus unusual expenses which contribute to the

economic burdens borne by the family does not exceed the low-income levels published by the Secretary under paragraph (c) of this section and the family has no substantial net financial assets;

(e) An applicant will be considered as not having resumed his or her health professions studies within two years following the date the individual ceased to be a student upon a certification so stating from the applicant; and

(f) An applicant will be considered as not reasonably expected to resume his or her health professions studies within two years following the date upon which he or she terminated these studies, based upon consideration of the reasons for the applicant's failure to complete these studies, taking into account such factors as academic, medical, or financial difficulties.

The Secretary will only repay education loans made subsequent to November 17, 1971.

[44 FR 29055, May 18, 1979, as amended at 61 FR 6123, Feb. 16, 1996; 61 FR 9532, Mar. 8, 1996]

§ 57.215 Records, reports, inspection, and audit.

(a) Each Federal capital contribution and Federal capital loan is subject to the condition that the school must maintain those records and file with the Secretary those reports relating to the operation of its health professions student loan funds as the Secretary may find necessary to carry out the purposes of the Act and these regulations. A school must submit required reports to the Secretary within 45 days of the close of the reporting period.

(1) A school which fails to submit a required report for its Federal capital contribution fund within 45 days of the close of the reporting period:

(i) Shall be prohibited from receiving new Federal capital contributions;

(ii) Must place the revolving fund and all subsequent collections in an insured interest-bearing account; and

(iii) May make no loan disbursements.

The above restrictions apply until the Secretary determines that the school is in compliance with the reporting requirement.

(2) A school that fails to submit a complete report within 6 months of the

close of the reporting period will be subject to termination. The Secretary will provide the school with a written notice specifying his or her intention to terminate the school's participation in the program and stating that the school may request, within 30 days of the receipt of this notice, a formal hearing. If the school requests a hearing, it must within 90 days of the receipt of the notice, submit material, factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely (i.e., fails to meet the 30-day requirement);

(ii) The school does not provide a statement of material, factual issues in dispute within the 90-day required period; or

(iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the school setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing, termination is still determined to be necessary, the school will be terminated from participation in the program and will be required to return the Federal share of the revolving fund to the Department. A school terminated for failure to submit a complete report within 6 months of the close of the reporting period must continue to pursue collections and may re-apply for participation in the program once it has submitted the overdue report.

(3) The school must also comply with the requirements of 45 CFR part 74 and section 798(e) of the Act concerning recordkeeping, audit, and inspection.

(b) The following student records must be retained by the school for 5 years after an individual student ceases to be a full-time student:

(1) Approved student applications for health professions student loans;

(2) Documentation of the financial need of applicants; and

(3) Copy of financial aid transcript(s).

§57.216

42 CFR Ch. I (10–1–11 Edition)

(c) The following repayment records for each individual borrower must be retained for at least 5 years from the date of retirement of a loan:

- (1) The amount and date of each loan;
- (2) The amount and date of each payment or cancellation;
- (3) Records of periods of deferment;
- (4) Date, nature and result of each contact with the borrower or proper endorser in the collection of an overdue loan;
- (5) Copies of all correspondence to or from the borrower and endorser;
- (6) Copies of all correspondence with collection agents related to the individual borrower;
- (7) Copies of all correspondence with a credit bureau related to an individual borrower; and
- (8) Copies of all correspondence relating to uncollectible loans which have been written off by the Federal Government or repaid by the school.

(d) The school must also retain other records as the Secretary may prescribe. In all cases where questions have arisen as a result of a Federal audit, the records must be retained until resolution of all questions.

(e) Institutional officials who have information which indicates the potential or actual commission of fraud or other offenses against the United States, involving these loan funds, should promptly provide this information to the appropriate Regional Office of Inspector General for Investigations.

(Approved by the Office of Management and Budget under control number 0915–0047)

[48 FR 25070, June 3, 1983, as amended at 50 FR 34421, Aug. 23, 1985; 53 FR 46549, Nov. 17, 1988; 56 FR 19294, Apr. 26, 1991; 57 FR 45734, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§57.216 What additional Department regulations apply to schools?

(a) Participating schools are advised that in addition to complying with the terms and conditions of these regulations, several other regulations apply under this subpart. These include, but are not limited to:

- 45 CFR part 76—Governmentwide Debarment and Suspension (nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance

through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in Health and Human Services programs or activities receiving Federal financial assistance

45 CFR part 93—New Restrictions on Lobbying

(b) The recipient may not discriminate on the basis of religion in the admission of individuals to its training programs.

[44 FR 29055, May 18, 1979, as amended at 56 FR 19294, Apr. 26, 1991; 57 FR 45734, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§57.216a Performance standard.

On June 30, 1984, and on each June 30 thereafter, except as provided in paragraph (b) of this section, each school must have a default rate (as calculated under paragraph (a) of this section) of not more than 5 percent.

(a) The default rate for each school shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of the school bears to the matured loans of the school. For this purpose:

(1) The term *defaulted principal amount outstanding* means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or canceled) on loans in default for more than 120 days; and

(2) The term *matured loans* means the total principal amount of all loans made by a school under this subpart minus the total principal amount of loans made by the school to students who are:

- (i) Enrolled in a full-time course of study at the school; or
- (ii) In their grace period.

(b) Any school that has a default rate greater than 5 percent on June 30 of any year will be required to:

(1) Reduce its default rate by 50 percent (or a school with a default rate below 10 percent must reduce its rate to 5 percent) by the close of the following 6-month period; and

(2) By the end of each succeeding 6-month period, reduce its default rate to 50 percent of the required rate for the previous 6-month period, until it reaches 5 percent.

(c) Any school subject to the provisions of paragraph (b) of this section which fails to comply with those requirements will receive no new HPSL funds and will be required to:

(1) Place the revolving fund monies and all subsequent collections into an insured interest-bearing account;

(2) Make no loan disbursements; and

(3) By the end of the succeeding 6-month period, reduce its default rate to 50 percent of the rate it failed to achieve under paragraph (b) of this section, or 5 percent. A school that meets this requirement will be permitted to resume the use of its health professions student loan funds, but must continue to comply with the requirements of paragraph (b)(2) of this section if its default rate is still greater than 5 percent.

(d) Any school subject to the provisions of paragraph (c)(3) of this section which fails to comply with those requirements will be subject to termination. The Secretary will provide the school with a written notice specifying his or her intention to terminate the school's participation in the program and stating that the school may request, within 30 days of the receipt of this notice, a formal hearing. If the school requests a hearing, it must within 90 days of the receipt of the notice, submit material, factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC metropolitan area. The Secretary will deny a hearing if:

(1) The request for a hearing is untimely (i.e., fails to meet the 30-day requirement);

(2) The school does not provide a statement of material, factual issues in dispute within the 90-day required period; or

(3) The statement of factual issues in dispute is frivolous or inconsequential. In the event that the Secretary denies a hearing, the Secretary will send a written denial to the school setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing, termination is still determined to be necessary, the school will be terminated from participation in the program and will be required to return the Federal share of the revolving fund to the Department. A school terminated for failure to comply with the provisions of paragraph (c)(3) of this section must continue to pursue collections and may reapply for participation in the program only when it has attained a default rate of 5 percent or less.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34423, Aug. 23, 1985, as amended at 52 FR 20988, June 3, 1987; 53 FR 46550, Nov. 17, 1988; 56 FR 19294, Apr. 26, 1991]

§ 57.217 Additional conditions.

The Secretary may with respect to any agreement entered into with any school under § 57.205, impose additional conditions prior to or at the time of any award when in his or her judgment these conditions are necessary to assure or protect the advancement of the purposes of the agreement, the interest of the public health, or the conservation of funds awarded.

§ 57.218 Noncompliance.

Wherever the Secretary finds that a participating school has failed to comply with the applicable provisions of the Act or the regulations of this subpart, he or she may, on reasonable notice to the school, withhold further payment of Federal capital contributions, and take such other action, including the termination of any agreement, as he or she finds necessary to enforce the Act and regulations. In this case no further expenditures shall be made from the health professions student loan fund or funds involved until the Secretary determines that there is no longer any failure of compliance.

Subpart D—Nursing Student Loans

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 835–842 of the Public Health Service Act, 77 Stat. 913–916, as amended by 99 Stat. 397–400, 536–537, and 102 Stat. 3160–3161 (42 U.S.C. 297 a–i).

SOURCE: 50 FR 34434, Aug. 23, 1985, unless otherwise noted.

§ 57.301 Applicability.

The regulations in this subpart apply to the Federal capital contributions made by the Secretary to public or other nonprofit schools of nursing for the establishment of nursing student loan funds and to loans made to students from these funds.

§ 57.302 Definitions.

As used in this subpart:

Academic year means the traditional, approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be of 9 months' duration.

Act means the Public Health Service Act, as amended.

Community health center means an entity as defined under section 330(a) of the Public Health Service Act, and in regulations at 42 CFR 51c.102(c).

Date upon which a student ceases to be a full-time or half-time student means the first day of the month which is nearest to the date upon which an individual ceases to be a full-time or half-time student, as defined in this section.

Default means the failure of a borrower of a loan made under this subpart to make an installment payment when due, or comply with any other term of the promissory note for such loan, except that a loan made under this subpart shall not be considered to be in default if the loan is discharged in bankruptcy, the borrower's repayment schedule has been renegotiated and the borrower is complying with the renegotiated schedule, or the loan is in forbearance.

Federal capital loan means a loan made by the Secretary to a school under section 827(a) of the Act, as in ef-

fect prior to July 29, 1975, the proceeds of which are to be returned to the Secretary.

Full-time student means a student who is enrolled in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a diploma in nursing, an associate degree in nursing or an equivalent degree, a baccalaureate degree in nursing or an equivalent degree, or a graduate degree in nursing.

Good standing means the eligibility of a student to continue in attendance at the school where he or she is enrolled as a student in accordance with the school's standards and practices.

Grace period means the period of 9 months beginning on the date upon which a student ceases to be a full-time or half-time student at a school of nursing.

Half-time student means a student who is enrolled in a school and pursuing a course of study which constitutes at least one-half of a full-time academic workload but less than a full-time academic workload, as determined by the school, leading to a diploma in nursing, an associate degree in nursing or an equivalent degree, a baccalaureate degree in nursing or an equivalent degree, or a graduate degree in nursing.

Indian Health Service health center means a health care facility (whether operated directly by the Indian Health Service or operated by a tribal contractor or grantee under the Indian Self-Determination Act), which is physically separated from a hospital, and which provides one or more clinical treatment services, such as physician, dentist or nursing services, available at least 40 hours a week for outpatient care to persons of Indian or Alaska Native descent.

Institutional capital contribution means the money provided by a school, in an amount not less than one-ninth of the Federal capital contribution, and deposited in a nursing student loan fund.

Migrant health center means an entity as defined under section 329(a) of the Public Health Service Act, and in regulations at 42 CFR 56.102(g).

National of the United States means: (1) A citizen of the United States, or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States, as defined in the Immigration and Nationality Act, at 8 U.S.C. 1101(a)(22).

Native Hawaiian health center means an entity (as defined in section 8 of Public Law 100-579)—

(a) Which is organized under the laws of the State of Hawaii,

(b) Which provides or arranges for health care services through practitioners licensed by the State of Hawaii, where licensure requirements are applicable,

(c) Which is a public or private non-profit entity, and

(d) In which Native Hawaiian health practitioners significantly participate in the planning, management, monitoring, and evaluation of health services.

Nursing facility means a facility as defined in section 1919(a) of the Social Security Act (SSA) (for fiscal year (FY) 1991 and subsequent fiscal years), except for FYs 1989 and 1990, the term means a “skilled nursing facility,” as such term is defined in section 1861(j) of the SSA, and an “intermediate care facility,” as such term is defined in section 1905(c) of such Act.

Nursing student loan means the amount of money advanced to a student by a school from a nursing student loan fund under a properly executed promissory note.

Registered nurse means an individual who has been licensed by a State Board of Nursing to practice professional nursing in accordance with State licensing laws requiring as a minimum one of the degrees or diplomas specified in this section.

Rural health clinic means an entity as defined under section 1861(aa)(2) of the Social Security Act, and in regulations at 42 CFR 491.2.

School means a public or other non-profit school of nursing, as defined in section 853 of the Act.

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

State means, in addition to the several States, the District of Columbia,

the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, the Republic of Palau, the Republic of the Marshall Islands, and the Federated States of Micronesia.

[50 FR 34434, Aug. 23, 1985, as amended at 52 FR 10195, Mar. 30, 1987; 53 FR 46554, Nov. 17, 1988; 56 FR 13771, Apr. 4, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.303 Application by school.

(a) Each school seeking a Federal capital contribution must submit an application at the time and in the form and manner that the Secretary may require. The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the regulations of this subpart, and the terms and conditions of the award.

(b) Each application will be reviewed to determine eligibility and the reasonableness of the amount of Federal support requested. The Secretary may require the applicant to submit additional data for this purpose.

(c) An application will not be approved unless an agreement between the Secretary and the applicant school for a Federal capital contribution under section 835 of the Act is reached.

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 13771, Apr. 4, 1991; 57 FR 45735, Oct. 5, 1992]

§ 57.304 Payment of Federal capital contributions and reallocation of funds remitted to the Secretary.

(a) *Annual payment.* The Secretary will make payments at a time determined by him or her, to each school with which he or she has entered into an agreement under the Act.

(1) For any fiscal year for which “set-aside” funds are available, the Secretary will first make payments in the manner described in (a)(2) of this section of not less than \$1,000,000 of the amount of Federal funds determined by the Secretary at the time of payment to be available for making loans under this subpart. These funds will be paid to schools submitting an application for “set-aside” funds to be used only

for the purpose of making loans to individuals qualified to receive loans under this subpart who, on the date they receive the loan, have not been employed on a full-time basis or been enrolled in any educational institution on a full-time basis for at least 7 years. An individual may not receive a loan under this subparagraph that exceeds \$500 for any academic year.

(2) If the total of the amounts requested for any fiscal year by all schools for Federal capital contributions minus the amount received under paragraph (a)(1) of this section exceeds the amount of Federal funds determined by the Secretary at the time of payment to be available for this purpose, the payment to each school will be reduced to whichever is smaller: (i) The amount requested in the application, or (ii) an amount which bears the same ratio to the total amount of Federal funds determined by the Secretary at the time of payment to be available for that fiscal year for the Nursing Student Loan program as the number of full-time students estimated by the Secretary to be enrolled in that school bears to the estimated total number of full-time students in all participating schools during that year.

(3) Amounts remaining after these payments are made will be distributed in accordance with this paragraph among schools whose applications requested more than the amount paid to them, but with whatever adjustments that may be necessary to prevent the total paid to any school from exceeding the total requested by it.

(b) *Method of payment.* The payment of Federal capital contributions to a school will be paid in a manner that avoids unnecessary accumulations of money in any nursing student loan fund.

(c) *Reallocation of funds remitted to the Secretary.* (1) All funds from a student loan fund established under this subpart which are remitted to the Secretary in any fiscal year shall be available for allotment under this subpart, in the same fiscal year and the succeeding fiscal year, to eligible nursing schools. In making these allotments, the Secretary shall give priority to nursing schools which established a student loan fund under this subpart

after September 30, 1975. The Secretary will make payments to eligible schools at a time determined by him or her, according to the procedures indicated in paragraphs (c)(2) and (c)(3) of this section.

(2) *Eligible schools which established a nursing student loan fund after September 30, 1975.* The Secretary will make awards first to those eligible schools that established a nursing student loan fund after September 30, 1975. If the total of the amounts requested for any fiscal year by these schools exceeds the amount of funds determined by the Secretary at the time of payment to be available for this purpose, the payment to each school will be reduced to whichever is smaller:

(i) The amount requested in the application, or

(ii) An amount which bears the same ratio to the total amount of returned funds determined by the Secretary at the time of payment to be available for that fiscal year for the Nursing Student Loan program as the number of full-time students estimated by the Secretary to be enrolled in that school bears to the estimated total number of full-time students in these eligible schools during that year.

Amounts remaining after these payments are made will be distributed in accordance with this paragraph among schools whose applications requested more than the amount paid to them, with whatever adjustments may be necessary to prevent the total paid to any school from exceeding the total requested by it.

(3) *Eligible schools which established a nursing student loan fund prior to October 1, 1975.* If there are funds remaining after making awards as specified by paragraph (c)(2) of this section, the Secretary will make awards to eligible schools which established a nursing student loan fund prior to October 1, 1975. If the total of the amounts requested for any fiscal year by these schools exceeds the amount of funds determined by the Secretary at the time of payment to be available for this purpose, the payment to each school will be reduced to whichever is smaller:

(i) The amount requested in the application, or

(ii) An amount which bears the same ratio to the total amount of returned funds determined by the Secretary at the time of payment to be available for that fiscal year for the Nursing Student Loan program as the number of full-time students estimated by the Secretary to be enrolled in that school bears to the estimated total number of full-time students in these eligible schools during that year.

Amounts remaining after these payments are made will be distributed in accordance with this paragraph among schools whose applications requested more than the amount paid to them, with whatever adjustments may be necessary to prevent the total paid to any school from exceeding the total requested by it.

[50 FR 34434, Aug. 13, 1985, as amended at 53 FR 46554, Nov. 17, 1988]

§ 57.305 Nursing student loan funds.

(a) *Funds established with Federal capital contributions.* Any fund established by a school with Federal capital contributions will be accounted for separately from other funds, providing a clear audit trail for all transactions. At all times the fund must contain monies representing the institutional capital contribution. The school must at all times maintain all monies relating to the fund in one or more interest-bearing accounts or investment instruments which meet OMB requirements established for Federal monies held by third parties, except that if the school documents that the costs associated with the use of an interest-bearing account would exceed expected earnings, the school is not required to maintain these monies in an interest-bearing account. The school must place all earnings into the fund but may first deduct from total earnings any reasonable and customary charges incurred through the use of an interest-bearing account. An institution shall exercise the level of care required of a fiduciary with regard to these deposits and investments, and shall be responsible for reimbursing the fund for any losses that occur due to the use of investments that are not federally insured.

(1) The Federal capital contribution fund is to be used by the school only for:

(i) Nursing student loans to full-time or half-time students;

(ii) Capital distribution as provided in section 839 of the Act or as agreed to by the school and the Secretary; and

(iii) Costs of litigation, costs associated with membership in credit bureaus, and to the extent specifically approved by the Secretary, other collection costs that exceed the usual expenses incurred in the collection of nursing student loans.

(2) A school must review the balance in the fund on at least a semi-annual basis to determine whether the fund balance compared with projected levels of expenditures and collections exceeds its needs. A school in closing status must review the balance in the fund on a quarterly basis. Monies identified as in excess of the school's needs must be reported, and the Federal share returned to the Federal Government, by the due date of the required report which identifies the excess monies. The school's determination is subject to the review and approval of the Secretary.

(b) *Funds established with Federal capital loans.* (1) Each Federal capital loan is subject to the terms of the promissory note executed by an authorized official on behalf of the borrowing school.

(2) The Federal capital loans must be carried in a special account of the school, to be used by the school only for: (i) Repayments of principal and interest on Federal capital loans; and (ii) costs of litigation, costs associated with membership in credit bureaus, and, to the extent specifically approved by the Secretary, other collection costs that exceed the usual expenses incurred in the collection of nursing student loans.

(c) Failure to comply with the requirements of this section will subject a school to the noncompliance provisions of § 57.318 and the Department's Claims Collections regulations (45 CFR part 30), as appropriate.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 40734, Aug. 15, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.306 Eligibility and selection of nursing student loan applicants.

(a) *Determination of eligibility.* (1) Applicants are eligible for consideration for a nursing student loan if they are:

(i) Residents of the United States and either a citizen or national of the United States, an alien lawfully admitted for permanent residence in the United States, a citizen of the Commonwealth of the Northern Mariana Islands, a citizen of the Republic of Palau, a citizen of the Republic of the Marshall Islands, or a citizen of the Federated States of Micronesia;

(ii) Enrolled, or accepted for enrollment in the school as full-time or half-time students;

(iii) In need of the amount of the loan to pursue the course of study at the school; and

(iv) Capable, in the opinion of the school, of maintaining good standing in the course of study.

(2) An applicant who has previously attended an institution of higher education must submit a financial aid transcript which includes at least the following data:

(i) Applicant's name and social security number;

(ii) Amounts and sources of loans and grants previously received by the applicant for study at an institution of higher education;

(iii) Whether the applicant is in default on any of these loans, or owes a refund on any grants;

(iv) Certification from each institution previously attended by the applicant that the applicant has received no financial aid, if applicable; and

(v) From each institution previously attended, the signature of an official authorized by the institution to sign such transcripts on behalf of the institution.

(b) *Selection of nursing student loan applicants and determinations of need.* The school will select qualified applicants, make reasonable determinations of need, and determine the amount of student loans.

(1) In selecting nursing student loan applicants the school will give preference to licensed practical nurses, and to persons with exceptional financial need. For purposes of this preference, a student will be considered to dem-

onstrate exceptional financial need if the school determines that the student's resources, as described in paragraph (b)(2)(i) of this section, do not exceed one-half of the costs of attendance at the school. Summer earnings, educational loans, veterans (G.I.) benefits, earnings during the school year, and Aid to Families with Dependent Children (AFDC) will not be considered as resources in determining whether an applicant meets these criteria for exceptional financial need, but will be considered in determining the amount of funds a student may receive.

(2) In determining whether a student is in need of a nursing student loan to pursue a full-time or half-time course of study at the school, the school will take into consideration:

(i) The financial resources available to the student by using one of the national need analysis systems or any other procedure approved by the Secretary of Education in combination with other information which the school has regarding the student's financial status; and

(ii) The costs reasonably necessary for the student's attendance at the school, including any special needs and obligations which directly affect the student's financial ability to attend the school on a full-time or half-time basis. The school must document the criteria used for determining these costs.

(c) *Verification of loan information.* The school must verify, to the best of its ability, the information provided by the student on the loan application. To comply with this requirement, a school may require that a student provide, for example: Photocopies of the parents', student's, and spouse's Federal income tax forms with original signatures for the most recent tax year (or certification that no Federal income tax return was filed); tax returns that are certified as having been received by the Internal Revenue Service; or other documentation that the school considers necessary to help assure that information on the loan application is correct.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34434, Aug. 23, 1985, as amended at 53 FR 46554, Nov. 17, 1988; 56 FR 13771, Apr. 4, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.307 Maximum amount of nursing student loans.

The total of the nursing student loans made from the fund to any student for an academic year may not exceed \$2,500, except that for each of the final 2 academic years of the program, the total must not exceed \$4,000. The maximum amount loaned during a 12-month period to any student enrolled in a school which provides a course of study longer than the 9-month academic year may be proportionately increased. The total of all nursing student loans to any student must not exceed \$13,000.

[56 FR 13771, Apr. 4, 1991]

§ 57.308 Nursing student loan promissory note.

(a) *Promissory note form.* Each nursing student loan must be evidenced by a properly executed promissory note in a form approved by the Secretary. The school must safeguard the promissory note against fire, theft, and tampering.

(1) Each promissory note must state that the loan will bear interest on the unpaid balance computed only for periods during which repayment of the loan is required, at the rate of 5 percent per year.

(2) Each promissory note must contain an acceleration clause provided by the Secretary, which will permit the acceleration of delinquent loans at the school's option.

(3) A copy of each executed note must be supplied by the school to the student borrower.

(b) *Security.* A school must require security or endorsement if the borrower is a minor and if, under the applicable State law, the note signed by him or her would not create a binding obligation. The school may not require security or endorsement in any other circumstances.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 13771, Apr. 4, 1991; 57 FR 45735, Oct. 5, 1992]

§ 57.309 Payment of nursing student loans.

(a) Nursing student loans from any fund may be paid to or on behalf of stu-

dent borrowers in installments considered appropriate by the school except that a school may not pay to or on behalf of any borrower more during any given installment period (e.g., semester, term, or quarter) than the school determines the student needs for that period.

(b) No payment may be made from a fund to or on behalf of any student borrower if at the time of the payment the borrower is not a full-time or half-time student.

§ 57.310 Repayment and collection of nursing student loans.

(a) Each nursing student loan, including accrued interest, will be repayable in equal or graduated periodic installments in amounts calculated on the basis of a 10-year repayment period. Repayment of a loan must begin 9 months after the student ceases to be a full-time or half-time student, except that if a borrower reenters the same or another school as a full-time or half-time student within the 9-month period, the date upon which interest will accrue and the repayment period will begin will be determined by the date upon which the student last ceases to be a full-time or half-time student at that school.

(1) The following periods will be excluded from the 10-year repayment period: (i) All periods up to a total of 3 years of active duty performed by the borrower as a member of the Army, Navy, Air Force, Marine Corps, Coast Guard, National Oceanic and Atmospheric Administration Corps or the U.S. Public Health Service Commissioned Corps;

(ii) All periods up to a total of 3 years of service as a volunteer under the Peace Corps Act; and

(iii) All periods up to a total of 10 years during which the borrower is pursuing a full-time or half-time course of study at a school leading to a baccalaureate degree in nursing or an equivalent degree, or to a graduate degree in nursing, or is otherwise pursuing advanced professional training in nursing (or training to be a nurse anesthetist). For purposes of this paragraph, "otherwise pursuing advanced professional training in nursing" shall include full-time or half-time training, beyond the

first diploma or degree in nursing received by the particular borrower, of at least 1 academic year which will advance the borrower's knowledge of and strengthen his or her skills in the provision of nursing services.¹

(2) Subject to the provisions of paragraph (b)(3) of this section, a borrower must establish a repayment schedule with the school providing for payments not less often than quarterly. Any borrower whose repayment becomes more than 60 days past due must be placed on a monthly repayment schedule by the school. A borrower may at his or her option and without penalty, prepay all or part of the principal and accrued interest at any time.

(3) A school may grant forbearance whenever extraordinary circumstances such as unemployment, poor health or other personal problems temporarily affect the borrower's ability to make scheduled loan repayments.

(b) *Collection of nursing student loans.*

(1) Each school at which a fund is established must exercise due diligence in the collection of nursing student loans due the fund. In the exercise of due diligence, a school must follow procedures which are at least as extensive and effective as those used in the collection of other student loan accounts due the school, and must use the steps outlined below in accordance with collection practices which are generally accepted among institutions of higher education:

(i) Conduct and document an entrance interview (individually or in groups) with the borrower prior to disbursing NSL funds in any academic year. During the entrance interview the school must obtain documentation which indicates that the borrower is aware of the rights and responsibilities associated with NSL funds and personal information which would assist in locating the borrower if he or she

fails to keep the school informed of his or her current address. The requirement of this subparagraph may be met by correspondence if the school determines that a face-to-face meeting (individually or in groups) is impracticable.

(ii) Conduct and document an exit interview (individually or in groups) with the borrower. During the exit interview, the school must provide each borrower with information necessary to carry out the terms of repayment, remind the borrower of the rights and responsibilities associated with NSL funds, and update the personal information collected prior to disbursing NSL funds which would assist in locating the borrower if he or she fails to keep the school informed of his or her current address. If the borrower terminates studies without advance notice, the school must document attempts to inform the borrower of the substance of the exit interview and to secure exit interview information from the borrower by mail.

(iii) Notify the borrower in writing of the impending repayment obligation at least twice during the grace period;

(iv) Notify a borrower who is in deferment status in writing of the impending repayment obligation 1 to 3 months prior to the expiration of the approved period of deferment;

(v) Perform regular billing;

(vi) Follow up past due payments with a series of at least four documented and reasonably spaced attempts to contact the borrower, at least three of which must be in writing at not more than 30-day intervals, prior to the loan becoming 120 days past due, provided that the school has a current address for the borrower;

(vii) Perform address searches when necessary;

(viii) Use collection agents, which may include the use of an internal collection agent;

(ix) Institute legal proceedings against borrowers after all other attempts at collection have failed, unless the school determines, subject to the approval of the Secretary, that such litigation would not be cost-effective; and

¹Individuals who received nursing student loans prior to July 1, 1969, remain subject to the repayment provisions of 42 CFR 57.314(a)(3)(1976) as adopted on February 4, 1974. These provisions can be found at 39 FR 16473 (May 9, 1974), and a copy can be obtained by writing the Division of Student Assistance, Bureau of Health Professions, 5600 Fishers Lane, Parklawn Building, room 8-34, Rockville, MD 20857.

(x) Become a member of a credit bureau and notify the credit bureau of accounts past due by more than 120 days. In place of one or more of the procedures outlined above schools may substitute collection techniques that are equally or more effective, but only after they have demonstrated the effectiveness of the techniques and obtained written approval from the Secretary.

(2) *Late charge.* (i) For any nursing student loan made after June 30, 1969, but prior to October 1, 1985, the school may fix a charge for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment under section 836(b)(2) of the Act, or cancellation or repayment under section 836(b)(3) of the Act, for any failure to file timely and satisfactory evidence of the entitlement. The amount of the charge may not exceed \$1 for the first month or part of a month by which the installment or evidence is late and \$2 for each succeeding month or part of a month. The school may elect to add the amount of this charge to the principal amount of the loan as of the day after the day on which the installment or evidence was due, or to make the amount of the charge payable to the school no later than the due date of the next installment following receipt of the notice of the charge by the borrower.

(ii) For any nursing student loan made on or after October 1, 1985, the school shall assess a charge for failure of the borrower to pay all or any part of an installment when the loan is more than 60 days past due and, in the case of a borrower who is entitled to deferment under section 836(b)(2) of the Act, for any failure to file satisfactory evidence of the entitlement within 60 days of the date payment would otherwise be due. No charge may be made if the loan is less than 61 days past due. The amount of this charge may not exceed an amount equal to 6 percent of the amount due at the time the charge is calculated. The school may elect to add the amount of this charge to the principal amount of the loan as of the day on which the charge is calculated, or to make the amount of the charge payable to the school no later than the due date of the next installment fol-

lowing receipt of the notice of the charge by the borrower.

(3) With respect to any nursing student loan made after June 30, 1969, the school may require the borrower to make payments of at least \$15 per month on all outstanding nursing student loans during the repayment period.

(4) A school must, on an annual basis, review and assess the collectibility of any loan more than 3 years past due. If the school determines that the prospects of future collection are promising enough to justify periodic review of the debt, and neither the statute of limitations nor the 10-year repayment period has expired, the school may retain the account for continued collections, provided that it makes an attempt at least semi-annually to collect from the borrower. When the due diligence procedures required by paragraph (b)(1) of this section have been exhausted, the school is responsible for determining the collection methods it will use for the semi-annual collection effort required on these loans. If the school determines that the prospects of future collection are not promising, or when the statute of limitations or the 10-year repayment period has expired, the loan must be considered uncollectible. A school may determine a loan to be uncollectible sooner than 3 years past due when it has evidence that the loan cannot be collected, but in no case should a school consider a loan as uncollectible if it has not been in default for at least 120 days. A school is not subject to the requirements in paragraphs (b)(4) (i) and (iii) of this section for loans that became uncollectible, as determined by the school, before January 1, 1983.

(i) A school must request permission to write off an uncollectible loan within 30 days of the determination that it is uncollectible or reimburse the fund in the full amount of the loan, pursuant to § 57.310(b)(4)(iii). The 30-day period for submitting the loan for write-off review begins on the date that the determination of uncollectibility is made, in accordance with paragraph (b)(4) of this section. In any instance where the Secretary determines that a

§57.311

school has failed to exercise due diligence in the collection of a loan, in accordance with the applicable regulatory requirements, the school will be required to place in the fund the full amount of principal, interest, and penalty charges that remains uncollected on the loan. Reimbursement must be made by the following June 30 or December 31, whichever is sooner, except that in no case will a school be required to reimburse the fund in less than 30 days following the Secretary's disapproval of the request for write-off approval.

(ii) If the Secretary determines that a school has exercised due diligence in the collection of a loan, in accordance with the applicable regulatory requirements, or if the school determines that the loan was uncollectible prior to January 1, 1983, the school will be permitted to reduce its accounts receivable for the NSL fund by the full amount of principal, interest, and penalty charges that remains uncollected on that loan and will not be required to return the Federal share of the loss to the Secretary.

(iii) If a school does not request permission to write off an uncollectible loan within the required timeframe, it must reimburse the fund for the full amount of principal, interest, and penalty charges that remains uncollected on that loan. This reimbursement must be made by the following June 30 or December 31, whichever is sooner, except that in no case will a school be required to reimburse the fund in less than 30 days following its determination that a loan is uncollectible.

(iv) Failure to comply with the requirements of this section will subject a school to the noncompliance provisions of §57.318 and the Department's Claims Collection regulations (45 CFR part 30), as appropriate.

(5) *Disclosure of taxpayer identity information.* Upon written request by the Secretary, the Secretary of the Internal Revenue Service (IRS) may disclose the address of any taxpayer who has defaulted on a nursing student loan, for use only by officers, employees, or agents of the Department, to locate the defaulted borrower to collect the loan. Any such mailing address may be disclosed by the Secretary to any school

42 CFR Ch. I (10–1–11 Edition)

from which the defaulted borrower received a nursing student loan, for use only by officers, employees, or agents of the school whose duties relate to the collection of nursing student loan funds, to locate the defaulted borrower to collect the loan. Any school which requests and obtains such address information must comply with the requirements of the Secretary and the IRS regarding the safeguarding and proper handling of this information.

(Approved by the Office of Management and Budget under control number 0915–0047)

[50 FR 34434, Aug. 23, 1985, as amended at 52 FR 10195, Mar. 30, 1987; 56 FR 13771, Apr. 4, 1991; 56 FR 40734, Aug. 15, 1991; 57 FR 45735, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§57.311 Cancellation of nursing student loans for disability or death.

(a) *Permanent and total disability.* The Secretary will cancel a borrower's indebtedness in accordance with section 836(b)(4) of the Act if the borrower is found to be permanently and totally disabled on recommendation of the school and as supported by whatever medical certification the Secretary may require. A borrower is totally and permanently disabled if he or she is unable to engage in any substantial gainful activity because of a medically determinable impairment, which the Secretary expects to continue for a long time or to result in death.

(b) *Death.* The Secretary will cancel a borrower's indebtedness in accordance with section 836(b)(4) of the Act upon the death of the borrower. The school to which the borrower was indebted must secure a certification of death or whatever official proof is conclusive under State law.

(Approved by the Office of Management and Budget under control number 0915–0047)

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 13772, Apr. 4, 1991]

§57.312 Repayment of loans for service in a shortage area.

(a) *Service in a shortage area.* Subject to the availability of funds, a person who:

(1) Has obtained a degree as specified in section 846(a)(1) of the Act;

(2) Has obtained one or more nursing student loans or any other loans necessary for costs (including tuition, books, fees, equipment, living and other expenses which the Secretary determines were necessary) of attending a school of nursing; and

(3) Enters into an agreement with the Secretary to serve as a full-time registered nurse for a period of not less than 2 years in an Indian Health Service health center, a Native Hawaiian health center, a public hospital, a migrant health center, a community health center, a nursing facility, a rural health clinic, or in a health facility determined by the Secretary to have a critical shortage of nurses, will have a portion of these loans repaid by the Secretary in accordance with paragraph (c) of this section. Prior to entering an agreement for repayment of loans, other than nursing student loans, the Secretary will require that satisfactory evidence be provided of the existence and reasonableness of the education loans (*i.e.*, a copy of the written loan agreement establishing the loan).

(b) When entering into agreements under paragraph (a) of this section, the Secretary shall give priority to:

(1) Applicants with the greatest financial need; and

(2) Applicants that, with respect to health facilities described in paragraph (a)(3) of this section, agree to serve in such facilities located in geographic areas with a shortage of and need for nurses, as determined by the Secretary.

(3) In addition to the priorities under paragraphs (b) (1) and (2) of this section, should specific needs warrant, the Secretary may establish additional preferences which will be announced from time to time in the FEDERAL REGISTER.

(c) *Repayment.* Loan repayment will be made by the Secretary to persons who meet the conditions set forth in paragraph (a) of this section. Payment will be as follows:

(1) Upon completion by the borrower of the first year of service as specified in the agreement, the Secretary will pay 30 percent of the principal of, and the interest on, each loan which was

unpaid as of the date the borrower began his or her service;

(2) Upon completion by the borrower of the second year of service, the Secretary will pay another 30 percent of the principal of, and the interest on, each loan which was unpaid as of the date the borrower began his or her service;

(3) Upon completion by the borrower of a third year of service, the Secretary will pay another 25 percent of the principal of, and the interest on, each loan which was unpaid as of the date the borrower began his or her service; and

(4) No more than 85 percent of the principal of any loan will be paid under this section.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 13772, Apr. 4, 1991; 61 FR 6123, Feb. 16, 1996]

§ 57.313 Loan cancellation for full-time employment as a registered nurse.

(a) *For loans made after November 18, 1971, and before September 29, 1979.* A person who: (1) Received one or more nursing student loans after November 18, 1971, and before September 29, 1979; (2) is in compliance with the requirements of title VIII of the Act and these regulations; and (3) engages in full-time employment as a registered nurse (including teaching in any of the fields of nurse training or service as an administrator, supervisor, or consultant in any of the fields of nursing) in any public or nonprofit private agency, institution, or organization (including neighborhood health centers) is entitled to have a portion of these nursing student loans canceled as follows: 15 percent of the total amount of the loans plus accrued interest on the loan which is unpaid on the first day of his or her service, for each of the first, second, and third year of service; and 20 percent of the total amount of the loan plus accrued interest on the loan for each complete fourth and fifth year of service thereafter, up to 85 percent of the total of the loans, plus accrued interest.

(b) *Continuation of provisions for cancellation of loans made prior to November 18, 1971.* A person who received one or more nursing student loans prior to

§ 57.313a

42 CFR Ch. I (10–1–11 Edition)

November 18, 1971, may still receive cancellation of these loans for service under section 836(h) of the Act. The regulations set forth in 42 CFR 57.316 (a) and (b)(6) (1976), as adopted on February 4, 1974, remain applicable to cancellation on this basis. The provisions can be found at 39 FR 16473 (May 9, 1974) and a copy can be obtained by writing to the Division of Student Assistance, Bureau of Health Professions, Room 8-34, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(c) The determination of whether a person is entitled to have any portion of his or her nursing student loan canceled for full-time employment as a registered nurse will be made by the institution to whose fund his or her loan is payable, upon receipt and evaluation of an application for cancellation from that person.

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 13772, Apr. 4, 1991; 57 FR 45735, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§ 57.313a Loan cancellation reimbursement.

In the event that insufficient funds are available to the Secretary in any fiscal year to enable him or her to pay to all schools their proportionate shares of all loans and interest canceled under this subpart for full-time employment as a nurse, death, or disability:

(a) Each school will be paid an amount bearing the same ratio to the total of the funds available for that purpose as the principal of loans canceled by that school in that fiscal year bears to the total principal of loans canceled by all schools in that year; and

(b) Any additional amounts to which a school is entitled will be paid by the Secretary at the time of distribution of the assets of the school's fund under section 839 of the Act.

§ 57.314 Repayment of loans made after November 17, 1971, for failure to complete a program of study.²

In the event that the Secretary undertakes to repay educational loans

under section 836(i) of the Act, he or she will use the following criteria to make a determination as to each applicant's eligibility:

(a) An applicant will be considered to have failed to complete the course of study in nursing for which an eligible education loan was made upon certification by a school of nursing that the individual ceased to be enrolled in the school subsequent to November 17, 1971;

(b) An applicant will be considered to be in exceptionally needy circumstances if, upon comparison of the income and other financial resources of the applicant with his or her expenses and financial obligations, the Secretary determines that repayment of the loan would constitute a serious economic burden on the applicant. In making this determination, the Secretary will take into consideration the applicant's net financial assets, his or her potential earning capacity, and the relationship of the income available to the applicant to the low-income levels published annually by the Secretary in the FEDERAL REGISTER;

(c) An applicant will be considered as not having resumed his or her nursing studies within 2 years following the date the individual ceased to be a student upon certification so stating from the applicant; and

(d) An applicant will be considered as not reasonably expected to resume his or her nursing studies within 2 years following the date upon which he or she terminated these studies, based upon consideration of the reasons for the applicant's failure to complete these studies, taking into account such factors as academic, medical, or financial difficulties. The Secretary will only repay education loans made after November 17, 1971.

[50 FR 34434, Aug. 23, 1985, as amended at 56 FR 13772, Apr. 4, 1991; 57 FR 45735, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§ 57.315 Records, reports, inspection, and audit.

(a) *Records and reports.* (1) Each Federal capital contribution and Federal capital loan is subject to the condition that the school must maintain those

²Effective November 26, 1984, the Secretary stopped accepting applications under § 57.314

because Federal funds are not available for this provision.

records and file with the Secretary those reports relating to the operation of its nursing student loan funds as the Secretary may find necessary to carry out the purposes of the Act and these regulations. A school must submit required reports to the Secretary within 45 days of the close of the reporting period.

(i) A school which fails to submit a required report for its Federal capital contribution fund within 45 days of the close of the reporting period:

(A) Shall be prohibited from receiving new Federal capital contributions;

(B) Must place the revolving fund and all subsequent collections in an insured interest-bearing account; and

(C) May make no loan disbursements.

The above restrictions apply until the Secretary determines that the school is in compliance with the reporting requirement.

(ii) A school that fails to submit a complete report within 6 months of the close of the reporting period will be subject to termination. The Secretary will provide the school with a written notice specifying his or her intention to terminate the school's participation in the program and stating that the school may request, within 30 days of the receipt of this notice, a formal hearing. If the school requests a hearing, it must within 90 days of the receipt of the notice, submit material, factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC metropolitan area. The Secretary will deny a hearing if:

(A) The request for a hearing is untimely (ie., fails to meet the 30-day requirement);

(B) The school does not provide a statement of material, factual issues in dispute within the 90-day required period; or

(C) The statement of factual issues in dispute is frivolous or inconsequential. In the event that the Secretary denies a hearing, the Secretary will send a written denial to the school setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing, termination is still determined to be necessary, the school will

be terminated from participation in the program and will be required to return the Federal share of the revolving fund to the Department. A school terminated for failure to submit a complete report within 6 months of the close of the reporting period must continue to pursue collections and may re-apply for participation in the program once it has submitted the overdue report.

(2) The following student records must be retained by the school for 5 years after the individual student ceases to be a full-time or half-time student:

(i) Approved student applications for nursing student loans;

(ii) Documentation of the financial need of applicants; and

(iii) Copy of financial aid transcripts.

(3) The following repayment records for each individual borrower must be retained for at least 5 years from the date of retirement of a loan:

(i) The amount and date of each loan;

(ii) The amount and date of each payment or cancellation;

(iii) Records of periods of deferment;

(iv) Date, nature, and result of each contract with the borrower or proper endorser in the collection of an overdue loan;

(v) Copies of all correspondence to or from the borrower and endorser;

(vi) Copies of all correspondence with a collection agency related to the individual borrower;

(vii) Copies of all correspondence with a credit bureau related to an individual borrower; and

(viii) Copies of all correspondence relating to uncollectible loans which have been written off by the Federal Government or repaid by the school.

(4) The school must also retain other records as the Secretary may prescribe. In all cases where questions have arisen as a result of a Federal audit, the records must be retained until resolution of all questions.

(b) *Inspection and audit.* (1) Any application for a Federal capital contribution will constitute the consent of the applicant school to inspection and fiscal audit, by the Secretary and the Comptroller General of the United States or any of their duly authorized representatives, of the fiscal and other

records of the applicant school which relate to the Federal capital contribution or Federal capital loan.

(2) The school must comply with the audit requirements of the Department of Health and Human Services' Administration of Grants regulations which are set forth in 45 CFR part 74.

(c) Institutional officials who have information which indicates the potential or actual commission of fraud or other offenses against the United States, involving these loan funds, should promptly provide this information to the appropriate Regional Office of Inspector General for Investigations.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34434, Aug. 23, 1985, as amended at 53 FR 46555, Nov. 17, 1988; 56 FR 13772, Apr. 4, 1991; 57 FR 45735, Oct. 1, 1992]

§57.316 What additional Department regulations apply to schools?

Participating schools are advised that in addition to complying with the terms and conditions of these regulations, several other regulations apply under this subpart. These include, but are not limited to:

45 CFR part 76—Governmentwide Debarment and Suspension (nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Service Act

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in Health and Human Services programs or activities receiving Federal financial assistance

45 CFR part 93—New Restrictions on Lobbying

[56 FR 13772, Apr. 4, 1991, as amended at 57 FR 45735, Oct. 5, 1992; 61 FR 6123, Feb. 16, 1996]

§57.316a Performance standard.

On June 30, 1986, and on each June 30 thereafter, except as provided in paragraph (b) of this section, each school must have a default rate (as calculated under paragraph (a) of this section) of not more than 5 percent.

(a) The default rate for each school shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of the school bears to the matured loans of the school. For this purpose:

(1) The term “defaulted principal amount outstanding” means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or canceled) on loans in default for more than 120 days; and

(2) The term “matured loans” means the total principal amount of all loans made by a school under this subpart minus the total principal amount of loans made by the school to students who are:

(i) Enrolled in a full-time or half-time course of study at the school; or

(ii) In their grace period.

(b) Any school that has a default rate greater than 5 percent on June 30, 1986, or on June 30 of any year thereafter will be required to:

(1) Reduce its default rate by 50 percent (or a school with a default rate below 10 percent must reduce its rate to 5 percent) by the close of the following 6-month period; and

(2) By the end of each succeeding 6-month period, reduce its default rate to 50 percent of the required rate for the previous 6-month period, until it reaches 5 percent.

(c) Any school subject to the provisions of paragraph (b) of this section which fails to comply with those requirements will receive no new NSL funds and will be required to:

(1) Place the revolving fund monies and all subsequent collections into an insured interest-bearing account;

(2) Make no loan disbursements; and

(3) By the end of the succeeding 6-month period, reduce its default rate to 50 percent of the rate it failed to achieve under paragraph (b) of this section, or 5 percent. A school that meets this requirement will be permitted to resume the use of its nursing student

loan funds, but must continue to comply with the requirements of paragraph (b)(2) of this section if its default rate is still greater than 5 percent.

A school that meets the requirements of subparagraph (c)(3) of this section will be permitted to resume the use of its NSL funds, but must continue to comply with the requirements of subparagraph (b)(2) of this section if its delinquency rate is still greater than 5 percent.

(d) Any school subject to the provisions of paragraph (c)(3) of this section which fails to comply with those requirements will be subject to termination. The Secretary will provide the school with a written notice specifying his or her intention to terminate the school's participation in the program and stating that the school may request, within 30 days of the receipt of this notice, a formal hearing. If the school requests a hearing, it must within 90 days of the receipt of the notice, submit material, factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC metropolitan area. The Secretary will deny a hearing if:

(1) The request for a hearing is untimely (i.e., fails to meet the 30-day requirement);

(2) The school does not provide a statement of material, factual issues in dispute within the 90-day required period; or

(3) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the school setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing, termination is still determined to be necessary, the school will be terminated from participation in the program and will be required to return the Federal share of the revolving fund to the Department. A school terminated for failure to comply with the provisions of paragraph (c)(3) of this section must continue to pursue collections and may reapply for participation in the program only when it has at-

tained a default rate of 5 percent or less.

(Approved by the Office of Management and Budget under control number 0915-0047)

[50 FR 34434, Aug. 23, 1985, as amended at 52 FR 10195, Mar. 30, 1987; 53 FR 46555, Nov. 17, 1988; 56 FR 13772, Apr. 4, 1991]

§ 57.317 Additional conditions.

The Secretary may, with respect to any agreement entered into with any school under § 57.305, impose additional conditions prior to or at the time of any award when in his or her judgment the conditions are necessary to assure or protect advancement of the purposes of the agreement, the interest of the public health, or the conservation of funds awarded.

§ 57.318 Noncompliance.

Whenever the Secretary finds that a participating school has failed to comply with the applicable provisions of the Act or the regulations of this subpart he or she may, on reasonable notice to the school, withhold further payments of Federal capital contributions and take other action, including the termination of any agreement, as he or she finds necessary to enforce the Act and regulations. In such case no further expenditures shall be made from the nursing student loan fund or funds involved until the Secretary determines that there is no longer any failure of compliance.

Subpart E—Grants for Construction of Nurse Training Facilities

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216.

§ 57.409 Good cause for other use of completed facility.

If, within 20 years after completion of construction (or, in the case of interim facilities prior to the time at which teaching in such facilities is moved to a permanent facility, whichever comes first), the facility shall cease to be used for any one or more of the purposes for which it was constructed, the Secretary, in determining whether there is good cause for releasing the applicant or other owner of the facility from the obligation so to use the facility, shall

§ 57.1501

42 CFR Ch. I (10–1–11 Edition)

take into consideration the extent to which:

(a) The facility will be devoted by the applicant or other owner to the teaching of other health personnel;

(b) There are reasonable assurances that for the remainder of such period other facilities not previously utilized for nurse training will be so utilized and are substantially the equivalent in nature and extent for such purposes.

[37 FR 20548, Sept. 30, 1972]

Subparts F–O [Reserved]

Subpart P—Loan Guarantees and Interest Subsidies to Assist in Construction of Teaching Facilities for Health Profession Personnel

AUTHORITY: Sec. 727, Public Health Service Act, 77 Stat. 170, as amended (42 U.S.C. 293g).

SOURCE: 38 FR 31836, Nov. 19, 1973, unless otherwise noted.

§ 57.1501 Applicability.

The regulations of this subpart are applicable to loan guarantees and interest subsidy payments made pursuant to section 729 of the Public Health Service Act (42 U.S.C. 293i) to assist nonprofit private entities which are eligible for grants under subpart B of this part in carrying out projects for construction of teaching facilities for health professions personnel.

§ 57.1502 Definitions.

As used in this subpart:

(a) All terms not defined herein shall have the same meanings as given them in section 724 of the Act.

(b) *Act* means the Public Health Service Act, as amended.

(c) *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 may be delegated.

(d) *School* means a school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, or public health which provides a course of study or a portion thereof which leads respectively to a degree of

doctor of medicine, doctor of dental surgery or an equivalent degree, doctor of osteopathy, doctor of optometry or an equivalent degree, doctor of podiatry or an equivalent degree, bachelor of science in pharmacy or an equivalent degree, doctor of veterinary medicine or an equivalent degree, or a graduate degree in public health, and which is accredited as provided in section 721(b)(1) of the Act.

(e) *Affiliated hospital* or *affiliated outpatient facility* means a hospital or outpatient facility (as defined in section 645 of the Act) which, although not owned by such school, has a written agreement with a school of medicine, osteopathy, or dentistry eligible for assistance under subpart B of this part, providing for effective control by the school of the health professions teaching program in the hospital or outpatient facility.

(f) *Nonprofit* as applied to any school, hospital, outpatient facility, or other entity means one which is owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure to the benefit of any private shareholder or individual.

(g) *Council* means the National Advisory Council on Health Professions Education (established pursuant to section 725 of the Act).

§ 57.1503 Eligibility.

(a) *Eligible applicants*. In order to be eligible for a loan guarantee or interest subsidy under this subpart, the applicant shall:

(1) Be a nonprofit private school of medicine, dentistry, osteopathy, pharmacy, optometry, podiatry, veterinary medicine, or public health, or any combination of such schools, or a nonprofit private affiliated hospital or affiliated outpatient facility: *Provided, however*, That in the case of an affiliated hospital or affiliated outpatient facility, an application which is approved by the school of medicine, osteopathy or dentistry with which the hospital or outpatient facility is affiliated and which otherwise complies with the requirements of subpart B of this part may be filed by any nonprofit private entity qualified to file an application under section 605 of the Act; and

(2) Otherwise meet the applicable requirements set forth in section 721(b) of the Act and § 57.103 with respect to eligibility for grants for construction of teaching facilities for health professions personnel.

(b) *Eligible loans.* Subject to the provisions of this subpart, the Secretary may guarantee payment, when due, of principal and interest on, or may pay interest subsidies with respect to, or may both guarantee and pay interest subsidies with respect to any loan or portion thereof made to an eligible applicant by a non-Federal lender: *Provided*, That no such guarantee or interest subsidy shall apply to any loan the interest on which is exempt from Federal income taxation.

§ 57.1504 Application.

Each applicant desiring to have a loan guaranteed or to have interest subsidies paid on its behalf, or any combination of such loan guarantee or interest subsidies, shall submit an application for such assistance in such form and manner and at such time as the Secretary may require.¹

(a) The application shall contain or be supported by such information as the Secretary may require to enable him to make the determinations required of him under the Act and this subpart.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any loan guarantee or agreement to pay interest subsidies, including the applicable regulations of this subpart.

[38 FR 31836, Nov. 19, 1973, as amended at 49 FR 38113, Sept. 27, 1984]

§ 57.1505 Approval of applications.

(a) *General.* Any application for loan guarantee or interest subsidies, or for a combination of both, may be approved by the Secretary, after consultation with the Council, only if he makes each

of the applicable determinations set forth in section 721(c) of the Act. In addition:

(1) Any such approval shall be subject to compliance by the applicant with the applicable provisions set forth in §§ 57.106, 57.107, 57.108, and 57.110: *Provided however*, That for purposes of the title assurance in § 57.107(a) the period shall be not less than 20 years or the term of the guaranteed loan, whichever is longer or in the case of interim facilities, the term of the guaranteed loan, and

(2) Any such application may be approved by the Secretary only if he determines:

(i) That the applicant will have sufficient financial resources to enable him to comply with the terms and conditions of the loan;

(ii) That the applicant has the necessary legal authority to finance, construct, and maintain the proposed project, to apply for and receive the loan, and to pledge or mortgage any assets or revenues to be given as security for such loan;

(iii) That the loan will be made only with respect to the initial permanent financing of the project;

(iv) That the loan will be secured by a lien against the facilities to be constructed or against other security satisfactory to the Secretary specified in § 57.2210;

(v) That the rate of interest on the loan does not exceed such percent per annum as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States; and

(vi) Such additional determinations as the Secretary finds necessary with respect to particular applications in order to protect the financial interests of the United States.

(b) *Loan guarantees.* In addition to the requirements of paragraph (a) of this section, any application for a loan guarantee may be approved by the Secretary only if he determines that the loan with respect to which such guarantee is sought would not be available to the applicant on reasonable terms and conditions without such guarantee. To assist the Secretary in making such

¹Applications and instructions are available from the Division of Facilities Conversion and Utilization, Bureau of Health Maintenance Organizations and Resources Development, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

determination, each applicant for a loan guarantee shall submit statements from at least three non-Federal institutions normally engaged in making long-term loans for construction, describing whether, and the terms and conditions under which, each institution would make a loan to the applicant for the project described in the application.

(c) *Interest subsidies.* In addition to the requirements of paragraph (a) of this section, any application for interest subsidies may be approved by the Secretary only if he determines that without such interest subsidy payments the applicant would not, over a substantial portion of the loan term, be able to repay the principal and interest of the loan without jeopardizing the quality of the educational program.

§ 57.1506 Priority.

(a) Priority in approving applications for loan guarantee and/or interest subsidies shall be determined in accordance with the factors specified in section 721(d) of the Act, and the following: (1) The relative need for increased enrollment and the availability of students; (2) the relative effectiveness of the project relative to the cost to the Federal Government; and (3) the relative ability of the applicant to make efficient and productive use of the facility constructed.

(b) In the case of applications to aid in the construction of new schools of medicine, osteopathy, or dentistry, the Secretary shall give special consideration to those applications which contain or are reasonably supported by assurances that, because of the use that will be made by such school of already existing facilities (including Federal medical or dental facilities), the school will be able to accelerate the date on which it will begin its teaching program.

§ 57.1507 Limitations applicable to loan guarantee.

(a) The amount of loan with respect to which a guarantee is made under this subpart shall be determined by the Secretary based upon such considerations as the availability of funds and the applicant's need therefor; *Provided*, That: (1) Subject to paragraph (a)(2) of

this section, no loan with respect to which a guarantee is made for any project under this subpart may be in an amount which, when added to the amount of any grant made with respect to such project under part B of title VII of the Act or any other law of the United States, or to the total of such grants, exceeds 90 percent of the eligible cost of construction of such project as determined by the Secretary;

(2) Notwithstanding paragraph (a)(1) of this section, the Secretary may in particular cases guarantee loans in excess of the amount specified in paragraph (a)(1) of this section where he determines that, because of special circumstances, such additional loan guarantee will further the purposes of part B of title VII of the Act. In making such determinations, the Secretary will in each case consider the following factors:

(i) The need for the project in the area to be served;

(ii) The availability of financing for the project on reasonable terms and conditions without such additional loan guarantee;

(iii) Whether the project can be constructed without such additional loan guarantee; and

(iv) Other relevant factors consistent with the purpose of part B of title VII of the Act and this subpart.

(3) In determining the cost of construction of the project there shall be excluded from such cost all fees, interest, and other charges relating or attributable to the financing of the project except the following:

(i) Reasonable fees attributable to services rendered by legal counsel in connection with such loan;

(ii) With the approval of the Secretary, reasonable fees attributable to the services of a financial advisor in assisting the applicant in securing the loan and arranging for repayment thereof; and

(iii) Interest attributable to the interim financing of construction of the project prior to the initial permanent financing thereof.

(b) No loan guarantee under this subpart shall apply to more than 90 percent of the loss of principal of and interest on such loan incurred by the

Public Health Service, HHS

§57.1512

holder of such loan upon default by the applicant.

§57.1508 Amount of interest subsidy payments; limitations.

The length of time for which interest subsidy payments will be made under the agreement, the amount of loan with respect to which such payments will be made, and the level of such payments shall be determined by the Secretary on the basis of the availability of funds and his determination of the applicant's need therefor taking into consideration his analysis of the present and reasonable projected future financial ability of the applicant to repay the principal and interest of the loan without jeopardizing the quality of its educational program: *Provided however*, That each such interest subsidy payment shall not exceed the amount necessary to reduce by 3 percent per annum the net effective interest rate otherwise payable on the loan or the portion thereof with respect to which such interest subsidy is paid.

§57.1509 Forms of credit and security instruments.

Each loan with respect to which a guarantee is made or interest subsidies are paid under this subpart shall be evidenced by a credit instrument and secured by a security instrument in such forms as may be acceptable to the Secretary.

§57.1510 Security for loans.

Each loan with respect to which a guarantee is made or interest subsidies are paid under this subpart shall be secured in a manner which the Secretary finds reasonably sufficient to insure repayment. The security may be one or a combination of the following:

(a) A first mortgage on the facility and site thereof.

(b) Negotiable stocks or bonds of a quality and value acceptable to the Secretary.

(c) A pledge of unrestricted and unencumbered income from an endowment or other trust fund acceptable to the Secretary.

(d) A pledge of a specified portion of annual general or special revenues of the applicant acceptable to the Secretary.

(e) Such other security as the Secretary may find acceptable in specific instances.

§57.1511 Opinion of legal counsel.

At appropriate stages in the application and approval procedure for a loan guarantee or interest subsidy, the applicant shall furnish to the Secretary a memorandum or opinion of legal counsel with respect to the legality of any proposed note issue, the legal authority of the applicant to issue the note and secure it by the proposed collateral, and the legality of the issue upon delivery. "Legal counsel" means either a law firm or individual lawyer, thoroughly experienced in the long-term financing of construction projects, and whose approving opinions have previously been accepted by lenders or lending institutions. The legal memorandum or opinion to be provided by legal counsel in each case shall be as follows:

(a) A memorandum, submitted with the application for a loan guarantee or interest subsidy, stating that the applicant is or will be lawfully authorized to finance, construct, and maintain the project, and to issue the proposed obligations and to pledge or mortgage the assets and/or revenues offered to secure the loan, citing the basis for such authority; and

(b) A final approving opinion, delivered to the Secretary at the time of delivery of the evidence of indebtedness to the lender, stating that the credit and security instruments executed by the applicant are duly authorized and delivered and that the indebtedness of the applicant is valid, binding, and payable in accordance with the terms on which the loan guarantee was approved by the Secretary.

§57.1512 Length and maturity of loans.

The repayment period for loans with respect to which guarantees are made or interest subsidies paid under this subpart shall be limited to 30 years: *Provided*, That:

(a) The Secretary may, in particular cases where he determines that a repayment period of less than 30 years is more appropriate to an applicant's

§ 57.1513

total financial plan, approve such shorter repayment period;

(b) The Secretary may, in particular cases where he determines that, because of unusual circumstances, the applicant would be financially unable to amortize the loan over a repayment period of 30 years, approve a longer requirement period which shall in no case exceed 40 years; and

(c) In no case shall a loan repayment period exceed the useful life of the facility to be constructed with the assistance of the loan.

§ 57.1513 Repayment.

Unless otherwise specifically authorized by the Secretary, each loan with respect to which a guarantee is made or interest subsidies are paid shall be repayable in substantially level total annual installments of principal and interest, sufficient to amortize the loan through the final year of the life of the loan.

§ 57.1514 Loan guarantee and interest subsidy agreements.

For each application for a loan guarantee or interest subsidy, or combination thereof, which is approved by the Secretary under this subpart, an offer to guarantee such loan and/or make interest subsidy payments with respect thereto will be sent to the applicant, setting forth the pertinent terms and conditions for the loan guarantee and/or interest subsidy, and will be conditioned upon the fulfillment of such terms and conditions. The accepted offer will constitute the loan guarantee agreement, the interest subsidy agreement, or the loan guarantee and interest subsidy agreement, as the case may be. Each such agreement shall include the applicable provisions set forth below:

(a) *Loan guarantee.* Each agreement pertaining to a loan guarantee shall include the following provisions:

(1) That the loan guarantee evidenced by the agreement shall be incontestable (i) in the hands of the applicant on whose behalf such loan guarantee is made except for fraud or misrepresentation on the part of such applicant, and (ii) as to any person who makes or contracts to make a loan to such applicant in reliance on such guarantee, ex-

42 CFR Ch. I (10–1–11 Edition)

cept for fraud or misrepresentation on the part of such other person.

(2) That the applicant shall be permitted to prepay up to 15 percent of the original principal amount of such loan in any calendar year without additional charge. The applicant and the lender may further agree that the applicant shall be permitted to prepay in excess of 15 percent of the original amount of the loan in any calendar year without additional charge, but no such payment in excess of 15 percent shall be made without the prior written approval of the Secretary.

(3) That if the applicant shall default in making periodic payment, when due, of the principal and interest on the loan guaranteed under the agreement, the holder of the loan shall promptly give the Secretary written notification of such default. The Secretary shall, immediately upon receipt of such notice, provide the holder with written acknowledgement of such receipt.

(4) That if such default in making periodic payment when due of the principal and interest on the guaranteed loan is not cured within 90 days after receipt by the Secretary of notice of such default, the holder of the loan shall have the right to make demand upon the Secretary, in such form and manner as the Secretary may prescribe, for payment of 90 percent of the amount of the overdue payments of principal and accrued interest, together with such reasonable late charges as are made in accordance with the terms of the credit instrument or security instrument evidencing or securing such loan. The Secretary shall pay such amount from funds available to him for these purposes.

(5) That in the event of exercise by the holder of the loan of any right to accelerate payment of such loan as a result of the applicant's default in making periodic payment when due of the principal and interest on the guaranteed loan, the Secretary shall, upon demand by the holder not less than 90 days after receipt by the Secretary of notification of such default, pay to such holder 90 percent of the total amount of principal and of interest on the loan remaining unpaid after the holder has exercised his right to foreclose upon and dispose of the security

and has applied the proceeds thereby received to reduce the outstanding balance of the loan, in accordance with applicable law and the terms of the security instrument.

(6) That the Secretary shall not guarantee any funds which are disbursed by a lender following notification by the Secretary to such lender that the Assurance executed by the Applicant under section 799A of the Act is no longer satisfactory.

(b) *Interest subsidy.* Each agreement pertaining to the payment of interest subsidies with respect to a loan shall include the following provisions:

(1) That the holder of the loan shall have a contractual right to receive from the United States interest subsidy payments in amounts sufficient to reduce by up to 3 percent per annum the net effective interest rate determined by the Secretary to be otherwise payable on such loan.

(2) That payments of interest subsidies pursuant to paragraph (b)(1) of this section will be made by the Secretary, in accordance with the terms of the loan with respect to which the interest subsidies are paid, directly to the holder of such loan, or to a trustee or agent designated in writing to the Secretary by such holder, until such time as the Secretary is notified in writing by the holder that such loan has been transferred. Pursuant to such written notification of transfer, the Secretary will make such interest payments directly to the new holder (transferee) of the loan: *Provided, however,* That it shall be the responsibility of the holder to remit any payments of interest subsidy to the new holder which the Secretary may have made to the holder after such transfer and prior to receipt of such written notice, and the Secretary shall not be liable to any party for amounts remitted to the holder prior to receipt of such written notice and acknowledgment in writing by the Secretary of receipt of such notice.

(3) That the holder of the loan will promptly notify the Secretary of any default or prepayment by the applicant with respect to the loan.

(4) In the event of any exercise by the holder of the loan of the right to accelerate payment of such loan, whether as

a result of default on the part of the applicant or otherwise, the Secretary's obligations with respect to the payment of interest subsidies shall cease.

(5) Where, during the life of the loan with respect to which interest subsidies are to be paid, the applicant ceases to use the facility for the purposes for which constructed, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That where the applicant is continuing to use the facility for purposes eligible for support under part B of title VII of the act, the Secretary may make a determination, based upon the health manpower needs of the community served by the facility as well as other relevant factors, to continue to make interest subsidy payments in accord with the agreement.

(6) Where during the life of the loan with respect to which interest subsidies are to be paid, it is determined, after an opportunity for a hearing pursuant to 45 CFR part 83, that the Assurance executed by the applicant under section 704 (or its predecessor, section 799A) of the Act, is no longer satisfactory, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That the Secretary shall resume making interest subsidy payments if he determines that a subsequent Assurance submitted by the applicant is satisfactory.

(7) Where during the life of the loan with respect to which interest subsidies are to be paid, it is determined by the Secretary, after an opportunity for a hearing pursuant to 45 CFR parts 80 and 81, that the applicant has ceased to comply with the Assurance it has executed under 45 CFR 80.4(d) concerning nondiscrimination on the basis of race, color or national origin, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That the Secretary shall resume making interest subsidy payments if he subsequently determines that the applicant has come into compliance with the requirements of title VI of the Civil Rights Act of 1964 and implementing regulations.

§ 57.1515

42 CFR Ch. I (10–1–11 Edition)

(8) Where during the life of the loan with respect to which interest subsidies are to be paid, it is determined by the Secretary after an opportunity for a hearing pursuant to title IX of the Education Amendments of 1972, that the applicant has ceased to comply with such title, and its implementing regulations, the Secretary's obligation with respect to the payment of interest subsidies shall cease: *Provided, however,* That the Secretary shall resume making interest subsidy payments if he subsequently determines that the applicant has come into compliance with the requirements of title IX of the Education Amendments of 1972 and implementing regulations.

(c) *General.* In addition to the applicable requirements of paragraphs (a) and (b) of this section, each agreement, whether pertaining to a loan guarantee or interest subsidy or both, shall contain such other provisions as the Secretary finds necessary in order to protect the financial interests of the United States.

[38 FR 31836, Nov. 19, 1973, as amended at 49 FR 38113, Sept. 27, 1984]

§ 57.1515 Loan closing.

Closing of any loan with respect to which a guarantee is made or interest subsidies are paid under this subpart shall be accomplished at such time as may be agreed upon by the parties to such loan and found acceptable to the Secretary.

§ 57.1516 Right of recovery-subordination.

(a) The United States shall be entitled to recover from the applicant for a loan guarantee under this subpart the amount of any payment made pursuant to such guarantee, unless the Secretary waives such right of recovery as provided in § 57.1517.

(b) Upon making of any payments pursuant to a loan guarantee under this subpart, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

§ 57.1517 Waiver of right of recovery.

In determining whether there is good cause for waiver of any right of recovery which he may have against any ap-

plicant by reason of any payments made pursuant to a loan guarantee under this subpart, the Secretary shall take into consideration the extent to which:

(a) The facility with respect to which the loan guarantee was made will continue to be devoted by the applicant or other owner to the teaching of health professions personnel, or to other purposes in the sciences related to health for which funds are available under part B of title VII of the act and these regulations;

(b) A hospital or outpatient facility will be used as provided for under title VI of the act;

(c) There are reasonable assurances that for the remainder of the repayment period of the loan other facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and extent for such purposes; and

(d) Such recovery would seriously curtail the training of qualified health professions personnel in the area served by the facility.

§ 57.1518 Modification of loans.

No official of the Department of Health and Human Services will approve any proposal to modify the terms of a loan guaranteed under title VII of the Public Health Service Act (42 U.S.C. 293 *et seq.*) and this subpart which would permit the use of the guaranteed loan (or the guarantee) as collateral for an issue of tax-exempt securities.

(Secs. 215 and 726, Public Health Service Act, 58 Stat. 690 and 85 Stat. 432, 42 U.S.C. 216 and 293i, as amended)

[48 FR 42984, Sept. 21, 1983]

Subparts Q–T [Reserved]

Subpart U—Armed Forces Health Professions Scholarship Program

AUTHORITY: Sec. 2(a), Pub. L. 92–426, 86 Stat. 719 (10 U.S.C. 2127(d)).

SOURCE: 38 FR 20447, Aug. 1, 1973, unless otherwise noted.

§ 57.2001 Applicability.

In the event the Secretary of Defense decides to enter into one or more contracts under 10 U.S.C. 2127(d), the regulations in this subpart outline considerations the Secretary of Defense will take into account in determining whether an accredited civilian educational institution has increased its total enrollment for the sole purpose of accepting members of the Armed Forces health professions scholarship program.

§ 57.2002 Definitions.

As used in this subpart:

(a) *Institution* means a college, university, or other institution or a department, division, or other administrative unit within a college, university, or other institution, which provides primarily or exclusively a course of study in medicine, dentistry, or other health profession, as determined under regulations prescribed by the Secretary of Defense, leading to a degree in one of said health professions, and which is accredited by an accrediting agency or association recognized by the United States Commissioner of Education.

(b) *Enrollment* in any fiscal year means the number of full-time students enrolled in an institution on October 15 of said year and pursuing a course of study which constitutes a full-time academic workload, as determined by the institution, leading to a degree in medicine, dentistry, or other health profession, as determined under regulations prescribed by the Secretary of Defense: *Provided*, That if the Secretary of Defense finds that a date other than October 15 would more accurately reflect an institution's enrollment in any fiscal year, the Secretary of Defense may use such other date in place of October 15 in making his determination under this subpart.

(c) *Fiscal year* means the Federal fiscal year beginning July 1 and ending on the following June 30.

(d) *Program* means the Armed Forces health professions scholarship program established under section 2(a) of the Uniformed Services Health Professions Revitalization Act of 1972 (86 Stat. 713, Pub. L. 92-426), and codified in chapter 105 of 10 U.S.C.

§ 57.2003 Determinations of increased enrollment solely for the program.

In the event the Secretary of Defense decides to enter into one or more contracts under 10 U.S.C. 2127(d), his determination as to whether an institution has increased its total enrollment in any fiscal year for the sole purpose of accepting members of the program will take into account the following considerations:

(a) A comparison of the total enrollment in said fiscal year with the total enrollments in immediately preceding fiscal years;

(b) Any increases in enrollment to which the institution has directly or indirectly committed itself in said fiscal year under: (1) Other Federal programs, such as those set forth in title VII and VIII of the Public Health Service Act (42 U.S.C. 292 *et seq.*), the Veterans' Administration Medical School Assistance and Health Manpower Training Act of 1972 (Pub. L. 92-541, 86 Stat. 1100 (38 U.S.C. 5070 *et seq.*)) and section 225 of the Public Health Service Act (sec. 5, Pub. L. 92-585, 86 Stat. 1293 (42 U.S.C. 234)); (2) programs of State or local governments or other public or private agencies, or (3) any legally binding arrangement: *Provided*, That insofar as a single increase may be applied to satisfy the commitments under two or more programs and/or other arrangements, said increase shall be considered to meet all such commitments;

(c) Any unusual factors, such as: (1) An institution having been newly established or (2) an institution experiencing what is for it an abnormal rate of attrition and/or admission.

Subpart V [Reserved]**Subpart W—Physician Shortage Area Scholarship Grants**

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216).

SOURCE: 39 FR 28730, Aug. 9, 1974, unless otherwise noted.

§ 57.2201 Applicability.

The regulations of this subpart are applicable to scholarship grants awarded under section 784 of the Public Health Service Act, which authorizes

the Secretary to award scholarship grants to students of medicine and osteopathy who agree to engage in the full-time practice of primary care for a prescribed period of time (a) in a physician shortage area or (b) in such manner as to assure that of the patients receiving medical care in such practice a substantial portion will consist of migratory agricultural workers or members of their families.

§ 57.2202 Definitions.

As used in this subpart, the following terms shall have the following meanings:

(a) *Act* means the Public Health Service Act, as amended.

(b) *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.

(c) *School* means a public or other nonprofit school of medicine or osteopathy which provides a course of study, or a portion thereof, which leads respectively to a degree of Doctor of Medicine or Doctor of Osteopathy and which is accredited as provided in section 721(b)(1)(B) of the Act.

(d) *Scholarship grant* means the amount of money awarded to an individual by the Secretary for an academic year pursuant to section 784(a) of the Act.

(e) *Full-time student* means a student who is enrolled, or accepted for enrollment, in a school and pursuing a course of study which constitutes a full-time academic workload, as determined by the school, leading to a degree specified in paragraph (c) of this section.

(f) *Academic year* means the traditional, approximately 9-month September to June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be of 9 months' duration.

(g) *National of the United States* means (1) a citizen of the United States or (2) a person who, though not a citizen of the United States, owes permanent allegiance to the United States (8 U.S.C. 1101(a)(22)).

(h) *Professional training* means the course of study leading to the degree of doctor of medicine or doctor of osteopathy, plus a period, not to exceed a total of four years, of internship and residency training.

(i) *Low-income background* as applied to any individual means that the individual comes from a family with an annual income below low-income levels developed pursuant to § 57.605(c).

(j) *The practice of primary care* means the provision of health services characterized by the delivery of first contact medicine, the assumption of longitudinal responsibility for the patient regardless of the presence or absence of disease, and the integration of the physical, psychological and social aspects of health care to the limits of the capability of the practitioner. For purposes of this section, primary care shall include the fields of general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology.

(k) *Migratory agricultural worker* means a domestic agricultural migratory worker as defined in § 56.102(d).

(l) *Physician shortage area* means an area designated by the Secretary pursuant to § 57.216(a)(5) as an area having a need for and shortage of physicians.

§ 57.2203 Eligibility.

To be eligible for a scholarship grant under this subpart, the applicant must:

(a) Be a national of the United States or a permanent resident of the Trust Territory of the Pacific Islands or a lawful permanent resident of the United States, Puerto Rico, the Virgin Islands or Guam;

(b) Be a full-time student in a school located in the United States, the Trust Territory of the Pacific Islands, Puerto Rico, the Virgin Islands, the Canal Zone, American Samoa or Guam; and

(c) Agree to engage in the full-time practice of primary care as defined in § 57.2202(j) in accord with conditions specified in § 57.2209.

§ 57.2204 Application.

Each eligible applicant desiring a scholarship grant under this subpart shall submit an application at such time and in such form as the Secretary may prescribe.

§ 57.2205 Priority for selection of scholarship recipients.

(a) When funds determined by the Secretary to be available for scholarship grants under this subpart are insufficient to permit the awarding of scholarships to all individuals applying therefor, the Secretary shall accord priority to eligible applicants as follows:

(1) First priority for scholarship grants shall be accorded to applicants who (i) are from a low-income background as defined in § 57.2202 (i), (ii) reside in a physician shortage area and (iii) agree to return to such area and engage in the full-time practice of primary care. For purposes of this paragraph, an individual resides in a physician shortage area if he presently is residing in such an area or if he (or his parents) resided in such an area in the year prior to his admission to an institution of higher education.

(2) Second priority shall be accorded to applicants meeting the criteria in paragraphs (a)(1) (ii) and (iii) of this section.

(3) Third priority shall be accorded to applicants meeting the criterion in paragraph (a)(1)(i) of this section.

(4) Fourth priority shall be accorded to other applicants.

(b) Where there are insufficient funds available to make scholarship grants to all members of any single priority grouping enumerated in paragraph (a) of this section, the following criteria will be used to accord priority within each affected priority group:

(1) Within the priority groupings specified in paragraphs (a) (1) and (2) of this section, the Secretary shall rank recipients according to the degree of the severity of shortage of physicians practicing primary care in such area. Scholarship grants shall be awarded within each priority group first to applicants within that grouping from physician shortage areas with the least favorable ratio of such physicians to the population to be served.

(2) Within the priority groupings specified in paragraphs (a) (3) and (4) of this section, the Secretary shall award scholarship grants within each priority group first to applicants who agree to practice primary care in a physician shortage area with a substantial por-

tion of migratory agricultural workers in such area; second, to applicants within that grouping who agree to practice in a physician shortage area; and third, to applicants within that grouping who agree to practice in such place or places, facility or facilities, and in such manner as the Secretary finds necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families.

§ 57.2206 Grant award.

The Secretary may award scholarship grants to individuals who have been selected to receive scholarship grants in accordance with § 57.2205. Any such award under this subpart shall state the specific conditions under which the award is being made and shall indicate the distribution between funds awarded to cover the costs of tuition and fees payable to the school and funds awarded for the costs of equipment, supplies, books, and living expenses payable to the individual.

§ 57.2207 Amount of scholarship grant.

(a) The amount of the scholarship grant to any student for any academic year shall be the total of (1) the lesser of (i) \$5,000 or (ii) the amount determined by the Secretary to be the cost of tuition and fees; plus (2) an allowance for equipment, supplies, books and living expenses which shall be the lesser of (i) \$3,600 or (ii) the difference between \$5,000 and the amount determined pursuant to paragraph (a)(1) of this section.

(b) The maximum amount of a scholarship grant during a 12-month period to any student enrolled in a school which provides a course of study longer than the traditional 9-month academic year may be proportionately increased.

§ 57.2208 Payment of scholarship grant.

The portion of a scholarship grant awarded for the costs of tuition and fees as indicated on the notice of grant award document will be paid directly to the school upon receipt of an invoice from the school. The portion of the scholarship grant awarded for the costs

of equipment, supplies, books, and living expenses will be paid to the individual in equal monthly installments.

§ 57.2209 Conditions of scholarship grant.

(a) Any scholarship grant made to any individual under this subpart shall be awarded upon the condition that such individual will, following completion of his professional training, engage in the full-time practice of primary care for a period of 12 continuous months for each academic year (*i.e.*, 9 months) for which a scholarship grant was made, as follows:

(1) In the case of any individual selected pursuant to § 57.2205(a) (1) or (2), such practice must be in the physician shortage area to which such individual agreed to return: *Provided however*, That if the Secretary determines at the time the individual proposes to engage in the required practice that such area is no longer a physician shortage area and cannot reasonably be expected to become such an area within 2 years from such time, such practice shall, at the option of the individual, be either in any then current physician shortage area, or in such place or places, facility, or facilities, and in such manner as the Secretary finds necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families.

(2) In the case of any individual selected pursuant to § 57.2205(a) (3) or (4), such practice must be in accordance with the agreement described in § 57.2205(b)(2) (*i.e.*, in a physician shortage area with a substantial portion of migratory agricultural workers in such area; a physician shortage area; or in such place or places, facility or facilities, and in such manner as may be necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families; as the case may be).

(b) Subject to the provision of § 57.2211(f) and except as provided in paragraph (c) of this section, any individual to whom the conditions of this section apply must complete the prac-

tice required by paragraph (a) of this section within a period beginning on the date of completion by the individual of his professional training, as determined by the Secretary, and not to exceed the period of practice determined in accordance with such paragraph (a) of this section, plus 6 months.

(c) Where an individual to whom the conditions of this section apply is currently performing an active duty service obligation under section 235 of the Act, the individual must complete the practice required by paragraph (a) of this section within a period beginning on the date of completion by the individual of his service obligation under section 225 of the Act or completion of his internship and residency training (not to exceed four years) if not previously received, whichever comes later, and not to exceed the period of practice determined in accordance with paragraph (a) of this section, plus 6 months.

(d) Where an individual has received scholarship grant support for four academic years, such individual shall be considered to have received scholarship grant support for only three academic years if the Secretary determines (1) that such individual has served his internship or residency in a hospital (i) which is located in a physician shortage area, or (ii) in which a substantial portion of the patients of such hospital consists of persons who are migratory agricultural workers or members of the families of such workers and (2) that while so serving such internship or residency, he has received training or professional experience designed to prepare him to engage in the practice of primary care.

(e) For purposes of paragraph (c)(2) of this section, (1) internships which will be recognized by the Secretary as providing training or professional experience designed to prepare an individual to engage in the practice of primary care are: Rotating internships without a major emphasis, rotating internships with an emphasis on internal medicine, rotating internships with an emphasis on pediatrics, rotating internships with an emphasis on obstetrics and gynecology, straight internships in internal

medicine, straight internships in pediatrics and straight internships in obstetrics and gynecology; *Provided*, That such internships are approved or provisionally approved by the Council on Medical Education of the American Medical Association or the Board of Trustees of the American Osteopathic Association; and

(2) Residencies which will be recognized as providing such training or experience are those in general practice, family practice, general internal medicine, general pediatrics and general obstetrics and gynecology; *Provided*, That such residencies are approved or provisionally approved by the Council on Medical Education of the American Medical Association or the Board of Trustees of the American Osteopathic Association.

(f) No individual who has received a scholarship grant under this subpart may enter into an agreement with the Secretary pursuant to section 741(f) of the Act until either (1) such individual has completed the practice required by paragraph (a) of this section, or (2) the Secretary has determined that the United States is entitled to recover from such individual an amount determined in accordance with §57.2210. In no case, however, shall a scholarship grant under this subpart be considered an educational loan for purposes of section 741(f) of the Act.

[39 FR 28730, Aug. 9, 1974, as amended at 41 FR 26685, June 29, 1976]

§57.2210 Failure to comply.

(a) Subject to the provision of §57.2211, if any individual fails to complete the course of study or fails, within the time period set forth in §57.2209(b), to meet the applicable conditions of practice imposed by receipt of a scholarship grant for the full number of months to which such condition is applicable, the United States shall be entitled to recover from such individual an amount determined in accordance with section 784(c)(3) of the Act; *Provided however*, That no interest shall accrue on any amount due the United States during any period for which the Secretary has suspended the obligation to repay pursuant to §57.2211(b).

§57.2211 Waiver or suspension.

(a) Any obligation of any individual under this subpart will be cancelled upon the death of such individual as documented by a certification of death, or such other official proof as is conclusive under State law, and submitted to the Secretary.

(b) Subject to the provision of paragraph (f) of this section, where an individual fails to complete the practice required by §57.2209(a) within the period prescribed in §57.2209(b), the Secretary may waive or suspend for such period as determined by the Secretary the obligation of such individual to repay pursuant to §57.2210 where the Secretary determines that compliance by such individual with such obligation (1) is impossible, or (2) would involve extreme hardship to such individual and enforcement of such obligation with respect to such individual would be against equity and good conscience.

(c) For purposes of paragraph (b)(1) of this section, compliance by an individual will be deemed impossible where the Secretary determines, on the basis of such information and documentation as he may require, that the individual is permanently and totally disabled.

(d) For purposes of paragraph (b)(2) of this section, in determining whether compliance by an individual would involve extreme hardship to such individual and would be against equity and good conscience, the Secretary will take into consideration the following:

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

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

(3) The reasons for the individual's failure to complete such practice within the prescribed period, such as problems of a personal nature; and

(4) The extent to which the individual is practicing his profession in a manner consistent with the purposes of section 784 of the Act.

(e) Where the Secretary determines that compliance by an individual with his obligation to engage in the practice of primary care in a specified shortage area pursuant to §57.2209(a) is impossible or would involve extreme hardship to such individual and enforcement of such obligation with respect to

such individual would be against equity and good conscience, the Secretary may waive such obligation and permit the individual at his option to practice either in any then current physician shortage area, or in such place or places, facility or facilities, and in such manner as the Secretary finds necessary to assure that, of the patients receiving medical care in such practice, a substantial portion will consist of persons who are migratory agricultural workers or members of their families. The Secretary will take into consideration in determining whether to grant a waiver under this paragraph the extent to which the individual has problems of a personal nature, e.g., physical or mental disability, terminal illness in the family, or need for financial support that cannot be supplied by the required service, which intrude upon the individual's ability to perform the required service in the specified shortage area.

(f) The Secretary may extend the period (prescribed in § 57.2209(b)) within which an individual must complete the practice required pursuant to § 57.2209(a) for a period not to exceed one year where the Secretary finds that (1) such individual is unable to complete such practice within such period because of a temporary physical or mental disability, or (2) completion by such individual of such practice within such period would involve extreme hardship to such individual and that failure to so extend such period would be against equity and good conscience.

Subparts AA–FF [Reserved]

Subpart GG—Payment for Tuition and Other Educational Costs

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 711, Public Health Service Act, 90 Stat. 2253; section 710, PHS Act, as redesignated by Pub. L. 97–35, 95 Stat. 915 (42 U.S.C. 292k).

§ 57.3201 To which programs do these regulations apply?

The regulations in this subpart establish the criteria to be used in determining allowable increases in tuition and other educational costs for which

the Secretary is responsible for payment under the following sections of the Public Health Service Act: The National Health Service Corps Scholarship Program (sec. 338A) (42 U.S.C. 2541) and the Indian Health Scholarship Program (awarded pursuant to sec. 338A–339G of the PHS Act) (25 U.S.C. 1613a). These programs are referred to herein as the “scholarship programs.” The regulations apply to increases in tuition and other educational costs occurring after the school year beginning immediately before October 1, 1981.

[57 FR 45745, Oct. 5, 1992]

§ 57.3202 How will allowable increases be determined?

(a) The Secretary is responsible for increases in tuition and other educational costs only if the same increase is charged to all students in the same category (for example, the same class year or place of residence) and without regard to whether the student is receiving support under the scholarship programs. A student participating in the scholarship programs may not be denied eligibility because of this participation for any discounts or rebates in tuition or other educational costs given to all other students in the same category at the institution.

(b) Institutions whose enrollment contains 25 percent or more students participating in the scholarship programs, and whose percentage increase in tuition and other educational costs in any school year exceeds the previous calendar year's average inflation rate as indicated by the *Consumer Price Index for All Urban Areas*, may be requested to provide the Secretary with detailed cost breakdowns justifying the increase.

(c) In the case of a school which is requested to provide the Secretary with cost increase justification under paragraph (b) of this section, the Secretary will be responsible for increases in tuition and other educational costs charged to students participating in the scholarship programs over the amount charged for the school year immediately preceding the increase only to the extent that they are: (1) Attributable to uncontrollable costs, such as fuel costs, mandated cost-of-living increases in wages, salaries and fringe

benefits, (2) attributable to costs of maintaining and improving the quality of the health professions education provided by the institution, such as hiring additional faculty to improve the faculty-student ratio, costs incurred in off-site training of students, and necessary improvements in teaching equipment. Increases in patient care and research costs are allowable as part of an increase in tuition and other educational costs only to the extent that they can be documented as clearly necessary to maintain and improve the quality of the education being supported; or (3) attributable to loss of revenue from other sources which was used solely for the maintenance and improvement of the educational system.

These three categories of valid escalators of tuition and other educational costs are exclusive. However, the examples *within* each category are merely illustrative and not meant to be inclusive.

(d) If the Secretary, after reviewing all available data, information, and justifications submitted by an institution, determines that an increase in tuition and other educational costs is not allowable under the criteria described in paragraph (a) or (c) of this section, the Secretary will provide the affected institution a detailed written explanation of the basis of that determination. The Secretary will be responsible for that portion of tuition and other educational costs the Secretary determines to be allowable.

[45 FR 71568, Oct. 29, 1980]

Subparts HH-PP [Reserved]

PART 58—GRANTS FOR TRAINING OF PUBLIC HEALTH AND ALLIED HEALTH PERSONNEL

Subparts A-F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

Sec.

- 59.1 To what programs do these regulations apply?
- 59.2 Definitions.
- 59.3 Who is eligible to apply for a family planning services grant?
- 59.4 How does one apply for a family planning services grant?
- 59.5 What requirements must be met by a family planning project?
- 59.6 What procedures apply to assure the suitability of informational and educational material?
- 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?
- 59.8 How is a grant awarded?
- 59.9 For what purposes may grant funds be used?
- 59.10 What other HHS regulations apply to grants under this subpart?
- 59.11 Confidentiality.
- 59.12 Additional conditions.

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

- 59.201 Applicability.
- 59.202 Definitions.
- 59.203 Eligibility.
- 59.204 Application for a grant.
- 59.205 Project requirements.
- 59.206 Evaluation and grant award.
- 59.207 Payments.
- 59.208 Use of project funds.
- 59.209 Civil rights.
- 59.210 Inventions or discoveries.
- 59.211 Publications and copyright.
- 59.212 Grantee accountability.
- 59.213 [Reserved]
- 59.214 Additional conditions.
- 59.215 Applicability of 45 CFR part 74.

Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a-4.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under

§ 59.2

section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). “Low-income family” also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity’s net earnings benefit, or may lawfully benefit, any private shareholder or individual.

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 includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

42 CFR Ch. I (10–1–11 Edition)

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other

Public Health Service, HHS

§ 59.5

services, assistance from or participation in any other program of the applicant.¹

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accord-

ance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

¹Section 205 of Pub. L. 94-63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both."

§ 59.6

42 CFR Ch. I (10–1–11 Edition)

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the com-

munity knowledgeable about the community's needs for family planning services.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

- (1) The number of patients, and, in particular, the number of low-income patients to be served;
- (2) The extent to which family planning services are needed locally;
- (3) The relative need of the applicant;
- (4) The capacity of the applicant to make rapid and effective use of the federal assistance;
- (5) The adequacy of the applicant's facilities and staff;
- (6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and
- (7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompetes for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent con-

tinuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

- 37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
- 42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure
- 45 CFR Part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments
- 45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

§ 59.11

45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000]

Subpart B [Reserved]

Subpart C—Grants for Family Planning Service Training

AUTHORITY: Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-1.

SOURCE: 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

§ 59.201 Applicability.

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a-1) to provide the training for personnel to carry out family planning service pro-

42 CFR Ch. I (10-1-11 Edition)

grams described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

§ 59.202 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act.

(b) *State* means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.

(c) *Nonprofit* private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(d) *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.

(e) *Training* means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

§ 59.203 Eligibility.

(a) *Eligible applicants.* Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided*, That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines (1) that such program is consistent with the purposes of this subpart and (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

§ 59.204 Application for a grant.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.¹ The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a-1, and 300a-4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

§ 59.205 Project requirements.

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

(a) Assurances that:

(1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

(2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.

(3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.

¹Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

(b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.

(c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.

(d) Provision of a method for development of the training curriculum and any attendant training materials and resources.

(e) Provision of a method for implementation of the needed training.

(f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.

(g) Provision of a method and criteria by which trainees will be selected.

§ 59.206 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:

(1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;

(2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:

(i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;

(ii) Improvement of the family planning services delivery skills of family planning and health services personnel;

(iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;

(iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to

§ 59.207

program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

(4) The administrative and management capability and competence of the applicant;

(5) The competence of the project staff in relation to the services to be provided; and

(6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either: (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by subpart Q of 35 CFR part 74.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such

42 CFR Ch. I (10–1–11 Edition)

times and in such form as the Secretary may direct.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 59.208 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

(c) The Secretary may approve the payment of grant funds to trainees for:

(1) Return travel to the trainee's point of origin.

(2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in,

be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

§ 59.210 Inventions or discoveries.

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, non-exclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 59.212 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from

the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) *Accounting for grant-related income—(1) Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout—(1) Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

§ 59.213

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973]

§ 59.213 [Reserved]

§ 59.214 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 59.215 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:

- A General.
- B Cash Depositories.
- C Bonding and Insurance.
- D Retention and Custodial Requirements for Records.
- F Grant-Related Income.
- G Matching and Cost Sharing.
- K Grant Payment Requirements.
- L Budget Revision Procedures.
- M Grant Closeout, Suspension, and Termination.
- O Property.
- Q Cost Principles.

[38 FR 26199, Sept. 19, 1973]

42 CFR Ch. I (10–1–11 Edition)

PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

Sec.

- 59a.1 Programs to which these regulations apply.
- 59a.2 Definitions.
- 59a.3 Who is eligible for a grant?
- 59a.4 How are grant applications evaluated?
- 59a.5 Awards.
- 59a.6 How may funds or materials be used?
- 59a.7 Other HHS regulations that apply.

Subpart B—Establishment of Regional Medical Libraries

- 59a.11 Programs to which these regulations apply.
- 59a.12 Definitions.
- 59a.13 Who is eligible for a grant?
- 59a.14 How to apply.
- 59a.15 Awards.
- 59a.16 What other conditions apply?
- 59a.17 Other HHS regulations that apply.

SOURCE: 56 FR 29189, June 26, 1991, unless otherwise noted.

Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources

AUTHORITY: 42 U.S.C. 286b–2, 286b–5.

§ 59a.1 Programs to which these regulations apply.

(a) The regulations of this subpart apply to grants of funds, materials, or both, for establishing, expanding, and improving basic medical library resources as authorized by section 474 of the Act (42 U.S.C. 286b–5).

(b) This subpart also applies to cooperative agreements awarded for this purpose. In these circumstances, references to “grant(s)” shall include “cooperative agreements(s).”

§ 59a.2 Definitions.

Undefined terms have the same meaning as provided in the Act. As used in this subpart:

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

Project period—See § 59a.5(c).

Related instrumentality means a public or private institution, organization, or agency, other than a medical library,

whose primary function is the acquisition, preservation, dissemination, and/or processing of information relating to the health sciences.

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegated.

§ 59a.3 Who is eligible for a grant?

Except as otherwise prohibited by law, any public or private nonprofit institution, organization, or agency authorized or qualified to carry on the functions of a medical library, and any public or private related instrumentality, is eligible for a grant under this subpart.

§ 59a.4 How are grant applications evaluated?

The Secretary shall evaluate grant applications using the officers and employees, and experts, consultants, or groups engaged by the Secretary for that purpose. The Secretary's evaluation shall consider the scope of library or related services for the population and purposes served by the applicant. This evaluation shall include consideration of the following information which must be set forth in the grant application and such other information the Secretary considers pertinent:

- (a) Evidence of the applicant's efficiency in providing services,
- (b) Amount of available equipment and other resources on hand to satisfy the needs of the area served by the facility,
- (c) Extent of coordination with other libraries and related facilities, and
- (d) Potential for testing or demonstration of new or improved techniques in health-sciences informational services.

(Approved by the Office of Management and Budget under control number 0925-0276)

§ 59a.5 Awards.

(a) *General.* Within the limits of funds available, the Secretary may award grants to those applicants whose proposals for establishments, expansion, or improvement will, in the Secretary's judgment, best promote the purposes of section 474 of the Act (42 U.S.C. 286b-5).

(b) *Determination of award amount.* An Award may not exceed \$1,000,000 or other amount established by law for any fiscal year.

(1) The scope of medical-library or related services provided by the applicant for the population and purposes it serves considering:

- (i) The number of graduate and undergraduate students, and physicians and other practitioners in health-related sciences making use of the applicant's library resources;
- (ii) The type and availability of library support staff;
- (iii) The type, size, and qualifications of the faculty of any school with which the applicant is affiliated;
- (iv) The staff of any hospitals or clinics with which the applicant's library is affiliated;
- (v) The geographic area served and, within that area, the medical-library or related services otherwise available; and

(2) The amount adequate to insure continuing financial support from non-Federal sources of the applicant's proposed activity during and after the period of award. The Secretary shall consider the level of non-Federal support for the proposed activity for periods prior to the fiscal year in which a grant is made. The Secretary shall require the applicant's assurance that non-Federal support will not be diminished as a result of the award and that adequate support for this activity will be continued during and after the period of Federal assistance.

(c) *Project period.* (1) the notice of grant award specifies how long the Secretary intends to support the project without requiring the project to re-compete for funds. This period, called the project period, will usually be for one to five years.

(2) Generally, the grant will initially be for one year at a time and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In

§ 59a.6

all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(3) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award for any approved application or portion of an approved application.

[56 FR 29189, June 26, 1991, as amended at 59 FR 59168, Nov. 16, 1994]

§ 59a.6 How may funds or materials be used?

The grantee shall expend funds or use materials provided by a grant under this subpart solely for the purposes for which the funds or materials were granted, in accordance with the pertinent provisions of the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles in subpart Q of 45 CFR part 74.

§ 59a.7 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not necessarily limited to:

- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR parts 6 and 8—Inventions and patents
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 76 subparts A–F—Government-wide debarment and suspension (non-procurement) and requirements for drug-free workplace (grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and ac-

42 CFR Ch. I (10–1–11 Edition)

tivities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

Subpart B—Establishment of Regional Medical Libraries

AUTHORITY: 42 U.S.C. 286b–2, 286b–6.

§ 59a.11 Programs to which these regulations apply.

(a) This subpart applies to grants made under section 475 of the Act (42 U.S.C. 286b–6). Grants are awarded to medical libraries to enable them to serve as regional medical libraries for their geographic areas. The purpose of the program is to develop a national system of regional medical libraries, each of which would have sufficient facilities to supplement the services of other medical libraries in its region.

(b) The purpose of the program may also be supported by contracts. Since the primary purpose of these contracts is to assist regional libraries and is not for the purpose of acquiring supplies or services for use of the Federal Government, the provisions of the Federal Acquisition Regulation (48 CFR chapter 1) do not apply. Any contract awarded pursuant to section 475 of the Act shall be subject to the applicable provisions of this subpart.

§ 59a.12 Definitions.

Underdefined terms have the same meaning as provided in the Act.

As used in this subpart:

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

Annual operating expenses means the average annual operating expenses for the actual years of operation or an estimated amount based on the expenses of libraries or institutions of similar size and function.

Board means the Board of Regents of the National Library of Medicine established by section 466 of the Act (42 U.S.C. 286a).

Geographic area means an area that forms an academically and professionally integrated region. Factors

considered are location and extent of communication facilities and systems, presence and distribution of educational and medical and health facilities and programs and other activities which, in the Secretary's opinion, justify the establishment and operation of a regional medical library.

Modify and increase means the use of Federal funds or materials to supplement rather than supplant non-Federal funds available for library resources and services.

Project period—See § 59a.15(b).

Secretary means the Secretary of Health and Human Services and any other official of the Department of Health and Human Services to whom the authority involved is delegated.

§ 59a.13 Who is eligible for a grant?

Except as otherwise prohibited by law, any public or private nonprofit organization which is authorized and qualified to operate a medical library is eligible for a grant under this subpart.

§ 59a.14 How to apply.

In addition to any other pertinent information which the Secretary may require, the applicant shall submit a grant application containing a detailed description of a program to provide health-sciences informational services for the geographic area in which it is located. The description shall include:

- (a) The need for services;
- (b) The adequacy of the applicant's existing or proposed facilities and resources to attain the purposes stated in the application;
- (c) The size and nature of the population to be served;
- (d) The region to be served;
- (e) Cooperative arrangements in effect, or proposed, with other qualified organizations; and
- (f) The justification for the funds requested.

(Approved by the Office of Management and Budget under control number 0925-0276)

§ 59a.15 Awards.

(a) *General*. The Secretary, with the advice of the Board in each case, shall award grants to those applicants whose arrangements and proposed services will, in the Secretary's judgment, have

the greatest potential for fulfilling the need for a regional medical library. The Secretary, in determining the priority assigned an applicant, must consider:

(1) The adequacy of the applicant's library in terms of collections, personnel, equipment, and other facilities; and

(2) The size and nature of the population to be served in the applicant's region.

(b) *Project period*. (1) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to compete for funds. This period, called the project period, will usually be for one to five years.

(2) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(3) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award for any approved application or portion of an approved application.

§ 59a.16 What other conditions apply?

Although the Secretary may approve exceptions which are consistent with program purposes, in addition to other terms, conditions, and assurances required by law, each grantee must meet the following requirements:

(a) *Use of funds*. Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and

§ 59a.17

the applicable cost principles in subpart Q of 45 CFR part 74.

(b) *Library resources*—(1) *Provision of services*. The grantee shall modify and increase its library resources to provide supportive services to other health-sciences informational activities.

(2) *Access to and fees for services*. The grantee shall provide free loan services to qualified users or, in lieu of loans, make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain. Reasonable fees may be charged for copies or other services (other than free loan services) provided by a grantee under this subpart: *Provided*, That equal access to the health-information resources of the region or of the national network is assured. These fees shall be designed to recover expenses. The grantee's access policies shall determine the qualifications of individuals or organizations for access to the services provided under the grant, so long as those policies are consistent with the mandatory service undertakings of the program. The Secretary may review the grantee's access policies to assure compliance with this requirement.

(Approved by the Office of Management and Budget under control number 0925-0276)

§ 59a.17 Other HHS regulations that apply.

Several other regulations apply to grants under this subpart. These include, but are not necessarily limited to:

- 42 CFR part 50, subpart A—Responsibilities of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science
- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
- 45 CFR parts 6 and 8—Inventions and patents
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR part 74—Administration of grants
- 45 CFR part 75—Informal grant appeals procedures
- 45 CFR part 76, subparts A–F—Government-wide debarment and suspension (non-procurement) and requirements for drug-free workplace (grants)
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and

42 CFR Ch. I (10–1–11 Edition)

Human Services—effectuation of title VI of the Civil Rights Act of 1964

- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

PART 60—HEALTH EDUCATION ASSISTANCE LOAN PROGRAM

Subpart A—General Program Description

Sec.

- 60.1 What is the HEAL program?

Subpart B—The Borrower

- 60.5 Who is an eligible student borrower?
- 60.6 Who is an eligible nonstudent borrower?
- 60.7 The loan application process.
- 60.8 What are the borrower's major rights and responsibilities?

Subpart C—The Loan

- 60.10 How much can be borrowed?
- 60.11 Terms of repayment.
- 60.12 Deferment.
- 60.13 Interest.
- 60.14 The insurance premium.
- 60.15 Other charges to the borrower.
- 60.16 Power of attorney.
- 60.17 Security and endorsement.
- 60.18 Consolidation of HEAL loans.
- 60.19 Forms.
- 60.20 The Secretary's collection efforts after payment of a default claim.
- 60.21 Refunds.

Subpart D—The Lender and Holder

- 60.30 Which organizations are eligible to apply to be HEAL lenders and holders?
- 60.31 The application to be a HEAL lender or holder.
- 60.32 The HEAL lender or holder insurance contract.
- 60.33 Making a HEAL loan.
- 60.34 HEAL loan account servicing.
- 60.35 HEAL loan collection.
- 60.36 Consequence of using an agent.
- 60.37 Forbearance.
- 60.38 Assignment of a HEAL loan.
- 60.39 Death and disability claims.

Public Health Service, HHS

§ 60.1

- 60.40 Procedures for filing claims.
- 60.41 Determination of amount of loss on claims.
- 60.42 Records, reports, inspection, and audit requirements for HEAL lenders and holders.
- 60.43 Limitation, suspension, or termination of the eligibility of a HEAL lender or holder.

Subpart E—The School

- 60.50 Which schools are eligible to be HEAL schools?
- 60.51 The student loan application.
- 60.52 The student's loan check.
- 60.53 Notification to lender or holder of change in enrollment status.
- 60.54 Payment of refunds by schools.
- 60.55 Administrative and fiscal procedures.
- 60.56 Records.
- 60.57 Reports.
- 60.58 Federal access to school records.
- 60.59 Records and Federal access after a school is no longer a HEAL school.
- 60.60 Limitation, suspension, or termination of the eligibility of a HEAL school.
- 60.61 Responsibilities of a HEAL school.

AUTHORITY: Sec. 215, of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); secs. 727–739A of the Public Health Service Act, 90 Stat. 2243, as amended, 93 Stat. 582, 99 Stat. 529–532, 102 Stat. 3122–3125 (42 U.S.C. 294–294I–1); renumbered as secs. 701–720, as amended by 106 Stat. 1994–2011 (42 U.S.C. 292–292p).

SOURCE: 48 FR 38988, Aug. 26, 1983, unless otherwise noted.

Subpart A—General Program Description

§ 60.1 What is the HEAL program?

(a) The Health Education Assistance Loan (HEAL) program is a program of Federal insurance of educational loans to graduate students in the fields of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, chiropractic, health administration and clinical psychology. The basic purpose of the program is to encourage lenders to make loans to students in these fields who desire to borrow money to pay for their educational costs. In addition, certain nonstudents (such as doctors serving as interns or residents) can borrow in order to pay the current interest charges accruing on earlier HEAL loans. By taking a HEAL loan, the borrower is obligated

to repay the lender or holder the full amount of the money borrowed, plus all interest which accrues on the loan.

(b) HEAL loans may be made by schools, banks, credit unions, State agencies, and other institutions eligible as lenders under § 60.30. HEAL school eligibility is described in § 60.50.

(c) The Secretary insures each lender or holder for the losses of principal and interest it may incur in the event that a borrower dies; becomes totally and permanently disabled; files for bankruptcy under chapter 11 or 13 of the Bankruptcy Act; files for bankruptcy under chapter 7 of the Bankruptcy Act and files a compliant to determine the dischargeability of the HEAL loan; or defaults on his or her loan. In these instances, if the lender or holder has complied with all HEAL statutes and regulations, and with the lender's or holder's insurance contract, and the Secretary pays the amount of the loss to the lender or holder, the borrower's loan is then assigned to the Secretary. Only at that time, the United States Government becomes the borrower's direct creditor and will actively pursue the borrower for repayment of the debt, including reporting the borrower's default on the loan to consumer credit reporting agencies or to the Internal Revenue Service for purposes of locating such taxpayer or for income tax refund offset, and referral to the Department of Justice for litigation.

(d) Any person who knowingly makes a false statement or misrepresentation in a HEAL loan transaction, bribes or attempts to bribe a Federal official, fraudulently obtains a HEAL loan, or commits any other illegal action in connection with a HEAL loan is subject to possible fine and imprisonment under Federal statute.

(e) *Calculating time periods.* In counting the number of days allowed to comply with any provisions of these regulations, Saturdays, Sundays, and holidays are to be included. However, if a due date falls on a Saturday, Sunday, or Federal holiday, the due date is the next Federal work day.

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 745, Jan. 8, 1987; 56 FR 42700, Aug. 29, 1991; 57 FR 28793, June 29, 1992]

Subpart B—The Borrower

§ 60.5 Who is an eligible student borrower?

To receive a HEAL loan, a student must satisfy the following requirements:

(a) He or she must be a citizen, national, or lawful permanent resident of the United States, permanent resident of the Trust Territory of the Pacific Islands (the Republic of Palau), the Republic of the Marshall Islands, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, or American Samoa, or lawful permanent resident of the Commonwealth of Puerto Rico, the Virgin Islands or Guam;

(b) He or she must be enrolled or accepted for enrollment at a HEAL school in a course of study that leads to one of the following degrees:

Doctor of Medicine
 Doctor of Osteopathic Medicine
 Doctor of Dentistry or equivalent degree
 Doctor of Veterinary Medicine or equivalent degree
 Doctor of Optometry or equivalent degree
 Doctor of Podiatric Medicine or equivalent degree
 Bachelor or Master of Science in Pharmacy or equivalent degree
 Graduate or equivalent degree in Public Health
 Doctor of Chiropractic or equivalent degree
 Doctoral degree in Clinical Psychology
 Masters or doctoral degree in Health Administration

(c) He or she must be carrying or plan to carry, during the period for which the loan is intended, the normal work load of a full-time student, as determined by the school. The student's work load may include any combination of courses, work experience, research or special studies that the school considers sufficient to classify the student as full time.

(d) If currently enrolled in school, he or she must be in good standing, as determined by the school.

(e)(1) In the case of a pharmacy student, he or she must have satisfactorily completed 3 years of training toward the pharmacy degree. These 3 years of training may have been taken at the pharmacy school or at a different school whose credits are accepted on transfer by the pharmacy school.

(2) The Doctor of Pharmacy degree is considered to be an equivalent degree if it is taken in a school that does not require the Bachelor or Master of Science in pharmacy as a prerequisite for the Doctor of Pharmacy degree.

(f) In the case of a medical, dental or osteopathic student enrolled in a 6-year program that the student may enter directly from secondary school, the student must be enrolled in the last 4 years of the program.

(g) He or she must agree that all funds received under the proposed loan will be used solely for tuition, other reasonable educational expenses, including fees, books, supplies and equipment, and laboratory expenses, reasonable living expenses, reasonable transportation costs (only to the extent that they are directly related to the borrower's education), and the HEAL insurance premium.

(h) He or she must require the loan to pursue the course of study at the school. This determination of the maximum amount of the loan will be made by the school, applying the considerations in § 60.51(f).

(i) If required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, he must have presented himself and submitted to registration under such section.

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986; 52 FR 745, Jan. 8, 1987; 57 FR 28793, June 29, 1992]

§ 60.6 Who is an eligible nonstudent borrower?

To receive a HEAL loan, a person who is not a student must satisfy all of the following requirements:

(a) He or she must have received a HEAL loan prior to August 13, 1981, for which he or she is required to make payments of interest, but not principal, during the period for which the new loan is intended. This may be the grace period or a period of internship, residency or deferment.

(b) He or she must continue to meet the citizenship, nationality, or residency qualifications required of student borrowers.

(c) He or she must agree that all funds received under the proposed loan

will be used solely for payment of currently accruing interest on HEAL loans and the HEAL insurance premium.

(d) If required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, he must have presented himself and submitted to registration under such section.

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986]

§ 60.7 The loan application process.

(a)(1)(i) A student seeking a HEAL loan applies to a participating lender for a HEAL loan by submitting an application form supplied by the school.

(ii) The applicant must fill out the applicant sections of the form completely and accurately.

(2) The student applicant must be informed of the Federal debt collection policies and procedures in accordance with the Department's Claims Collection Regulation (45 CFR part 30) prior to the student receiving the loan. The applicant must sign a certification statement attesting that the applicant has been notified of the actions the Federal Government can take in the event that the applicant fails to meet the scheduled payments. This signed statement must be maintained by the school and the lender or holder as part of the borrower's official record.

(3) A student applicant must have his or her school complete a portion of the application providing information relating to:

(i) The applicant's eligibility for the loan.

(ii) The cost of his or her education; and

(iii) The total financial resources that are actually available to the applicant for his or her costs of education for the period covered by the proposed HEAL loan, as determined in accordance with § 60.51(f), and other student aid that the applicant has received or will receive for the period covered by the proposed HEAL loan.

(4) The student applicant must certify on the application that the information provided reflects the applicant's total financial resources actually available for his or her costs of education for the period covered by the

proposed HEAL loan and the applicant's total indebtedness, and that the applicant has no other financial resources that are available to the applicant or that the applicant will receive for the period covered by the proposed HEAL loan.

(5) A student applicant must certify on the application that if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, he has presented himself and submitted to registration under such section.

(b) The applicant pursuing a full-time course of study at an institution of higher education that is a "participating school" in the Guaranteed Student Loan Program but is not pursuing a course of study listed in § 60.5(b), applies for a HEAL loan as a nonstudent under paragraph (c) of this section.

(c)(1)(i) A nonstudent seeking a HEAL loan applies to a participating lender for a HEAL loan by submitting an application form supplied by the lender.

(ii) The applicant must fill out the applicant sections of the form completely and accurately.

(2) The nonstudent applicant must be informed of the Federal debt collection policies and procedures in accordance with the Department's Claims Collection Regulation (45 CFR part 30) prior to the nonstudent receiving the loan. The applicant must sign a certification statement attesting that the applicant has been notified of the actions the Federal Government can take in the event that the applicant fails to meet the scheduled payments. This signed statement will be maintained by the lender or holder as part of the borrower's official record.

(3) A nonstudent applicant must have his or her employer or institution, whichever is relevant, certify on the application that the applicant is:

(i) Enrolled as a full-time student in an eligible school, as described in § 60.12;

(ii) A participant in an accredited internship or residency program, as described in § 60.11(a);

(iii) A member of the Armed Forces of the United States;

(iv) A Peace Corps volunteer;

§ 60.8

42 CFR Ch. I (10–1–11 Edition)

(v) A member of the National Health Service Corps; or

(vi) A full-time VISTA volunteer under Title I of the Domestic Volunteer Service Act of 1973.

(4) The nonstudent applicant seeking a HEAL loan during the grace period applies to the lender directly.

(5) A nonstudent applicant must certify on the application that if required under section 3 of the Military Selective Service Act to present himself for and submit to registration under such section, he has presented himself and submitted to registration under such section.

(6) The nonstudent applicant must certify on the application that the information provided reflects the applicant's total financial resources and indebtedness.

(Approved by the Office of Management and Budget under control numbers 0915–0038 and 0915–0108)

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986; 52 FR 746, Jan. 8, 1987; 57 FR 28794, June 29, 1992]

§ 60.8 What are the borrower's major rights and responsibilities?

(a) *The borrower's rights.* (1) Once the terms of the HEAL loan have been established, the lender or holder may not change them without the borrower's consent.

(2) The lender must provide the borrower with a copy of the completed promissory note when the loan is made. The lender or holder must return the original note to the borrower when the loan is paid in full.

(3) A lender must disburse HEAL loan proceeds as described in § 60.33(f).

(4) The lender or holder must provide the borrower with a copy of the repayment schedule before repayment begins.

(5) If the loan is sold from one lender or holder to another lender or holder, or if the loan is serviced by a party other than the lender or holder, the buyer must notify the borrower within 30 days of the transaction.

(6) The borrower does not have to begin repayment until 9 full months after leaving school or an accredited internship or residency program as described in § 60.11.

(7) The borrower is entitled to deferment from repayment of the principal and interest installments during periods described in § 60.12.

(8) The borrower may prepay the whole or any portion of the loan at any time without penalty.

(9) The lender or holder must allow the borrower to repay a HEAL loan according to a graduated repayment schedule.

(10) The borrower's total loan obligation is cancelled in the event of death or total and permanent disability.

(11) To assist the borrower in avoiding default, the lender or holder may grant the borrower forbearance. Forbearance, including circumstances in which the lender or holder must grant forbearance, is more fully described in § 60.37.

(12) Any borrower who received a fixed interest rate HEAL loan in excess of 12 percent per year may enter into an agreement with the lender which made this loan for the reissuance of the loan in accordance with section 739A of the Public Health Service Act.

(b) *The borrower's responsibilities.* (1) The borrower must pay any insurance premium that the lender may require as more fully described in § 60.14.

(2) The borrower must pay all interest charges on the loan as required by the lender or holder.

(3) The borrower must immediately notify the lender or holder in writing in the event of:

(i) Change of address;

(ii) Change of name;

(iii) Failure to enroll in a HEAL school for the period for which the loan is intended;

(iv) Transfer to another school;

(v) Withdrawal from a HEAL school or change in status to less than full-time attendance at a HEAL school;

(vi) Graduation;

(vii) Failure to enter into or interruption in an internship or residency program; or

(viii) Change of status that authorizes deferment.

(4) The borrower must repay the loan in accordance with the repayment schedule.

(5) A borrower may not have a HEAL loan discharged in bankruptcy during

the first 5 years of the repayment period. This prohibition against the discharge of a HEAL loan applies to bankruptcy under *any* chapter of the Bankruptcy Act, including Chapter 13. A borrower may have a HEAL loan discharged in bankruptcy after the first 5 years of the repayment period only upon a finding by the Bankruptcy Court that the non-discharge of such debt would be unconscionable and upon the condition that the Secretary shall not have waived his or her rights to reduce any Federal reimbursements or Federal payments for health services under any Federal law in amounts up to the balance of the loan.

(6) If the borrower fails to make payments on the loan on time, the total amount to be repaid by the borrower may be increased by additional interest, late charges, attorney's fees, court costs, and other collection charges. In addition, the Secretary may offset amounts attributable to an unpaid loan from reimbursements or payment for health services provided under any Federal law to a defaulted borrower practicing his or her profession.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 746, Jan. 8, 1987; 57 FR 28794, June 29, 1992]

Subpart C—The Loan

§ 60.10 How much can be borrowed?

(a) *Student borrower.* An eligible student may borrow an amount to be used solely for expenses, as described in § 60.5(g), incurred or to be incurred over a period of up to an academic year and disbursed in accordance with § 60.33(f). The maximum amount he or she may receive for that period shall be determined by the school in accordance with § 60.51(f) within the following limitations:

(1) A student enrolled in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry or podiatric medicine may borrow up to \$80,000 under this part. The amount received may not exceed \$20,000 in any academic year.

(2) A student enrolled in a school of public health, pharmacy, chiropractic, or a graduate program in health ad-

ministration, clinical psychology, or allied health may borrow up to \$50,000 under this part. The amount received may not exceed \$12,500 per academic year.

(3) For purposes of this paragraph, an academic year means the traditional approximately 9-month September-to-June annual session. For the purpose of computing academic year equivalents for students who, during a 12-month period, attend for a longer period than the traditional academic year, the academic year will be considered to be 9 months in length.

(4) The student's estimated cost of attendance shall not exceed the estimated cost of attendance of all students in like circumstances pursuing a similar curriculum at that school.

(b) *Non-student borrower.* An eligible nonstudent may borrow amounts under this authority with the following restrictions:

(1) In no case may an eligible nonstudent borrower receive a loan that is greater than the sum of the HEAL insurance premium plus the interest that is expected to accrue and must be paid on the borrower's HEAL loans during the period for which the new loan is intended.

(2) An eligible nonstudent in the field of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine may borrow up to \$80,000 under this part including loans obtained while the borrower was a student. The loan amount may not exceed \$20,000 in any 12-month period.

(3) An eligible nonstudent in the field of pharmacy, public health, chiropractic, health administration, or clinical psychology may borrow up to \$50,000 under this part including loans obtained while the borrower was a student. The loan amount received under this part may not exceed \$12,500 in any 12-month period.

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986; 52 FR 746, Jan. 8, 1987; 57 FR 28794, June 29, 1992]

§ 60.11 Terms of repayment.

(a) *Commencement of repayment.* (1) The borrower's repayment period must begin the first day of the 10th month after the month he or she ceases to be a full-time student at a HEAL school.

§ 60.11

42 CFR Ch. I (10–1–11 Edition)

The 9-month period before the repayment period begins is popularly called the “grace period.”

(i) *Postponement for internship or residency program.* However, if the borrower becomes an intern or resident in an accredited program within 9 full months after leaving school, then the borrower’s repayment period must begin the first day of the 10th month after the month he or she ceases to be an intern or resident. For a borrower who receives his or her first HEAL loan on or after October 22, 1985, this postponement of the beginning of the repayment period for participation in an internship or residency program is limited to 4 years.

(ii) *Postponement for fellowship training or educational activity.* For any HEAL loan received on or after October 22, 1985, if the borrower becomes an intern or resident in an accredited program within 9 full months after leaving school, and subsequently enters into a fellowship training program or an educational activity, as described in § 60.12(b)(1) and (2), within 9 months after the completion of the accredited internship or residency program or prior to the completion of such program, the borrower’s repayment period begins on the first day of the 10th month after the month he or she ceases to be a participant in the fellowship training program or educational activity. Postponement of the commencement of the repayment period for either activity is limited to 2 years.

(iii) *Non-student borrower.* If a nonstudent borrower obtains another HEAL loan during the grace period or period of internship, residency, or deferment (as defined in § 60.12), the borrower must begin to repay this loan when repayment on the borrower’s other HEAL loans begins or resumes.

(2) An accredited internship or residency program must be approved by one of the following accrediting agencies:

(i) Accreditation Council for Graduate Medical Education.

(ii) Council on Optometric Education.

(iii) Commission on Accreditation of Dental and Dental Auxiliary Programs.

(iv) American Osteopathic Association.

(v) Council on Podiatry Education.

(vi) American Council on Pharmaceutical Education.

(vii) Council on Education for Public Health.

(viii) American College of Veterinary Surgeons.

(ix) Council on Chiropractic Education.

(b) *Length of repayment period.* In general, a lender or holder must allow a borrower at least 10 years, but not more than 25 years, to repay a loan calculated from the beginning of the repayment period. A borrower must fully repay a loan within 33 years from the date that the loan is made.

(1) For a HEAL borrower who received any HEAL loan prior to October 22, 1985, periods of deferment (as described in § 60.12) are not included when calculating the 10 to 25 or 33 year limitations.

(2) For a borrower who receives his or her first HEAL loan on or after October 22, 1985, periods of deferment (as described in § 60.12) are included when calculating the 33 year limitation, but are not included when calculating the 10 to 25 year limitation.

(c) *Prepayment.* The borrower may prepay the whole or any part of the loan at any time without penalty.

(d) *Minimum annual payment.* During each year of repayment, a borrower’s payments to all holders of his or her HEAL loans must total the interest that accrues during the year on all of the loans, unless the borrower, in the promissory note or other written agreement, agrees to make payments during any year or any repayment period in a lesser amount.

(e) *Repayment schedule agreement.* At least 30 and not more than 60 days before the commencement of the repayment period, a borrower must contact the holder of the loan to establish the precise terms of repayment. The borrower may select a monthly repayment schedule with substantially equal installment payments or a monthly repayment schedule with graduated installment payments that increase in amount over the repayment period. If the borrower does not contact the lender or holder and does not respond to contacts from the lender or holder, the lender or holder may establish a

monthly repayment schedule with substantially equal installment payments, subject to the terms of the borrower's HEAL note.

(f) *Supplemental repayment agreement.*

(1) A lender or holder and a borrower may enter into an agreement supplementing the regular repayment schedule agreement. Under a supplemental repayment agreement, the lender or holder agrees to consider that the borrower has met the terms of the regular repayment schedule as long as the borrower makes payments in accordance with the supplemental schedule.

(2) The purpose of a supplemental repayment agreement is to permit a lender or holder, at its option, to offer a borrower a repayment schedule based on other than equal or graduated payments. (For example, a supplemental repayment agreement may base the amount of the borrower's payments on his or her income.)

(3) The supplemental schedule must contain terms which, according to the Secretary, do not unduly burden the borrower and do not extend the Secretary's insurance liability beyond the number of years specified in paragraph (b) of this section. The supplemental schedule must be approved by the Secretary prior to the start of repayment.

(4) The lender or holder may establish a supplemental repayment agreement over the borrower's objection only if the borrower's written consent to enter into a supplemental agreement was obtained by the lender at the time the loan was made.

(5) A lender or holder may assign a loan subject to a supplemental repayment agreement only if it specifically notifies the buyer of the terms of the supplemental agreement. In such cases, the loan and the supplemental agreement must be assigned together.

(Approved by the Office of Management and Budget under control numbers 0915-0043 and 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986; 53 FR 6097, Feb. 29, 1988; 57 FR 28794, June 29, 1992]

§ 60.12 Deferment.

(a) After the repayment period has commenced, installments of principal

and interest need not be paid during any period:

(1) During which the borrower is pursuing a full-time course of study at a HEAL school or at an institution of higher education that is a "participating school" in the Guaranteed Student Loan Program;

(2) Up to 4 years during which the borrower is a participant in an accredited internship or residency program, as described in § 60.11(a)(2). For a borrower who receives his or her first HEAL loan on or after October 22, 1985, this total of 4 years for an internship or residency program includes any period of postponement of the repayment period, as described in § 60.11(a)(1);

(3) Up to 3 years during which the borrower is a member of the Armed Forces of the United States;

(4) Up to 3 years during which the borrower is in service as a volunteer under the Peace Corps Act;

(5) Up to 3 years during which the borrower is a member of the National Health Service Corps; or

(6) Up to 3 years during which the borrower is a full-time volunteer under title I of the Domestic Volunteer Service Act of 1973.

(b) For any HEAL loan received on or after October 22, 1985, after the repayment period has commenced, installments of principal and interest need not be paid during any period for up to 2 years during which the borrower is a participant in:

(1) A fellowship training program, which:

(i) Is directly related to the discipline for which the borrower received the HEAL loan;

(ii) Begins within 12 months after the borrower ceases to be a participant in an accredited internship or residency program, as described in § 60.11(a)(2), or prior to the completion of the borrower's participation in such program;

(iii) Is a full-time activity in research or research training or health care policy;

(iv) Is not a part of, an extension of, or associated with an internship or residency program, as described in § 60.11(a)(2);

(v) Pays no stipend or one which is not more than the annual stipend level

established by the Public Health Service for the payment of uniform levels of financial support for trainees receiving graduate and professional training under Public Health Service grants, as in effect at the time the borrower requests the deferment; and

(vi) Is a formally established fellowship program which was not created for a specific individual; or

(2) A full-time educational activity at an institution defined by section 435(b) of the Higher Education Act of 1965 which:

(i) Is directly related to the discipline for which the borrower received the HEAL loan;

(ii) Begins within 12 months after the borrower ceases to be a participant in an accredited internship or residency program, as described in § 60.11(a)(2), or prior to the completion of the borrower's participation in such program;

(iii) Is not a part of, an extension of, or associated with an internship or residency program, as described in § 60.11(a)(2); and

(iv) Is required for licensure, registration, or certification in the State in which the borrower intends to practice the discipline for which the borrower received the HEAL program loan.

(c) (1) To receive a deferment, including a deferral of the onset of the repayment period (see § 60.11(a)), a borrower must at least 30 days prior to, but not more than 60 days prior to, the onset of the activity and annually thereafter, submit to the lender or holder evidence of his or her status in the deferment activity and evidence that verifies deferment eligibility of the activity (with the full expectation that the borrower will begin the activity). It is the responsibility of the borrower to provide the lender or holder with all required information or other information regarding the requested deferment. If written evidence that verifies eligibility of the activity and the borrower for the deferment, including a certification from an authorized official (e.g., the director of the fellowship activity, the dean of the school, etc.), is received by the lender or holder within the required time limit, the lender or holder must approve the deferment. The lender or holder may

rely in good faith upon statements of the borrower and the authorized official, except where those statements or other information conflict with information available to the lender or holder. When those verification statements or other information conflict with information available to the lender or holder, to indicate that the applicant fails to meet the requirements for deferment, the lender or holder may not approve the deferment until those conflicts are resolved.

(2) For those activities described in paragraphs (b)(1) or (b)(2) of this section, the borrower may request that the Secretary review a decision by the lender or holder denying the deferment by sending to the Secretary copies of the application for deferment and the lender's or holder's denial of the request. However, if information submitted to the lender or holder conflicts with other information available to the lender or holder, to indicate that the borrower fails to meet the requirements for deferment, the borrower may not request a review until such conflicts have been resolved. During the review process, the lender or holder must comply with any requests for information made by the Secretary. If the Secretary determines that the fellowship or educational activity is eligible for deferment and so notifies the lender or holder, the lender or holder must approve the deferment.

(Approved by the Office of Management and Budget under control numbers 0915–0034 and 0915–0108)

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986; 53 FR 6097, Feb. 29, 1988; 57 FR 28795, June 29, 1992]

§ 60.13 Interest.

(a) *Rate.* At the lender's option, the interest rate on the HEAL loan may be calculated on a fixed rate or on a variable rate basis. However, whichever method is selected must continue over the life of the loan, except where the loan is consolidated with another HEAL loan.

(1) For all loans made on or after October 22, 1985, for each calendar quarter, the Secretary determines the maximum annual HEAL interest rate by determining the average of the bond equivalent rates reported for the 91-day

U.S. Treasury bills auctioned for the preceding calendar quarter, adding 3 percentage points, and rounding that amount to the next higher one-eighth of 1 percent.

(2) Interest that is calculated on a fixed rate basis is determined for the life of the loan during the calendar quarter in which the loan is executed. It may not exceed the rate determined for that quarter by the Secretary under paragraph (a)(1) of this section.

(3) Interest that is calculated on a variable rate basis varies every calendar quarter throughout the life of the loan as the market price of U.S. Treasury bills changes. For any quarter it may not exceed the rate determined by the Secretary under paragraph (a)(1) of this section.

(4) The Secretary announces the rate determined under paragraph (a)(1) of this section on a quarterly basis through a notice published in the FEDERAL REGISTER.

(b) *Compounding of interest.* Interest accrues from the date the loan is disbursed until the loan is paid in full. Unpaid accrued interest shall be compounded not more frequently than semiannually and added to principal. However, a lender or holder may postpone the compounding of interest before the beginning of the repayment period or during periods of deferment or forbearance and add interest to principal at the time repayment of principal begins or resumes.

(c) *Payment.* Repayment of principal and interest is due when the repayment period begins. A lender or holder must permit a borrower to postpone paying interest before the beginning of the repayment period or during a period of deferment or forbearance. In these cases, payment of interest begins or resumes on the date repayment of principal begins or resumes.

(d) *Usury laws.* No provision of any Federal or State law that limits the rate or amount of interest payable on loans shall apply to a HEAL loan.

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644, Aug. 28, 1986; 57 FR 28795, June 29, 1992]

§ 60.14 The insurance premium.

(a) *General.* (1) The Secretary insures each lender or holder for the losses of

principal and interest it may incur in the event that a borrower dies; becomes totally and permanently disabled; files for bankruptcy under chapter 11 or 13 of the Bankruptcy Act; files for bankruptcy under chapter 7 of the Bankruptcy Act and files a complaint to determine the dischargeability of the HEAL loan; or defaults on his or her loan. For this insurance, the Secretary charges the lender an insurance premium. The insurance premium is due to the Secretary on the date of disbursement of the HEAL loan.

(2) The lender may charge the borrower an amount equal to the cost of the insurance premium. The cost of the insurance premium may be charged to the borrower by the lender in the form of a one-time special charge with no subsequent adjustments required. The lender may bill the borrower separately for the insurance premium or may deduct an amount attributable to it from the loan proceeds before the loan is disbursed. In either case, the lender must clearly identify to the borrower the amount of the insurance premium and the method of calculation.

(3) If the lender does not pay the insurance premium on or before 30 days after disbursement of the loan, a late fee will be charged on a daily basis at the same rate as the interest rate that the lender charges for the HEAL loan for which the insurance premium is past due. The lender may not pass on this late fee to the borrower.

(4) HEAL insurance coverage ceases to be effective if the insurance premium is not paid within 60 days of the disbursement of the loan.

(5) Except in cases of error, premiums are not refundable by the Secretary, and need not be refunded by the lender to the borrower, even if the borrower graduates or withdraws from the school, defaults, dies or becomes totally and permanently disabled.

(b) *Rate.* The rate of the insurance premium shall not exceed the statutory maximum. The Secretary announces changes in the rate of the insurance premium through a notice published in the FEDERAL REGISTER.

(c) *Method of calculation—(1) Student borrowers.* For loans disbursed prior to July 22, 1986, the lender must calculate the insurance premium on the basis of

§ 60.15

the number of months beginning with the month following the month in which the loan proceeds are disbursed to the student borrower and ending 9 full months after the month of the student's anticipated date of graduation. For loans disbursed on or after July 22, 1986, the insurance premium shall be calculated as a one-time flat rate on the principal of the loan at the time of disbursement.

(2) *Non-student borrowers.* For loans disbursed prior to July 22, 1986, the lender must calculate the insurance premium for nonstudent borrowers on the basis of the number of months beginning with the month following the month in which the loan proceeds are disbursed to the borrower and ending at the conclusion of the month preceding the month in which repayment of principal is expected to begin or resume on the borrower's previous HEAL loans. For loans disbursed on or after July 22, 1986, the insurance premium shall be calculated as a one-time flat rate on the principal of the loan at the time of disbursement.

(3) *Multiple installments.* In cases where the lender disburses the loan in multiple installments, the insurance premium is calculated for each disbursement.

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30644 Aug. 28, 1986; 52 FR 746, Jan. 8, 1987; 56 FR 42700, Aug. 29, 1991; 57 FR 28795, June 29, 1992]

§ 60.15 Other charges to the borrower.

(a) *Late charges.* If the borrower fails to pay all of a required installment payment or fails to provide written evidence that verifies eligibility for the deferment of the payment within 30 days after the payment's due date, the lender or holder will require that the borrower pay a late charge. A late charge must be equal to 5 percent of the unpaid portion of the payment due.

(b) *Collection charges.* The lender or holder may also require that the borrower pay the holder of the note for reasonable costs incurred by the holder or its agent in collecting any installment not paid when due. These costs may include attorney's fees, court costs, telegrams, and long-distance phone calls. The holder may not charge the borrower for the normal costs asso-

42 CFR Ch. I (10-1-11 Edition)

ciated with preparing letters and making personal and local telephone contacts with the borrower. A service agency's fee for normal servicing of a loan may not be passed on to the borrower, either directly or indirectly. No charges, other than those authorized by this section, may be passed on to the borrower, either directly or indirectly, without prior approval of the Secretary.

(c) *Other loan making costs.* A lender may not pass on to the borrower any cost of making a HEAL loan other than the costs of the insurance premium.

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 747, Jan. 8, 1987; 57 FR 28795, June 29, 1992]

§ 60.16 Power of attorney.

Neither a lender nor a school may obtain a borrower's power of attorney or other authorization to endorse a disbursement check on behalf of a borrower. The borrower must personally endorse the check and may not authorize anyone else to endorse it on his or her behalf.

§ 60.17 Security and endorsement.

(a) A HEAL loan must be made without security.

(b) With one exception, it must also be made without endorsement. If a borrower is a minor and cannot under State law create a legally binding obligation by his or her own signature, a lender may require an endorsement by another person on the borrower's HEAL note. For purposes of this paragraph, an "endorsement" means a signature of anyone other than the borrower who is to assume either primary or secondary liability on the note.

§ 60.18 Consolidation of HEAL loans.

HEAL loans may be consolidated as follows provided that the lender or holder must first inform the borrower of the effect of the consolidation on the interest rate and explain to the borrower that he or she is not required to agree to the consolidation:

(a) If a lender or holder holds two or more HEAL loans made to the same borrower, the lender or holder and the borrower may agree to consolidate the loans into a single HEAL loan obligation evidenced by one promissory note.

(b) A HEAL loan may be consolidated with any other loan only if:

(1) The consolidation will not result in terms less favorable to the borrower than if no consolidation had occurred, and

(2) The Federal Government does not, as a result of the consolidation, become liable for any payment of principal or interest for a Guaranteed Student Loan under the provisions of section 439(o) of the Higher Education Act of 1965.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 57 FR 28795, June 29, 1992]

§ 60.19 Forms.

All HEAL forms are approved by the Secretary and may not be changed without prior approval by the Secretary. HEAL forms shall not be signed in blank by a borrower, a school, a lender or holder, or an agent of any of these. The Secretary may prescribe who must complete the forms, and when and to whom the forms must be sent. All HEAL forms must contain a statement that any person who knowingly makes a false statement or misrepresentation in a HEAL loan transaction, bribes or attempts to bribe a Federal official, fraudulently obtains a HEAL loan, or commits any other illegal action in connection with a HEAL loan is subject to possible fine and imprisonment under Federal statute.

[52 FR 747, Jan. 8, 1987, as amended at 57 FR 28795, June 29, 1992]

§ 60.20 The Secretary's collection efforts after payment of a default claim.

After paying a default claim on a HEAL loan, the Secretary attempts to collect from the borrower and any valid endorser in accordance with the Federal Claims Collection Standards (4 CFR parts 101 through 105), the Office of Management and Budget Circular A-129, issued May 9, 1985, and the Department's Claims Collection Regulation (45 CFR part 30). The Secretary attempts collection of all unpaid principal, interest, penalties, administrative costs, and other charges or fees, except in the following situations:

(a) *The borrower has a valid defense on the loan.* The Secretary refrains from collection against the borrower or endorser to the extent of any defense that the Secretary concludes is valid. Examples of a valid defense include expiration of the statute of limitations and infancy.

(b) *A school owes the borrower a refund for the period covered by the loan.* In this situation, the Secretary refrains from collection to the extent of the unpaid refund if the borrower assigns to the Secretary the right to receive the refund.

(c) *The school or lender or holder is the subject of a lawsuit or Federal administrative proceeding.* In this situation, if the Secretary determines that the proceeding involves allegations that, if proven, would provide the borrower with a full or partial defense on the loan, then the Secretary may suspend collection activity on all or part of a loan until the proceeding ends. The Secretary suspends collection activity only for so long as the proceeding is being energetically prosecuted in good faith and the allegations that relate to the borrower's defense are reasonably likely to be proven.

(d) *The borrower dies or becomes totally and permanently disabled.* In this situation, the Secretary terminates all collection activity against the borrower. If the borrower dies or becomes totally and permanently disabled, the Secretary also terminates all collection activity against any endorser.

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 747, Jan. 8, 1987; 57 FR 28795, June 29, 1992]

§ 60.21 Refunds.

(a) *Student authorization.* By applying for a HEAL loan, a student authorizes a participating school to make payment of a refund that is allocable to a HEAL loan directly to the original lender (or to a subsequent holder of the loan note, if the school has knowledge of the holder's identity).

(b) *Treatment by lenders or holders.* (1) A holder of a HEAL loan must treat a refund payment received from a HEAL school as a downward adjustment in the principal amount of the loan.

(2) When a lender receives a school refund check for a loan it no longer holds, the lender must transfer that

§ 60.30

payment to the holder of the loan and either inform the borrower about the refund check and where it was sent or, if the borrower's address is unknown, notify the current holder that the borrower was not informed. The current holder must provide the borrower with a written notice of the refund payment.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 57 FR 28795, June 29, 1992]

Subpart D—The Lender and Holder

§ 60.30 Which organizations are eligible to apply to be HEAL lenders and holders?

(a) A HEAL lender may make and hold loans under the HEAL program.

(b) The following types of organizations are eligible to apply to the Secretary to be HEAL lenders:

(1) A financial or credit institution (including a bank, savings and loan association, credit union, or insurance company) which is subject to examination and supervision in its capacity as a lender by an agency of the United States or of the State in which it has its principal place of business;

(2) A pension fund approved by the Secretary;

(3) An agency or instrumentality of a State;

(4) A HEAL school; and

(5) A private nonprofit entity, designated by the State, regulated by the State, and approved by the Secretary.

(c) The following types of organizations are eligible to apply to the Secretary to be HEAL holders:

(1) Public entities in the business of purchasing student loans;

(2) The Student Loan Marketing Association (popularly known as "Sallie Mae"); and

(3) Other eligible lenders.

(d) HEAL holders must comply with any provisions in the regulations required of HEAL lenders including, but not limited to, provisions regarding applications, contracts, and due diligence.

[48 FR 38988, Aug. 26, 1983, as amended at 57 FR 28795, June 29, 1992]

42 CFR Ch. I (10-1-11 Edition)

§ 60.31 The application to be a HEAL lender or holder.

(a) In order to be a HEAL lender or holder, an eligible organization must submit an application to the Secretary annually.

(b) In determining whether to enter into an insurance contract with an applicant and what the terms of that contract should be, the Secretary may consider the following criteria:

(1) Whether the applicant is capable of complying with the requirements in the HEAL regulations applicable to lenders and holders;

(2) The amount and rate of loans which are currently delinquent or in default, if the applicant has had prior experience with similar Federal or State student loan programs; and

(3) The financial resources of the applicant.

(c) The applicant must develop and follow written procedures for making, servicing and collecting HEAL loans. These procedures must be reviewed during the biennial audit required by § 60.42(d). If the applicant uses procedures more stringent than those required by §§ 60.34 and 60.35 for its other loans of comparable dollar value, on which it has no Federal, State, or other third party guarantee, it must include those more stringent procedures in its written procedures for servicing and collecting its HEAL loans.

(d) The applicant must submit sufficient materials with his or her application to enable the Secretary to fairly evaluate the application in accordance with these criteria.

(Approved by the Office of Management and Budget under control numbers 0915-0034 and 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 747, Jan. 8, 1987; 57 FR 28796, June 29, 1992]

§ 60.32 The HEAL lender or holder insurance contract.

(a)(1) If the Secretary approves an application to be a HEAL lender or holder, the Secretary and the lender or holder must sign an insurance contract. Under this contract, the lender or holder agrees to comply with all the laws, regulations, and other requirements applicable to its participation in the HEAL program and the Secretary

agrees to insure each eligible HEAL loan held by the lender or holder against the borrower's default, death, total and permanent disability, bankruptcy under chapter 11 or 13 of the Bankruptcy Act, or bankruptcy under chapter 7 of the Bankruptcy Act when the borrower files a complaint to determine the dischargeability of the HEAL loan. The Secretary's insurance covers 100 percent of the lender's or holder's losses on both unpaid principal and interest, except to the extent that a borrower may have a defense on the loan other than infancy.

(2) HEAL insurance, however, is not unconditional. The Secretary issues HEAL insurance on the implied representations of the lender that all the requirements for the initial insurability of the loan have been met. HEAL insurance is further conditioned upon compliance by the holder of the loan with the HEAL statute and regulations, the lender's or holder's insurance contract, and its own loan management procedures set forth in writing pursuant to § 60.31(c). The contract may contain a limit on the duration of the contract and the number or amount of HEAL loans a lender may make or hold. Each HEAL lender has either a standard insurance contract or a comprehensive insurance contract with the Secretary, as described below.

(b) *Standard insurance contract.* A lender with a standard insurance contract must submit to the Secretary a borrower's loan application for HEAL insurance on each loan that the lender determines to be eligible. The Secretary notifies the lender whether the loan is or is not insurable, the amount of the insurance, and the expiration date of the insurance commitment. A loan which has been disbursed under a standard contract of insurance prior to the Secretary's approval of the application is considered not to have been insured.

(c)(1) *Comprehensive insurance contract.* A lender with a comprehensive insurance contract may disburse a loan without submitting an individual borrower's loan application to the Secretary for approval. All eligible loans made by a lender with this type of contract are insured immediately upon disbursement.

(2) The Secretary will revoke the comprehensive contract of any lender who utilizes procedures which are inconsistent with the HEAL statute and regulations, the lender's insurance contract, or its own loan management procedures set forth in writing pursuant to § 60.31(c), and require that such lenders disburse HEAL loans only under a standard contract. When the Secretary determines that the lender is in compliance with the HEAL statute and regulations and its own loan management procedures set forth in writing pursuant to § 60.31(c), the lender may reapply for a comprehensive contract.

(3) In providing comprehensive contracts, the Secretary shall give priority to eligible lenders that:

(i) Make loans to students at interest rates below the rates prevailing during the period involved; or

(ii) Make loans under terms that are otherwise favorable to the student relative to the terms under which eligible lenders are generally making loans during the period involved.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 747, Jan. 8, 1987; 56 FR 42701, Aug. 29, 1991; 57 FR 28796, June 29, 1992]

§ 60.33 Making a HEAL loan.

The loan-making process includes the processing of necessary forms, the approval of a borrower for a loan, determination of a borrower's creditworthiness, the determination of the loan amount (not to exceed the amount approved by the school), the explanation to a borrower of his or her responsibilities under the loan, the execution of the promissory note, and the disbursement of the loan proceeds. A lender may rely in good faith upon statements of an applicant and the HEAL school contained in the loan application papers, except where those statements are in conflict with information obtained from the report on the applicant's credit history, or other information available to the lender. Except where the statements are in conflict with information obtained from the applicant's credit history or other information available to the lender, a lender making loans to nonstudent borrowers may rely in good faith upon

statements by the borrower and authorizing officials of internship, residency, or other programs for which a borrower may receive a deferment.

(a) *Processing of forms.* Before making a HEAL loan, a lender must determine that all required forms have been completed by the borrower, the HEAL school, the lender, and the authorized official for an internship, a residency, or other deferment activity.

(b) *Approval of borrower.* A lender may make a HEAL loan only to an eligible student or nonstudent borrower.

(c) *Lender determination of the borrower's creditworthiness.* The lender may make HEAL loans only to an applicant that the lender has determined to be creditworthy. This determination must be made at least once for each academic year during which the applicant applies for a HEAL loan. An applicant will be determined to be "creditworthy" if he or she has a repayment history that has been satisfactory on any loans on which payments have become due. The lender may not determine that an applicant is creditworthy if the applicant is currently in default on any loan (commercial, consumer, or educational) until the delinquent account is made current or satisfactory arrangements are made between the affected lender(s) and the HEAL applicant. The lender must obtain documentation, such as a letter from the authorized official(s) of the affected lender(s) or a corrected credit report indicating that the HEAL applicant has taken satisfactory actions to bring the account into good standing. It is the responsibility of the HEAL loan applicant to assure that the lender receives each such documentation. No loan may be made to an applicant who is delinquent on any Federal debt until the delinquent account is made current or satisfactory arrangements are made between the affected agency and the HEAL applicant. The lender must receive a letter from the authorized Federal official of the affected Federal agency stating that the borrower has taken satisfactory actions to bring the account into good standing. It is the responsibility of the loan applicant to assure that the lender has received each such letter. The absence of any previous credit, however, is not an in-

dication that the applicant is not creditworthy and is not to be used as a reason to deny the status of creditworthy to an applicant. The lender must determine the creditworthiness of the applicant using, at a minimum, the following:

(1) A report of the applicant's credit history obtained from an appropriate consumer credit reporting agency, which must be used in making the determinations required by paragraph (c) of this section; and

(2) For student applicants only, the certification made by the applicant's school under § 60.51(e).

(d) *Determination of loan amount.* A lender may not make a HEAL loan in an amount that exceeds the permissible annual and aggregate maximums described in § 60.10.

(e) *Promissory note.* (1) Each loan must be evidenced by a promissory note approved by the Secretary. A lender must obtain the Secretary's prior approval of the note form before it makes a HEAL loan evidenced by a promissory note containing any deviation from the provisions of the form most currently approved by the Secretary. The lender must give the borrower a copy of each executed note.

(2) The lender must explain to the borrower that the loan must be repaid and that the loan proceeds may be applied toward educational expenses only.

(f) *Disbursement of HEAL loan.* (1) A lender must disburse HEAL loan proceeds:

(i) To a student borrower, by means of a check or draft payable jointly to the student borrower and the HEAL school. Except where a lender is also a school, a lender must mail the check or draft to the school. A lender may not disburse the loan proceeds earlier than is reasonably necessary to meet the cost of education for the period for which the loan is made.

(ii) To a nonstudent borrower, by means of a check or draft payable to the borrower. However, when a previous loan is held by a different lender, the current lender must make the HEAL loan disbursement check or draft payable jointly to the borrower and the holder of the previous HEAL loan for which interest is payable.

(2) Effective July 1, 1987, a lender must disburse the HEAL loan proceeds in two or more installments unless the loan is intended to cover a period of no more than one-half an academic year. The amount disbursed at one time must correspond to the borrower's educational expenses for the period for which the disbursement is made, and must be indicated by the school on the borrower's application. If the loan is intended for more than one-half an academic year, the school must indicate on the borrower's application both the approximate dates of disbursement and the amount the borrower will need on each such date. In no case may the lender disburse the proceeds earlier than is reasonably necessary to meet the costs of education for the period for which the disbursement or the loan is made.

(g) If the lender determines that the applicant is not creditworthy, pursuant to paragraph (c) of this section, the lender must not approve the HEAL loan request. If the applicant is a student, the lender must notify the applicant and the applicant's school named on the application form of the denial of a HEAL loan, stating the reason for the denial.

(h) The lender must report a borrower's HEAL indebtedness to one or more national credit bureaus within 120 days of the date the final disbursement on the loan is made.

(Approved by the Office of Management and Budget under control numbers 0915-0043, 0915-0108, and 0915-0144)

[48 FR 38988, Aug. 26, 1983, as amended at 51 FR 30645, Aug. 28, 1986; 52 FR 748, Jan. 8, 1987; 57 FR 28796, June 29, 1992; 58 FR 67349, Dec. 21, 1993]

§ 60.34 HEAL loan account servicing.

HEAL loan account servicing involves the proper maintenance of records, and the proper review and management of accounts. Generally accepted account servicing standards ensure that collections are received and accounted for, delinquent accounts are identified promptly, and reports are produced comparing actual results to previously established objectives.

(a) *Borrower inquiries.* A lender or holder must respond on a timely basis to written inquiries and other commu-

nications from a borrower and any endorser of a HEAL loan.

(b) *Conversion of loan to repayment status.* (1) At least 30 and not more than 60 days before the commencement of the repayment period, the lender or holder must contact the borrower in writing to establish the terms of repayment. Lenders or holders may not charge borrowers for the additional interest or other charges, penalties, or fees that accrue when a lender or holder does not contact the borrower within this time period and a late conversion results.

(2) Terms of repayment are established in a written schedule that is made a part of, and subject to the terms of, the borrower's original HEAL note.

(3) The lender or holder may not surrender the original promissory note to the borrower until the loan is paid in full. At that time, the lender or holder must give the borrower the original promissory note.

(c) *Borrower contacts.* The lender or holder must notify each borrower by a written contact, which has an address correction request on the envelope, of the balance owed for principal, interest, insurance premiums, and any other charges or fees owed to the lender, at least every 6 months from the time the loan is disbursed. The lender or holder must use this notice to remind the borrower of the option, without penalty, to pay all or part of the principal and accrued interest at any time.

(d) *Skip-tracing.* If, at any time, the lender or holder is unable to locate a borrower, the lender or holder must initiate skip-tracing procedures as described in § 60.35(a)(2).

(Approved by the Office of Management and Budget under control numbers 0915-0043 and 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 748, Jan. 8, 1987; 57 FR 28796, June 29, 1992]

§ 60.35 HEAL loan collection.

A lender or holder must exercise due diligence in the collection of a HEAL loan with respect to both a borrower and any endorser. In order to exercise due diligence, a lender or holder must implement the following procedures when a borrower fails to honor his or her payment obligations:

(a)(1) When a borrower is delinquent in making a payment, the lender or holder must remind the borrower within 15 days of the date the payment was due by means of a written contact. If payments do not resume, the lender or holder must contact both the borrower and any endorser at least 3 more times at regular intervals during the 120-day delinquent period following the first missed payment of that 120-day period. The second demand notice for a delinquent account must inform the borrower that the continued delinquent status of the account will be reported to consumer credit reporting agencies if payment is not made. Each of the required four contacts must consist of at least a written contact which has an address correction request on the envelope. The last contact must consist of a telephone contact, in addition to the required letter, unless the borrower cannot be contacted by telephone. The lender or holder may choose to substitute a personal contact for a telephone contact. A record must be made of each attempt to contact and each actual contact, and that record must be placed in the borrower's file. Each contact must become progressively firmer in tone. If the lender or holder is unable to locate the borrower and any endorser at any time during the period when the borrower is delinquent, the lender or holder must initiate the skip-tracing procedures described in paragraph (a)(2) of this section.

(2) If the lender or holder is unable to locate either the borrower or the endorser at any time, the lender or holder must initiate and use skip-tracing activities which are at least as extensive and effective as those it uses to locate borrowers delinquent in the repayment of its other loans of comparable dollar value. To determine the correct address of the borrower, these skip-tracing procedures should include, but need not be limited to, contacting any other individual named on the borrower's HEAL application or promissory note, using such sources as telephone directories, city directories, postmasters, drivers license records in State and local government agencies, records of members of professional associations, consumer credit reporting agencies, skip locator services, and records at

any school attended by the borrower. All skip-tracing activities used must be documented. This documentation must consist of a written record of the action taken and its date and must be presented to the Secretary when requesting preclaim assistance or when filing a default claim for HEAL insurance.

(b) When a borrower is 90 days delinquent in making a payment, the lender or holder must immediately request preclaim assistance from the Public Health Service. The Secretary does not pay a default claim if the lender or holder fails to request preclaim assistance.

(c) Prior to the filing of a default claim, a lender or holder must use, at a minimum, collection practices that are at least as extensive and effective as those used by the lender or holder in the collection of its other loans. These practices must include, but need not be limited to:

(1) Using collection agents, which may include its own collection department or other internal collection agents;

(2) Immediately notifying an appropriate consumer credit reporting agency regarding accounts overdue by more than 60 days; and

(3) Commencing and prosecuting an action for default unless:

(i) In the determination of the Secretary that:

(A) The lender or holder has made reasonable efforts to serve process on the borrower involved and has been unsuccessful in these efforts; or

(B) Prosecution of such an action would be fruitless because of the financial or other circumstances of the borrower;

(ii) For loans made before November 4, 1988, the loan involved was made in an amount of less than \$5,000; or

(iii) For loans made on or after November 4, 1988, the loan involved was made in an amount of less than \$2,500.

(d) If the Secretary's preclaim assistance locates the borrower, the lender or holder must implement the loan collection procedures described in this section. When the Secretary's preclaim assistance is unable to locate the borrower, a default claim may be filed by the lender as described in § 60.40. The

Secretary does not pay a default claim if the lender or holder has not complied with the HEAL statute and regulations or the lender's or holder's insurance contract.

(e) If a lender or holder does not sue the borrower, it must send a final demand letter to the borrower and any endorser at least 30 days before a default claim is filed.

(f) If a lender or holder sues a defaulted borrower or endorser, it may first apply the proceeds of any judgment against its reasonable attorney's fees and court costs, whether or not the judgment provides for these fees and costs.

(g) *Collection of chapter 7 bankruptcies.*

(1) If a borrower files for bankruptcy under chapter 7 of the Bankruptcy Act and does not file a complaint to determine the dischargeability of the HEAL loan, the lender or holder is responsible for monitoring the bankruptcy case in order to pursue collection of the loan after the bankruptcy proceedings have been completed.

(i) For any loan for which the lender or holder had not begun to litigate against the borrower prior to the imposition of the automatic stay, the period of the automatic stay is to be considered as an extended forbearance authorized by the Secretary, in addition to the 2-year period of forbearance which lenders and holders are authorized to grant without prior approval from the Secretary. Only periods of delinquency following the date of receipt (as documented by a date stamp) of the discharge of debtor notice (or other written notification from the court or the borrower's attorney of the end of the automatic stay imposed by the Bankruptcy Court) can be included in determining default, as described in § 60.40(c)(1)(i). The lender or holder must attempt to reestablish repayment terms with the borrower in writing no more than 30 days after receipt of the discharge of debtor notice (or other written notification from the court or the borrower's attorney of the end of the automatic stay imposed by the Bankruptcy Court), in accordance with the procedures followed at the end of a forbearance period. If the borrower fails to make a payment as scheduled, the lender or holder must attempt to

obtain repayment through written and telephone contacts in accordance with the intervals established in paragraph (a)(1) of this section, and must perform the other HEAL loan collection activities required in this section, before filing a default claim.

(ii) For any loan for which the lender or holder had begun to litigate against the borrower prior to the imposition of the automatic stay, the lender or holder must, upon written notification from the court or the borrower's attorney that the bankruptcy proceedings have been completed, either resume litigation or treat the loan in accordance with paragraph (g)(1)(i) of this section.

(2) If the lender or holder has not received written notification of discharge within 12 months of the date that the borrower filed for bankruptcy, the lender or holder must contact the court and the borrower's attorney (if known) within 30 days to determine if the bankruptcy proceedings have been completed. If no response is received within 30 days of the date of these contacts, the lender or holder must resume its collection efforts, in accordance with paragraph (g)(1) of this section. If a written response from the court or the borrower's attorney indicates that the bankruptcy proceedings are still underway, the lender or holder is not to pursue further collection efforts until receipt of written notice of discharge, except that follow-up in accordance with this paragraph must be done at least once every 12 months until the bankruptcy proceedings have been completed.

(3) If, despite the lender or holder's compliance with required procedures, a loan subject to the requirements of paragraph (g)(1) of this section is discharged, the lender or holder must file a claim with the Secretary within 10 days of the initial date of receipt (as documented by a date stamp) of written notification of the discharge from the court or the borrower's attorney, in accordance with the procedures set forth in § 60.40(c)(4). The lender or holder also must file with the bankruptcy court an objection to the discharge of the HEAL loan, and must include with the claim documentation showing that

§ 60.36

the bankruptcy proceedings were handled properly and expeditiously (e.g., all documents sent to or received from the bankruptcy court, including evidence which shows the period of the bankruptcy proceedings).

(Approved by the Office of Management and Budget under control numbers 0915-0100 and 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 749, Jan. 8, 1987; 57 FR 28796, June 29, 1992]

§ 60.36 Consequence of using an agent.

The delegation of functions to a servicing agency or other party does not relieve a lender or holder of its responsibilities under the HEAL program.

[57 FR 28797, June 29, 1992]

§ 60.37 Forbearance.

(a) *Forbearance* means an extension of time for making loan payments or the acceptance of smaller payments than were previously scheduled to prevent a borrower from defaulting on his or her payment obligations. A lender or holder must notify each borrower of the right to request forbearance.

(1) Except as provided in paragraph (a)(2) of this section, a lender or holder must grant forbearance whenever the borrower is temporarily unable to make scheduled payments on a HEAL loan and the borrower continues to repay the loan in an amount commensurate with his or her ability to repay the loan. Any circumstance which affects the borrower's ability to repay the loan must be fully documented.

(2) If the lender or holder determines that the default of the borrower is inevitable and that forbearance will be ineffective in preventing default, the lender or holder may submit a claim to the Secretary rather than grant forbearance. If the Secretary is not in agreement with the determination of the lender or holder, the claim will be returned to the lender or holder as disapproved and forbearance must be granted.

(b) A lender or holder must exercise forbearance in accordance with terms that are consistent with the 25- and 33-year limitations on the length of repayment (described in § 60.11) if the lender or holder and borrower agree in writing to the new terms. Each for-

42 CFR Ch. I (10-1-11 Edition)

bearance period may not exceed 6 months.

(c) A lender or holder may also exercise forbearance for periods of up to 6 months in accordance with terms that are inconsistent with the minimum annual payment requirement if the lender or holder complies with the requirements listed in paragraphs (c) (1) through (4) of this section. Subsequent renewals of the forbearance must also be documented in accordance with the following requirements:

(1) The lender or holder must reasonably believe that the borrower intends to repay the loan but is currently unable to make payments in accordance with the terms of the loan note. The lender or holder must state the basis for its belief in writing and maintain that statement in its loan file on that borrower.

(2) Both the borrower and an authorized official of the lender or holder must sign a written agreement of forbearance.

(3) If the agreement between the borrower and lender or holder provides for deferment of all payments, the lender or holder must contact the borrower at least every 3 months during the period of forbearance in order to remind the borrower of the outstanding obligation to repay.

(4) The total period of forbearance (with or without interruption) granted by the lender or holder to any borrower must not exceed 2 years. However, when the borrower and the lender or holder believe that there are bona fide reasons why this period should be extended, the lender or holder may request a reasonable extension beyond the 2-year period from the Secretary. This request must document the reasons why the extension should be granted. The lender or holder may grant the extension for the approved time period if the Secretary approves the extension request.

(Approved by the Office of Management and Budget under control number 915-0108)

[57 FR 28797, June 29, 1992]

§ 60.38 Assignment of a HEAL loan.

A HEAL note may not be assigned except to another HEAL lender, the Student Loan Marketing Association

(popularly known as “Sallie Mae”), or a public entity in the business of purchasing student loans, and except as provided in §60.40. In this section “seller” means any kind of assignor and “buyer” means any kind of assignee.

(a) *Procedure.* A HEAL note assigned from one lender or holder to another must be subject to a blanket endorsement together with other HEAL notes being assigned or must individually bear effective words of assignment. Either the blanket endorsement or the HEAL note must be signed and dated by an authorized official of the seller. Within 30 days of the transaction, the buyer must notify the following parties of the assignment:

(1) The Secretary;

(2) The borrower. The notice to the borrower must contain a clear statement of all the borrower’s rights and responsibilities which arise from the assignment of the loan, including a statement regarding the consequences of making payments to the seller subsequent to receipt of the notice; and

(3) The borrower’s school, as shown on the application form supporting the loan purchased by the buyer, if the borrower is enrolled in school.

(b) *Risks assumed by the buyer.* Upon acquiring a HEAL loan, a new holder assumes responsibility for the consequences of any previous violations of applicable statutes, regulations, or the terms of the note except for defects under §60.41(d). A HEAL note is not a negotiable instrument, and a subsequent holder is not a holder in due course. If the borrower has a valid legal defense that could be asserted against the previous holder, the borrower can also assert the defense against the new holder. In this situation, if the new holder files a default claim on a loan, the Secretary denies the default claim to the extent of the borrower’s defense. Furthermore, when a new holder files a claim on a HEAL loan, it must provide the Secretary with the same documentation that would have been required of the original lender.

(c) *Warranty.* Nothing in this section precludes the buyer of a HEAL loan from obtaining a warranty from the seller covering certain future reductions by the Secretary in computing

the amount of insurable loss, if any, on a claim filed on the loan. The warranty may only cover reductions which are attributable to an act or failure to act of the seller or other previous holder. The warranty may not cover matters for which the buyer is charged with responsibility under the HEAL regulations.

(d) *Bankruptcy.* If a lender or holder assigns a HEAL loan to a new holder, or a new holder acquires a HEAL loan under 20 U.S.C. 1092a (the Combined Payment Plan authority), and the previous holder(s) subsequently receives court notice that the borrower has filed for bankruptcy, the previous holder(s) must forward the bankruptcy notice to the purchaser within 10 days of the initial date of receipt, as documented by a date stamp, except that if it is a chapter 7 bankruptcy with no complaint for dismissal, the previous holder(s) must file the notice with the purchaser within 30 days of the initial date of receipt, as documented by a date stamp. The previous holder(s) also must file a statement with the court notifying it of the change of ownership. Notwithstanding the above, the current holder will not be held responsible for any loss due to the failure of the prior holder(s) to meet the deadline for giving notice if such failure occurs after the current holder purchased the loan.

(Approved by the Office of Management and Budget under control numbers 0915-0034 and 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 749, Jan. 8, 1987; 56 FR 42701, Aug. 29, 1991; 57 FR 28797, June 29, 1992]

§ 60.39 Death and disability claims.

(a) *Death.* The Secretary will discharge a borrower’s liability on the loan in accordance with section 738 of the Act upon the death of the borrower. The holder of the loan may not attempt to collect on the loan from the borrower’s estate or any endorser. The holder must secure a certification of death or whatever official proof is conclusive under State law. The holder must return to the sender any payments, except for refunds under §60.21, received from the estate of the borrower or paid on behalf of the borrower after the date of death.

§ 60.40

42 CFR Ch. I (10–1–11 Edition)

(b) *Disability.* (1) The Secretary will discharge a borrower's liability on the loan in accordance with section 738 of the Act if the borrower is found to be permanently and totally disabled on recommendation of the holder of the loan and as supported by whatever medical certification the Secretary may require. A borrower is totally and permanently disabled if he or she is unable to engage in any substantial gainful activity because of a medically determinable impairment, which the Secretary expects to continue for a long and indefinite period of time or to result in death.

(2) After being notified by the borrower or the borrower's representative that the borrower claims to be totally and permanently disabled, the holder of the loan may not attempt to collect on the loan from the borrower or any endorser. The holder must promptly request that the Secretary determine whether a borrower has become totally and permanently disabled. With its request, the holder must submit medical evidence no more than 4 months old that it has obtained from the borrower or the borrower's representative.

(3) If the Secretary determines that the borrower is totally and permanently disabled, the lender or holder must return to the borrower any payments, except for refunds under § 60.21, that it receives after being notified that the borrower claims to be totally and permanently disabled.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 57 FR 28797, June 29, 1992]

§ 60.40 Procedures for filing claims.

(a) A lender or holder must file an insurance claim on a form approved by the Secretary. The lender or holder must attach to the claim all documentation necessary to litigate a default, including any documents required to be submitted by the Federal Claims Collection Standards, and which the Secretary may require. Failure to submit the required documentation and to comply with the HEAL statute and regulations or the lender's or holder's insurance contract will result in a claim not being honored. The Secretary may deny a claim that is not

filed within the period specified in this section. The Secretary requires for all claims at least the following documentation:

(1) The original promissory note;

(2) An assignment to the United States of America of all right, title, and interest of the lender or holder in the note;

(3) The loan application;

(4) The history of the loan activities from the date of loan disbursement through the date of claim, including any payments made; and

(5) A Borrower Status Form (HRSA-508), documenting each deferment granted under § 60.12 or a written statement from an appropriate official stating that the borrower was engaged in an activity for which he or she was entitled to receive a deferment at the time the deferment was granted.

(b) The Secretary's payment of a claim is contingent upon receipt of all required documentation and an assignment to the United States of America of all right, title, and interest of the lender or holder in the note underlying the claim. The lender or holder must warrant that the loan is eligible for HEAL insurance.

(c) In addition, the lender or holder must comply with the following requirements for the filing of default, death, disability, and bankruptcy claims:

(1) *Default claims.* *Default* means the persistent failure of the borrower to make a payment when due or to comply with other terms of the note or other written agreement evidencing a loan under circumstances where the Secretary finds it reasonable to conclude that the borrower no longer intends to honor the obligation to repay the loan. In the case of a loan repayable (or on which interest is payable) in monthly installments, this failure must have persisted for 120 days. In the case of a loan repayable (or on which interest is payable) in less frequent installments, this failure must have persisted for 180 days. If, for a particular loan, an automatic stay is imposed on collection activities by a Bankruptcy Court, and the lender or holder receives written notification of the automatic stay prior to initiating legal proceedings against the borrower, the 120-

or 180-day period does not include any period prior to the end of the automatic stay.

(i) If a lender or holder determines that it is not appropriate to commence and prosecute an action against a default borrower pursuant to § 60.35(c)(3), it must file a default claim with the Secretary within 30 days after a loan has been determined to be in default.

(ii) If a lender files suit against a defaulted borrower and does not pursue collection of the judgment obtained as a result of the suit, it must file a default claim with the Secretary within 60 days of the date of issuance of the judgment. If a lender or holder files suit against a defaulted borrower, and pursues collection of the judgment obtained as a result of the suit, these collection activities must begin within 60 days of the date of issuance of the judgment. If the lender or holder is unable to collect the full amount of principal and interest owed, a claim must be filed within 30 days of completion of the post-judgment collection activities. In either case, the lender or holder must assign the judgment to the Secretary as part of the default claim.

(iii) In addition to the documentation required for all claims, the lender or holder must submit with its default claim at least the following:

- (A) Repayment schedule(s);
- (B) A collection history, if any;
- (C) A final demand letter;
- (D) The original or a copy of all correspondence relevant to the HEAL loan to or from the borrower (whether received by the original lender, a subsequent holder, or an independent servicing agent);
- (E) A claims collection litigation report; and

(F) If the defaulted borrower filed for bankruptcy under chapter 7 of the Bankruptcy Act and did not file a complaint to determine the dischargeability of the loan, all documents sent to or received from the bankruptcy court, including evidence which shows the period of the bankruptcy proceedings.

(iv) If a lender or holder files a default claim on a loan and subsequently receives written notice from the court or the borrower's attorney that the borrower has filed for bankruptcy

under chapter 11 or 13 of the Bankruptcy Act, or under chapter 7 with a complaint to determine the dischargeability of the loan, the lender or holder must file that notice with the Secretary within 10 days of the lender or holder's initial date of receipt, as documented by a date stamp. If the borrower is declaring bankruptcy under chapter 7 of the Bankruptcy Act, and has not filed a complaint to determine the dischargeability of the loan, the lender or holder must file the written notice with the Secretary within 30 days of the lender's or holder's initial date of receipt, as documented by a date stamp. If the Secretary has not paid the claim at the time the lender or holder receives that notice, upon receipt of the notice, the lender or holder must file with the bankruptcy court a proof of claim, if applicable, and an objection to the discharge or compromise of the HEAL loan. If the Secretary has paid the claim, the lender or holder must file a statement with the court notifying it that the loan is owned by the Secretary.

(2) *Death claims.* A lender or holder must file a death claim with the Secretary within 30 days after the lender or holder obtains documentation that a borrower is dead. In addition to the documentation required for all claims, the lender or holder must submit with its death claim those documents which verify the death, including an official copy of the Death Certificate.

(3) *Disability claims.* A lender or holder must file a disability claim with the Secretary within 30 days after it has been notified that the Secretary has determined a borrower to be totally and permanently disabled. In addition to the documentation required for all claims, the lender or holder must submit with its claim evidence of the Secretary's determination that the borrower is totally and permanently disabled.

(4) *Bankruptcy claims.* For a bankruptcy under chapter 11 or 13 of the Bankruptcy Act, or a bankruptcy under chapter 7 of the Bankruptcy Act when the borrower files a complaint to determine the dischargeability of the HEAL loan, the current holder must file a claim with the Secretary within 10 days of the initial date of receipt of

court notice or written notice from the borrower's attorney that the borrower has filed for bankruptcy under chapter 11 or chapter 13, or has filed a complaint to determine the dischargeability of the HEAL loan under chapter 7. The initial date of receipt of the written notice must be documented by a date stamp. The lender or holder must file with the bankruptcy court a proof of claim, if applicable, and an objection to the discharge or compromise of the HEAL loan. In addition to the documentation required for all claims, with its claim the lender or holder must submit to the Secretary at least the following:

- (i) Repayment schedule(s);
- (ii) A collection history, if any;
- (iii) A proof of claim, where applicable;
- (iv) An assignment to the United States of America of its proof of claim, where applicable;
- (v) All pertinent documents sent to or received from the bankruptcy court; and
- (vi) A statement of any facts of which the lender is aware that may form the basis for an objection to the bankrupt's discharge or an exception to the discharge.
- (vii) The notice of the first meeting or creditors, or an explanation as to why this is not included;
- (viii) In cases where there is defective service, a declaration or affidavit attesting to the fact that the lender or holder was not directly served with the notice of meeting of creditors. This declaration or affidavit must also indicate when and how the lender or holder learned of the bankruptcy; and
- (ix) In cases where there is defective service due to the borrower's failure to list the proper creditor, a copy of the letter sent to the borrower at the time of purchase of the HEAL loan by the current holder, or a sample letter with documentation indicating when the letter was sent to the borrower.

(Approved by the Office of Management and Budget under control numbers 0915–0036 and 0915–0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 750, Jan. 8, 1987; 56 FR 42701, Aug. 29, 1991; 57 FR 28798, June 29, 1992]

§ 60.41 Determination of amount of loss on claims.

(a) *General rule.* HEAL insurance covers the unpaid balance of principal and interest on an eligible HEAL loan, less the amount of any judgment collected pursuant to default proceedings commenced by the eligible lender or holder involved. In determining whether to approve an insurance claim for payment, the Secretary considers legal defects affecting the initial validity or insurability of the loan. The Secretary also deducts from a claim any amount that is not a legally enforceable obligation of the borrower except to the extent that the defense of infancy applies. The Secretary further considers whether all holders of the loan have complied with the requirements of the HEAL regulations, including those concerned with the making, servicing, and collecting of the loan, the timely filing of claims, and the submission of documents with a claim.

(b) *Special rules for loans acquired by assignment.* If a claim is filed by a lender or holder that obtained a loan by assignment, that lender or holder is not entitled to any payment under this section greater than that to which a previous holder would have been entitled. In particular, the Secretary deducts from the claim any amounts that are attributable to payments made by the borrower to a prior holder of the loan before the borrower received proper notice of the assignment of the loan.

(c) *Special rules for loans made by school lenders.* (1) If the loan for which a claim is filed was originally made by a school and the claim is filed by that school, the Secretary deducts from the claim an amount equal to any unpaid refund that the school owes the borrower.

(2) If the loan for which a claim is filed was originally made by a school but the claim is filed by another lender or holder that obtained the note by assignment, the Secretary deducts from the claim an amount equal to any unpaid refund that the school owed the borrower prior to the assignment.

(d) *Circumstances under which defects in claims may be cured or excused.* The Secretary may permit a lender or holder to cure certain defects in a specified manner as a condition for payment of a

default claim. The Secretary may excuse certain defects if the holder submitting the default claim satisfies the Secretary that the defect did not contribute to the default or prejudice the Secretary's attempt to collect the loan from the borrower. The Secretary may also excuse certain defects if the defect arose while the loan was held by another lender or holder and the holder submitting the default claim satisfies the Secretary that the assignment of the loan was an arm's length transaction, that the present holder did not know of the defect at the time of the sale and that the present holder could not have become aware of the defect through an examination of the loan documents.

(e) *Payment of insured interest.* The payment on an approved claim covers the unpaid principal balance and interest that accrues through the date the claim is paid, except:

(1) If the lender or holder failed to submit a claim within the required period after the borrower's default; death; total and permanent disability; or filing of a petition in bankruptcy under chapter 11 or 13 of the Bankruptcy Act, or under chapter 7 where the borrower files a complaint to determine the dischargeability of the HEAL loan; the Secretary does not pay interest that accrued between the end of that period and the date the Secretary received the claim.

(2) If the Secretary returned the claim to the lender or holder for additional documentation necessary for the approval of the claim, the Secretary pays interest only for the first 30 days following the return of the claim to the lender or holder.

[48 FR 38988, Aug. 26, 1983, as amended at 56 FR 42702, Aug. 29, 1991; 57 FR 28798, June 29, 1992]

§ 60.42 Records, reports, inspection, and audit requirements for HEAL lenders and holders.

(a) *Records.* (1) A lender or holder must keep complete and accurate records of each HEAL loan which it holds. The records must be organized in a way that permits them to be easily retrievable and allows the ready identification of the current status of each loan. The required records include:

- (i) The loan application;
- (ii) The original promissory note;
- (iii) The repayment schedule agreement;
- (iv) Evidence of each disbursement of loan proceeds;
- (v) Notices of changes in a borrower's address and status as a full-time student;
- (vi) Evidence of the borrower's eligibility for a deferment;
- (vii) The borrower's signed statement describing his or her rights and responsibilities in connection with a HEAL loan;
- (viii) The documents required for the exercise of forbearance;
- (ix) Documentation of the assignment of the loan; and
- (x) Evidence of a borrower's creditworthiness, including the borrower's credit report.

(2) The lender or holder must maintain for each borrower a payment history showing the date and amount of each payment received on the borrower's behalf, and the amounts of each payment attributable to principal and interest. A lender or holder must also maintain for each loan a collection history showing the date and subject of each communication with a borrower or endorser for collection of a delinquent loan. Furthermore, a lender or holder must keep any additional records which are necessary to make any reports required by the Secretary.

(3) A lender or holder must retain the records required for each loan for not less than 5 years following the date the loan is repaid in full by the borrower. However, in particular cases the Secretary may require the retention of records beyond this minimum period. A lender or holder must keep the original copy of an unpaid promissory note, but may store all other records in microform or computer format.

(4) The lender or holder must maintain accurate and complete records on each HEAL borrower and related school activities required by the HEAL program. All HEAL records shall be maintained under security and protected from fire, flood, water leakage, other environmental threats, electronic data system failures or power fluctuations, unauthorized intrusion for use, and theft.

§ 60.43

42 CFR Ch. I (10–1–11 Edition)

(b) *Reports.* A lender or holder must submit reports to the Secretary at the time and in the manner required by the Secretary.

(c) *Inspections.* Upon request, a lender or holder must afford the Secretary, the Comptroller General of the United States, and any of their authorized representatives access to its records in order to assure the correctness of its reports.

(d) The lender or holder must comply with the Department's biennial audit requirements of section 705 of the Act.

(e) Any lender or holder who has information which indicates potential or actual commission of fraud or other offenses against the United States, involving these loan funds, must promptly provide this information to the appropriate Regional Office of Inspector General for Investigations.

(Approved by the Office of Management and Budget under control numbers 0915–0043 and 0915–0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 750, Jan. 8, 1987; 57 FR 28798, June 29, 1992]

§ 60.43 Limitation, suspension, or termination of the eligibility of a HEAL lender or holder.

(a) The Secretary may limit, suspend, or terminate the eligibility under the HEAL program of an otherwise eligible lender or holder that violates or fails to comply with any provision of title VII, part A, subpart I of the Act as amended (42 U.S.C. 292–292p), these regulations, or agreements with the Secretary concerning the HEAL program. Prior to terminating a lender or holder's participation in the program, the Secretary will provide the entity an opportunity for a hearing in accordance with the procedures under paragraph (b) of this section.

(b) The Secretary will provide any lender or holder subject to termination with a written notice, sent by certified mail, specifying his or her intention to terminate the lender or holder's participation in the program and stating that the entity may request, within 30 days of the receipt of this notice, a formal hearing. If the entity requests a hearing, it must, within 90 days of the receipt of the notice, submit material, factual issues in dispute to demonstrate that there is cause for a hear-

ing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC metropolitan area. The Secretary will deny a hearing if:

(1) The request for a hearing is untimely (i.e., fails to meet the 30-day requirement);

(2) The lender or holder does not provide a statement of material, factual issues in dispute within the 90-day required period; or

(3) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial, by certified mail, to the lender or holder setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing, termination is still determined to be necessary, the lender or holder will be terminated from participation in the program. An entity will be permitted to reapply for participation in the program when it demonstrates, and the Secretary agrees, that it is in compliance with all HEAL requirements.

(c) This section does not apply to a determination that a HEAL lender fails to meet the statutory definition of an "eligible lender."

(d) This section also does not apply to administrative action by the Department of Health and Human Services based on any alleged violation of:

(1) Title VI of the Civil Rights Act of 1964, which is governed by 45 CFR part 80;

(2) Title IX of the Education Amendments of 1972, which is governed by 45 CFR part 86;

(3) The Family Educational Rights and Privacy Act of 1974 (section 438 of the General Education Provisions Act, as amended), which is governed by 34 CFR part 99; or

(4) Title XI of the Right to Financial Privacy Act of 1978, Pub. L. 95–630 (12 U.S.C. 3401–3422).

(Approved by the Office of Management and Budget under control number 0915–0144)

[48 FR 38988, Aug. 26, 1983, as amended at 57 FR 28799, June 29, 1992; 58 FR 67349, Dec. 21, 1993]

Subpart E—The School**§ 60.50 Which schools are eligible to be HEAL schools?**

(a) In order to participate in the HEAL program, a school must enter into a written agreement with the Secretary. In the agreement, the school promises to comply with provisions of the HEAL law and the HEAL regulations. For initial entry into this agreement and for the agreement to remain in effect, a school must satisfy the following requirements:

(1) The school must be legally authorized within a State to conduct a course of study leading to one of the following degrees:

Doctor of Medicine
 Doctor of Osteopathic Medicine
 Doctor of Dentistry or equivalent degree
 Bachelor or Master of Science in Pharmacy or equivalent degree
 Doctor of Optometry or equivalent degree
 Doctor of Veterinary Medicine or equivalent degree
 Doctor of Podiatric Medicine or equivalent degree
 Graduate or equivalent degree in Public Health
 Doctor of Chiropractic or equivalent degree
 Doctoral degree of Clinical Psychology
 Masters or doctoral degree in Health Administration

For the purposes of this section, the term "State" includes, in addition to the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands (the Republic of Palau), the Republic of the Marshall Islands, and the Federated States of Micronesia.

(2)(i) The school must be accredited by a recognized agency approved for that course of study by the Secretary of Education, as described in paragraph (a)(2)(ii) of this section, except where a school is not eligible for accreditation solely because it is too new. A new school is eligible if the Secretary of Education determines that it can reasonably expect to be accredited before the beginning of the academic year following the normal graduation date of its first entering class. The Secretary of Education makes this determination after consulting with the appropriate

accrediting agency and receiving reasonable assurance to that effect.

(ii) The approved accrediting agencies are:

(A) Liaison Committee on Medical Education.

(B) American Osteopathic Association.

(C) Commission on Dental Accreditation.

(D) Council on Education of American Veterinary Medical Association.

(E) Council on Optometric Education.

(F) Council on Podiatric Medical Education.

(G) American Council on Pharmaceutical Education.

(H) Council on Education for Public Health.

(I) Council on Chiropractic Education.

(J) Accrediting Commission on Education for Health Services Administration.

(K) Committee on Accreditation of American Psychological Association.

(b) If a HEAL school undergoes a change of controlling ownership or form of control, its agreement automatically expires at the time of that change. The school must enter into a new agreement with the Secretary in order to continue its participation in the HEAL program.

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 751, Jan. 8, 1987; 57 FR 28799, June 29, 1992]

§ 60.51 The student loan application.

When the student completes his or her portion of the student loan application and submits it to the school, the school must do the following:

(a) Accurately and completely fill out its portion of the HEAL application;

(b) Verify, to the best of its ability, the information provided by the student on the HEAL application, including, but not limited to, citizenship status and Social Security number. To comply with this requirement, the school may request that the student provide a certified copy of his or her birth certificate, his or her naturalization papers, and an original Social Security card or copy issued by the Federal Government, or other documentation that the school may require. The school must assure that the applicant's

§ 60.52

42 CFR Ch. I (10–1–11 Edition)

I-151 or I-551 is attached to the application, if the applicant is required to possess such identification by the United States;

(c) Certify that the student is eligible to receive a HEAL loan, according to the requirements of § 60.5;

(d) Review the financial aid transcript from each institution previously attended by the applicant on at least a half-time basis to determine whether the applicant is in default on any loans or owes a refund on any grants. The school may not approve the HEAL application or disburse HEAL funds if the borrower is in default on any loans or owes a refund on any educational grants, unless satisfactory arrangements have been made between the borrower and the affected lender or school to resolve the default or the refund on the grant. If the financial aid transcript has been requested, but has not been received at the time the applicant submits his or her first HEAL application, the school may approve the application and disburse the first HEAL installment prior to receipt of the transcript. Each financial aid transcript must include at least the following data:

(1) Student's name;

(2) Amounts and sources of loans and grants previously received by the student for study at an institution of higher education;

(3) Whether the student is in default on any of these loans, or owes a refund on any grants;

(4) Certification from each institution attended by the student that the student has received no financial aid, if applicable; and

(5) From each institution attended, the signature of an official authorized by the institution to sign such transcripts on behalf of the institution.

(e) State that it has no reason to believe that the borrower may not be willing to repay the HEAL loan;

(f) Make reasonable determinations of the maximum loan amount approvable, based on the student's circumstances. The student applicant determines the amount he or she wishes to borrow, up to this maximum amount. Only then may the school certify an eligible application. In determining the maximum loan amount ap-

provable, the school will calculate the difference between:

(1) The total financial resources available to the applicant for his or her costs of education for the period covered by the proposed HEAL loan, and other student aid that the applicant has received or will receive during the period covered by the proposed HEAL loan. To determine the total financial resources available to the applicant for his or her costs of education for the period covered by the proposed HEAL loan (including familial, spousal, or personal income or other financial assistance that the applicant has received or will receive), the school must consider information provided through one of the national need analysis systems or any other procedure approved by the Secretary of Education, in addition to any other information which the school has regarding the student's financial situation. The school may make adjustments to the need analysis information only when necessary to accurately reflect the applicant's actual resources, and must maintain in the borrower's record documentation to support the basis for any adjustments to the need analysis information; and

(2) The costs reasonably necessary for each student to pursue the same or similar curriculum or program within the same class year at the school for the period covered by the proposed HEAL loan, using a standard student budget. The school must maintain in its general office records the criteria used to develop each standard student budget. Adjustments to the standard student budget may be made only to the extent that they are necessary for the student to complete his or her education, and documentation must be maintained in the borrower's record to support the basis for any adjustments to the standard student budget.

(g) Comply with the requirements of § 60.61.

(Approved by the Office of Management and Budget under control numbers 0915-0038 and 0915-0108)

[52 FR 751, Jan. 8, 1987, as amended at 57 FR 28799, June 29, 1992]

§ 60.52 The student's loan check.

(a) When a school receives from a HEAL lender a loan disbursement

Public Health Service, HHS

§ 60.56

check or draft payable jointly to the school and to one of its students, it must:

(1) If the school receives the instrument after the student is enrolled, obtain the student's endorsement, retain that portion of funds due the school, and disburse the remaining funds to the student.

(2) If the school receives the instrument before the student is enrolled, it must, prior to endorsing the instrument, send the instrument to the student to endorse and return to the school. The school may then retain that portion of funds then due the school but must hold the remaining funds for disbursement to the student at the time of enrollment. However, if the student is unable to meet other educational expenses due before the time of enrollment, the school may obtain the student's endorsement and disburse to the student that portion of funds required to meet these other educational expenses.

(b) If a school determines that a student does not plan to enroll, the school must return a loan disbursement check or draft to the lender within 30 days of this determination.

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 751, Jan. 8, 1987]

§ 60.53 Notification to lender or holder of change in enrollment status.

Each school must notify the holder of a HEAL loan of any change in the student's enrollment status within 30 days following the change in status. Each notice must contain the student's full name under which the loan was received, the student's current name (if different), the student's Social Security number, the date of the change in the enrollment status, or failure to enroll as scheduled for any academic period as a full-time student, the student's latest known permanent and temporary addresses, and other information which the school may decide is necessary to identify or locate the student. If the school does not know the identity of the current holder of the HEAL loan, it must notify the HEAL Program Office of a change in the student's enrollment status. This notification is not required for vacation periods and leaves of absence or other tem-

porary interruptions which do not exceed one academic term.

(Approved by the Office of Management and Budget under control number 0915-0108)

[52 FR 751, Jan. 8, 1987, as amended at 57 FR 28799, June 29, 1992]

§ 60.54 Payment of refunds by schools.

A participating school must pay that portion of a refund that is allocable to a HEAL loan directly to the original lender (or to a subsequent holder of the loan note, if the school has knowledge of the holder's identity). At the same time, the school must provide to the borrower written notice that it is doing so.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 57 FR 28799, June 26, 1992]

§ 60.55 Administrative and fiscal procedures.

Each school must establish and maintain administrative and fiscal procedures necessary to achieve the following objectives:

- (a) Proper and efficient administration of the funds received from students who have HEAL loans;
- (b) Protection of the rights of students under the HEAL program;
- (c) Protection of the United States from unreasonable risk of loss due to defaults; and
- (d) Compliance with applicable requirements for HEAL schools.

§ 60.56 Records.

(a) In addition to complying with the requirements of section 739(b) of the Act, each school must maintain an accurate, complete, and easily retrievable record with respect to each student who has a HEAL loan. The record must contain all of the following information:

- (1) Student's name, address, academic standing and period of attendance;
- (2) Name of the HEAL lender, amount of the loan, and the period for which the HEAL loan was intended;
- (3) If a noncitizen, documentation of the student's alien registration status.
- (4) Amount and source of other financial assistance received by the student

§ 60.57

during the period for which the HEAL loan was made;

(5) Date the school receives the HEAL check or draft and the date it either gives it to the student or returns it to the lender (if the school is not the lender);

(6) Date the school disburses the loan to a student (if the school is the lender);

(7) Date the school signs the loan check or draft (if the school is a copayee);

(8) Amount of tuition, fees and other charges paid by the student to the school for the academic period covered by the loan and the dates of payment;

(9) Photocopy of each HEAL check or draft received by the student;

(10) Documentation of each entrance interview, including the date of the entrance interview and the signature of the borrower indicating that the entrance interview was conducted;

(11) Documentation of the exit interview, including the date of the exit interview and the signature of the borrower indicating that the exit interview was conducted, or documentation of the date that the school mailed exit interview materials to the borrower if the borrower failed to report for the exit interview;

(12) A photocopy made by the school of the borrower's I-151 or I-551, if the borrower is required to possess such identification by the United States, or other documentation, if obtained by the school, to verify citizenship status and Social Security number (e.g., a certified copy of the borrower's birth certificate or a photocopy made by the school of the borrower's original Social Security card or copy issued by the Federal government);

(13) Documentation of the calculations made which compare the financial resources of the applicant with the cost of his or her education at the school;

(14) Copy(s) of the borrower's financial aid transcript(s);

(15) The standard budget used for the student, and documentation to support the basis for any deviations made to the standard budget;

(16) Copies of all correspondence between the school and the borrower or

42 CFR Ch. I (10-1-11 Edition)

between the school and the lender or its assignee regarding the loan;

(17) Copy of each form used by the school in connection with the loan; and

(18) Expected postgraduate destination of borrower.

(b) The school must maintain the record for not less than 5 years following the date the student graduates, withdraws or fails to enroll as a full-time student. The school may store the records in microform or computer format.

(c) The school must comply with the Department's biennial audit requirements of section 705 of the Act.

(d) The school must develop and follow written procedures for the receipt, verification of amount, and disbursement of HEAL checks or drafts. These procedures must be maintained in the school's policies and procedures manuals or other general office records.

(Approved by the Office of Management and Budget under control number 0915-0108)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 751, Jan. 8, 1987; 57 FR 28799, June 29, 1992]

§ 60.57 Reports.

A school must submit reports to the Secretary at the times and in the manner the Secretary may reasonably prescribe. The school must retain a copy of each report for not less than 5 years following the report's completion, unless otherwise directed by the Secretary. A school must also make available to a HEAL lender or holder, upon the lender's or holder's request, the name, address, postgraduate destination and other reasonable identifying information for each of the school's students who has a HEAL loan.

(Approved by the Office of Management and Budget under control number 0915-0108)

[57 FR 28799, June 29, 1992]

§ 60.58 Federal access to school records.

For the purposes of audit and examination, a HEAL school must provide the Secretary of Health and Human Services, the Comptroller General of the United States, and any of their authorized representatives access to the records that the school is required to keep and to any documents and records

pertinent to the administration of the HEAL Program.

§ 60.59 Records and Federal access after a school is no longer a HEAL school.

In the event a school ceases to participate in the HEAL program, the school (or its successor, in the case of a school which undergoes a change in ownership) must retain all required HEAL records and provide the Secretary of Health and Human Services, the Comptroller General of the United States, and any of their authorized representatives access to them.

§ 60.60 Limitation, suspension, or termination of the eligibility of a HEAL school.

(a) The Secretary may limit, suspend, or terminate the eligibility under the HEAL program of an otherwise eligible school that violates or fails to comply with any provision of title VII, part A, subpart I of the Act as amended (42 U.S.C. 292-292p), these regulations, or agreements with the Secretary concerning the HEAL program. Prior to terminating a school's participation in the program, the Secretary will provide the school an opportunity for a hearing in accordance with the procedures under paragraph (b) of this section.

(b) The Secretary will provide any school subject to termination with a written notice, sent by certified mail, specifying his or her intention to terminate the school's participation in the program and stating that the school may request, within 30 days of the receipt of this notice, a formal hearing. If the school requests a hearing, it must, within 90 days of the receipt of the notice, submit material, factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC metropolitan area. The Secretary will deny a hearing if:

(1) The request for a hearing is untimely (i.e., fails to meet the 30-day requirement);

(2) The school does not provide a statement of material, factual issues in

dispute within the 90-day required period; or

(3) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial, by certified mail, to the school setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing, termination is still determined to be necessary, the school will be terminated from participation in the program. A school will be permitted to reapply for participation in the program when it demonstrates, and the Secretary agrees, that it is in compliance with all HEAL requirements.

(c) This section does not apply to a determination that a HEAL school fails to meet the statutory definition of an "eligible school."

(d) This section does not apply to administrative action by the Department of Health and Human Services based on any alleged violation of The Family Educational Rights and Privacy Act of 1974 (section 438 of the General Education Provisions Act, as amended), as governed by 34 CFR part 99.

(Approved by the Office of Management and Budget under control number 0915-0144)

[48 FR 38988, Aug. 26, 1983, as amended at 52 FR 752, Jan. 8, 1987; 58 FR 67350, Dec. 21, 1993]

§ 60.61 Responsibilities of a HEAL school.

(a) A HEAL school is required to carry out the following activities for each HEAL applicant or borrower:

(1) Conduct and document an entrance interview with each student (individually or in groups) no later than prior to the loan recipient's first HEAL disbursement in each academic year that the loan recipient obtains a HEAL loan. The school must inform the loan recipient during the entrance interview of his or her rights and responsibilities under a HEAL loan, including the consequences for noncompliance with those responsibilities, and must gather personal information which would assist in locating the loan recipient should he or she depart from the school without receiving an exit interview. A school may meet this requirement through correspondence where the

school determines that a face-to-face meeting is impracticable.

(2) Conduct and document an exit interview with each HEAL loan recipient (individually or in groups) within the final academic term of the loan recipient's enrollment prior to his or her anticipated graduation date or other departure date from the school. The school must inform the loan recipient in the exit interview of his or her rights and responsibilities under each HEAL loan, including the consequences for noncompliance with those responsibilities. The school must also collect personal information from the loan recipient which would assist the school or the lender or holder in skiptracing activities and to direct the loan recipient to contact the lender or holder concerning specific repayment terms and options. A copy of the documentation of the exit interview, including the personal information collected for skiptracing activities, and any other information required by the Secretary regarding the exit interview must be sent to the lender or holder of each HEAL loan within 30 days of the exit interview. If the loan recipient departs from the school prior to the anticipated date or does not receive an exit interview, the exit interview information must be mailed to the loan recipient by the school within 30 days of the school's knowledge of the departure or the anticipated departure date, whichever is earlier. The school must request that the loan recipient forward any required information (e.g., skiptracing information, request for deferment, etc.) to the lender or holder. The school must notify the lender or holder of the loan recipient's departure at the same time it mails the exit interview material to the loan recipient.

(3) Verify the accuracy and completeness of information provided by each student on the HEAL loan application, particularly in regard to the HEAL eligibility requirements, by comparing the information with previous loan applications or other records or information provided by the student to the school. Notify the potential lender of any discrepancies which were not resolved between the school and the student.

(4) Develop and implement procedures relating to check receipt and release which keep these functions separate from the application preparation and approval process and assure that the amount of the HEAL loan check(s) does(do) not exceed the approved total amount of the loan and the statutory maximums. Checks must not be cashed without the borrower's personal endorsement. Documentation of these procedures and their usage shall be maintained by the school.

(5) Maintain accurate and complete records on each HEAL borrower and related school activities required by the HEAL program. All HEAL records shall be properly safeguarded and protected from environmental threats and unauthorized intrusion for use and theft.

(6) Maintain documentation of the criteria used to develop the school's standard student budgets in the school's general records, readily available for audit purposes, and maintain in each HEAL borrower's record a copy of the standard budget which was actually used in the determination of the maximum loan amount approvable for the student, as described in § 60.51.

(7) Notify the lender or its assignee of any changes in the student's name, address, status, or other information pertinent to the HEAL loan not more than 30 days after receiving information indicating such a change.

(b) Any school which has information which indicates potential or actual commission of fraud or other offenses against the United States involving these loan funds must promptly provide this information to the appropriate Regional Office of Inspector General for Investigations.

(c) The school will be considered responsible and the Secretary may seek reimbursement from any school for the amount of a loan in default on which the Secretary has paid an insurance claim, if the Secretary finds that the school did not comply with the applicable HEAL statute and regulations, or its written agreement with the Secretary. The Secretary may excuse certain defects if the school satisfies the Secretary that the defect did not contribute to the default or prejudice the Secretary's attempt to collect the loan from the borrower.

Public Health Service, HHS

§ 60.61

(d) A school is authorized to withhold services from a HEAL borrower who is in default on a HEAL loan received while enrolled in that school, except in instances where the borrower has filed for bankruptcy. Such services may include, but are not limited to academic transcripts and alumni services. Defaulted HEAL borrowers who have filed for bankruptcy shall provide court documentation that verifies the filing for bankruptcy upon the request of the school. Schools will also supply this information to the Secretary upon request. All academic and financial aid transcripts that are released on a de-

faulted HEAL borrower must indicate on the transcript that the borrower is in default on a HEAL loan. It is the responsibility of the borrower to provide the school with documentation from the lender, holder, or Department when a default has been satisfactorily resolved, in order to obtain access to services that are being withheld, or to have the reference to default removed from the academic and financial aid transcripts.

(Approved by the Office of Management and Budget under control number 0915-0108)

[52 FR 752, Jan. 8, 1987, as amended at 57 FR 28799, June 29, 1992; 58 FR 67350, Dec. 21, 1993]