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SUBCHAPTER D—GRANTS

PART 50—POLICIES OF GENERAL APPLICABILITY

Subpart A—Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Sec.
50.101 Applicability.
50.102 Definitions.
50.103 Assurance—Responsibilities of PHS awardee and applicant institutions.
50.104 Reporting to the OSI.
50.105 Institutional compliance.

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

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 programs 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—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

50.601 Purpose.
50.602 Applicability.
50.603 Definitions.
50.604 Institutional responsibility regarding conflicting interests of investigators
50.605 Management of conflicting interests.
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.

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Subpart A—Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

AUTHORITY: Sec. 493, Public Health Service Act, as amended, 99 Stat. 874–875 (42 U.S.C. 289b); Sec. 501(f), Public Health Service Act, as amended, 102 Stat. 4213 (42 U.S.C. 290aa(f)).

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§ 50.101 Applicability.

This subpart applies to each entity which applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act. It requires each such entity to establish uniform policies and procedures for investigating and reporting instances of

alleged or apparent misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act. This subpart does not supersede and is not intended to set up an alternative to established procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters.

§ 50.102 Definitions.

As used in this subpart:

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

Inquiry means information gathering and initial factfinding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

Institution means the public or private entity or organization (including federal, state, and other agencies) that is applying for financial assistance from the PHS, e.g., grant or cooperative agreements, including continuation awards, whether competing or noncompeting. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activities.

Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

Misconduct or *Misconduct in Science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

OSI means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

OSIR means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where scientific misconduct has been established.

PHS means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial assistance to support scientific activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.

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.

§ 50.103 Assurance—Responsibilities of PHS awardee and applicant institutions.

(a) *Assurances.* Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant:

(1) Has established an administrative process, that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and

(2) Will comply with its own administrative process and the requirements of this Subpart.

(b) *Annual Submission.* An applicant or recipient institution shall make an annual submission to the OSI as follows:

(1) The institution's assurance shall be submitted to the OSI, on a form prescribed by the Secretary, as soon as possible after November 8, 1989, but no later than January 1, 1990, and updated annually therefter on a date specified by OSI. Copies of the form may be requested through the Director, OSI.

(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.

(c) *General Criteria.* In general, an applicant institution will be considered to be in compliance with its assurance if it:

(1) Establishes, keeps current, and upon request provides the OSIR, the OSI, and other authorized Departmental officials the policies and procedures required by this subpart.

(2) Informs its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

(3) Takes immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.

(4) Informs, in accordance with this subpart, and cooperates with the OSI with regard to each investigation of possible misconduct.

(d) *Inquiries, Investigations, and Reporting—Specific Requirements.* Each applicant's policies and procedures must provide for:

(1) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

(2) Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

(3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

(4) Notifying the Director, OSI, in accordance with §50.104(a) when, on the basis of the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in §50.104(b) exist.

(5) Notifying the OSI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the OSI may then immediately notify the Department's Office of Inspector General.

(6) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.

(7) Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment

or revision, and included as part of the investigatory file.

(8) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

(9) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

(10) Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.

(11) Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out.

(12) Keeping the OSI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

(13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(14) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

(15) Notifying the OSI of the final outcome of the investigation.

§ 50.104 Reporting to the OSI.

(a)(1) An institution's decision to initiate an investigation must be reported in writing to the Director, OSI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. Information provided through the notification will be held in confidence to the extent permitted by law, will not be disclosed as part of the peer review and Advisory Committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

(2) An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

(3) Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under § 50.103(d), a report of such planned termination, including a description of the reasons for such termination, shall be made to OSI, which will then decide whether further investigation should be undertaken.

(4) The final report submitted to the OSI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by the institution.

(5) If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the OSI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous

examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health hazard involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

§ 50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

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 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.

(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 adminstered 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 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:

Race and ethnicity designation (please check)

Black (not of Hispanic origin) _____

Hispanic _____

Asian or Pacific Islander _____

American Indian or Alaskan native _____

White (not of Hispanic origin) _____

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.

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 _____

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993]

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. 95–210, 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.

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 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 programs 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 Health Resources and Services Administration; the Centers for Disease Control and Prevention; the Agency for Toxic Substances and Disease Registry; the Food and Drug Administration; and the Office of the Assistant Secretary for Public Health and Science. For purposes of this regulation, the entities are hereinafter referred to as ''agencies.''

[63 FR 66062, Dec. 1, 1998]

§ 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 assistance 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 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—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

AUTHORITY: 42 U.S.C. 216, 289b–1, 299c–3.

SOURCE: 60 FR 35815, July 11, 1995; 60 FR 39076, July 31, 1995, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

§ 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of

this subpart by each Institution, to each Investigator participating in such research (see § 50.604(a)); provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

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).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests, ''Investigator'' includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

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 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 and product development. 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.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from the applicant institution;

(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;

(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(4) Income from service on advisory committees or review panels for public or nonprofit entities;

(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102–564.

§ 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

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

(1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

(3) The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) The Institution will otherwise comply with this subpart.

§ 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-

funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must 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 funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, 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 and/or other information that may be available, the PHS Awarding Component may decide that a particular 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, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 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 conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

§ 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart.

They include, but are not necessarily 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—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
45 CFR part 76—Government-wide debarment and suspension (non-procurement)
45 CFR part 79—Program Fraud Civil Remedies
45 CFR part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

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

Sec.
51.1 Scope.
51.2 Defintitions.

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 from a provider of mental health services.

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

SOURCE: 63 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 restrains; 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 impatient 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 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 recordkeeping 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 required 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 recordkeeping 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 metal 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:

(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.

(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 recordkeeping 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 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 recordkeeping 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.

(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 extend 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 disputes 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 pursing 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 program 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 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 addressing 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 very 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 confidentiality 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 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 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:

(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;

[1] Healthy 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).

(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 otherwise 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.

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.

[59 FR 36707, July 19, 1994]

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?
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 appropriate, 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
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 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 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.

(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, 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.

§ 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 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 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, nonexclusive, 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.

§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 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).

(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.

(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 Proverty 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.

(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 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 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 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]

PARTS 51d–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 party 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 programs, 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 a single individual designated by the grantee in the grant application and approved by the Secretary, who is 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 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]

§ 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 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 reapplication.

[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 recompete 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 awards pursuant to two or more concurrent applications, each dealing with one or more specified aspects of the project.

(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 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]

§ 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 objectively 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

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).

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, 285a–3, 285a–6(c)(1)(E), 285a–7(c)(1)(G), 285b–4, 285c–5, 285d–6, 285e–2, 285e–3, 285f–1, 285g–5, 285g–7, 285m–3, 285n–2, 285o–2, 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, strengthening or expansion, and operation of research and demonstration and/or multipurpose centers in the health fields described in this paragraph. Specifically, these regulations apply to national cancer research and demonstration centers (including payments for construction, but not including the acquisition of land), as authorized by section 414 of the Act; national cancer research and demonstration centers with respect to breast cancer, as authorized by section 417 of the Act; national cancer research and demonstration centers with respect to prostate cancer, as authorized by section 417A of the Act; 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, but not including the acquisition of land), as authorized by section 422 of the Act; research and training centers in diabetes mellitus and related endocrine and metabolic diseases (including digestive, kidney, and urologic diseases), and research and training centers regarding nutritional disorders, including obesity, as authorized by section 431 of the Act; multipurpose arthritis and musculoskeletal diseases centers (including payments for alteration, remodeling, improvement, expansion, and repair of existing buildings, and the provision of equipment necessary to make them suitable for use as a center, but not construction), as authorized by Section 441 of the Act; Alzheimer's disease centers, as authorized by section 445 of the Act; Claude D. Pepper Older Americans Independence Centers, as authorized by section 445A of the Act; research centers regarding chronic fatigue syndrome, as authorized by section 447 of the Act; research centers with respect to contraception and infertility, as authorized by section 452A of the Act; child health research centers, as authorized by section 452C of the Act; multipurpose deafness and other communication disorders centers (including payments for alteration, remodeling, improvement, expansion, and repair of existing buildings, and the provision of equipment necessary to make them suitable for use as a center, but not construction), as authorized by section 464C of the Act; national alcohol research centers, as authorized by section 464J of the Act; national drug abuse research centers, as authorized by section 464N of the Act; and centers for acquired immunodeficiency syndrome research (including payments

for renovation and leasing of existing buildings, and the provision of equipment necessary to make them suitable for use as a center, but not construction), as authorized by section 2316 of the Act.

(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]

§ 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:

(1) 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;

(2) For purposes of grants authorized by section 417 of the Act, an agency or institution which provides for planning and conducting basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer;

(3) For purposes of grants authorized by section 417A of the Act, an agency or institution which provides for planning and conducting basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer;

(4) 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;

(5) 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; kidney and urologic diseases; or nutritional disorders, including obesity;

(6) For purposes of grants authorized by section 441 of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research into arthritis and musculoskeletal diseases and orthopedic procedures, and provides training and information programs for health professionals and the general public;

(7) For purposes of grants authorized by section 445 of the Act, an entity (including a university medical center) 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;

(8) For purposes of grants authorized by section 445A of the Act, an entity which conducts research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which includes research on the treatments, and on medical devices and other medical interventions regarding these diseases, disorders, and complications that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals;

(9) 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;

(10) 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;

(11) 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;

(12) 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 health professionals 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;

(13) For purposes of grants authorized by section 464J of the Act, an entity engaged in long-term interdisciplinary research relating to alcoholism and other alcohol problems;

(14) For purposes of grants authorized by section 464N of the Act, an entity for interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse; or

(15) For purposes of grants authorized by section 2316 of the Act, an entity for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immunodeficiency syndrome.

(16) As provided in the section of the Act authorizing the particular program or on the determination of the Director, a center may include the facilities of a single institution or a consortium of cooperating institutions and, if practical, may be part of an equitable geographical distribution of centers with proven research capabilities.

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 recompete for funds.

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55108, Oct. 24, 1996]

§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 414, 417, 417A, 422, 445, 445A, 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 431, 441, 452C, 464C, 464J, and 464N 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]

§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

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 for Protection from Research Risks, NIH (Revised September 1986).

[NOTE: This policy is subject to change, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Bethesda, MD 20892–7507 (301–496–7005; 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]

§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) 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 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 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 Office of the Federal Register, 800 North Capital Street, NW, Suite 700, Washington, DC. 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 Architecture 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 (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).

§ 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 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 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
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

(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 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;

[1] Applications and instructions are available from the Division of Cancer Research Resources and Centers, Education Branch, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20205.

(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
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 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.

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 members 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

[2] Applications 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.

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]

§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 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.

(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
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 Grants; matters to be reviewed.
52h.8 Grants; review criteria.
52h.9 Unsolicited contract proposals; matters to be reviewed.

52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.
52h.11 Contract projects and proposals; review criteria.
52h.12 Applicability of other regulations.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351 (42 U.S.C. 289*l*–4); sec. 955(a), Pub. L. 97–35, 95 Stat. 590 (42 U.S.C. 300z–7(e)).

SOURCE: 43 FR 7862, Feb. 24, 1978, unless otherwise noted.

§52h.1 Applicability.

The regulations in this part apply to:

(a) Applications for grants for biomedical and behavioral research, under the Act to the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration. These regulations do 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.

(b) Biomedical and behavorial research and development contract projects administered by the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration.

(c) Applications for grants and contracts under section 2008 of the Act.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289*l*–4))

[45 FR 35328, May 27, 1980, as amended at 47 FR 50261, Nov. 5, 1982; 49 FR 38111, Sept. 27, 1984]

§52h.2 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Project period* has the same meaning as in 42 CFR part 52.

(c) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(d) *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 said other official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Peer review group* means a group of experts qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications or contract projects in those fields.

(f) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(g) *Development* means the systematic use of knowledge and understanding gained from research, directed toward creating useful materials, devices, systems, or methods.

(h) *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 of a subject and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods. The terms include (but are not limited to) development and utilization of resources, testing, demonstrations, clinical trials, preparation of reports, and production of experimental or test models necessary or incidental to a research and/or development activity, but exclude quantity production and routine product testing and quality control.

(i) *Project concept* means the basic purpose, scope, and objectives of the project.

(j) *Project approach* means the methodology to be followed and the resources needed in carrying out the project.

(k) *Contract proposal* means a written offer to enter into a contract, submitted to an awarding official by an individual or non-Federal organization, and including as 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.

(l) *Solicited contract proposal* has the same meaning as in 41 CFR 3–1.353(b)(2).

(m) *Unsolicited contract proposal* has the same meaning as in 41 CFR 3–4.5201.

(n) *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 competitive 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.

§ 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act (5 U.S.C. App. I), Department of Health and Human Services (45 CFR part 11), implementing regulations and chapter 9 of the Department of Health and Human Services General Administration Manual[1] will govern the establishment and operation of peer review groups, including that meetings shall be open to the public except as determined by the Secretary.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, and the Administrator of the Health Resources and Services Administration will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9 and 52h.10 within their respective agencies.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289*l*–4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§ 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 will be governed by Chapter 9 of the Department of Health and Human Services General Administration Manual.[1]

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, 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 individual has done so, and the quality of such research;

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; 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.

(c) Not more than one-fourth of the members of any peer review group to which these regulations are applicable may be officers or employees of the

[1] The Department of Health and Human Services General Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Printing Office, Washington, DC 20402.

United States. For purposes of the preceding sentence, membership on such groups does not make an individual an officer or employee of the United States.

§52h.5 Conflict of interest.

(a) Members of peer review groups covered by this part are subject to relevant provisions in title 18 of the United States Code, relating to criminal activity, the Department of Health and Human Services Standards of Conduct (45 CFR part 73), and Executive Order 11222, as amended.

(b) In addition to any restrictions imposed under paragraph (a) of this section:

(1) No member of a peer review group may participate in or be present during any review by said group of a grant application, contract project, or contract proposal in which, to the member's knowledge, any of the following has a financial interest: (i) The member or his or her spouse, parent, child, or partner, (ii) any organization in which the member or his or her spouse, parent, child, or partner is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated, or (iii) any organization with which the member or his or her spouse, parent, child, or partner is negotiating or has any arrangement concerning prospective employment or other similar association.

(2) In the event any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a grant application, contract project, or contract proposal, that group is disqualified and the review will be conducted by another group with the expertise to do so. If there is no other group with the requisite expertise, the review will be conducted by an ad hoc group no more than 50 percent of whose members may be from the disqualified group. The composition of any such ad hoc group will be determined in accordance with §52h.4(b) and §52h.4(c) of this part and, to the extent feasible, §52h.4(a) of this part.

(3) Where a member of a peer review group participates in or is present during:

(i) Development or review of a project approach or request for proposals by said group or

(ii) Review by said group under §52h.10(b) or §52h.10(c), i.e. after the issuance of a request for proposals, no contract may thereafter be awarded as the result of such development or review to said member, his or her spouse, parent, child, or partner or any organization in which the member, his or her spouse, parent, child, or partner was serving as officer, director, trustee, partner, or employee at the time of such development or review or with which the member, his or her spouse, parent, child, or partner was negotiating or had any arrangement concerning prospective employment at said time.

(4) No member of a peer review group may participate in any review under this part 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 preaward or postaward) as an officer or employee of the United States.

(c) Where permissible under the statutes, standards, and order cited in paragraph (a) of this section, the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, the Administrator of the Health Resources and Services Administration, or their designees may waive the requirements in paragraph (b) of this section if he or she determines that there is no other practical means for securing appropriate expert advice on a particular grant application, contract project, or contract proposal.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 315, 92 Stat. 3436 (42 U.S.C. 289*l*–4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§52h.6 Availability of information.

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 in the Freedom of Information Act (5 U.S.C. 552), the Federal Advisory Committee Act (5 U.S.C. App. I), the Privacy Act (5 U.S.C. 552a), and implementing Department of Health and Human Services regulations (45 CFR parts 5, 5b).

§ 52h.7 Grants; matters to be reviewed.

(a) No awarding official will make 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 said group has made recommendations concerning the scientific merit of such application. In addition, where under applicable law an awarding official is required to secure the approval or advice of a national advisory council or board concerning an application, said application will not be considered by the council or board unless it has been reviewed by a peer review group in accordance with the provisions of this part and said 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 for by law, such recommendations are advisory only and not binding on the awarding official or national advisory council or board.

§ 52h.8 Grants; review criteria.

In carrying out its review under § 52h.7, the peer review group will take into account, among other factors:

(a) The significance and originality from a scientific or technical standpoint of the goals of the proposed research;

(b) The adequacy of the methodology proposed to carry out the research;

(c) The qualifications and experience of the principal investigator and proposed staff;

(d) The reasonable availability of resources necessary to the research;

(e) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(f) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

§ 52h.9 Unsolicited contract proposals; matters to be reviewed.

(a) No awarding official will 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 (pursuant to procedures set forth in 41 CFR subpart 3–4.52) and said group has made recommendations concerning the scientific merit of such proposal.

(b) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official.

§ 52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.

(a) Subject to paragraph (b) of this section, no awarding official will 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 in accordance with the provisions of this part and said group has made recommendations concerning the scientific merit of said concept. Where in the judgment of the awarding official the project approach has been sufficiently well defined by the time the review required by the preceding sentence is conducted, this review and the resulting recommendations shall include the project approach as well.

(b) The awarding official may waive the requirements of paragraph (a) of this section for peer review before issuing a request for contract proposals if he determines that the accomplishments of essential program objectives would otherwise be placed in jeopardy and any further delay would clearly 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 such circumstances, the awarding official will not award a contract based on the request for contract proposals unless the proposals received in response to the request have been reviewed by a peer review group and that group has

made recommendations concerning the scientific merit of the project concept and of the approaches outlined in the proposals. The request for proposals will indicate that the project concept has not been reviewed by a peer review group and that no award will be made until such review is conducted and recommendations made based on such review.

(c) The Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, the Administrator of the Health Resources and Service Administration, or their designees may identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group in accordance with the provisions of this part and that group has made recommendations concerning the scientific merit of the proposals.

(d) Except to the extent otherwise provided for by law, such recommendations are advisory only and not binding on the awarding official.

(Sec. 215, Public Health Service Act, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, Public Health Service Act, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 2891–4); sec. 955(a), Pub. L. 97–35, 95 Stat. 590 (42 U.S.C. 300z–7(e)))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§ 52h.11 Contract projects and proposals; review criteria.

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group will take into account, among other 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 these 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 will take into account, among other factors, those criteria in § 52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited contract proposals under § 52h.10(c) the peer review group will evaluate each proposal in accordance with the criteria set forth in the request for proposals.

§ 52h.12 Applicability of other regulations.

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals appearing elsewhere in this title, title 41, or title 45 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

[1] Redesignated as 42 CFR part 405 at 42 FR 52826, Sept. 30, 1977.

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 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 compliance 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 determination 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 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 assurance. 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 nonprofit 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 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 empolyee 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 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 carrry 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:

(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.

(l) *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 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 migratory 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, 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, nonexclusive, 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 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 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).

(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:

(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, 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. 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

(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 (l) 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 cooperative 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 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.

§ 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

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.

Subpart F—Grants for Nurse Anesthetist Traineeships

57.501 To what programs do these regulations apply?
57.502 Definitions.
57.503 Who is eligible to apply for a grant?
57.504 How will applications be evaluated?
57.505 How long does grant support last?
57.506 How is the amount of the award determined?
57.507 For what purposes may grant funds be spent?
57.508 What financial support is available to trainees?
57.509 Who is eligible for financial assistance as a trainee?
57.510 What are the requirements for traineeships and the appointment of trainees?
57.511 Duration of traineeships.
57.512 Termination of traineeships.
57.513 What additional Department regulations apply to grantees?
57.514 Additional conditions.

Subpart G [Reserved]

Subpart H—Grants for Physician Assistant Training Programs

57.701 Applicability.
57.702 Definitions.
57.703 Eligibility.
57.704 Application.
57.705 Project requirements.
57.706 Evaluation of applications.
57.707 Grant award.
57.708 Grant payments.
57.709 Purposes for which grant funds must be spent.
57.710 What additional Department regulations apply to grantees?
57.711 What other audit and inspection requirements apply to grantees?
57.712 Additional conditions.

Subpart I—Programs for the Training of Physician Assistants

57.801 Purpose and scope.
57.802 Definitions.
57.803 Requirements.

Subparts J–K [Reserved]

Subpart L—Grants for Residency Training and Advanced Education in the General Practice of Dentistry

57.1101 To what projects do these regulations apply?
57.1102 Definitions.
57.1103 What entities are eligible to apply for a grant?
57.1104 How must an entity apply for a grant?
57.1105 What requirements must a project meet?
57.1106 How will applications be evaluated?
57.1107 How will grant awards be made?
57.1108 How will grant payments be made?
57.1109 Purposes for which grant funds may be spent.
57.1110 What additional Department regulations apply to grantees?
57.1111 What other audit and inspection requirements apply to grantees?
57.1112 What additional conditions apply to grantees?

Subparts M–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.
57.1504 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.

Subpart Q—Grants for Predoctoral, Graduate, and Faculty Development Education Programs in Family Medicine

57.1601 To what programs do these regulations apply?
57.1602 Definitions.
57.1603 Who is eligible to apply for a grant?
57.1604 What requirements must a project meet?
57.1605 How will applications be evaluated?
57.1606 How long does grant support last?
57.1607 For what purposes may grant funds be spent?
57.1608 What additional Department regulations apply to grantees?
57.1609 What other audit and inspection requirements apply to grantees?
57.1610 Additional conditions.

Subpart R—Grants for the Establishment of Departments of Family Medicine

57.1701 To what programs do these regulations apply?
57.1702 Definitions.
57.1703 Who is eligible to apply for a grant?
57.1704 Program requirements.
57.1705 How will applications be evaluated?
57.1706 How long does grant support last?
57.1707 For what purposes may grant funds be spent?
57.1708 What additional Department regulations apply to grantees?
57.1709 What other audit and inspection requirements apply to grantees?
57.1710 Additional conditions.

Subpart S—Educational Assistance to Individuals From Disadvantaged Backgrounds

57.1801 To what grant program do these regulations apply?
57.1802 Definitions.
57.1803 Who is eligible to apply for a grant?
57.1804 Who is eligible for educational assistance?
57.1805 Program requirements.
57.1806 How will applications be evaluated?
57.1807 How long does grant support last?
57.1808 For what purposes may grant funds be spent?
57.1809 What additional Department regulations apply to grantees?
57.1810 What other audit and inspection requirements apply to grantees?
57.1811 Additional conditions.

Subpart 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—Grants for Centers of Excellence

57.2101 To what projects do these regulations apply?
57.2102 Definitions.
57.2103 Who is eligible to apply for a grant?
57.2104 Project requirements.
57.2105 How will applications be evaluated?
57.2106 How long does grant support last?
57.2107 For what purposes may grant funds be spent?
57.2108 What additional Department regulations apply to grantees?
57.2109 What other audit and inspection requirements apply to grantees?
57.2110 Additional conditions.

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.

Subpart X [Reserved]

Subpart Y—Grants for Nurse Practitioner and Nurse Midwifery Programs

57.2401 Applicability.
57.2402 Definitions.
57.2403 Eligibility.
57.2404 Application.
57.2405 Project requirements.
57.2406 Evaluation and grant awards.
57.2407 Grant payments.
57.2408 Expenditure of grant funds.
57.2409 What additional Department regulations apply to grantees?
57.2410 Additional conditions.
APPENDIX TO SUBPART Y—GUIDELINES FOR NURSE PRACTITIONER AND NURSE MIDWIFERY PROGRAMS

Subpart Z—Grants for Advanced Nurse Education Programs

57.2501 Applicability.
57.2502 Definitions.
57.2503 Eligibility.
57.2504 Application.
57.2505 Project requirements.
57.2506 Evaluation and grant awards.
57.2507 Grant payments.
57.2508 Expenditure of grant funds.
57.2509 What additional Department regulations apply to grantees?
57.2510 Additional conditions.

Subparts AA–BB [Reserved]

Subpart CC—Scholarships for Students of Exceptional Financial Need

57.2801 To what programs do these regulations apply?
57.2802 Definitions.
57.2803 How to apply for a grant.
57.2804 Students eligible for scholarships.
57.2805 Amount of scholarship award.
57.2806 How is the amount of grant award determined?
57.2807 For what purposes may grant funds be spent?
57.2808 What additional Department regulations apply to grantees?
57.2809 What other records, audit, and inspection requirements apply to grantees?
57.2810 Additional conditions.

Subpart DD—Financial Assistance for Disadvantaged Health Professions Students

57.2901 To what program do these regulations apply?
57.2902 Definitions.
57.2903 How to apply for a grant.
57.2904 Eligibility and selection of aid recipients.
57.2905 Amount of student award.
57.2906 How is the amount of the grant award determined?
57.2907 For what purposes may grant funds be spent?
57.2908 What additional Department regulations apply to grants?
57.2909 What other records, audit, and inspection requirements apply to schools?
57.2910 Additional conditions.

Subpart EE—Grants for Residency Training in Preventive Medicine

57.3001 To what programs do these regulations apply?
57.3002 Definitions.
57.3003 Who is eligible to apply for a grant?
57.3004 Project requirements.
57.3005 How will applications be evaluated?
57.3006 How long does grant support last?
57.3007 How is the amount of the grant award determined?
57.3008 For what purposes may grant funds be spent?
57.3009 What additional Department regulations apply to grantees?
57.3010 What other audit and inspection requirements apply to grantees?
57.3011 Additional conditions.

Subpart FF—Grants for Residency Training and Faculty Development in General Internal Medicine and/or General Pediatrics

57.3101 To what projects do these regulations apply?
57.3102 Definitions.
57.3103 Who is eligible to apply for a grant?
57.3104 What activities must be addressed in an application?
57.3105 Project requirements.
57.3106 How will applications be evaluated?
57.3107 How long does grant support last?
57.3108 How is the amount of the grant award determined?
57.3109 For what purposes may grant funds be spent?
57.3110 What additional Department regulations apply to grantees?
57.3111 What other audit and inspection requirements apply to grantees?
57.3112 Additional conditions.

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–LL [Reserved]

Subpart MM—Area Health Education Center Program

57.3801 To what programs do these regulations apply?
57.3802 Definitions.
57.3803 Who is eligible to apply for a cooperative agreement?
57.3804 Project requirements.
57.3805 When do the requirements of §57.3804 apply?
57.3806 How will applications be evaluated?
57.3807 How is the amount of the award determined?
57.3808 How long does support under a cooperative agreement last?
57.3809 For what purposes may cooperative agreement funds be spent?
57.3810 How will the Department participate in a cooperative agreement?
57.3811 What additional Department regulations apply to awardees?

57.3812 What other audit and inspection requirements apply?
57.3813 Additional conditions.

Subpart NN [Reserved]

Subpart OO—Grants for Geriatric Education Centers

57.4001 To what projects do these regulations apply?
57.4002 Definitions.
57.4003 Who is eligible to apply for a grant?
57.4004 Program requirements.
57.4005 How will applications be evaluated?
57.4006 How long does grant support last?
57.4007 For what purposes may grant funds be spent?
57.4008 What additional Department regulations apply to grantees?
57.4009 What other audit and inspection requirements apply to grantees?
57.4010 Additional conditions.

Subpart PP—Grants for Faculty Training Projects in Geriatric Medicine and Dentistry

57.4101 To what projects do these regulations apply?
57.4102 Definitions.
57.4103 Who is eligible to apply for a grant?
57.4104 For what projects may grant funds be requested?
57.4105 Project requirements.
57.4106 How will applications be evaluated?
57.4107 How long does grant support last?
57.4108 What financial support is available to fellows?
57.4109 Who is eligible for financial assistance as a fellow?
57.4110 What are the requirements for fellowships and the appointment of fellows?
57.4111 Termination of fellowships.
57.4112 For what purposes may grant funds be spent?
57.4113 What additional Department regulations apply to grantees?
57.4114 What other audit and inspection requirements apply to grantees?
57.4115 Additional conditions.

Subparts A–B [Reserved]

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).

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[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 borrower'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 a 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 HPSL 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 regarding the safeguarding and proper handling of this information.

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[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.

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[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 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 account, 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 regualtions. 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 reapply 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).

(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.

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[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 wil 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 effect 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 nonprofit 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 nonprofit 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.

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[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 demonstrate 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.

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[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 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 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

[1] Individuals 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 following 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

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 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.

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[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

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

[2] Effective 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 reapply 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 attained 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

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]

Subpart F—Grants for Nurse Anesthetist Traineeships

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 67 Stat. 631 (42 U.S.C. 216); sec. 831(a) of the Public Health Service Act, 93 Stat. 580, as amended by 96 Stat. 2061, and 99 Stat. 396–397 (42 U.S.C. 297–1).

SOURCE: 53 FR 9116, Mar. 21, 1988, unless otherwise noted.

§ 57.501 To what programs do these regulations apply?

These regulations apply to grants awarded to public or private nonprofit institutions for the purpose of providing traineeships to registered nurses enrolled in nurse anesthetist training programs.

§ 57.502 Definitions.

Act means the Public Health Service Act, as amended.

Fiscal Year means the Federal fiscal year, beginning October 1 and ending the following September 30.

National of the United States means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States (as defined in 8 U.S.C. 1101(a)(22), the Immigration and Nationality Act).

Nonprofit refers to the status of an entity 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.

Nurse anesthetist means a registered nurse who has successfully completed a nurse anesthetist training program.

Nurse anesthetist training program means a full-time educational program which:

(1) Is designed to qualify registered nurses as nurse anesthetists;

(2) Is accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs; and

(3) Has students enrolled in the program who are beyond the twelfth month of study.

Registered nurse means a person who has graduated from a school of nursing and is licensed to practice as a registered/professional nurse in a State.

School of nursing means a collegiate, associate degree, or diploma 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 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.

Trainee means a student who is receiving a traineeship from a grant under this subpart.

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.503 Who is eligible to apply for a grant?

Any public or private nonprofit institution which is located in a State and administers a nurse anesthetist training program is eligible to apply for a grant by submitting an application at the time and in the form that the Secretary may prescribe.

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992]

§ 57.504 How will applications be evaluated?

Within the limits of funds available, the Secretary will award a grant to each eligible institution whose application is found to meet the requirements

of section 831(a) of the Act and these regulations. In determining the funding of applications, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

§ 57.505 How long does grant support last?

(a) The Notice of Grant Award specifies the period during which grant funds are available for obligation by the grantee. This period, called the budget period, will not exceed 1 year.

(b) The grant will initially be funded for 1 year, and subsequent awards will also be for 1 year at a time. Decisions about the amount of all awards will be made by formula as described in § 57.506 of these regulations. In all cases awards require a determination by the Secretary that funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate the United States in any way to make any additional award with respect to any approved application or portion of an approved application. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992]

§ 57.506 How is the amount of the award determined?

(a) The Secretary will use the following formula to determine the amount of the grant to be awarded to each approved nurse anesthetist training program:

$$G = F \times \frac{N}{E}$$

G represents the amount of grant to be awarded. F represents the amount of traineeship funds appropriated to implement section 831(a) in the fiscal year in which application is made. E represents the total number of full-time students enrolled beyond the twelfth month of study in all the approved applicant nurse anesthetist training programs. N represents the number of full-time students enrolled beyond the twelfth month of study in the applicant nurse anesthetist training program. Should special factors for determining the funding of applications be announced from time to time in the FEDERAL REGISTER, N will be adjusted upward for those applicants meeting the specific criteria as announced. (This adjustment will result in the award of additional traineeship funds to successful applicants who meet the criteria of the special factors.)

(b) Students will be counted as of October 15 of the Federal fiscal year in which application is made.

§ 57.507 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart for traineeships according to § 57.508, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) A grantee may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of the budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and made available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's need for that period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992]

§ 57.508 What financial support is available to trainees?

Expenditures from traineeship funds are limited to:

(a) Tuition and fees, in accordance with the established rates of the institution, except as limited by the Secretary.

(b) Stipends in whatever amount the grantee determines that each trainee needs to pursue the training program, as long as that amount does not exceed the limits established by the Public Health Service. Stipends may only be paid to the trainee in monthly installments.

(c) A transportation allowance for travel to field training if the site is beyond a reasonable commuting distance and requires the trainee to establish a temporary new residence. However, the grantee may not pay an allowance for daily commuting from the new place of residence to the field training headquarters.

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992]

§ 57.509 Who is eligible for financial assistance as a trainee?

To be eligible for a traineeship, a registered nurse must:

(a) Be a resident 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;

(b) Be enrolled as a full-time student beyond the twelfth month of study in a nurse anesthetist training program;

(c) Demonstrate financial need, as determined by the institution; and

(d) Not be receiving concurrent support for the same training from another Federal education award which provides a stipend or otherwise duplicates financial provisions except education benefits under the Veteran's Readjustment Benefits Act and loans from Federal sources.

(Approved by the Office of Management and Budget under control number 0915–0060)

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.510 What are the requirements for traineeships and the appointment of trainees?

(a)(1) The grantee must complete a statement which documents the appointment of each trainee. To complete this statement the grantee must require each trainee to provide information and documentation of his or her eligibility.

(2) The statement of appointment must be completed by the beginning of the training period or as soon thereafter as possible if the trainee receives notice of his or her traineeship appointment after the training period has begun. The statement of appointment must include information to document the eligibility of the trainee and certify that there will be compliance with all applicable Public Health Service terms and conditions governing the appointment. The program director must sign the statement on behalf of the grantee, and the trainee must sign it thus certifying the statements are true and complete. The original copy of the statement must be retained by the grantee to be available for program review and financial audit. A copy shall be provided to the trainee for his or her records.

(b) The grantee may not require trainees to perform any work which is not an integral part of the nurse anesthetist training program and required for all students in the program, or to perform services which detract from or prolong their training.

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[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992]

§ 57.511 Duration of traineeships.

The initial appointment to a traineeship must be made for a full academic year, not to exceed 12 months, except that a shorter appointment may be made when necessary to enable the trainee to complete the training program. A second appointment may not exceed 6 months. The total period of support for any trainee may not exceed 18 months.

§ 57.512 Termination of traineeships.

(a) The grantee must terminate a traineeship:

(1) Upon request of the trainee;

(2) If the trainee withdraws from the grantee institution; or

(3) If the grantee determines that:

(i) The trainee is no longer an enrolled student; or

(ii) The trainee is not eligible or able to continue in accordance with its standards and practices.

(b) The grantee must deposit any Federal portion of the tuition refund owed to a trainee into the grant account and provide written notice to the trainee that it is doing so.

(Approved by the Office of Management and Budget under control number 0915–0060)

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45735, Oct. 5, 1992]

§ 57.513 What additional Department regulations apply to grantees?

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 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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying.

[53 FR 9116, Mar. 21, 1988, as amended at 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.514 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart G [Reserved]

Subpart H—Grants for Physician Assistant Training Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 783(a)(1) of the Public Health Service Act, 90 Stat. 2314, and 99 Stat. 524 (42 U.S.C. 295g–3(a)(1)); redesignated as sec. 788(d) and amended by 102 Stat. 3135 (42 U.S.C. 295g–8(d)); renumbered as sec. 750, as amended by Pub. L. 102–408, 106 Stat. 2044 (42 U.S.C. 293n).

§ 57.701 Applicability.

The regulations in this subpart apply to the award of grants to public or private nonprofit schools of medicine or osteopathic medicine, and other public or private nonprofit entities under section 750 of the Public Health Service Act (42 U.S.C. 293n) to meet the costs of projects to plan, develop, and operate or maintain programs for the training of physician assistants.

[57 FR 45736, Oct. 5, 1992; 57 FR 53815, Nov. 12, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.702 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Budget period means the interval of time into which the approved activity is divided for budgetary and reporting purposes, as specified in the grant award document.

Health professional shortage area means an area designated under section 332 of the Act.

Nonprofit refers to the status of an entity 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.

Physician assistant means an individual who is qualified by academic and clinical training to provide patient care services under the supervision and

responsibility of a doctor of medicine or osteopathic medicine and who meets the requirements of 42 CFR 57.802.

Primary care means health care which may be initiated by the patient or the provider, or both, in a variety of settings, and which consists of a broad range of personal health care services including promotion and maintenance of health, prevention of illness and disability, basic care during acute and chronic phases of illness, guidance and counseling of individuals and families, and referral to other health care providers and community resources when appropriate. In providing the services

(1) The physical, emotional, social, and economic status of the patient is considered in the context of his or her cultural and environmental background, including the family and community, and

(2) The patient is provided timely access to the health care system.

Program for the Training of Physician Assistants or *Program* means a program for the training of physician assistants as defined in 42 CFR 57.801–57.803.

Project director means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

Project period means the total time for which support for a project has been approved including any extensions of the project.

School of medicine or *school of osteopathic medicine* means a public or private nonprofit school which provides training leading respectively to a degree of doctor of medicine or a degree of doctor of osteopathic medicine, and which is accredited as provided in section 799(1)(E) of the Act.

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.

Supervised clinical practice means supervised clinical practice as defined in 42 CFR 57.802.

[44 FR 36178, June 21, 1979, as amended at 52 FR 24160, June 29, 1987; 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.703 Eligibility.

Any public or private nonprofit school of medicine or osteopathic medicine or public or private nonprofit entity located in a State is eligible to apply for a grant under this subpart.

[57 FR 45736, Oct. 5, 1992]

§ 57.704 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

(b) 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 terms and conditions of any award, including the regulations of this subpart.

(c) In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart must contain:

(1) A detailed description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of section 750 of the Act and this subpart, in particular, the requirements of § 57.705. This must include a budget for the proposed project and a justification for the amount of grant funds requested.

(2) A copy of all laws and regulations pertaining to the practice of physician assistants in the State or States in which the applicant's supervised clinical practice will be conducted and in which the applicant will be encouraging its graduates to work.

(3) A description of the present employment of any graduates of the program, to the extent available, and a description of the methods to be used by the program in placing its graduates.

(Approved by the Office of Management and Budget under control number 0915–0060)

[44 FR 36178, June 21, 1979, as amended at 49 FR 38112, Sept. 27, 1984; 52 FR 24160, June 29, 1987; 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.705 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project must conduct its program for the training of physician assistants in accordance with the requirements in 42 CFR 57.803.

(b) The program must (1) be accredited as an Educational Program for the Physician Assistant by the American Medical Association's Committee on Allied Health Education and Accreditation, or (2) have received a Letter of Review from the Accreditation Review Committee on Education for the Physician Assistant.

(c) The program must be operational no later than 12 months after the award of a grant under this subpart.

(d) The project must be conducted under the direction of the project director who must be employed full-time at the grantee institution(s). If the project director becomes unable to function in this capacity, the Secretary must be notified as soon as possible.

(e) The project must evaluate the supervised clinical practice conducted by the program with respect to:

(1) The variety of patient contact and care experiences afforded to participating students;

(2) The adequacy and quality of supervision provided to participating students; and

(3) The adequacy of the physical setting or settings in which the supervised clinical practice takes place.

(f)(1) The project must provide on an annual basis, upon request and in a format acceptable to the Secretary, information in the aggregate regarding student characteristics, student attrition rate and student performance.

(2) The project must provide on an annual basis, upon request and in a format acceptable to the Secretary, information in the aggregate regarding the employment of its graduates including place of employment.

(Approved by the Office of Management and Budget under control number 0915–0060)

[37 FR 20543, Sept. 30, 1972, as amended at 45 FR 41420, June 19, 1980; 52 FR 24160, June 29, 1987; 57 FR 45736, Oct. 5, 1992]

§ 57.706 Evaluation of applications.

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will approve or disapprove all applications filed in accordance with § 57.704, taking into consideration:

(1) The degree to which the project plan adequately provides for meeting the requirements set forth in § 57.705 and 42 CFR 57.803;

(2) The potential effectiveness of the project in carrying out the purposes of section 750 of the Act and this subpart;

(3) The capability of the applicant to carry out the proposed project;

(4) The local, regional, and national needs the project proposes to serve;

(5) The adequacy of the project's plan for placing graduates in health professional shortage areas;

(6) The soundness of the fiscal plan for assuring effective use of grant funds;

(7) The potential of the project to continue on a self-sustaining basis after the period of grant support; and

(8) The adequacy of the project's plan to develop and use methods designed to attract and maintain minority and disadvantaged students to train as physician assistants.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may

from time to time announce in the FEDERAL REGISTER.

[44 FR 36178, June 21, 1979, as amended at 52 FR 24160, June 29, 1987; 53 FR 14792, Apr. 26, 1988; 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.707 Grant award.

(a) *General.* (1) Within the limits of funds available for this purpose, the Secretary may award grants to those applicants whose projects will, in his or her judgment best promote the purposes of section 750 of the Act as determined in accordance with § 57.706.

(2) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(3) 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 of an approved project. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

(b) The Secretary will determine the amount of any award on the basis of his or her estimate of the sum necessary for the cost (including both direct and indirect costs) of the project.

(c) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, existence of legislative authority, 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.

[44 FR 36178, June 21, 1979, as amended at 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.708 Grant payments.

The Secretary will 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.

[44 FR 36178, June 21, 1979]

§ 57.709 Purposes for which grant funds must be spent.

(a) Grant funds must be spent solely for carrying out the approved project under section 750 of the Act, these regulations, the terms and conditions of the grant award, and applicable cost principles specified in subpart Q of 45 CFR part 74.

(b) Grant funds may not be spent for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[44 FR 36178, June 21, 1979, as amended at 52 FR 24160, June 29, 1987; 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.710 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They 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—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 83—Regulation of 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 HHS programs or activities receiving Federal financial assistance.
45 CFR part 93—New restrictions on lobbying.

[52 FR 24161, June 29, 1987, as amended at 57 FR 45736, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.711 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6124, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.712 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 or her judgment, these conditions are necessary to assure or protect advancement of the grant, the interest of the public health, or the conservation of grant funds.

[44 FR 36177, June 21, 1979. Redesignated at 52 FR 24161, June 29, 1987]

Subpart I—Programs for the Training of Physician Assistants

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 701(8)(B), 90 Stat. 2247, as amended by 95 Stat. 913 and 99 Stat. 525–526 (42 U.S.C. 292a(8)(B)); renumbered as sec. 750, as amended by Pub. L. 102–408, 106 Stat. 2044 (42 U.S.C. 293n).

§ 57.801 Purpose and scope.

(a) Section 750 of the Public Health Service Act (42 U.S.C. 293n) requires the Secretary to develop regulations for programs for the training of physician assistants. The purpose of this subpart is to comply with this requirement.

(b) The regulations in this subpart apply to all programs for the training of physician assistants supported under title VII of the Public Health Service Act.

[44 FR 36177, June 21, 1979, as amended at 52 FR 24160, June 29, 1987; 61 FR 6124, Feb. 16, 1996]

§ 57.802 Definitions.

For purpose of this subpart:

Academic year means the approximately 9–12 month period of time during which the program is in session.

Disease prevention is the health strategy which emphasizes the development of individual and community measures to protect against disease or environmental hazards and their harmful consequence.

Full-time student means a student who is enrolled in a program and pursuing a course of study which constitutes a full-time academic workload, as determined by the program, and which leads to a degree, diploma, or certificate of completion.

Geriatric medicine is the prevention, diagnosis, care and treatment of illness and disability as required by the distinct needs of the elderly.

Health professional shortage area means an area designated under section 322 of the Public Health Service Act.

Health promotion is the health strategy which emphasizes individual responsibility for one's health, and community efforts to maintain and enhance well-being through lifestyle changes.

Home health care is the provision of medical and other health care services to maintain or restore the health of an ill or disabled person in their place of residence.

Medical director means the individual responsible for providing competent medical direction of the program.

Physician assistant means an individual who is qualified by academic and clinical training to provide patient care services under the supervision and responsibility of a doctor of medicine

or osteopathic medicine. At a minimum, the physician assistant is competent to:

(1) Do the initial and follow-up evaluation of patients of various age groups in any setting to elicit a detailed and accurate history, perform an appropriate physical examination, and record and present pertinent data, including interpretive recommendations, in a manner meaningful to the physician;

(2) Perform or assist in the performance of routine laboratory and related studies as appropriate for a specific practice setting, such as blood studies, urinalyses, and electrocardiographic tracings;

(3) Perform routine therapeutic procedures such as injections, immunizations, and the assessment, suturing, and care of wounds;

(4) Instruct and counsel patients regarding physical and mental health, including matters such as nutrition, illness, treatment, normal growth and development, and age, sex, or lifestyle risk factors;

(5) Perform the following functions in a hospital setting: patient work-ups, making patient rounds, recording patient progress notes, accurately and appropriately transcribing or executing standing orders and other specific orders at the direction of the supervising physician, and compiling and recording detailed progress reports and narrative case summaries;

(6) Deliver or assist in the delivery of services, including the review and monitoring of treatment and therapy plans, to patients requiring initial or continuing care in settings other than a hospital, such as the home, nursing homes, and extended care facilities;

(7) Evaluate and treat life-threatening emergency situations;

(8) Interact with those community health services and other community resources which will facilitate the patient's care and continuity of care.

Primary care means primary care, as defined in 42 CFR 57.702.

Supervised clinical practice means direct participation in patient care by observation, examination, and performance of procedures as are appropriate for the assigned role of the student for the purposes of instruction under the guidance and responsibility of a physician who holds a full and unrestricted license in the State in which the supervised clinical practice is located.

[44 FR 36177, June 21, 1979, as amended at 52 FR 24160, June 29, 1987; 57 FR 45737, Oct. 5, 1992]

§ 57.803 Requirements.

A program for the training of physician assistants must:

(a)(1) Be accredited as an Educational Program for the Physician Assistant by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(2) Have received a Letter of Review from the Accreditation Review Committee on Education for the Physician Assistant for its plans for a program for the training of physician assistants;

(b) Have a medical director who is licensed to practice medicine or osteopathic medicine in the State in which the program is located (or any State if the program is conducted by a Federal health facility) and who is experienced in the delivery of the type of health care services for which the program provides training;

(c) Have an enrollment of not less than eight full-time students in each class;

(d) Be a minimum of 1 academic year in length;

(e) Consist of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction;

(f) Provide training to students in the areas of primary care, health promotion, disease prevention, geriatric medicine and home health care;

(g) Develop and use methods designed to encourage graduates of the program to work in health professional shortage areas, such as periods of supervised clinical practice in those areas;

(h) Develop and use methods for placing graduates in positions for which they have been trained, including methods for placing graduates in positions in health professional shortage areas; and

(i) Develop and use a method for evaluating the effectiveness of the program in training physician assistants, including:

(1) Evaluation by faculty and students of the program in relation to its objectives;

(2) Evaluation of student performance in classroom instruction and supervised clinical practice; and

(3) Evaluation of the number of graduates employed and the characteristics of their employment, such as geographical location, setting, and functions performed; and

(4) Award a degree, diploma, or certificate of completion to individuals who have successfully completed the program.

[44 FR 36177, June 21, 1979, as amended at 52 FR 24160, June 29, 1987; 57 FR 45737, Oct. 5, 1992]

Subparts J–K [Reserved]

Subpart L—Grants for Residency Training and Advanced Education in the General Practice of Dentistry

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 786(b) of the Public Health Service Act, 90 Stat. 2317, as amended by 99 Stat. 540–541 (42 U.S.C. 295g–6(b)); redesignated as sec. 785 and amended by 102 Stat. 3130–3131 (42 U.S.C. 295g–5); renumbered as sec. 749, as amended by Pub. L. 102–408, 106 Stat. 2043–2044 (42 U.S.C. 293m).

§ 57.1101 To what projects do these regulations apply?

These regulations apply to the award of grants under section 749 of the Public Health Service Act (42 U.S.C. 293m) to public or private nonprofit schools of dentistry and to accredited postgraduate dental training institutions to meet the costs of projects to:

(a) Plan, develop and operate an approved residency training program in the general practice of dentistry or an approved advanced educational program in the general practice of dentistry; and

(b) Provide financial assistance (in the form of traineeships and fellowships) to participants in such a program who are in need of financial assistance and who plan to practice general dentistry.

[52 FR 19145, May 21, 1987, as amended at 57 FR 45737, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.1102 Definitions.

As used in this subpart:

Accredited postgraduate dental training institution means a public or private nonprofit institution which operates a postgraduate dental training program that has received an accreditation classification of ''accreditation eligible,'' ''preliminary provisional approval,'' ''provisional approval,'' ''conditional approval,'' or ''approval'' by the Commission on Dental Accreditation.

Act means the Public Health Service Act, as amended.

Approved residency training program, approved advanced educational program, or *program* means a general practice residency program or an advanced educational program in general dentistry which has received an accreditation classification of ''accreditation eligible,'' ''preliminary provisional approval,'' ''provisional approval,'' ''conditional approval,'' or ''approval'' by the Commission on Dental Accreditation.

Budget period means an interval of time into which the project period is divided for budgetary purposes, as specified in the grant award document.

Nonprofit refers to the status of an entity which is a corporation or association, or is owned or 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.

Practice of general dentistry means a practice of dentistry in which the dentist:

(1) Serves as a patient's first contact with the dental care system and provides the means of timely entry into that system;

(2) Evaluates the patient's general medical status and relates this to anticipated dental treatment;

(3) Assumes continuing responsibility for the patient's dental care and provides a comprehensive range of services which will minimize the need for patient referral; and

(4) Coordinates dental treatment provided by dental specialists and by dental auxiliary personnel, including dental hygienists, dental assistants, and expanded function dental auxiliaries.

Project period means the total time for which support for a project has been approved, including any extensions thereof.

School of dentistry means a public or private nonprofit school which provides training leading to a degree of doctor of dentistry or an equivalent degree and which is accredited as provided in section 799(1)(E) of the Act.

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.

[43 FR 54931, Nov. 24, 1978, as amended at 52 FR 19145, May 21, 1987; 57 FR 45737, Oct. 5, 1992; 61 FR 6124, Feb. 16, 1996]

§ 57.1103 What entities are eligible to apply for a grant?

Any public or private nonprofit school of dentistry or accredited postgraduate dental training institution located in a State is eligible to apply for a grant.

[57 FR 45737, Oct. 5, 1992]

§ 57.1104 How must an entity apply for a grant?

(a) To apply for a grant under this subpart, each entity shall submit an application in the form and at such time as the Secretary may prescribe.

(b) 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 terms and conditions of any award including the regulations of this subpart.

(c) In addition to other pertinent information that the Secretary may require, an application for a grant under this subpart must contain:

(1) A full and adequate description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart; and

(2) A budget justification for the funds requested. If the applicant requests funds for stipend support of participants, the applicant must provide evidence showing that income available from other sources, including income derived from services of the participants in the program, will be insufficient to pay their stipends and that grant funds will not be used to supplant other available funds.

(Approved by the Office of Management and Budget under control number 0915–0060)

[43 FR 54931, Nov. 24, 1978, as amended at 49 FR 38112, Sept. 27, 1984; 52 FR 19145, May 21, 1987; 57 FR 45737, Oct. 5, 1992; 62 FR 51374, Oct. 1, 1997]

§ 57.1105 What requirements must a project meet?

A project supported under this subpart must meet the following requirements:

(a) The general practice residency or advanced education program in general dentistry must be accredited by the American Dental Association Commission on Dental Accredation;

(b) Each project must have at least two participants enrolled in the training program; and

(c) Each participant who receives stipend support must sign a statement of intent to work in the practive of general dentistry.

[62 FR 51374, Oct. 1, 1997]

§ 57.1106 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposal as contained in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will award grants to applicants whose

projects will best promote the purposes of section 749 of the Act. The Secretary will approve or disapprove applications filed in accordance with §7thnsp;57.1104, taking into consideration, among other factors, the degree to which:

(1) The proposal addresses the legislative intent of the program and has a well-documented rationale;

(2) The objectives of the proposed project are consistent with the program's rationale, and are measurable and achievable within the project period;

(3) The proposed project's methodology is consistent with the objectives and explained in appropriate detail;

(4) The evaluation is linked to the objectives and addresses the project outcomes;

(5) The applicant demonstrates the administrative and managerial capability to carry out the proposed project;

(6) The proposed budget is complete, appropriate, cost-effective, and clearly justified;

(7) The plan for institutionalizing the project outcomes is specific and realistic; and

(8) The proposal plans to attract, maintain, and graduate minority and disadvantaged students.

(b) In determining the funding of applications approved under paragraph 9a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[62 FR 51374, Oct. 1, 1997]

§ 57.1107 How will grant awards be made?

(a) *General.* (1) Within the limit of funds available, the Secretary will award grants to those applicants whose approved projects will, in his or her judgment, best promote the purposes of section 749 of the Act, as determined in accordance with § 57.1106.

(2) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 3 years.

(3) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, existence of legislative authority, 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.

(4) Neither the approval of any project nor the award of any grant 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 any portion of an approved project. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

(b) *Determination of grant amount.* The Secretary will determine the amount of any award under this subpart on the basis of his or her estimate of the sum necessary for the cost (including both direct and indirect costs) of the project. In addition, in determining the amount of stipend support to be made available for the general practice residency program, the amount of any stipend must be limited to that portion of the annual amount normally paid to other residents by the applicant which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds, including the incomes derived from the residents' services. For the advanced educational program in general dentistry, stipends for participants (who are postdoctoral students) must be paid in accordance with established Public Health Service postdoctoral stipend rates.

[43 FR 54931, Nov. 24, 1978, as amended at 57 FR 45737, Oct. 5, 1992; 61 FR 6125, Feb. 16, 1996]

§ 57.1108 How will grant payments be made?

The Secretary will, 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.

[43 FR 54931, Nov. 24, 1978]

§ 57.1109 Purposes for which grant funds may be spent.

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

(c) Grants funds may not be used for sectarian instruction or for any religious purpose.

[43 FR 54931, Nov. 24, 1978, as amended at 52 FR 19146, May 21, 1987; 57 FR 45738, Oct. 5, 1992]

§ 57.1110 What additional Department regulations apply to grantees?

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 46—Protection of human subjects
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 83—Regulation for the administration and enforcement of section 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying.

[52 FR 19146, May 21, 1987, as amended at 57 FR 45738, Oct. 5, 1992; 61 FR 6125, Feb. 16, 1996]

§ 57.1111 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6125, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.1112 What additional conditions apply to grantees?

The Secretary may with respect to any grant award 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 approved activity, the interest of the public health, or the conservation of grant funds.

[43 FR 54931, Nov. 24, 1978. Redesignated at 52 FR 19146, May 21, 1987; 57 FR 45738, Oct. 5, 1992]

Subparts M–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 eligiblity 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 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

[1] Applications 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.

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 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 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, except 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 applicants 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.

(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 applicant 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]

Subpart Q—Grants for Predoctoral, Graduate, and Faculty Development Education Programs in Family Medicine

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 786(a) of the Public Health Service Act, 90 Stat. 2316, and as amended by 102 Stat. 3146 (42 U.S.C. 295g–6(a)); renumbered as sec. 747, as amended by Pub. L. 102–408, 106 Stat. 2042–2043 (42 U.S.C. 293k).

§ 57.1601 To what programs do these regulations apply?

These regulations apply to the award of grants under section 747 of the Public Health Service Act (42 U.S.C. 293k) to schools of medicine or osteopathic medicine, hospitals, and other public or

private nonprofit entities for projects to: (a) Plan, develop, and operate, or participate in predoctoral, graduate, or faculty development educational programs in family medicine; and (b) provide financial assistance to trainees participating in predoctoral or graduate educational programs who are in need of financial assistance and who plan to practice family medicine or to trainees in faculty development programs who plan to teach in family medicine training programs.

[57 FR 45738, Oct. 5, 1992, as amended at 61 FR 6125, Feb. 16, 1996]

§ 57.1602 Definitions.

Act means the Public Health Service Act, as amended.

Clerkship means supervised clinical training in a specific field of medicine for predoctoral medical (M.D. or D.O.) students.

Faculty development program means a systematic training program to increase faculty competence in teaching skills and in other areas related to academic responsibilities.

Family medicine means the field of medicine, including osteopathic general practice, in which the physician:

(a) Serves as a physician of first contact with families and with patients of all ages and provides a means of entry into the health care system;

(b) Evaluates the patient's total health needs, provides personal medical care within one or more fields of medicine, and refers the patient, when indicated, to appropriate sources of care while preserving the continuity of care;

(c) Assumes responsibility with the patient for comprehensive and continuous health care and acts as a leader or coordinator of others providing health services; and

(d) Considers the patient's total health care within the context of his or her environment, including the community and the family or comparable social units.

Hospital means a public or other nonprofit hospital which is accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association.

Nonprofit refers to the status of an entity 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.

Osteopathic internship program means an internship which emphasizes family medicine and is approved by the American Osteopathic Association.

Preceptorship means an educational experience in which the trainee works individually with a designated physician, the preceptor, who teaches and personally supervises clinical activity.

Predoctoral training program means an educational program in family medicine, including courses, clerkships or preceptorships in family medicine, which is part of a course of study leading to the degree of doctor of medicine or osteopathic medicine, and student assistantships in family medicine.

Residency training program means:

(a) A residency program in family practice which is fully or provisionally accredited by the Accreditation Council for Graduate Medical Education; or

(b) A postdoctoral program in osteopathic general practice which emphasizes family medicine and is approved by the American Osteopathic Association.

School of medicine or osteopathic medicine means a public or private nonprofit school in a State which provides training leading, respectively, to a degree of doctor of medicine or to a degree of doctor of osteopathic medicine and which is accredited as provided in section 799(1)(E) of the Act.

Secretary means the Secretary of Health and Human Services and any other officer or employer 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.

Student assistantship means a research program in family medicine for

predoctoral medical (M.D. or D.O.) students.

Trainee means a medical (M.D. or D.O.) student, intern, resident, or physician participating in a training program supported by a grant under these regulations.

[45 FR 68895, Oct. 16, 1980, as amended at 49 FR 11613, Mar. 26, 1984; 57 FR 45738, Oct. 5, 1992; 61 FR 6125, Feb. 16, 1996]

§ 57.1603 Who is eligible to apply for a grant?

(a) For predoctoral training programs, an applicant must be a school of medicine or osteopathic medicine located in a State.

(b) For graduate and faculty development training programs, an applicant must be located in a State and be a school of medicine or osteopathic medicine, a hospital, or a public or private nonprofit entity which provides either health or educational programs as one of its major functions.

(c) Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

[45 FR 68895, Oct. 16, 1980, as amended at 57 FR 45738, Oct. 5, 1992]

§ 57.1604 What requirements must a project meet?

(a) *General requirements.* A project supported under this subpart must meet the following requirements:

(1) Each project must have a project director who works at the grantee institution or training site institution, has relevant training and experience, and has been approved by the Secretary to direct the project.

(2) Each project must have an appropriate administrative and organizational plan and appropriate faculty, staff, and facility resources for the achievement of stated objectives.

(3) Each project must systematically evaluate the educational program including trainees and faculty preceptors, the administration of the program and the degree to which program and educational objectives are met.

(4) Each project, other than a faculty development project, must use ambulatory care settings where family medicine is practiced and in which an adequate portion of the clinical training is conducted.

(5) Each project, other than a faculty development project, must have a family medicine curriculum which:

(i) Is appropriate for the academic level of the trainees and the specific length and nature of the educational program;

(ii) Supplements any practical (including clinical) experiences with related education activities; and

(iii) Emphasizes subjects pertinent to:

(A) Ambulatory care;

(B) Psychosocial skills and topics; and

(C) Related nonclinical areas relevant to the practitioner of family medicine.

(b) *Additional requirements for predoctoral training programs.* In addition to the requirements of paragraph (a) of this section, projects for predoctoral training programs must also meet the following additional requirements:

(1) The training program must be sponsored and supervised by an appropriate administrative unit in family medicine, the faculty of which participates in the preparation of the preclerkship curriculum and required courses and activities, for which faculty may be interdisciplinary, such as physical diagnosis and clinical pathological conferences, and which coordinates the predoctoral offering of clerkships and other clinical experiences oriented to family medicine.

(2) Each training program must be part of an integrated institutional strategy to provide education and training in family medicine designed to encourage an appropriate percentage of its graduates, annually, to seek graduate training in family medicine and eventually to enter a career in family medicine.

(3) For projects which include preceptorships in family medicine:

(i) The project must provide medical (M.D. or D.O.) students with ambulatory care training in a community setting.

(ii) Preceptors must have practices which are consistent with the principles of family medicine and must be

selected by the administrative unit in family medicine.

(iii) Stipend support from grant funds may be given to trainees who are not receiving academic credit for the preceptorship only if they (A) need it; (B) indicate an interest in working in the field of family medicine; and (C) engage in the preceptorship full time for at least 4 consecutive weeks. Stipend support from grant funds may be given to trainees who are receiving academic credit for the preceptorship only when the three conditions above are met and, additionally, when the trainee incurs extraordinary living expenses due to participation in the preceptorship.

(4) For projects for student assistantships:

(i) A family medicine faculty member of the administrative unit, identified under paragraph (b)(1) of this section, must supervise each student assistant.

(ii) The grantee must give preference in admission to the training program to applicants considering a career in academic family medicine.

(iii) Stipend support from grant funds may be given to trainees who are not receiving academic credit for the assistantship only if they (A) need it; (B) indicate an interest in working in the field of family medicine; and (C) engage in the assistantship full time for at least 8 consecutive weeks. Stipend support from grant funds may be given to trainees who are receiving academic credit for the assistantship only when the three conditions above are met and, additionally, when the trainees incurs extraordinary living expenses, due to participation in the assistantship.

(c) *Additional requirements for graduate training projects (except faculty development).* In addition to the requirements of paragraph (a) of this section, projects for approved or accredited residency training programs must meet the following additional requirements:

(1) Each program must have a supervisor of training with appropriate experience and training who is responsible for coordination and supervision of training in the program.

(2) Each program must use an appropriate resident or intern recruitment and selection process which assures that residents and interns in the program have applied specifically for training in the approved graduate training program.

(3) Each program must provide education for a sufficient number of interns or residents to provide an adequate collegial environment for the educational program and to enhance cost efficiency.

(4) Each program must have an adequate number of qualified faculty with training and experience in family medicine, behavioral sciences, and liaison specialties, for the number of interns or resident in the program. The faculty of the program must engage in periodic educational activities to improve their teaching skills.

(5) Each program must provide an appropriate amount of clinical training for each intern or resident in ambulatory care settings emphasizing family medicine in each year of the training program. This training will be for the purpose of assuring an adequate education in the principles of the practice of family medicine throughout the program. In addition, each training program must provide clinical training in other ambulatory care settings relevant to family medicine, such as emergency units.

(6) Each program must have adequate facilities for the provision of the educational activities and, in particular, have family medicine ambulatory care space sufficient to provide an adequate clinical experience for the interns or residents.

(7) Each intern or resident must serve a sufficient number of families and individual patients with a variety of health care needs to provide the trainee with a broad clinical experience.

(d) *Additional requirements for faculty development programs.* (1) Each project must have a curriculum which:

(i) Directly applies to family medicine training programs;

(ii) Emphasizes improvement of pedagogical skills for clinical and classroom settings; and

(iii) Uses didactic and nondidactic teaching strategies.

(2) Only physicians who teach or intend to teach in family medicine are eligible to participate as trainees in the program.

(3) Each program must have a sufficient number of trainees participating during the conduct of any educational activities to provide a collegial environment and to make the program cost efficient.

(4) Stipend support from grant funds may be no longer than 24 cumulative months for any trainee.

(5) To be eligible for financial assistance from grant funds, a trainee must:

(i) Intend to teach in family medicine training program on a full-time basis; and

(ii) Be a full-time participant in the training program for at least 3 months.

[45 FR 68895, Oct. 16, 1980, as amended at 49 FR 11613, Mar. 26, 1984; 54 FR 50374, Dec. 6, 1989; 57 FR 45738, Oct. 5, 1992]

§ 57.1605 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will approve projects which best promote the purposes of section 747 of the Act and these regulations. The Secretary will consider, among other factors:

(1) The degree to which the proposed project provides for the project requirements in § 57.1604;

(2) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner; and

(3) The potential of the project to continue on a self-sustaining basis.

(b) In determining the funding of projects approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[45 FR 68895, Oct. 16, 1980, as amended at 49 FR 11613, Mar. 26, 1984; 53 FR 14792, Apr. 26, 1988; 61 FR 6125, Feb. 16, 1996]

§ 57.1606 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels 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.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate 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. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[45 FR 68895, Oct. 16, 1980, as amended at 57 FR 45739, Oct. 5, 1992]

§ 57.1607 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any

unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[45 FR 68895, Oct. 16, 1980, as amended at 57 FR 45739, Oct. 5, 1992]

§ 57.1608 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They 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—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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying.

[49 FR 38113, Sept. 27, 1984; 49 FR 40406, Oct. 16, 1984, as amended at 57 FR 45739, Oct. 5, 1992; 61 FR 6125, Feb. 16, 1996]

§ 57.1609 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6125, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.1610 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 68895, Oct. 16, 1980. Redesignated at 49 FR 11613, Mar. 26, 1984]

Subpart R—Grants for the Establishment of Departments of Family Medicine

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 780, Public Health Service Act, 90 Stat. 2311, as amended by 95 Stat. 221 and 102 Stat. 3146 (42 U.S.C. 295g); renumbered as sec. 747, as amended by Pub. L. 102–408, 106 Stat. 2042–2043 (42 U.S.C. 293k).

§ 57.1701 To what programs do these regulations apply?

These regulations apply to the award of grants under section 747 of the Public Health Service Act (42 U.S.C. 293k) to schools of medicine and osteopathic medicine to meet the costs of projects to establish, maintain, or improve academic administrative units to provide clinical instruction in family medicine. These projects may include:

(a) The planning and development of model predoctoral, faculty development, and graduate medical education programs; and

(b) Academic and clinical activities relevant to the field of family medicine.

[48 FR 20215, May 4, 1983, as amended at 57 FR 45739, Oct. 5, 1992; 60 FR 28067, May 30, 1995]

§ 57.1702 Definitions.

Academic administrative unit or *unit* means a department, division, or other formal academic unit of a school of medicine or osteopathic medicine or clinical campuses of such schools that

provides clinical instruction in family medicine.

Act means the Public Health Service Act, as amended.

Clinical campus means a geographically separate educational entity of an accredited medical school that is recognized and identified as a clinical campus by the American Academy of Family Physicians and that has been given the responsibility to coordinate or provide all clinical training for that clinical campus.

Family medicine includes ''osteopathic general practice'' and means the field of medicine in which the physician:

(a) Serves as a physician of first contact with families and patients of all ages and provides a means of entry into the health care system;

(b) Evaluates the patient's total health needs, provides personal medical care within one or more fields of medicine, and refers the patient, when indicated, to appropriate sources of care while preserving the continuity of care;

(c) Assumes responsibility with the patient for comprehensive and continuous health care and acts as a leader or coordinator of others providing health services; and

(d) Considers the patient's total health care within the context of his or her environment, including the community and the family or comparable social units.

Nonprofit refers to the status of an entity 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.

Other major clinical units means formal academic units at the applicant school or its clinical campus that offer clinical instruction in internal medicine, obstetrics and gynecology, pediatrics, psychiatry, or surgery.

Residency training program means a 3-year residency program in family practice that is fully or provisionally accredited by the Accreditation Council for Graduate Medical Education, or the equivalent of such a program as determined by the Secretary. In the case of osteopathic medicine, a postgraduate program of no less than 2 years' duration, including the osteopathic internship, as approved or provisionally approved by the American Osteopathic Association will be deemed such an equivalent.

School of medicine or *osteopathic medicine* means a public or private nonprofit school in a State which provides training leading, respectively, to a degree of doctor of medicine or to a degree of doctor of osteopathic medicine and which is accredited as provided in section 799(1)(E) of the Act.

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.

[48 FR 20215, May 4, 1983, as amended at 57 FR 45739, Oct. 5, 1992; 60 FR 28067, May 30, 1995; 61 FR 6125, Feb. 16, 1996]

§ 57.1703 Who is eligible to apply for a grant?

Any school of medicine or osteopathic medicine which is located in a State is eligible to apply for a grant. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

[57 FR 45739, Oct. 5, 1992]

§ 57.1704 Program requirements.

Existing units supported under this subpart must meet all the requirements of this section no later than 12 months after initial award of the grant. Units which are being established with the aid of grants under this subpart must meet the requirement of paragraph (a) of this section no later than 12 months after initial award, and the remaining requirements of this section no later than 24 months after initial award of the grant. However, within the first 12 months of grant support,

units which are being established must submit a continuation application. This application is expected to include a plan which details, in a format determined by the applicant, how the remaining project requirements will be met by the end of the second year of grant support. In addition to units that are initially establishing under this subpart, those that change organizational status (i.e., from division to department) are also considered establishing units for the purpose of this subpart. Those that maintain organizational status are considered existing units.

(a) Each project must have a project director, who works at the grantee institution in an administrative unit of the grantee institution on an appointment consistent with other major departments, heads or will head the unit, and has relevant training and experience in family medicine.

(b) The unit must have academic status comparable to that of one of the other major clinical units at the institution.

(c) The unit must have administrative autonomy comparable to that of other academic units.

(d) The unit must have control over a residency training program. The program must have the capacity to enroll a total of at least 9 interns or residents annually. A unit whose applicant school or clinical campus does not have a residency program accredited under its direct authority will be considered as meeting this requirement if it has a written affiliation agreement with a hospital which conducts a residency program as described.

(e) The unit (or units in the case of schools with one or more decentralized units) must have responsibility for providing instruction to each member of the student body who is engaged in an education program leading to a degree in doctor of medicine or doctor of osteopathic medicine. The amount of mandatory and elective curriculum must be comparable to the amount of mandatory and elective curriculum time required for other major clinical units at the school.

(f) The unit must have, in the judgment of the Secretary, a sufficient number of full-time faculty to conduct the instruction. The number of family medicine faculty in the unit must be comparable to that of full-time faculty responsible for conducting the instruction of one of the other major clinical units either at the school or at the clinical campus, whichever is the same as the unit receiving the grant funds.

(g) Each project must evaluate the program of instruction required in paragraph (f) of this section, including evaluation of faculty competence, the administration of the program, and the degree to which program objectives are met.

(h) Where projects include the planning and development of model predoctoral, faculty development, or graduate medical education programs, those programs must be designed to eventually meet the requirements of the regulations implementing section 747 of the Act, 42 CFR part 57, subpart Q.

(Approved by the Office of Management and Budget under control number 0915—0060)

[48 FR 20215, May 4, 1983, as amended at 57 FR 45739, Oct. 5, 1992; 60 FR 28067, May 30, 1995]

§ 57.1705 How will applications be evaluated?

As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will award grants to applicants whose projects will best promote the purposes of section 747 of the Act and this subpart. The Secretary will consider, among other factors:

(a) The degree to which the proposed project adequately provides for the project requirements in § 57.1704;

(b) The administrative and management capability of the applicant to carry out the proposed project in a cost-effective manner;

(c) The qualifications of the proposed staff and faculty of the unit; and

(d) The potential of the project to continue on a self-sustaining basis.

[48 FR 20215, May 4, 1983, as amended at 60 FR 28067, May 30, 1995]

§ 57.1706 How long does grant support last?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for 1 year and subsequent noncompeting continuation awards will also be for 1 year at a time. Decisions regarding noncompeting continuation awards and the funding levels 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, noncompeting continuation awards require a determination by the Secretary 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, shall commit or obligate the United States in any way to make any additional, supplemental, noncompeting continuation or other award with respect to any approved application or portion of an approved application. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[48 FR 20215, May 4, 1983, as amended at 57 FR 45739, Oct. 5, 1992]

§ 57.1707 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, the terms and conditions of the grant award, and the applicable cost principles in subpart Q of 45 CFR part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amount awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[48 FR 20215, May 4, 1983, as amended at 57 FR 45740, Oct. 5, 1992]

§ 57.1708 What additional Department regulations apply to grantees?

Several other regulations apply to grants under the 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 46—Protection of human subjects

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 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 HHS Programs or activities receiving Federal financial assistance

45 CFR part 93—New restrictions on lobbying.

[49 FR 38114, Sept. 27, 1984, as amended at 57 FR 45740, Oct. 5, 1992; 61 FR 6125, Feb. 16, 1996]

§ 57.1709 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[60 FR 38970, July 31, 1995]

§ 57.1710 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[48 FR 20215, May 4, 1983]

Subpart S—Educational Assistance to Individuals From Disadvantaged Backgrounds

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 787 of the Public Health Service Act, 90 Stat. 2317, as amended by 95 Stat. 923, 99 Stat. 541, and 102 Stat. 3131–3132 (42 U.S.C. 295g–7); renumbered as sec. 740, as amended by Pub. L. 102–408, 106 Stat. 2032–2033 (42 U.S.C. 293d).

§ 57.1801 To what grant program do these regulations apply?

These regulations apply to grants to eligible schools and entities under section 740 of the Public Health Service Act (42 U.S.C. 293d) to assist individuals from disadvantaged backgrounds to enter and graduate from health professions schools and schools of allied health.

[47 FR 54438, Dec. 3, 1982, as amended at 61 FR 6125, Feb. 16, 1996]

§ 57.1802 Definitions.

Act means the Public Health Service Act, as amended.

Allied health professions means professions which support, complement, or supplement the professional functions of physicians, dentists, and other health professionals in the delivery of health care to patients, or assist environmental engineers and other personnel in environmental health control and preventive medicine activities.

Community-based program means a program whose organizational headquarters is located in and which primarily serves: A Metropolitan Statistical Area, as designated by the Office of Management and Budget; a Bureau of Economic Analysis, U.S. Department of Commerce designated nonmetropolitan economic area; a county; or Indian tribe(s) as defined in 42 CFR 36.102(c), i.e., an Indian tribe, band, nation, rancheria, Pueblo, colony or community, including an Alaska Native Village or regional or village corporation.

Health professions means the professions of medicine, dentistry, osteopathic medicine, pharmacy, optometry, podiatric medicine, veterinary medicine, public health, chiropractic, health administration, and clinical psychology.

Health professions schools means schools of medicine, dentistry, osteopathic medicine, pharmacy, optometry, podiatric medicine, veterinary medicine, public health, chiropractic, graduate programs in health administration, or graduate programs in clinical psychology, as defined in section 799(1)(A), (B), (C), and (D) of the Act and as accredited in section 799(1)(E) of the Act.

National of the United States (as defined in 8 U.S.C. 1101(a)(22), the Immigration and Nationality Act) means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

Nonprofit refers to the status of an entity 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.

School of allied health means a public or private nonprofit college, junior college, university or hospital-based educational entity which provides or is accredited to provide a degree program in

an allied health discipline and which meets all the criteria in section 799(4) of the Act.

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.

[45 FR 73052, Nov. 4, 1980, as amended at 47 FR 54438, Dec. 3, 1982; 56 FR 40564, Aug. 15, 1991; 57 FR 45740, Oct. 5, 1992; 61 FR 6125, Feb. 16, 1996]

§ 57.1803 Who is eligible to apply for a grant?

(a) Health professions schools, schools of allied health, and public or private nonprofit health or educational entities which are located in a State and provide health or educational programs as one of their major functions may apply for a grant under this subpart. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

(b) Applicants which offer degree programs in the allied health professions must meet relevant standards and guidelines established by appropriate:

(1) Accrediting bodies recognized by the Secretary of Education, or

(2) Federal or State agencies.

[45 FR 73052, Nov. 4, 1980, as amended at 56 FR 40565, Aug. 15, 1991; 57 FR 45740, Oct. 5, 1992]

§ 57.1804 Who is eligible for educational assistance?

To be eligible for educational assistance under this program, an individual must:

(a) Be a resident 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;

(b) Have completed at least the junior year of high school (or its equivalent), except in the case of Model Demonstration programs; and

(c) Come from a disadvantaged background. For this program, an individual from a disadvantaged background is one who:

(1) Comes from an environment that has inhibited the individual from obtaining the knowledge, skill, and abilities required to enroll in and graduate from a health professions school, or from a program providing education or training in an allied health profession; or

(2) Comes from a family with an annual income below a level based on low income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary will periodically publish these income levels in the FEDERAL REGISTER.

[45 FR 73052, Nov. 4, 1980, as amended at 47 FR 54438, Dec. 3, 1982; 56 FR 40565, Aug. 15, 1991; 61 FR 6126, Feb. 16, 1996]

§ 57.1805 Program requirements.

(a) The Secretary will award grants to meet the cost of carrying out one or more of the following five purposes:

(1) To identify individuals from disadvantaged backgrounds for education in the health or allied health professions through the development and application of criteria for this purpose, and to recruit these individuals through motivational activities which may involve dissemination of information, exposure to role models and health facilities, and counseling.

(2) To provide individuals from disadvantaged backgrounds, for a period prior to their entry into a regular course of education of such a school, preliminary education designed to assist them to complete successfully such regular course of education in a health professions school or school of allied health, or to refer them to institutions

which provide it. Preliminary education in this context is education designed to expand the academic ability of disadvantaged students during their preprofessional training. It may not include classes already taught as part of the regular course of education leading to a high school diploma or undergraduate degree. It may not be offered to students before they complete the junior year of high school.

(3) To provide information to individuals from disadvantaged backgrounds about financial aid available to students in health professions schools, or schools of allied health, or schools and entities which provide training necessary to qualify for enrollment in health professions schools or schools of allied health.

(4) To facilitate the entry of individuals from disadvantaged backgrounds into health professions schools or schools of allied health by engaging in activities which assist them to compete for admission, such as instruction designed to improve their performance on admission tests, and by assisting admission committees with the evaluation of disadvantaged applicants.

(5) To provide counseling or other retention services, such as tutorial assistance and assistance in adjusting to the environment of the school, which are designed to help individuals from disadvantaged backgrounds who are enrolled in health professions schools or schools of allied health to complete this education.

(b) The grantee must carry out at least two of the five purposes, even if grant funds are requested or awarded for only one of them.

(c) The grantee must evaluate its program based on the plan provided in the grant application.

(d) Grantees which: (1) Are schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic, podiatric medicine, and public and private nonprofit schools that offer graduate programs in clinical psychology; and

(2) Have a proportionate enrollment of individuals from disadvantaged backgrounds that is less than 200 percent of the national average percentage of such individuals in all schools of each health professions discipline must assure the Secretary that during a period of 3 years, commencing on the date of the award of the grant, they will increase their first-year enrollment of individuals from disadvantaged backgrounds by at least 20 percent over enrollments in the base year of 1987.

[45 FR 73052, Nov. 4, 1980, as amended at 56 FR 40565, Aug. 15, 1991; 56 FR 43648, Sept. 3, 1991; 57 FR 45740, Oct. 5, 1992]

§ 57.1806 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will decide which applications to approve by considering, among other factors:

(1) The degree to which the proposed project adequately provides for the requirements in § 57.1805;

(2) The number and types of individuals who can be expected to benefit from the project;

(3) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner;

(4) The adequacy of the staff and faculty;

(5) The soundness of the budget; and

(6) The potential of the project to continue without further support under this program.

(b) Within the limits of funds available, the Secretary will award grants to approved applicants with projects that will best promote the purposes of section 740 of the Act. Of the amounts appropriated under this section for any fiscal year, 10 percent shall be obligated for community-based programs and 70 percent shall be obligated for grants to institutions of higher education and not more than 5 percent of such funds may be obligated for grants having the primary purpose of informing individuals about the existence and

general nature of health careers. Section 740(a)(2)(G) authorizes the payment of such stipends as the Secretary may approve for participants in a project for any period of education at any school eligible for a grant under this subpart.

(c) *Funding priority*. (1) In determining the funding of applications approved under paragraph (a) of this section, the Secretary shall give priority to schools described in § 57.1805(d), beginning in fiscal year 1992—

(i) Which previously received a grant under this subpart and increased its first-year enrollment of individuals from disadvantaged backgrounds by at least 20 percent over that enrollment in the base year 1987 by the end of 3 years from the date of the award of the HCOP grant; and

(ii) Which had not previously received a grant under this subpart that increased its first-year enrollment of individuals from disadvantaged backgrounds by at least 20 percent over that enrollment in the base year 1987, over any period of time.

(2) In addition, should specific needs warrant, the Secretary will also consider other special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[45 FR 73052, Nov. 4, 1980, as amended at 56 FR 40565, Aug. 15, 1991; 56 FR 43648, Sept. 3, 1991; 61 FR 6126, Feb. 16, 1996]

§ 57.1807 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 3 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be funded for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of factors such 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.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate 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. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[45 FR 73052, Nov. 4, 1980, as amended at 56 FR 40565, Aug. 15, 1991; 57 FR 45740, Oct. 5, 1992]

§ 57.1808 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Any balance of federally-obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during the budget period it becomes apparent to the Secretary that the amount of Federal funds provided and made available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts provided by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

(c) The grantee may spend grant funds to provide one round trip for each individual in the program between his or her residence and the training site if:

(1) The training site is beyond a reasonable commuting distance and requires the individual to establish a temporary new residence; and

(2) The educational assistance is not offered at a time when the individual would be at the training site as a student in a regular course of education

leading to a high school diploma, associate degree, undergraduate degree, or degree in the health or allied health professions.

(d) The grantee may spend grant funds to pay individuals in the program a stipend when the grantee determines that:

(1) The condition in paragraph (c)(2) of this section exists;

(2) No other Federal financial assistance program is authorized to provide this support; and

(3) The individual needs this support to participate in the program.

(e) The grantee may not spend grant funds to pay tuition or fees, train program staff, retrain health professionals, or for sectarian instruction, or for any religious purpose.

[45 FR 73052, Nov. 4, 1980, as amended at 56 FR 40566, Aug. 15, 1991]

§ 57.1809 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They 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—Governmentwide debarment and suspension (non-procurement) 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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on Lobbying

[49 FR 38114, Sept. 27, 1984, as amended at 56 FR 40566, Aug. 15, 1991; 57 FR 45740, Oct. 5, 1992; 61 FR 6126, Feb. 16, 1996]

§ 57.1810 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6126, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.1811 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73052, Nov. 4, 1980]

Subpart 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—Grants for Centers of Excellence

AUTHORITY: Sec. 788A of the Public Health Service Act, Pub. L. 100–97, 101 Stat. 713–714 (42 U.S.C. 295g–8a), and redesignated as section 782, as amended by Pub. L. 100–607, 102 Stat. 3136 (42 U.S.C. 295g–2); renumbered as sec. 739, as amended by Pub. L. 102–408, 106 Stat. 2027–2031 (42 U.S.C. 293c).

SOURCE: 54 FR 28067, July 5, 1989, unless otherwise noted.

§ 57.2101 To what projects do these regulations apply?

These regulations apply to grants awarded to public or nonprofit private health professions schools under section 739 of the Public Health Service Act (42 U.S.C. 293c) to assist such schools in supporting programs of excellence in health professions education for minority individuals.

[54 FR 28067, July 5, 1989, as amended at 61 FR 6126, Feb. 16, 1996]

§ 57.2102 Definitions.

Act means the Public Health Service Act, as amended.

Health professions school means any accredited school of medicine, dentistry, osteopathic medicine, pharmacy, optometry, podiatric medicine, veterinary medicine, public health, and chiropractic or graduate programs in health administration, or graduate programs in clinical psychology, as defined in section 799(1) (A), (B), (C), and (D) of the Act and as accredited in section 799(1)(E) of the Act.

Minority means an individual whose race/ethnicity is classified as American Indian or Alaskan Native, Asian or Pacific Islander, Black, or Hispanic.

Nonprofit refers to the status of an entity 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.

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.

[54 FR 28067, July 5, 1989, as amended at 57 FR 45740, Oct. 5, 1992; 61 FR 6126, Feb. 16, 1996]

§ 57.2103 Who is eligible to apply for a grant?

A health professions school described in section 799(1) (A), (B), (C), and (D) of the Act which has received support under section 788B (Advanced Financial Distress Assistance) of the Act for Fiscal Year 1987, may apply for a grant under this subpart. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at the time the Secretary may prescribe.

[54 FR 28067, July 5, 1989, as amended at 57 FR 45740, Oct. 5, 1992; 61 FR 6126, Feb. 16, 1996]

§ 57.2104 Project requirements.

(a) The Secretary will award grants to meet the cost of carrying out three or more of the following six purposes, one of which must be the purpose provided in paragraph (a)(1) of this section:

(1) Develop a plan to achieve institutional improvements, including financial independence, to enable such school to support programs of excellence in health professions education for minority individuals. This plan must be submitted within 6 months of the date of grant award;

(2) Improve the capacity of such school to recruit and retain faculty;

(3) Provide improved access to the library and information resources of such school;

(4) Establish, strengthen, or expand programs to enhance the academic performance of students in such school;

(5) Establish, strengthen, or expand programs to increase the number and quality of applicants for admission to such school. Activities designed to increase the number and quality of applicants to these schools may not be offered to students prior to the ninth grade; and

(6) Develop curricula and carry out faculty training programs in order to enable such school to become, for the Nation's health care providers, a resource with respect to the health problems of minority communities, such as higher infant mortality rates and higher incidences of acquired immunodeficiency syndrome.

(b) Each project must evaluate its program based on the evaluation plan provided in the grant application.

§ 57.2105 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will decide which applications to approve by considering, among other factors:

(1) The degree to which the applicant can arrange to continue the proposed project beyond the federally funded project period;

(2) The degree to which the proposed project meets three or more of the purposes as described in § 57.2104;

(3) The relationship of the objectives of the proposed project to the goals of the plan that will be developed pursuant to § 57.2104(a)(1);

(4) The administration and managerial ability of the applicant to carry out the project in a cost effective manner;

(5) The adequacy of the staff and faculty to carry out the program;

(6) The soundness of the budget for assuring effective utilization of grant funds, and the proportion of total program funds which come from non-federal sources and the degree to which they are projected to increase over the grant period;

(7) The number of individuals who can be expected to benefit from the project; and

(8) The overall impact the project will have on strengthening the school's capacity to train minority health professionals and increase the supply of minority health professionals available to serve minority populations in underserved areas.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[38 FR 20447, Aug. 1, 1973, as amended at 61 FR 6126, Feb. 16, 1996]

§ 57.2106 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 3 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding the continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress, including the degree that the projected portion of non-federal funds supporting the project has been met, and management practices, the existence of legislative authority, 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.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate 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. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

§ 57.2107 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried foward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

(c) The grantee may spend grant funds to pay individual participants in the program a per diem when the grantee determines that—

(1) The training program requires the individual to establish a temporary new residence;

(2) The program is offered at a time when the individual would not be at the training site in a regular course of education or employed as a faculty member at that institution; and

(3) No other Federal financial assistance program is authorized to provide this support.

(d) The grantee may spend grant funds to provide one round trip per participant between the place of residence and the training site, provided that conditions in paragraphs (c)(1) and (2) of this section are met.

(e) The grantee may not spend grant funds for stipends, licensing exams, loan or scholarship support, support of research faculty or projects and related activities, establishment of research centers, establishment of planning offices, support of commercial ventures, entertainment, dependency allowances, new construction of facilities, acquisition of land, fund raising, or for sectarian instruction or any religious purpose.

[54 FR 28067, July 5, 1989, as amended at 57 FR 45740, Oct. 5, 1992]

§ 57.2108 What additional Department regulations apply to grantees?

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 46—Protection of human subjects
45 CFR part 74—Administration of grants
45 CFR part 75—Informal grant appeals procedures
45 CFR part 76—Governmentwide Debarment and Suspension (non-procurement) 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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying.

[54 FR 28067, July 5, 1989, as amended at 57 FR 45740, Oct. 5, 1992; 61 FR 6126, Feb. 16, 1996]

§ 57.2109 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6126, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.2110 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

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 portion 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 practice 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.

Subpart X [Reserved]

Subpart Y—Grants for Nurse Practitioner and Nurse Midwifery Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 822(a) of the Public Health Service Act, 89 Stat. 361, as amended by 99 Stat. 394–395 and 548 (42 U.S.C. 296m).

§ 57.2401 Applicability.

The regulations of this subpart are applicable to the award of grants to public or private nonprofit schools of nursing and public health, public or private nonprofit schools of medicine which received grants under section 822(a) of the Public Health Service Act (42 U.S.C. 296m) prior to October 1, 1985, public or private nonprofit hospitals, and other public or private nonprofit entities under section 822(a) to meet the cost of projects to (a) plan, develop, and operate, (b) expand, or (c) maintain programs for the education of nurse practitioners or nurse midwives.

[57 FR 45741, Oct. 5, 1992]

§ 57.2402 Definitions.

As used in this subpart:

(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) *Council* means the National Advisory Council on Nursing Education and Practice (established by section 851 of the Act).

(d) *School of nursing* means a collegiate associate degree, or diploma school of nursing.

(e) *Collegiate school of nursing* means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, and including advanced education related to such program of education provided by such school, but only if such program, or such unit, college or university is accredited as provided in section 853(6) of the Act.

(f) *Associate degree school of nursing* means a department, division or other administrative unit in a junior college, community college, college, or university which provides primarily or exclusively a 2-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if such program, or such unit, college, or university is accredited as provided in section 853(6) of the Act.

(g) *Diploma school of nursing* means a school affiliated with a hospital or university, or an independent school, which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that such program has been satisfactorily completed, but only if such program, or such affiliated school or

such hospital or university or such independent school is accredited as provided in section 853(6) of the Act.

(h) *School of medicine* means a school which provides education leading to a degree of doctor of medicine and which is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education.

(i) *School of public health* means a school which provides education leading to a graduate degree in public health and which is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education.

(j) *Nonprofit* refers to the status of an entity 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.

(k) *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.

(l) *Program director* means a qualified individual designated by the grantee and approved by the Secretary who is to be functionally responsible for the education program being supported under this subpart.

(m) *Project period* mean the total time for which support for a project has been approved, including any extensions thereof.

(n) *Budget period* means the interval of time into which the approved activity is divided for budgetary and reporting purposes.

(o) *Programs for the education of nurse practitioners or nurse midwives* means full-time educational programs for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) which meets the guidelines prescribed by the Secretary in the Appendix to this subpart and which has as its objective the education of nurses (including pediatric and geriatric nurses) who will, upon completion of their studies in such programs, be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities (where appropriate), and other health care institutions.

(p) *Nurse practitioner* means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care including the ability to:

(1) Assess the health status of individuals and families through health and medical history taking, physical examination, and defining of health and developmental problems;

(2) Institute and provide continuity of health care to clients (patients), work with the client to insure understanding of and compliance with the therapeutic regimen within established protocols, and recognize when to refer the client to a physician or other health care provider;

(3) Provide instruction and counseling to individuals, families, and groups in the areas of health promotion and maintenance, including involving such persons in planning for their health care; and

(4) Work in collaboration with other health care providers and agencies to provide, and where appropriate, coordinate services to individuals and families.

(q) *Nurse-midwife* means a registered nurse who has completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care to women and babies including the management of normal antepartum, intrapartum, and postpartum care as well as family planning and gynecology.

(r)(1) *Primary health care* means care which may be initiated by the client or provider in a variety of settings and which consists of a broad range of personal health care services including:

(i) Promotion and maintenance of health;

(ii) Prevention of illness and disability;

(iii) Basic care during acute and chronic phases of illness;

(iv) Guidance and counseling of individuals and families;

(v) Referral to other health care providers and community resources when appropriate; and

(vi) Nurse midwifery services (when appropriate).

(2) In providing such services—

(i) The physical, emotional, social, and economic status, as well as the cultural and environmental backgrounds, of individuals, families, and communities (where applicable) are considered;

(ii) The client is provided access to the health care system; and

(iii) A single provider or team of providers, along with the client, is responsible for the continuing coordination and management of all aspects of basic health services needed for individual and family care.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27342, July 21, 1987; 57 FR 45741, Oct. 5, 1992; 61 FR 6126, Feb. 16, 1996]

§ 57.2403 Eligibility.

(a) *Eligible applicants.* To be eligible for a grant under this subpart the applicant shall:

(1) Be a public or private nonprofit school of nursing or public health, a public or private nonprofit school of medicine which received grants under this subpart prior to October 1, 1985, public or private nonprofit hospital; or other public or private nonprofit entity; and

(2) Be located in a State.

(b) *Eligible projects.* A grant under this subpart may be made to an eligible applicant to meet the cost of:

(1) A project to plan, develop, and operate a program for the education of nurse practitioners or nurse midwives (which will be in operation no later than 12 months after the award of a grant under this subpart);

(2) A project to expand a program for the education of nurse practitioners or nurse midwives through one or a combination of the following activities:

(i) A planned increase in student enrollment;

(ii) The addition to the program of one or more fields of clinical practice;

(iii) The addition of a new education site for the total program; or

(3) A project to maintain a program for the education of nurse practitioners and nurse midwives.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27343, July 21, 1987; 57 FR 45741, Oct. 5, 1992]

§ 57.2404 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in such form and at such time as the Secretary may prescribe.

(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 award, including the regulations of this subpart.

(c) In addition to such other pertinent information as the Secretary may require, an application for a grant under this subpart shall contain the following:

(1) A full and adequate description of the proposed project, including:

(i) Information concerning the need for and significance of the proposed project.

(ii) A description of the setting in which the education program will be conducted and the primary health care needs to which such program will be responsive.

(iii) A detailed description of the planning and developmental activities to be carried out or which have been accomplished by the applicant.

(iv) A detailed time plan for each year of the project period, identifying target dates for project activities and including any plans for continuing such activities beyond the project period.

(v) A description of specific measurable objectives for the proposed project consistent with the purposes of section 822 of the Act.

(vi) A detailed plan for achieving the stated objectives of the proposed project.

(vii) A description of the program curriculum, including course content and the number of hours of classroom instruction, supervised laboratory, and clinical practice.

(viii) A plan and methodology for evaluating the education program in

accordance with the requirements of § 57.2405(c).

(ix) Where the education includes a preceptorship, a description of such preceptorship, including length, type of practice, and amount of faculty supervision.

(x) A description of recruitment plans and criteria for the selection and admission of students.

(xi) An estimate of the number of students to be enrolled during the project period.

(xii) In the case of a project to expand a nurse practitioner or nurse midwifery education program, a description of the manner in which the program is to be expanded and a plan for achieving such expansion during the project period.

(2) Evidence satisfactory to the Secretary that the applicant has secured any required institutional clearances and approvals for the planning, development, and operation of the program.

(3) Information concerning the background and qualifications of the program director, staff, and consultants.

(4) Evidence satisfactory to the Secretary that the applicant will have available adequate faculty, staff facilities, clinical practice settings, and equipment for the conduct of the proposed project.

(5) A description of any written agreements with other institutions or organizations for carrying out the proposed project.

(6) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

(7) A description of financial resources available to the applicant to assure the sound establishment, maintenance, and continuation of the proposed project beyond the project period.

(d) The application shall contain an assurance satisfactory to the Secretary that—

(1) In the case of a project to plan, develop, and operate a program for the education of nurse practitioners or nurse midwives, such program will upon its development meet the guidelines set forth in the Appendix of this subpart, or

(2) In the case of a project to expand or maintain a program for the education of nurse practitioners or nurse midwives, such program meets the guidelines set forth in the appendix to this subpart.

(Approved by the Office of Management and Budget under control number 0915–0060)

[42 FR 60883, Nov. 29, 1977, as amended at 49 FR 38114, Sept. 27, 1984; 52 FR 27343, July 21, 1987; 57 FR 45741, Oct. 5, 1992]

§ 57.2405 Project requirements.

A project supported under this subpart shall be conducted in accordance with the following requirements:

(a) The project shall conduct its program for the education of nurse practitioners or nurse midwives in accordance with the guidelines prescribed by the Secretary and set forth in the Appendix to this subpart.

(b) The program director shall be responsible for the conduct of the education program unless replaced by another individual found by the Secretary to be qualified to carry out such responsibilities. Where the program director becomes unable to function in such capacity, the Secretary shall be notified as soon as possible.

(c) In accordance with the plan set forth in its approved application, the project shall evaluate the effectiveness of the program in relation to its purposes and objectives.

(Approved by the Office of Management and Budget under control number 0915–0060)

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27343, July 21, 1987; 61 FR 51788, Oct. 4, 1996]]

§ 57.2406 Evaluation and grant awards.

(a) *Evaluation.* (1) Within the limits of funds available for such purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his judgment best promote the purposes of section 822 of the Act, taking into consideration:

(i) The degree to which the project plan adequately provides for meeting the requirements set forth in § 57.2405 and the appendix to this subpart;

(ii) The potential effectiveness of the proposed project in carrying out the education purposes of section 822 of the Act and this subpart;

(iii) The capability of the applicant to carry out the proposed project;

(iv) The extent to which the project has joint program direction by qualified nurse and physician educators;

(v) The soundness of the fiscal plan for assuring effective utilization of grant funds; and

(vi) The potential of the project to continue on a self-sustaining basis after the project period.

(2) Pursuant to section 822(a)(1) of the Act, the Secretary will give special consideration to:

(i) Projects for programs for the education of nurse practitioners or nurse midwives who will practice in health professional shortage areas (designated under section 332 of the Act); and

(ii) Projects for education programs which emphasize education respecting the special problems of geriatric patients (particularly problems in the delivery of preventive care, acute care, and long-term care, including home health care and institutional care to such patients) and education to meet the particular needs of nursing home patients and patients confined to their homes.

(3) In determining the funding of applications approved under paragraph (a)(1) of this section, the Secretary will also consider other special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

(b) *Grant awards.* (1) The Secretary will determine the amount of any award on the basis of his or her estimate on the sum necessary for the cost (including both direct and indirect costs) of the project.

(2) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which such funds will be available for obligation by the grantee.

(3) Neither the approval of any project nor the award of any grant 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 at such times and in such form as the Secretary may prescribe.

(c) *Noncompeting continuation awards.* If a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved project if (1) the application is for a project which meets the regulations of this subpart and (2) on the basis of such progress and accounting records as may be required, the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period. If the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (b)(1) of this section. If the Secretary decides not to continue supporting a project for an additional budget period, he will notify the grantee in writing before the end of the current budget period. In addition, the Secretary may provide financial support for the orderly phaseout of the supported project, if he determines that such support is necessary.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27343, July 21, 1987; 53 FR 14792, Apr. 26, 1988; 57 FR 45741, Oct. 5, 1992]

§ 57.2407 Grant payments.

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

[42 FR 60883, Nov. 29, 1977]

§ 57.2408 Expenditure of grant funds.

(a) Any funds granted pursuant to this subpart shall be expended solely for carrying out the approved project in accordance with section 822 of the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74; *Provided,* That such funds shall not be expended for sectarian instruction or for any religious purpose.

(b) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27343, July 21, 1987; 57 FR 45741, Oct. 5, 1992]

§ 57.2409 What additional Department regulations apply to grantees?

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 46—Protection of Human Subjects.
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 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 HHS Programs Activities Receiving Federal Financial Assistance.
45 CFR part 93—New restrictions on lobbying.

[52 FR 27344, July 21, 1987, as amended at 57 FR 45741, Oct. 5, 1992; 61 FR 6126, Feb. 16, 1996]

§ 57.2410 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 the public health, or the conservation of grant funds.

[43 FR 43416, Sept. 25, 1978. Redesignated at 52 FR 27344, July 21, 1987]

APPENDIX TO SUBPART Y—GUIDELINES FOR NURSE PRACTITIONER AND NURSE MIDWIFERY PROGRAMS

The guidelines set forth below have been prescribed by the Secretary after consultation with appropriate educational organizations and professional nursing and medical organizations, as required by section 822(a)(2)(B) of the Public Health Service Act.

A. *Definitions.* 1. ''Programs for the education of nurse pactitioners or nurse midwives'' means a full-time educational program for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) which meets the guidelines prescribed herein and which has as its objective the education of nurses (including pediatric and geriatric nurses) who will, upon completion of their studies in such program be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, where appropriate, and other health care institutions.

2. ''Nurse practitioner'' means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care including the ability to:

a. Assess the health status of individuals and families through health and medical history taking, physical examination, and defining of health and developmental problems;

b. Institute and provide continuity of health care to clients (patients), work with the client to insure understanding of and compliance with the therapeutic regimen within established protocols, and recognize when to refer the client to a physician or other health care provider;

c. Provide instruction and counseling to individuals, families and groups in the areas

of health promotion and maintenance, including involving such persons in planning for their health care; and

d. Work in collaboration with other health care providers and agencies to provide, and where appropriate, coordinate services to individuals and families.

3. ''Nurse-midwife'' means a registered nurse who has completed a formal program of study designed to prepare registered nurses to perform in an expanded role in the delivery of primary health care to women and babies including the management of normal antepartum, intrapartum, and postpartum care as well as family planning and gynecology.

4. ''Primary health care'' means care which may be initiated by the client or provider in a variety of settings and which consists of a broad range of personal health care services including:

a. Promotion and maintenance of health;

b. Prevention of illness and disability;

c. Basic care during acute and chronic phases of illness;

d. Guidance and counseling of individuals and families; and

e. Referral to other health care providers and community resources when appropriate; and

f. Nurse midwifery services (where appropriate).

In providing such services (i) the physical, emotional, social, and economic status, as well as the cultural and environmental backgrounds of individuals, families, and communities (where applicable) are considered; (ii) the client is provided access to the health care system; and (iii) a single provider or team of providers, along with the client, is responsible for the continuing coordination and management of all aspects of basic health services needed for individual and family care.

B. *Organization and administration.* 1. A nurse practitioner or nurse-midwifery education program shall have active collaboration with nurses and physicians who have expertise relevant to the nurse practitioner or nurse midwife role and primary health care, to assist in the planning, development, and operation of such a program. In addition, where the institution or organization conducting the program is other than a school of nursing, medicine, or public health, such collaboration shall be with nurses and physicians who are affiliated with either a collegiate school of nursing, school of medicine, or school of public health.

2. Co-program directors from nursing and medicine are recommended.

C. *Student enrollment.* 1. A nurse practitioner or nurse midwifery education program shall have an enrollment of not less than six full-time equivalent students in each class.

2. All students enrolled in a nurse practitioner or nurse midwifery education program must be licensed to practice nursing (a) at the time of enrollment, or (b) in the case of a program leading to a graduate degree in nursing, at or prior to the time of completion of a program.

3. The policies for the recruitment and selection of students shall be consistent with the requirements of the sponsoring institution and developed in cooperation with the faculty responsible for conducting the education. Admission criteria shall take into consideration the educational background and work experience of applicants.

D. *Length of program.* A nurse practitioner or nurse midwifery education program shall be a minimum of 1 academic year (or 9 months) in length and shall include at least 4 months (in the aggregate) of classroom instruction.

E. *Curriculum.* 1. A nurse practitioner or nurse midwifery education program shall be a discrete program consisting of classroom instruction and faculty-supervised clinical practice designed to teach registered nurses the knowledge and skills needed to perform the functions of a nurse practitioner or nurse midwife specified in the defintion of that term as set forth in these guidelines. The curriculum shall be developed and implemented cooperatively by nurse educators, physicans, and appropriate representatives of other health disciplines. The following are examples of broad areas of program content which should be included: Communications and interviewing (history taking); basic physical examination including basic pathophysiology; positive health maintenance; care during acute and chronic phases of illness; management of chronic illness; health teaching and counseling; role realignment and establishment of collaborative roles with physicians and other health care providers; and community resources. The program content, both classroom instruction and clinical practice, should be developed so that the nurse practitioner or nurse midwife is prepared to provide primary health care as defined in these guidelines.

2. The curriculum may include a preceptorship, in which the student is assigned to a designated preceptor (a nurse practitioner, nurse midwife, or physician) who is responsible for teaching, supervising, and evaluating the student and for providing the student with an environment which permits observation and active participation in the delivery of primary health care. If a preceptorship is included, it shall be under the direction and supervision of the faculty.

F. *Faculty qualifications.* A nurse practitioner or nurse midwifery education program shall have a sufficient number of qualified nursing and medical (and other related professional) faculty with academic preparation and clinical expertise relevant to their areas

of teaching responsibility and with demonstrated ability in the development and implementation of educational programs.

G. *Resources.* 1. A nurse practitioner or nurse midwifery education program shall have available sufficient educational and clinical resources including a variety of practice settings, particularly in ambulatory care.

2. Clinical practice facilities shall be adequate in terms of space and equipment, number of clients, diversity of client age, and need for care, number of students enrolled in the program, and other students using the facility for education purposes.

3. Where the institution or organization conducting the program does not provide the clinical practice settings itself, it shall provide for such settings through written agreements with other appropriate institutions or organizations.

4. Where the institution or organization conducting the program is other than a school of nursing, medicine, or public health, it shall provide for sufficient educational expertise through writtten agreeements with a collegiate school of nursing, school of medicine, or school of public health.

[42 FR 60883, Nov. 29, 1977, as amended at 43 FR 27837, June 27, 1978; 52 FR 27344, July 21, 1987; 57 FR 45741, Oct. 5, 1992]

Subpart Z—Grants for Advanced Nurse Education Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 821 of the Public Health Service Act, 89 Stat. 361; as amended by 95 Stat. 930, 99 Stat. 394 and 548, and Pub. L. 102–408, 106 Stat. 2072 (42 U.S.C. 296l).

§ 57.2501 Applicability.

The regulations of this subpart apply to the award of grants to public and private nonprofit collegiate schools of nursing under section 821 of the Public Health Service Act (42 U.S.C. 296l) to meet the costs of projects to:

(a) Plan, develop, and operate new programs; or

(b) Significantly expand existing programs leading to advanced degrees that prepare nurses to serve as nurse educators or public health nurses, or in other clinical nurse specialties determined by the Secretary to require advanced education.

[61 FR 6127, Feb. 16, 1996]

§ 57.2502 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Advanced nurse education program means a program of study in a collegiate school of nursing which leads to masters' and doctoral degrees and which prepares nurses to serve as nurse educators, administrators, or researchers or to serve in clinical nurse specialties determined by the Secretary to require advanced education.

Budget period means the interval of time into which the approved activity is divided for budgetary purposes, as specified in the grant award document.

Collegiate school of nursing means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to masters' and doctoral degrees in nursing, and including advanced education related to this type of educational program provided by the school, but only if the program, or unit, college or university is accredited.

Construction means (1) the construction of new buildings and the acquisition, expansion, remodeling, replacement, and alteration of existing buildings including architects' fees but not including the cost of acquisition of land (except in the case of acquisition of an existing building), offsite improvements, living quarters, or patient-care facilities, and (2) equipping new buildings and existing buildings, whether or not acquired, expanded, remodeled, or altered.

Council means the National Advisory Council on Nurse Education and Practice established by section 851(a) of the Act.

Nonprofit refers to the status of an entity 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.

Professional nurse means a registered nurse who has received initial nursing preparation from a diploma, associate

degree, or collegiate school of nursing as defined in section 853 of the Act and who is currently licensed to practice nursing.

Project period means the total time for which support for a project has been approved, as specified in the grant award document.

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.

[43 FR 43416, Sept. 25, 1978, as amended at 48 FR 45113, Oct. 3, 1983; 52 FR 27346, July 21, 1987; 57 FR 45741, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2503 Eligibility.

(a) *Eligible applicants.* To be eligible for a grant under this subpart the applicant shall:

(1) Be a public or private nonprofit collegiate school of nursing.

(2) Be located in a State.

(b) *Eligible projects.* A grant under this subpart may be made to an eligible applicant to meet the cost of:

(1) A project to plan, develop, and operate an advanced nurse education program. The planning period of this project is limited to 1 year. The project must enroll students before the end of the project period;

(2) A project to significantly expand an advanced nurse education program through one or more of the following activities:

(i) The addition to the masters' or doctoral program of a new clinical, research, or functional (administration or teaching) specialty area,

(ii) A planned increase in student enrollment during the project period, or

(iii) The addition of a new educational site for the program; or

[43 FR 43416, Sept. 25, 1978, as amended at 48 FR 45113, Oct. 3, 1983; 52 FR 27346, July 21, 1987; 57 FR 45741, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2504 Application.

(a) Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

(b) The application shall be signed 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 award, including the regulations of this subpart.

(c) In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart shall contain:

(1) A proposal for a project to:

(i) Plan, develop, and operate; or

(ii) Significantly expand an advanced nurse education program;

(2) Information documenting the need for the proposed project;

(3) A description of specific attainable and measurable objectives for the proposed project consistent with the purposes of section 821 of the Act;

(4) A detailed plan for achieving and measuring the stated objectives of the proposed project;

(5) A description of the anticipated impact of the proposed project, including its potential contribution to nursing;

(6) Evidence satisfactory to the Secretary that the applicant will have available adequate resources for the conduct of the proposed project, including adequate faculty, staff, equipment, facilities, and an appropriate clinical practice setting or settings;

(7) A detailed budget for the proposed project and a justification of the amount of grant funds requested;

(8) A description of any Federal financial support related to the proposed project which the applicant is currently receiving;

(9) A detailed timetable for carrying out the activities of the proposed project, including any plans for continuing activities beyond the project period;

(10) A description of the background and qualifications of the project staff and any proposed consultants;

(11) Information concerning the source and number of potential students for the education program and a description of plans, if any, to encourage graduates of the education program to practice in States in need of nurses prepared in the specialty in which education is to be provided;

(12) A plan to sustain the project beyond the period during which Federal assistance is available; and

(13) A plan to attract and retain a higher than average number of minority and financially needy students.

(d) In the case of a project to significantly expand an advanced nurse education program, the application shall contain an assurance satisfactory to the Secretary that the applicant will expend, in carrying out the program for which a grant under this subpart is sought, an amount of non-Federal funds (excluding costs of construction) at least as great as the average amount of non-Federal funds (excluding expenditures of a nonrecurring nature, including costs of construction) expended for this purpose during the 3 fiscal years immediately preceding the fiscal year for which the grant is sought.

(Approved by the Office of Management and Budget under control number 0915–0060)

[43 FR 43416, Sept. 25, 1978, as amended at 48 FR 45113, Oct. 3, 1983; 52 FR 27346, July 21, 1987; 57 FR 45741, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2505 Project requirements.

(a) A project supported under this subpart shall be conducted in accordance with its approved application.

(b) A project supported under this subpart shall enroll professional nurses, as defined in § 57.2502, or students who will be professional nurses, as defined in § 57.2502, at or prior to completion of the advanced nurse education program.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27347, July 21, 1987]

§ 57.2506 Evaluation and grant awards.

(a) *Evaluation.* Within the limits of funds available for this purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will, in his or her judgment, best promote the purposes of section 821 of the Act, taking into consideration among other pertinent factors:

(1) The need for the proposed project including, with respect to projects to provide education in professional nursing specialties determined by the Secretary to require advanced education:

(i) The current or anticipated need for professional nurses educated in the specialty; and

(ii) The relative number of programs offering advanced education in the specialty;

(2) The need for nurses in the specialty in which education is to be provided in the State in which the education program is located, as compared with the need for these nurses in other States;

(3) The degree to which the applicant proposes to recruit students from States in need of nurses in the specialty in which education is to be provided, and to promote their return to these States following education;

(4) The degree to which the applicant proposes to encourage graduates to practice in States in need of nurses in the specialty in which education is to be provided;

(5) The potential effectiveness of the proposed project in carrying out the educational purposes of section 821 of the Act and this subpart;

(6) The capability of the applicant to carry out the proposed project;

(7) The soundness of the fiscal plan for assuring effective utilization of grant funds; and

(8) The potential of the project to continue on a self-sustaining basis after the period of grant support; and

(9) The degree to which the applicant proposes to attract, retain and graduate minority and financially needy students.

(b) *Funding preference.* In determining the funding of applications approved under paragraph (a) of this section, the

Secretary may from time to time announce in the FEDERAL REGISTER special factors relating to national needs.

(c) *Grant awards.* (1) The Secretary will determine the amount of any award on the basis of his or her estimate on the sum necessary for the cost (including both direct and indirect costs) of the project.

(2) All grant awards shall be in writing and shall set forth the amount of funds granted and the period for which the funds will be available for obligation by the grantee.

(3) Neither the approval of any project nor the award of any grant 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 in a form and at the time that the Secretary may require.

(d) *Noncompeting continuation awards.* Within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved project on the basis of an application and those progress and accounting records which may be required. If the Secretary finds that the project's activities during the current budget period justify continued support of the project for an additional budget period, and the Secretary decides to continue support, the amount of the grant award will be determined in accordance with paragraph (c)(1) of this section. If the Secretary decides not to continue support for an additional budget period, he or she will notify the grantee in writing before the end of the current budget period. The Secretary may provide financial support for the orderly phase-out of the supported project, if he or she determines that this support is necessary.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27347, July 21, 1987; 52 FR 28511, July 30, 1987; 53 FR 14792, Apr. 26, 1988; 61 FR 6127, Feb. 16, 1996]

§ 57.2507 Grant payments.

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

[43 FR 43416, Sept. 25, 1978]

§ 57.2508 Expenditure of grant funds.

(a) Any funds granted under 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 section 821 of the Act, the regulations of this subpart, the terms and conditions of the award, except that funds shall not be expended for sectarian instruction or for any religious purpose.

(b) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[43 FR 43416, Sept. 25, 1978, as amended at 52 FR 27347, July 21, 1987; 57 FR 45742, Oct. 5, 1992]

§ 57.2509 What additional Department regulations apply to grantees?

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 46—Protection of Human Subjects.

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 83—Regulation for the Administration and Enforcement of Section 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 HHS Programs or Activities Receiving Federal Financial Assistance.

45 CFR part 93—New restrictions on lobbying.

[52 FR 27347, July 21, 1987, as amended at 57 FR 45742, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2510 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 or her 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.

[43 FR 43416, Sept. 25, 1978. Redesignated at 52 FR 27347, July 21, 1987]

Subparts AA–BB [Reserved]

Subpart CC—Scholarships for Students of Exceptional Financial Need

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 758 of the Public Health Service Act, 90 Stat. 2289, as amended by 102 Stat. 3126–3127 (42 U.S.C. 294z); renumbered as sec. 736, as amended by Pub. L. 102–408, 106 Stat. 2022 (42 U.S.C. 293).

SOURCE: 45 FR 40583, June 16, 1980, unless otherwise noted.

§ 57.2801 To what programs do these regulations apply?

These regulations apply to grants under section 736 of the Public Health Service Act (42 U.S.C. 293) for scholarships for full-time students of exceptional financial need.

[45 FR 40583, June 16, 1980, as amended at 57 FR 45742, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2802 Definitions.

Act means the Public Health Service Act, as amended.

Full-time student means a student 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 degree from a health professions school, as specified in section 799(1)(A) of the Act.

Health professions school or *school* means, for this subpart, a public or private nonprofit school of medicine, osteopathic medicine, dentistry, optometry, podiatric medicine, pharmacy, or veterinary medicine providing a course of study, or a portion thereof, as defined in section 799(1)(A) of the Act and as accredited in section 799(1)(E) of the Act.

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).

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department 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.

[45 FR 40583, June 16, 1980, as amended at 57 FR 45742, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2803 How to apply for a grant.

(a) Any health professions school located in a State may apply for a grant. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

(b) In addition to other information that the Secretary may require, an application must contain:

(1) A listing of eligible scholarship recipients in order of greatest financial need, indicating resident or nonresident status as well.

(2) The name of the need analysis service used in evaluating the financial status of applicants.

(Approved by the Office of Management and Budget under control number 0915–0028)

[45 FR 40583, June 16, 1980, as amended at 57 FR 45743, Oct. 5, 1992]

§ 57.2804 Students eligible for scholarships.

(a) A scholarship may be awarded only to a student who:

(1) Is a resident 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.

(2) Has been accepted for enrollment as a full-time student by a health professions school.

(3) Has exceptional financial need as determined under paragraph (b) of this section.

(b)(1) For the purpose of this subpart, a student will have exceptional financial need if the school determines that his or her resources, as described in (b)(2) of this section, do not exceed the lesser of $5,000 or one-half of the cost of attendance at the school.

(2) The school will determine the financial resources of a student by using one of the national need analysis systems or any other procedure approved by the Secretary of Education and 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, or other family members. Student summer earnings, educational loans, veterans (G.I) benefits and earnings during the school year will not be considered resources for purposes of this subpart.

(3) The school will determine cost of attendance at the school by considering expenses 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) A recipient of a National Health Service Corps Scholarship, under section 751 of the Act, or an Indian Health Scholarship, under section 757 of the Act, is ineligible for a scholarship under this subpart.

(Approved by the Office of Management and Budget under control number 0915–0028)

[45 FR 40583, June 16, 1980, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2805 Amount of scholarship award.

A scholarship will consist of:

(a) The tuition of the student in such school year;

(b) The cost of all other reasonable educational expenses including fees, books, and laboratory expenses of the student for the school year; and

(c) A stipend of $400 per month (adjusted in accordance with section 338A(g)(3) of the Act) for 12 consecutive months beginning with the first month of the school year.

[45 FR 40583, June 16, 1980, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2806 How is the amount of grant award determined?

(a) A school which receives a grant under this subpart must award each scholarship successively to the eligible individual as specified in § 57.2803(b)(1) of greatest financial need at that school.

(b) The Secretary will make a randomized list of all eligible applicant

schools of medicine, dentistry and osteopathic medicine and a second randomized list of all remaining eligible applicant schools. To the extent of available funds, the Secretary will award grant funds sufficient for one scholarship to each eligible applicant school on the first list, and then proceed to the list of all other eligible applicant schools and award one scholarship to each school in the same manner. These scholarships must go to students who have no financial resources for the first year of study at the school, as determined under § 57.2804. The Secretary will then allocate any remaining funds according to paragraph (c) of this section.

(c)(1) Proceeding in sequence through the list of schools of medicine, dentistry and osteopathic medicine, the Secretary will award each school of medicine, dentistry, and osteopathic medicine sufficient grant funds for a second scholarship which must be given to a student with no financial resources as determined under § 57.2804. This procedure will be repeated until all the scholarship requests of the applicant schools of medicine, osteopathic medicine, and dentistry for scholarships for students with no financial resources have been satisfied or until all the available grant funds have been allocated. If there are additional grant funds, the Secretary will then proceed to the list of all other eligible applicant schools and will allocate scholarships for students with no financial resources using the same procedure.

(2) If additional grant funds remain after fulfilling all requests for scholarships for students with no financial resources at all eligible applicant schools, using the method described in paragraph (c)(1) of this section the Secretary will allocate funds for scholarships to students who have resources from one to 500 dollars. With any remaining funds after completion of these awards, the Secretary will, in the same manner, award grants for scholarships to students with resources in increments of $500 until all grant funds are awarded or students who have $5,000 in resources or 50 percent of the cost of education at the school have received awards.

[45 FR 40583, June 16, 1980, as amended at 57 FR 45743, Oct. 5, 1992]

§ 57.2807 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application, the authorizing legislation, terms and conditions of the grant award, and these regulations.

(b) The grantee must discontinue all scholarship payments and remit the unused balance of the scholarship to the Federal Government in the event that a recipient ceases to be a full-time student at the school.

§ 57.2808 What additional Department regulations apply to grantees?

Several other regulations apply to these grants. They 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 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 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 HHS programs or activities receiving Federal financial assistance

45 CFR part 93—New restrictions on lobbying.

[49 FR 38114, Sept. 27, 1984, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996]

§ 57.2809 What other records, audit, and inspection requirements apply to grantees?

(a) Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

(b) The grantee must also maintain: (1) A record of all applications for scholarships, and the basis for approving or disapproving each application, including a copy of the total need analysis and determination of resources for each applicant and documentation for any changes made to the need analysis report used by the school; (2) A record of the amount of funds awarded to each recipient.

(Approved by the Office of Management and Budget under control number 0915–0028)

[45 FR 40583, June 16, 1980, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6127, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.2810 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart DD—Financial Assistance for Disadvantaged Health Professions Students

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 787 of the Public Health Service Act, 90 Stat. 2309, as amended by 95 Stat. 923, 99 Stat. 541 (42 U.S.C. 295g–7); renumbered as sec. 740, as amended by Pub. L. 102–408, 106 Stat. 2032–2033 (42 U.S.C. 293d).

SOURCE: 52 FR 18675, May 18, 1987, unless otherwise noted.

§ 57.2901 To what program do these regulations apply?

These regulations apply to grants to eligible schools under section 740(a)(2)(F) and (d) of the Public Health Service Act for financial assistance for disadvantaged health professions students of exceptional financial need.

[52 FR 18675, May 18, 1987, as amended at 61 FR 6128, Feb. 16, 1996]

§ 57.2902 Definitions.

Act means the Public Health Service Act, as amended.

Full-time student means a student 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 degree from a school of medicine, school of osteopathic medicine, or school of dentistry, as specified in section 799(1)(A) of the Act.

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).

School means a public or private nonprofit school of medicine, osteopathic medicine, or dentistry, as defined in section 799(1)(A) of the Act.

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 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.

[52 FR 18675, May 18, 1987, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.2903 How to apply for a grant.

(a) Any school located in a State may apply for a grant. Each school seeking a grant 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.

§ 57.2904 Eligibility and selection of aid recipients.

(a) *Determination of eligibility*. An individual is eligible for consideration for financial assistance under this program if he or she:

(1) Is a resident 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.

(2) Is enrolled or has been accepted for enrollment as a full-time student at a school;

(3) Comes from a disadvantaged background. For purposes of this program, an individual from a disadvantaged background is one who—

(i) Comes from an environment that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from a school; or

(ii) Comes from a family with an annual income below a level based on low income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary for use in all health professions programs. The Secretary will periodically publish these income levels in the FEDERAL REGISTER; and

(4) Has exceptional financial need. For purposes of this program, a student will have exceptional financial need if the school determines that the student's resources, as described in paragraph (b)(1) of this section, do not exceed the lesser of $5,000 or one-half of the cost of attendance at the school. Student summer earnings, educational loans, veterans (G.I.) benefits, and earnings during the school year will not be considered resources for purposes of determining whether a student has exceptional financial need.

(b) *Selection of aid recipients.* The school will select qualified recipients and determine the amount of aid to be awarded to provide its needy students with the maximum possible benefit.

(1) In determining the amount of aid an eligible student needs to pursue a full-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. The school must take into account, regardless of the tax status of the student, the expected contribution from parents, spouse, self, or (as appropriate) other family members. In making this determination, the school must consider 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 and documentation of the total income for the most recent tax year), and may require tax returns that are certified as having been received by the Internal Revenue Service (IRS); and

(ii) The costs reasonably necessary for the student's attendance at the school. The school must document the criteria used for determining these costs. This documentation must include resource materials used by the school to determine the dollar amount for each category of expenses in its standard student budgets.

(2) The school must select aid recipients in order of greatest need, as determined by the school. The school may consider other scholarship, grant, or

fellowship funds that a student has received or will receive for the award period when determining the order of greatest need.

(Approved by the Office of Management and Budget under control number 0915–0028)

[52 FR 18675, May 18, 1987, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.2905 Amount of student award.

(a) The total award made under this program to any student, plus all other sources of aid the student has received or will receive for the award period, may not exceed the amount the school determines that the student needs to meet the costs of education (i.e., tuition, fees, books, equipment, other expenses required by the school, and reasonable living expenses) for the period covered by the award. The total award made under this program to any student may be less than the amount the school determines that the student needs to meet the costs of education for the period covered by the award.

(b) The total award made under this program to any student for a school year may not exceed $10,000. The maximum amount awarded during a 12-month period to any student enrolled in a school which provides a full-time course of study longer than the traditional 9-month school year may be proportionately increased.

(c) The school must disburse this award to the student in payments based on the student's need during each academic period (e.g. semester, quarter, trimester) of a school year.

§ 57.2906 How is the amount of the grant award determined?

(a) The amount of the grant to each eligible school will be the amount requested in its application, except that if the total of the amounts requested for any fiscal year by all schools for these funds exceeds the amount of Federal funds determined by the Secretary at the time of payment to be available for this purpose, the grant 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 grant award to be available for that fiscal year for this program as the number of eligible students at the school bears to the total number of eligible students at all participating schools during that year.

(b) Amounts remaining after the calculation described in paragraph (a) will be distributed in accordance with paragraph (a)(2) of this section among schools whose applications requested more than the amount paid to them, but with whatever adjustments may be necessary to prevent the total grant to any school from exceeding the amount requested by it.

§ 57.2907 For what purposes may grant funds be spent?

(a) A school shall only spend funds it receives under this subpart in accordance with the approved application, the authorizing legislation, terms and conditions of the grant award, and these regulations.

(b) The school must discontinue all payments to a recipient in the event that the recipient ceases to be a full-time student at the school, and must remit any unused balance of funds to the Federal Government in the event it is unable to make full use of its grant award during the award period.

§ 57.2908 What additional Department regulations apply to grants?

Several other regulations apply to these grants. They include, but are not limited to, the following:

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 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 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 HHS Programs or Activities Receiving Federal Financial Assistance

45 CFR part 93—New restrictions on lobbying.

[52 FR 18675, May 18, 1992, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.2909 What other records, audit, and inspection requirements apply to schools?

(a) Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

(b) The school must also maintain the following records in computer, electronic, microfiche, microfilm, or paper form:

(1) A record of all recipients of aid under this program which includes, for each recipient, a copy of the total need analysis and determination of resources, documentation for any changes made to the need analysis report used by the school, documentation that the recipient met the eligibility requirements, a copy of the student budget used to determine the recipient's costs of attendance, and documentation of other sources of aid received by the recipient;

(2) A record of the amount of funds awarded to each recipient; and

(3) A record of each institutional application for funding, including documentation to support the number of eligible students listed on each application and how they met the eligibility criteria.

(c) Institutional officials who have information which indicates the potential or actual commission of fraud or other offenses against the United States, involving these 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 0915–0028)

[52 FR 18675, May 18, 1987, as amended at 61 FR 6128, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.2910 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of an award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart EE—Grants for Residency Training in Preventive Medicine

AUTHORITY: Sec. 793 of the Public Health Service Act, 95 Stat. 928 (42 U.S.C. 295h–1c); redesignated as section 788(c) of the Public Health Service Act, 102 Stat. 3134–3135 (42 U.S.C. 295g–8(e)); renumbered as sec. 763, as amended by Pub. L. 102–408, 106 Stat. 2047 (42 U.S.C. 294b).

§ 57.3001 To what programs do these regulations apply?

These regulations apply to the award of grants under section 763 of the Public Health Service Act (42 U.S.C. 294b) to schools of medicine, osteopathic medicine and public health to meet the costs of projects to (a) plan and develop new approved residency training programs and to maintain or improve existing approved residency training programs in preventive medicine and (b) provide financial assistance to residency trainees enrolled in such programs.

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.3002 Definitions.

Academic year means course work sufficient to satisfy the requirements for the Master of Public Health degree or its equivalent which is required by all approved residency programs. In the usual situation, this course work is taken during a single year.

Act means the Public Health Service Act, as amended.

Approved residency training program means the entirety or that part of a residency training program in preventive medicine which is fully or provisionally accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association.

Clinical year means postgraduate training which provides experience in direct patient care including ambulatory and inpatient experience. The one year of required training can be provided in an accredited program in one of the recognized clinical specialties or through clinical training sponsored by a preventive medicine residency training program. The clinical year is generally a prerequisite for the preventive medicine residency training program or the first year of such program.

Field year means specialized instruction and supervised experience in the resident's selected area of emphasis, and is usually one year in duration. The field year is usually the last year of the preventive medicine residency training program and is generally conducted at a site remote from that of such program.

Fields of Preventive Medicine means the following group of basic components common to all preventive medicine specialties (a) biostatistics, (b) epidemiology, (c) administration of health and medical programs, (d) environmental hazards to health, (e) social, cultural and behavorial factors in medicine, and (f) the application of preventive principles in clinical practice.

Full-time faculty means an individual or individuals who are employed as faculty of a school of medicine, osteopathic medicine or public health on a full-time basis as defined by the general policies of the applicant institution.

Nonprofit refers to the status of an entity 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.

Preventive Medicine is a specialized area of medical practice composed of distinct disciplines which use skills focusing on the health of defined populations in order to promote and maintain health and well-being and prevent disease, disability, and premature death. The specialties of preventive medicine are: General preventive medicine, public health, occupational health, and aerospace medicine.

Program Director means an individual appointed by the grantee institution to direct and supervise the residency training program who is certified or otherwise qualified as required by the Accreditation Council for Graduate Medical Education.

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

State means, 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.

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45743, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.3003 Who is eligible to apply for a grant?

Accredited public or private nonprofit schools of medicine, osteopathic medicine or public health located in a State are eligible to apply for a grant. Each eligible applicant desiring a grant under this subpart shall submit an application at the time and in such a form that the Secretary may prescribe. To be eligible for a grant, an applicant must demonstrate that it has, or will have by the end of 1 year of grant support, full-time faculty with training and experience in the fields of preventive medicine and support from other faculty members trained in public health and other relevant specialties and disciplines.

(Approved by the Office of Management and Budget under control number 0915–0060)

[57 FR 45743, Oct. 5, 1992]

§ 57.3004 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) Each project must have a project director who works at the grantee institution on an appointment consistent with other major departments, heads or will head the unit, and has relevant training and experience in preventive medicine.

(b) Each project must have an appropriate administrative and organizational plan and appropriate staff and facility resources for the achievement of stated objectives.

(c) Each project must systematically evaluate the educational program, including the performance and competence of trainees and faculty, the administration of the program, and the degree to which program and educational objectives are met.

(d) All field experiences must be supervised by a qualified faculty member.

(e) All applicants must either demonstrate an increase in minority and disadvantaged residents or show evidence of efforts to recruit minority and disadvantaged residents.

(Approved by the Office of Management and Budget under control number 0915—0060)

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45744, Oct. 5, 1992]

§ 57.3005 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will decide which applications to approve by considering, among other factors:

(1) The potential effectiveness of the proposed project in carrying out the training purposes of section 763 of the PHS Act;

(2) The extent of responsiveness to the project requirements described in § 57.3004;

(3) The administrative and management capability of the applicant to carry out the proposed project in a cost-effective manner;

(4) The degree to which the proposed training program emphasizes health promotion and disease prevention;

(5) The degree to which the applicant demonstrates institutional commitment to the proposed program; and

(6) The history of the program including number of residents who successfully completed the program.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[51 FR 11031, Apr. 1, 1986, as amended at 53 FR 14792, Apr. 26, 1988; 57 FR 45744, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.3006 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 3 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, existence of legislative authority, 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.

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

grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45744, Oct. 5, 1992]

§ 57.3007 How is the amount of the grant award determined?

(a) The amount of any award will be limited to that portion of the annual program costs which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds. Moreover, the amount of any stipend will be limited to that portion of the annual amount normally paid to other residents by the applicant which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds. The applicant must document attempts to pursue other sources of funding.

(b) Stipend support may only be given to residents in the academic and field years of training, and support to each resident is limited to 2 years of training, excluding the clinical year.

(Approved by the Office of Management and Budget under control number 0915–0060)

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45744, Oct. 5, 1992]

§ 57.3008 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45744, Oct. 5, 1992]

§ 57.3009 What additional Department regulations apply to grantees?

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 46—Protection of human subjects

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 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 HHS programs or activities receiving Federal financial assistance

45 CFR part 93—New restrictions on lobbying.

[51 FR 11031, Apr. 1, 1986, as amended at 57 FR 45744, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.3010 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6128, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.3011 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[51 FR 11031, Apr. 1, 1986]

Subpart FF—Grants for Residency Training and Faculty Development in General Internal Medicine and/or General Pediatrics

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, 63 Stat. 35 (42 U.S.C. 216); sec. 784 of the Public Health Service Act, 90 Stat. 2315, as amended by 95 Stat. 922–923 and 99 Stat. 540 (42 U.S.C. 295g–4); renumbered as sec. 748, as amended by Pub. L. 102–408, 106 Stat. 2043 (42 U.S.C. 293l).

§ 57.3101 To what projects do these regulations apply?

The regulations of this subpart apply to grants to schools of medicine and osteopathic medicine and public or private nonprofit hospitals and other public or private nonprofit entities under section 748 of the Public Health Service Act (42 U.S.C. 293l) to assist in meeting the cost of projects—

(a) To plan, develop and operate approved residency training programs in internal medicine and/or pediatrics which emphasize the training of residents for the practice of general internal medicine and/or general pediatrics;

(b) To provide financial assistance (in the form of traineeships and fellowships) to residents who are participants in this type of program, and who plan to practice general internal medicine and/or general pediatrics;

(c) To plan, develop and operate a program for the training of physicians who plan to teach in a general internal medicine and/or general pediatrics training program; and

(d) To provide financial assistance (in the form of traineeships or fellowships) to physicians who are participants in any such program and who plan to teach in a general internal medicine and/or general pediatrics training program.

[53 FR 50408, Dec. 15, 1988, as amended at 57 FR 45744, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.3102 Definitions.

For purposes of this subpart:

Act means the Public Health Service Act, as amended.

Approved residency training program or *program* is the entirety or that part of a residency training program which is fully or provisionally accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association and which emphasizes the training of residents for the practice of general internal medicine or general pediatrics.

Faculty development program means a systematic training program to increase faculty competence in teaching skills and in other areas related to academic responsibility.

Health professional shortage area means an area designated under section 332 of the Act.

Nonprofit refers to the status of an entity 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.

Nurse practitioner means a nurse practitioner as defined in 42 CFR 57.2402.

Practice of general internal medicine or general pediatrics means a practice which is limited to adult or child and adolescent medicine respectively, and in which the physician:

(1) Serves as physician of first contact with the patient and provides a timely means of entry into the health care system;

(2) Evaluates the patient's health needs, provides personal health care

and refers the patient, if indicated, to appropriate sources of health care while preserving the continuity of care;

(3) Assumes with the patient responsibility for the patient's longitudinal and comprehensive (including preventive and psychosocial) health care and acts as coordinator of the provision of health services to the patient;

(4) Considers the patient's health care within the context of his or her environment including the community and family or comparable social units; and

(5) Where applicable, plans and shares the above functions with other physicians.

Project director means a fully licensed physician on the faculty of the grantee, designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

School of medicine and osteopathic medicine means a public or private nonprofit school which provides training leading respectively to a degree of doctor of medicine or to a degree of doctor of osteopathic medicine and which is accredited as provided in section 799(1)(E) of the Act.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department 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.

Trainee means an allopathic or osteopathic general internist or general pediatrician participating in a faculty development training program supported by a grant under section 748 and receiving stipend support for such grant.

[45 FR 51202, Aug. 1, 1980, as amended at 49 FR 6906, Feb. 24, 1984; 53 FR 50408, Dec. 15, 1988; 57 FR 45744, Oct. 5, 1992; 61 FR 6128, Feb. 16, 1996]

§ 57.3103 Who is eligible to apply for a grant?

Any school of medicine or osteophathic medicine, public or private nonprofit hospital or any other public or private nonprofit entity, located in a State, may apply for a grant under this subpart. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

[57 FR 45744, Oct. 5, 1992]

§ 57.3104 What activities must be addressed in an application?

In addition to other pertinent information which the Secretary may require, an application for a grant under this subpart must contain the following:

(a) A proposal for a project to plan, develop, and operate an approved residency training or faculty development program in internal medicine and/or pediatrics—

(1) Which emphasizes the training of residents for the practice of general internal medicine and/or general pediatrics and faculty for teaching in such programs, and

(2) Which may provide financial assistance to residents and trainees who are participants in the programs and who plan to practice or teach in general internal medicine and/or general pediatrics.

(b) A full and adequate description of the proposed project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart.

(c) A description of the resources to be used by the applicant for the conduct of the proposed project, including faculty, staff, equipment, facilities, and appropriate clinical practice settings (including those which are used to meet the requirements of § 57.3105(j) and (l)).

(d) In programs other than faculty development, a description of the type and amount of training to be offered to residents in each year of each residency program in accordance with the requirements of § 57.3105 with special attention to the requirements of § 57.3105(a)(11).

(e) In programs other than faculty development, the number of residents to be enrolled in each program, at each level of training, for each year of the project period.

(f) A detailed budget for the proposed project and a justification of the amount of grant funds requested.

(g) Documentation showing that funds available from other sources will be insufficient to meet the costs of the project and that grant funds will not be used to supplant other available funds.

(h) If stipend support is requested by an applicant to provide a portion of the salary of residents enrolled in the program, documentation showing that income available from alternative sources, including income derived from the services of the residents in the program, will be insufficient to pay their salaries and that grant funds will not be used to supplant other available funds. Stipend support requested for trainees in the faculty development program must be paid in accordance with established Public Health Service postdoctoral stipend levels.

(Approved by the Office of Management and Budget under control number 0915–0060)

[45 FR 51202, Aug. 1, 1980, as amended at 49 FR 6906, Feb. 24, 1984; 53 FR 50408, Dec. 15, 1988]

§ 57.3105 Project requirements.

(a) For each residency program, a project must:

(1) Have a residency program director.

(2) Employ an individual with relevant experience or training who is responsible for curriculum development and evaluation.

(3) Employ faculty members experienced in the practice of general internal medicine and/or general pediatrics who participate as instructors at principal training settings.

(4) Employ individual(s) with formal education in behavioral sciences who participate in the preparation and implementation of the curriculum and in clinical consultation.

(5) Use a resident recruitment and selection process which assures that residents in the program have applied specifically for training in a program that emphasizes the practice of general internal medicine and/or general pediatrics.

(6) Provide financial assistance from grant funds only to residents who have signed statements of their intention to specialize or work in the practice of general internal medicine and/or general pediatrics.

(7) Have, in each program of a school of medicine, at least four residents in training by the beginning of the second year of Federal support, and at least 12 residents in training by the beginning of the fourth year of Federal support. By the beginning of the fourth year of Federal support, a program may meet this requirement with less than 12 residents in training if the number of internal medicine or pediatric residents in primary care training is at least 50 percent of the total number of internal medicine or pediatric residents at the institution. The Secretary may suspend this requirement for a period which he or she finds appropriate if the Secretary determines that a grantee has made a good faith effort to comply with the requirement and has met the other requirements of this Subpart and the Act, but is unable to have the required number of residents in the program due to circumstances beyond its control.

(8) Have, in each program of a school of osteopathic medicine, at least two residents in training by the beginning of the second year of Federal support; and at least six residents in training in 3-year programs and at least four residents in training in 2-year programs by the beginning of the fourth year of Federal support. The Secretary may suspend any of these requirements for a period which he or she finds appropriate if the Secretary determines a grantee has made a good faith effort to comply with the requirement and has met the other requirements of this Subpart and the Act, but is unable to have the required number of residents in the program due to circumstances beyond its control.

(9) Plan to have residents distributed so that there is no decrease in numbers of residents in successive levels of training by the time the program is fully operational.

(10) Use one or more ambulatory care training settings which actively promote the practice of general internal medicine and/or general pediatrics, and which:

(i) Attract patients for primarily longitudinal and comprehensive (including psychosocial and preventive) health care;

(ii) Organize personnel, including residents, into functional units providing comprehensive health services and provide residents with experience working with various types of health personnel;

(iii) Have systems for referring patients to other specialists, and subspecialists, which assure coordination with the patients' own practitioners of general internal medicine and/or general pediatrics;

(iv) Use an appointment system which facilitates the assignment of patients to their practitioner of general internal medicine and/or general pediatrics or to a particluar team of practitioners; and

(v) Use a medical record system which:

(A) Gives practitioners of general internal medicine and/or general pediatrics ready access to a patient's medical records including data relating to members of the patient's family which is pertinent to the patient's care;

(B) Is suitable for audit by organizations or individuals who perform this work with adequate safeguards against unauthorized disclosures; and

(C) Assures systematic review of the records.

(11) Make provision for each resident to serve a panel of patients and/or families who recognize him or her as their provider of longitudinal and comprehensive (including preventive and psychosocial) health care. The panel must be sufficiently numerous and varied to provide the resident with broad clinical experience. The clinical experience must be scheduled principally in ambulatory care settings as described in paragraph (a)(10) of this section.

(12) Offer ambulatory care training relevant to general internal medicine and/or general pediatrics in settings such as emergency rooms and specialty clinics.

(13) Have a planned curriculum which:

(i) Supplements the residents' inpatient and ambulatory patient care experiences with related educational activities such as courses, presentations, discussions, and reading assignments;

(ii) Emphasizes subjects pertaining to:

(A) Ambulatory care;

(B) Psychosocial skills and topics; and

(C) Non-clinical areas relevant to the practitioner of general internal medicine and/or general pediatrics; and

(iii) Is annually evaluated, using previously established criteria and objectives in a manner which includes the participation of residents.

(14) Develop and use systematic procedures to assess the individual resident's needs and to assist in educational planning and evaluation of the resident's competence.

(b) For each faculty development program, a project must:

(1) Have a project director who is employed by the grantee or training institution, has relevant training and experience, and has been approved by the Secretary to direct the project;

(2) Have an appropriate administrative and organizational plan and appropriate faculty, staff and facility resources to achieve the stated objectives;

(3) Have a curriculum which:

(i) Directly applies to general internal medicine and/or general pediatrics,

(ii) Emphasizes improvement of pedagogical skills and techniques for clinical teaching in classroom and ambulatory health care settings, and

(iii) Uses structured didactic and experiential teaching strategies.

(iv) With respect to training programs of 9 or more months duration, the curriculum must also include:

(A) A research component, with a research project to be completed by each trainee, and

(B) An administrative component which addresses the non-teaching roles and functions of faculty;

(4) Systematically evaluate the educational program, including trainees and faculty, the administration of the program, and the degree to which the

program and educational objectives are met;

(5) Have as trainees only physicians who teach or plan teaching careers in general internal medicine and/or general pediatrics;

(6) To be eligible for stipend support from grant funds, a trainee must:

(i) Be a general internist or a general pediatrician,

(ii) Intend to teach in a general internal medicine and/or general pediatrics program on a full-time basis,

(iii) Be a full-time participant in the training project for at least 3 months, and

(iv) Receive less than full institutional salary during the period of Federal support of stipends; and

(7) Stipend support from grant funds may be no longer than 24 cumulative months for any trainee.

[45 FR 51202, Aug. 1, 1980, as amended at 49 FR 6906, Feb. 24, 1984; 53 FR 50409, Dec. 15, 1988; 54 FR 51745, Dec. 18, 1989; 57 FR 45744, Oct. 5, 1992]

§ 57.3106 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will award grants to applicants whose projects best promote the purposes of section 748 of the Act. The Secretary will take into consideration, among other factors:

(1) The degree to which the proposed project adequately provides for the project requirements set forth in § 57.3105;

(2) The administrative and management capability of the applicant to carry out the proposed project in a cost-effective manner;

(3) The qualifications of the proposed staff and faculty;

(4) The potential of the project to continue on a self-sustaining basis; and

(5) For faculty development programs, the applicant must demonstrate the institution's commitment to general internal medicine and/or general pediatrics as defined under § 57.3102.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary shall give priority to applicants that demonstrate a commitment to general internal medicine and general pediatrics in their medical education training programs. However, should specific needs warrant, the Secretary will consider any other special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[45 FR 51202, Aug. 1, 1980, as amended at 53 FR 14792, Apr. 26, 1988; 53 FR 50409, Dec. 15, 1988; 61 FR 6128, Feb. 16, 1996]

§ 57.3107 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels 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.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate 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. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[45 FR 51202, Aug. 1, 1980, as amended at 53 FR 50409, Dec. 15, 1988; 57 FR 45744, Oct. 5, 1992]

§ 57.3108 How is the amount of the grant award determined?

The amount of any award will be limited to that portion of the annual program costs which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds. Further, the amount of any stipend will be limited to that portion of the annual amount normally paid to other residents by the applicant which the Secretary determines, on the basis of the documentation required in the application, cannot reasonably be paid from other available funds, including the incomes derived by the hospital from the residents' services.

[45 FR 51202, Aug. 1, 1980]

§ 57.3109 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds provided and made available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts provided by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[45 FR 51202, Aug. 1, 1980, as amended at 53 FR 50409, Dec. 15, 1988; 57 FR 45745, Oct. 5, 1992]

§ 57.3110 What additional Department regulations apply to grantees?

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 46—Protection of human subjects
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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying.

[49 FR 38115, Sept. 27, 1984, as amended at 57 FR 45745, Oct. 5, 1992; 61 FR 6129, Feb. 16, 1996]

§ 57.3111 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6129, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.3112 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity,

the interest of the public health, or the conservation of grant funds.

[45 FR 51202, Aug. 1, 1980]

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. 254l) 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–LL [Reserved]

Subpart MM—Area Health Education Center Program

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 781, Public Health Service Act, 90 Stat. 2312 (42 U.S.C. 295g–1), as amended.

SOURCE: 48 FR 7446, Feb. 22, 1983, unless otherwise noted.

§ 57.3801 To what programs do these regulations apply?

The regulations of this subpart apply to cooperative agreements entered into by the Secretary under section 781 of the Public Health Service Act (42 U.S.C. 295g–1) with schools of medicine or osteopathy for the planning, development, and operation of area health education center programs.

§ 57.3802 Definitions.

Act means the Public Health Service Act.

Allied health personnel means individuals as defined in 42 CFR 58.502.

Area health education center or *center* means a public or nonprofit private entity which has a cooperative arrangement with one or more schools of medicine or osteopathy for the planning, development, and operation of an area health education center program. A center must be an entity which is recognized under the laws of the State in which it is located and which has as one of its principal functions the operation of the area health education center.

Area health education center program or *project* means a cooperative program among one or more schools of medicine or osteopathy and one or more area health education centers, which is capable of performing the functions described in sections 781(c) and (d) (2) of the Act and § 57.3804 of these regulations, and which is designed to improve the distribution, supply, quality, utilization, and efficiency of health personnel in the health services delivery system and to encourage the regionalization of educational responsibilities of health professions schools.

Cooperative agreement means a legal instrument that reflects an assistance relationship between the Federal Government and the recipient in which substantial programmatic involvement is anticipated between the Federal agency and the recipient during performance of the contemplated activity.

Clerkship means supervised clinical training.

Continuing medical education or *continuing education* means any education for the purpose of maintaining or enhancing the knowledge, attitudes or abilities of a health professional in his or her field which does not lead to any formal advanced standing in the profession.

Health professional means any physician, dentist, optometrist, podiatrist, pharmacist, nurse, nurse practitioner, physician assistant or allied health personnel.

Nurse practitioner means an individual as defined in 42 CFR 57.2402.

Physician assistant means an individual as defined in 42 CFR 57.802.

Preceptorship means an educational experience in which the student works with a designated health professional, the preceptor, who teaches in the student's field of study and personally supervises the student's clinical activity.

School of medicine, osteopathy, dentistry, optometry, podiatry, pharmacy, public health or veterinary medicine means a school as defined in section 701(4) of the Act which is accredited as provided in section 772(b) of the Act.

School of nursing means a collegiate, associate degree or diploma school of nursing as defined in section 853 of the Act.

Training center for allied health professions means a training center as defined in 42 CFR 58.402

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, only the District of Columbia, the Commonwealth of Puerto Rico,

the Commonwealth of Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 57.3803 Who is eligible to apply for a cooperative agreement?

(a) Any public or nonprofit private school of medicine or osteopathy located in a State is eligible to submit a proposal.

(b) More than one accredited school of medicine or osteopathy may submit a joint proposal for the planning, development and operation of an area health education center program. In this case, each school must conduct the activities required by section 781(c) of the Act and § 57.3804(d) of these regulations.

§ 57.3804 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) Each area health education center program must have a program director who holds a faculty appointment at a medical or osteopathic school participating in the program and who is responsible for the overall direction and coordination of the program.

(b) Each area health education center program must have a program advisory committee to advise the program director on all aspects of the conduct of the program including administration, education and evaluation. This committee must include representatives of schools and programs of health professions which actively participate in the area health education center program under § 57.3804(d)(5) of this subpart and section 781(c)(4) of the Act, individuals with training and experience in the fields of medicine or osteopathy, dentistry, nursing, and an allied health profession, as well as a representative of each of the centers cooperating in the program.

(c) Each area health education center program must annually evaluate its activities to ascertain the extent to which it is meeting the purposes described in section 781(a) of the Act.

(d) *Requirements for schools of medicine or osteopathy*. A school of medicine or osteopathy participating in an area health education program (with the exception of a school whose only function is to provide resources by purchase agreement to a center) must meet the following requirements. However, a school of medicine or osteopathy must fulfill the requirement of § 57.3804(d)(4) only if no other school of medicine or osteopathy participating in the program meets this requirement. Each school of medicine or osteopathy must:

(1) Have a cooperative arrangement with an area health education center, as evidenced by a written agreement. This agreement must provide at a minimum that the schools participating in the program will perform the following functions:

(i) Provide faculty to assist in the conduct of the center's educational activities, as necessary;

(ii) Provide an agreed upon amount of funds to the center to assist the center in meeting the costs of its activities, including those described in section 781(d)(2) of the Act;

(iii) Be responsible for the quality of the education received in the center, including evaluating the quality of the educational programs required by section 781(d)(2) of the Act and the performance of its students while receiving clinical training in the center. The area health education center must agree to conduct the activities described in section 781(d)(2) of the Act and these regulations, and assist the schools participating in the program in meeting the requirements in section 781(c) of the Act and these regulations.

(2) Provide for the active participation in the program by individuals who are associated with the administration of the school, and staff or faculty members of each of the departments (or specialties if the school has no departments) of internal medicine, pediatrics, obstetrics and gynecology, surgery, psychiatry and family medicine. These persons may participate in the program in either the school or center and must perform, among others, the following functions: provide guidance on educational program or curriculum development and operation; instruct students (including residents and other practicing health professionals); perform student or program evaluation; and assist in program administration.

(3) Conduct no less than 10 percent of all undergraduate medical or osteopathic clinical education of the school in one or more centers and in clinical settings which are part of or affiliated with a center and in which the center arranges and supports the clinical education. The school shall assure that, annually, the ratio of student weeks of clinical education received by its undergraduate students in centers to the total number of student weeks of clinical education received by its undergraduate students, in any location, is no less than 0.10. For purposes of this paragraph, undergraduate medical or osteopathic clinical education means any clerkships, preceptorships, or other educational activities which are offered in the following fields: family medicine, internal medicine and its subspecialties, pediatrics and its subspecialties, dermatology, obstetrics and gynecology, surgery and its subspecialties, anesthesiology, psychiatry and its subspecialties, neurology, physical medicine and rehabilitation, emergency medicine, nuclear medicine and general preventive medicine, including community medicine. Courses, seminars, and other educational programs which are entirely didactic or laboratory in nature or which are primarily in anatomy, biochemistry, physiology, microbiology, pharmacology, or pathology are not included in this definition.

(i) The Secretary may waive, for good cause shown, all or part of the requirement of this paragraph if another such school participating in the same program meets the requirement.

(ii) To obtain a waiver, a school must submit a written request to the Secretary fully describing and documenting the good cause and stating which school meets the requirement. This request must include the following information:

(A) The extent to which the school for which the waiver has been requested has attempted to meet this requirement. A description of efforts and the reasons why the school cannot meet the requirement must demonstrate that the school has made a good faith effort, but constraints beyond its control have caused these efforts to be unsuccessful.

(B) The length of time for which this waiver is requested, and a plan and timetable for meeting the requirement.

(C) The alternative mechanisms the schools will use to provide clinical experiences in locations removed from the site of the teaching facilities where the major part of the educational program of any participating schools is conducted if the waiver is granted.

(4) Be responsible for, or conduct a program for the training of physician assistants, which meets the requirements of 42 CFR part 57, subpart I, or nurse practitioners, which meets the requirements of 42 CFR part 57, subpart Y, appendix. If one school which is participating in the area health education center program provides for or conducts a program for the training of physician assistants or nurse practitioners meeting this requirement, other schools participating in the program may, but need not, provide for or conduct a physician assistant or nurse practitioner program. Where the school is responsible for, but does not conduct one of these programs, it must participate in the presentation, review, and evaluation of one of these programs at an affiliated institution so that at least part of the education in the program is provided by faculty of the school. The school must give special consideration to the enrollment in these programs of individuals from or who plan to practice in the area served by the center by either:

(i) Giving preference to applicants whose place of residence has been in the area served by the center at any time prior to application; or

(ii) Obtaining a signed statement from applicants, indicating an intent to practice the skills acquired in the program in the areas.

(5) Provide for the active participation of at least two schools or programs of other health professions in the educational program conducted in the area served by the center(s). In meeting this requirement:

(i) One of the participating schools or programs must be a school of dentistry, if there is one affiliated with the university with which the school of medicine or osteopathy is affiliated;

(ii) Only the following schools or programs of other health professions may

be included to meet the requirement of this paragraph:

(A) Training centers for the allied health professions;

(B) Schools of nursing;

(C) Schools of optometry;

(D) Schools of pharmacy;

(E) Schools of podiatry; or

(F) Schools of public health.

(iii) Each school or program participating in the area health education center program under this paragraph must have a written agreement with the school(s) of medicine or osteopathy, under which the school or program agrees to assist and participate, as is appropriate, in the activities of each center as required under section 781(d)(2) of the Act.

(iv) Each school or program participating in the area health education center under this paragraph must have a written agreement with each center, under which the school or program agrees to provide some or all of its students with educational experiences in the center or in settings affiliated with the center, and the center agrees to arrange for and support the provision of the educational programs. This agreement may be part of the agreement required by paragraph (d)(1) of this section.

(e) *Requirements for area health education centers.* Each area health education center participating in an area health education center program must:

(1) Designate either a geographic area or medically underserved population which it will serve (''the area served by the center''). This area or population must be in a location remote from the main site of the teaching facilities of the schools which participate in the program. For purposes of this requirement,

(i) A medically underserved population means the population of a geographic area designated as a primary medical personnel shortage area under section 332 of the Act or a population group designated under section 332 of the Act as having a shortage of primary medical care personnel;

(ii) An area or population will meet this requirement if its location is removed from the site of the teaching facilities where the major part of the educational program of any participating school is conducted. The area served by the center must not duplicate, in whole or in part, the area served by any other center.

(2) Provide for or conduct training in health education services, in the area served by the center. This training must consist of courses and programs to train health professionals to instruct the public or patients in medical self-help, disease prevention, accident prevention, nutrition, physical fitness, and other subjects relating to health maintenance, and must include the principles of nutrition, the evaluation of nutritional status, and nutritional counseling. The training must be oriented toward the ethnic and cultural backgrounds of the people in the area.

(3) Assess the health manpower needs of the area served by the center and assist in the planning and development of training programs to meet these needs. In meeting this requirement, the center should work with existing health systems agencies designated for the area served by the center and other appropriate entities by cooperatively developing and sharing data on health personnel needs of the area for the next 10 years and in developing a plan for training programs to meet these needs. In areas where HSAs exist, the planned training programs must be consistent with the health personnel projections developed by the health systems agencies. At a minimum, the center must assess the need for (i) personnel to provide health education and nutrition counseling services; (ii) primary care health personnel including physicians in family practice, general internal medicine, general pediatrics, and obstetrics and gynecology, physician assistants, and nurse practitioners; (iii) mental health practitioners; (iv) dentists; and (v) nurses. In carrying out its responsibility to assess health personnel needs in the area, the center shall, to the maximum extent practicable, use existing data (including data used for the designation of shortage areas under sections 332 and 836(h) of the Act).

(4) Provide for or conduct a rotating osteopathic internship or medical residency training program in family practice, general internal medicine or general pediatrics, or osteopathy in which

no fewer than six persons are enrolled in first-year positions in the program. If one center which is participating in the area health education center program provides for or conducts a medical residency training program meeting this requirement, other centers participating in the program may, but need not, provide for or conduct a medical residency training program in these fields. In meeting this requirement:

(i) A family practice residency for allopathic and osteopathic physicians must meet the requirements of section 786(a) of the Act, and implementing regulations.

(ii) A general internal medicine or general pediatrics residency must meet the requirements of 42 CFR 57.3104, except for the requirements in paragraphs (h) and (i) of that section.

(iii) The center must conduct the medical residency training program at a site which is part of the center or provide for the conduct of this program, by written affiliation agreement with an appropriate entity located in the area served by the center.

(5) Provide opportunities for continuing medical education (including education in disease prevention) to all physicians and other health professionals practicing within the area served by the center. This continuing medical education must include courses, seminars, lectures, grand rounds, clinical pathological conferences, mini-residencies, library services, or in-house training, as appropriate, for all health professionals in the area. In meeting this requirement:

(i) The center must assess the need for providing continuing medical education taking into consideration the numbers, needs and location of health professionals in the area as well as educational activities available through other entities.

(ii) The center must announce the availability of continuing medical education activities offered in the center, as well as those provided through other entities in the area, through appropriate and usual distribution channels.

(6) Provide continuing medical education and other educational support services to the National Health Service Corps (Corps) members assigned to the area served by the center, after notification of the assignment(s) by the Secretary. In meeting this requirement, the center must:

(i) Establish an organized program which will provide for the assessment of the continuing medical education needs of the members of the Corps and offer to members of the Corps, at a cost not to exceed the cost to any other participant, continuing medical education relevant to these identified needs.

(ii) Assist in identifying resources for and encouraging the provision of:

(A) Consultation services, if needed, including telephone consultation to Corps personnel.

(B) A patient referral system, if necessary, to Corps patients and assistance to these patients in obtaining laboratory and pathological services at accessible locations.

(C) Supervision and consultation for non-physician and non-dentist members of the Corps in the area.

(D) Temporary substitutes for Corps personnel, as needed.

(7) Encourage the utilization of nurse practitioners and physician assistants in the area and the recruitment of individuals for training in these professions at the participating medical or osteopathic schools. In meeting this requirement, the center must:

(i) Inform potential employers in the area regarding the following, among other subjects;

(A) The function and utilization of nurse practitoners and physician assistants;

(B) State laws and regulations governing nurse practitioners and physician assistants; and

(C) Reimbursement and malpractice coverage for services rendered by nurse practitioners and physician assistants.

(ii) Determine employment opportunities for nurse practitioners and physician assistants and participate in referral and recruitment of persons for these positions.

(iii) Distribute information in the area concerning the nurse practitioner or physician assistant training program(s) provided for or conducted by the schools of medicine or osteopathy participating in the program, and participate in recruiting persons in the area for the programs.

(8) Arrange and support educational opportunities for medical and other students at affiliated health facilities, ambulatory care centers, and health agencies throughout the area served by the center. In meeting this requirement, the center must:

(i) Coordinate the conduct of the following programs, including assisting in their planning and development, obtaining the necessary resources and providing administrative support services for:

(A) Clinical education for undergraduate medical or osteopathic students in at least family practice, general internal medicine or general pediatrics;

(B) Education for undergraduate and, as appropriate, graduate students, at a school of dentistry, if one is participating in the program;

(C) Education for students of the other schools or programs participating in the area health education center program under paragraph (d)(5) of this section; and

(D) Orientation for high school and post-high school students in schools in the area to develop awareness of health careers and health opportunities.

(9) Have an advisory board of which at least 75 percent of the members are persons from the area served by the center, including health service providers and consumers. For this purpose, health service providers are individuals who derive more than 10 percent of their annual income from the health care industry. In meeting this requirement:

(i) The advisory board must be reasonably divided between:

(A) Providers of health care, including at least one physician, dentist, nurse, and allied health professional who is actively engaged in the practice of his or her profession in the area served by the center; and

(B) Consumers, including students, who reside in the area and are broadly representative of the population in the area in terms of demographic factors, such as race, ethnic background and sex. The advisory board shall advise the chief administrative official of the center on all major policies concerning the operation of the center, on the establishment of center program priorities and on other issues, as necessary.

§ 57.3805 When do the requirements of § 57.3804 apply?

(a) The period of time in which any entity will have to meet all the requirements or § 57.3804 will be negotiated on a case-by-case basis, depending upon the nature and scope of the planned area health education center program. No cooperative agreement, however, shall provide funds solely for the planning or development of a program for a period of longer than two years.

(b) Each area health education center program must begin planning for at least one center during the first year of support so that at least one center is fully operational and meets all the applicable requirements of § 57.3804 during the third year of support. Additional centers may be phased in during the first four years of Federal support except that once planning for any center is initiated, it must become fully operational and meet all the applicable requirements of § 57.3804 within three years.

(c) Each school with which the Secretary enters into a cooperative agreement under this subpart must meet all the requirements of § 57.3804 during the first four years of Federal support, except that once planning to add any school is initiated, it must meet all the applicable requirements of § 57.3804 within three years.

§ 57.3806 How will applications be evaluated?

(a) After consulting with the National Advisory Council on Health Professions Education established by section 702 of the Act, the Secretary will award cooperative agreements to applicants whose projects will best promote the purposes of section 781 of the Act and these regulations, taking into consideration among other factors:

(1) The degree to which the proposed project adequately provides for the program requirements set forth in § 57.3804;

(2) The capability of the applicant to carry out the proposed project; and

(3) The extent of the need of the area to be served by the proposed area health education center.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[48 FR 7446, Feb. 22, 1983, as amended at 53 FR 14792, Apr. 26, 1988]

§ 57.3807 How is the amount of the award determined?

(a) The amount of the award will be based on the Secretary's estimate of the sum necessary for the approved activity.

(b) The Secretary will not provide in any year under this subpart more than 75 percent of the total operating funds of an area health education center program.

§ 57.3808 How long does support under a cooperative agreement last?

(a) The cooperative agreement will specify the length of time the Secretary intends to support the project without requiring the project to recompete for funds. In addition, the maximum period during which a project may be funded will be specified in each cooperative agreement.

(b) Generally, the project will initially be funded for one year, and subsequent continuation awards will also be for one year at a time. A school which enters into a cooperative agreement must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding levels of these continuation awards will be made after consideration of such factors as the applicant'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.

(c) Neither the approval of any application nor the entering into of any cooperative agreement 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.

(d) Any balance of federally obligated funds remaining unobligated by the school at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the school for that period, including any unobligated balance carried forward from prior periods, exceeds the school's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 57.3809 For what purposes may cooperative agreement funds be spent?

(a) A school which is awarded a cooperative agreement shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the cooperative agreement award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) The area health education center program must spend at least 75 percent of the funds provided under this subpart in any year in area health education centers.

(c) Schools which are awarded cooperative agreements may not spend cooperative agreement funds for sectarian instruction or for any religious purpose.

§ 57.3810 How will the Department participate in a cooperative agreement?

The Secretary anticipates substantial Federal involvement in the management of the project supported under the cooperative agreement. This involvement may include, as determined necessary, the following activities, among others:

(a) Reviewing and approving plans, upon which continuation of the cooperative agreement is contingent, to permit appropriate direction and conduct of activities;

(b) Reviewing and approving all contracts between the cooperating school of medicine, other health professions schools, and area health education centers;

(c) Participating with project staff in the development of funding projections;

(d) Developing with project staff data collection systems and procedures; and

(e) Participating with project staff in the design of project evaluation protocols and methodologies.

§ 57.3811 What additional Department regulations apply to awardees?

Several other regulations apply to cooperative agreements 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 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

45 CFR part 83—Regulation for the administration and enforcement of sections 799A and 845 of the Public Health Service Act[1]

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 38115, Sept. 27, 1984]

§ 57.3812 What other audit and inspection requirements apply?

Each school which enters into a cooperative agreement must, in addition to the requirements of 45 CFR part 74, meet the requirements of section 705 of the Act concerning audit and inspection.

§ 57.3813 Additional conditions.

The Secretary may impose additional conditions on any award before or at the time of any award if the Secretary determines that these conditions are necessary to assure or protect the advancement of the approved activity, the continued viability of the school, the interest of the public health, or the conservation of public funds.

Subpart NN [Reserved]

Subpart OO—Grants for Geriatric Education Centers

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); sec. 788(d) of the Public Health Service Act, 99 Stat. 542 (42 U.S.C. 295g–8); redesignated as sec. 789(a), as amended by Pub. L. 100–607, 102 Stat. 3136–37 (42 U.S.C. 295g–9(a)); renumbered as sec. 777(a), as amended by Pub. L. 102–408, 106 Stat. 2052–54 (42 U.S.C. 294o).

SOURCE: 54 FR 5617, Feb. 6, 1989, unless otherwise noted.

§ 57.4001 To what projects do these regulations apply?

These regulations apply to grants to eligible schools and programs under section 777(a) of the Public Health Service Act for geriatric training projects.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992; 58 FR 66298, Dec. 20, 1993]

§ 57.4002 Definitions.

Act means the Public Health Service Act, as amended.

Allied health professional means a health professional who has received a certificate, an associate's degree, a bachelor's degree, a master's degree, a

[1] Section 799A of the Public Health Service Act was redesignated as section 704 by Pub. L. 94–484; section 845 of the Public Health Service Act was redesignated as section 855 by Pub. L. 94–63.

doctoral degree, or postbaccalaureate training, in a science relating to health care and meets the requirements as established in section 799(5) of the Act.

Budget period means the interval of time into which the project period is divided for budgetary and reporting purposes, as specified in the grant award document.

Continuing education means structured educational programs for practicing health professionals and allied health professionals for the purpose of improving the knowledge and skills in geriatrics of such practitioners with respect to treatment of the health problems of elderly individuals.

Geriatrics is the total health and social care of the elderly.

Geriatric Medicine means the prevention, diagnosis, care and treatment of illness and disability as required by the distinct needs of the elderly.

Graduate program in clinical social work and *graduate program in marriage and family therapy* means an accredited graduate program as defined in section 799(1)(C) of the Act.

Graduate program in mental health practice means a graduate program in clinical psychology, clinical social work, or marriage and family therapy (section 799(1)(D) of the Act).

Health professional means, for purposes of this subpart, any allopathic or osteopathic physician, dentist, optometrist, podiatrist, pharmacist, professional nurse (as defined in § 57.2502), and nurse practitioner (as defined in § 57.2402), physician assistant, chiropractor, clinical psychologist, health administrator, or allied health professional.

Health professions schools means any school of medicine, dentistry, osteopathic medicine, pharmacy, optometry, podiatric medicine, veterinary medicine, public health, chiropractic, graduate programs in health administration, or graduate programs in clinical psychology, as defined in section 799(1)(A), (B), (C), and (D) of the Act and as accredited in section 799(1)(E) of the Act.

Nonprofit refers to the status of an entity 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.

Program for the training of physician assistants means any educational programs as defined in section 799(3) of the Act.

Project director means an individual designated by the grantee in the grant application and approved by the Secretary to direct the project being supported under this subpart.

Project period means the total time for which support for a project has been approved including any extensions of the project.

School of allied health means a public or private nonprofit junior college, college, university or hospital-based educational entity which provides or is accredited to provide a program of education to enable individuals to become allied health professionals or to provide additional training for allied health professionals and which meets the criteria set forth in section 799(4) of the Act.

School of nursing means a collegiate, associate degree, or diploma school of nursing in a State (section 853(2) of the Act).

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.

Training and retraining of faculty means a program to train and retrain faculty to provide geriatric instruction which is not a 1-year retraining program for faculty in schools of medicine and osteopathic medicine in geriatrics or a 1-year or 2-year internal medicine or family medicine fellowship program as identified in section 777(3)(A) and (B) of the Act.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992; 58 FR 66298, Dec. 20, 1993; 61 FR 6129, Feb. 16, 1996]

§ 57.4003 Who is eligible to apply for a grant?

Any public or private nonprofit health professions school, school of allied health, or program for the training of physician assistants located in a State may apply for a grant under this subpart. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at the time the Secretary may prescribe.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992]

§ 57.4004 Program requirements.

(a) The Secretary will award grants to meet the cost of carrying out one or more of the following six purposes:

(1) Improve the training of health professionals in geriatrics;

(2) Develop and disseminate curricula relating to the treatment of the health problems of elderly individuals;

(3) Expand and strengthen instruction in methods of geriatric treatment;

(4) Support the training and retraining of faculty;

(5) Support continuing education of health professionals and allied health professionals who provide geriatric treatment; and

(6) Establish new affiliations with nursing homes, chronic and acute disease hospitals, ambulatory care centers, and senior centers in order to provide students with clinical training in geriatric medicine.

(b) Projects must include one or more of the activities in paragraphs (a) (1) through (6) of this section for four or more types of health professionals as defined in § 57.4002 of this subpart.

(c) Each project must evaluate the program systematically, including the determination of a baseline at the outset of the project and the measurement of the degree to which program and educational objectives are met.

[54 FR 5617, Feb. 6, 1989, as amended at 58 FR 66299, Dec. 20, 1993]

§ 57.4005 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will decide which applications to approve by considering, among other factors:

(1) The degree to which the proposed project adequately provides for the project requirement described in § 57.4004;

(2) The extent to which the rationale and specific objectives of the project are based upon a needs assessment of the status of geriatrics training in the institutions to be assisted and/or the geographic area to be served;

(3) The ability of the project to achieve the project objectives within the proposed geographic area;

(4) The adequacy of educational facilities and clinical training settings to accomplish objectives;

(5) The adequacy of organizational arrangement involving professional schools and other organizations necessary to carry out the project;

(6) The adequacy of the qualifications and experience in geriatrics of the project director, staff and faculty;

(7) The administrative and managerial ability of the applicant to carry out the proposed project in a cost-effective manner; and

(8) The potential of the project to continue on a self-sustaining basis.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992; 58 FR 66299, Dec. 20, 1993]

§ 57.4006 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 3 years. The maximum period of support, including

the initial project period and competitive extensions, may not exceed 6 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, existence of legislative authority, 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.

(c) Neither the approval of any application nor the award of any grant shall commit or obligate 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. For continuation support, grantees must make separate application at such times and in such a form as the Secretary may prescribe.

[54 FR 5617, Feb. 6, 1989, as amended at 58 FR 66299, Dec. 20, 1993]

§ 57.4007 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992]

§ 57.4008 What additional Department regulations apply to grantees?

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 46—Protection of human subjects
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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992; 61 FR 6129, Feb. 16, 1996]

§ 57.4009 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6129, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 57.4010 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart PP—Grants for Faculty Training Projects in Geriatric Medicine and Dentistry

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); sec. 789(b) of the PHS Act, as amended by Public Law 100–607, 102 Stat. 3136–3138 (42 U.S.C. 295g–9(b)); renumbered as sec. 777(b), as amended by Pub. L. 102–408, 106 Stat. 2052–54 (42 U.S.C. 294o).

SOURCE: 55 FR 37481, Sept. 12, 1990, unless otherwise noted.

§ 57.4101 To what projects do these regulations apply?

These regulations apply to grants to eligible schools and programs under section 777(b) of the Act (42 U.S.C. 294o) for the purpose of providing support for projects to train physicians and dentists who plan to teach geriatric medicine, geriatric psychiatry, or geriatric dentistry, including traineeships, and fellowships for participation in these programs.

[59 FR 63902, Dec. 12, 1994]

§ 57.4102 Definitions.

Act means the Public Health Service Act, as amended.

Budget period means the interval of time (usually 12 months) into which the project period is divided for budgetary and funding purposes.

Elderly means a population with health care conditions and needs which differ significantly from those of younger people, which are often complicated by the physical, behavioral, and social changes associated with aging. This would include all persons over 60, but may include slightly younger people who are subject to similar physical and/or mental conditions.

Extended care facility means a health care institution or distinct part of an institution that furnishes, in lieu of hospitalization, room and board and medically-prescribed skilled nursing care or rehabilitative services 24 hours a day by an organized health care staff.

Fellow means an allopathic physician, osteopathic physician, or dentist participating in a retraining program or fellowship program supported by a grant under section 777(b).

Fellowship program means a 2-year organized training effort sponsored by an allopathic or osteopathic medical school, a teaching hospital, or a graduate medical education program which is designated to provide training for—

(1) Physicians who have completed a graduate medical education program in internal medicine, family medicine (including osteopathic general practice), psychiatry, neurology, gynecology, or rehabilitation medicine; and

(2) Dentists who have demonstrated a commitment to an academic career and who have completed postdoctoral dental training, including postdoctoral dental education programs or who have relevant advanced training or experience.

Full-time teaching physician means an allopathic or osteopathic physician who is a faculty member of the grantee institution and who is engaged in teaching, research, clinical, and administrative activities normally performed by teaching faculty employed on a full-time basis, as defined by the grantee institution.

Full-time teaching dentist means a dentist who is a faculty member and who is engaged in teaching, research, clinical, and administrative activities normally performed by teaching faculty employed on a full-time basis, as defined by the institution. The dental faculty member does not have to be employed by the grantee institution but can be a dental faculty member at another institution which has an affiliation agreement with the grantee institution.

Full-time training means full-time training, as defined by the grantee institution.

Geriatric dentistry means the provision of dental care for elderly persons, particularly those with one or more chronic or debilitating, physical or

mental illnesses with associated medication or psychosocial problems.

Geriatric medicine means the prevention, diagnosis, and medical treatment of illness and disability as required by the needs of the elderly.

Geriatric psychiatry means the prevention, diagnosis, evaluation and treatment of mental disorders and disturbances seen in older adults.

Graduate medical education program means a program sponsored by a school of medicine, a school of osteopathic medicine, a hospital, or a public or private nonprofit institution, which:

(1) Offers postgraduate medical training in the specialties and subspecialties of medicine; and

(2) Has been accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association through its Committee on Postdoctoral Training.

Grantee means an entity that receives a grant and assumes legal and financial responsibility both for the awarded funds and for the performance of the grant-supported activity.

Longitudinal care means the provision of medical or dental care to the same panel of elderly patients for a period of at least 9 months in each year of training.

Part-time teaching dentist means a dentist who is a faculty member and who is engaged in teaching, research, clinical, and administrative activities normally performed by teaching faculty employed on a part-time basis, as defined by the institution. The dental faculty member does not have to be employed by the grantee institution but can be a dental faculty member at another institution which has an affiliation agreement with the grantee institution.

Postdoctoral dental education program means a program sponsored by a school of dentistry, a hospital, or a public or private nonprofit institution, which:

(1) Offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency; and

(2) Has been accredited by the Commission on Dental Accreditation.

Primary care means health care which may be initiated by the patient or the provider, or both, in a variety of settings, and which consists of a broad range of personal health care services including promotion and maintenance of health, prevention of illness and disability, basic care during acute and chronic phases of illness, guidance and counseling of individuals and families, and referral to other health care providers and community resources when appropriate. In providing the services:

(1) The physical, emotional, social, and economic status of the patient is considered in the context of his or her cultural and environmental back ground, including the family and community; and

(2) The patient is provided timely access to the health care system.

Project means all activities, including training programs, specified or described in a grant application as approved for funding.

Project director means an individual designated by the recipient and approved by the Secretary to direct the project being supported under section 777(b).

Project period means the total time for which support for a project has been approved, including any extension thereof, by the awarding unit.

Relevant advanced training or experience means at least one of the following: (1) Completion of at least a 12-month graduate training program in a health-related discipline, the basic sciences, or education; (2) a minimum of 2 years of teaching experience in an accredited dental education program of which at least 12 months were devoted in part to issues pertaining to the care of older adults; or (3) a minimum of 2 years of clinical practice, of which at least 12 months were devoted in part to managing older dental patients in a hospital, long-term care facility, or other setting.

Retraining program means a 1-year program of full-time individualized training in clinical geriatrics and geriatric research for physicians who are faculty members in departments of internal medicine, family medicine (including osteopathic general practice), gynecology, geriatrics, or psychiatry at schools of medicine and osteopathic medicine, and dentists who are faculty members at schools of dentistry or at hospital departments of dentistry.

School of medicine or *school of osteopathic medicine* means a public or private nonprofit school which provides training leading, respectively, to a degree of doctor of medicine or a degree of doctor of osteopathic medicine, and which is accredited as provided in section 799(1)(E) of the Act.

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.

Teaching hospital means a public or private nonprofit hospital which is:

(1) Accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association; and

(2) Operates at least one postdoctoral training program which is fully or provisionally accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association.

[55 FR 37481, Sept. 12, 1990, as amended at 56 FR 29194, June 26, 1991; 57 FR 45746, Oct. 5, 1992; 59 FR 63902, Dec. 12, 1994; 61 FR 6129, Feb. 16, 1996]

§ 57.4103 Who is eligible to apply for a grant?

Public or private nonprofit schools of medicine, schools of osteopathic medicine, teaching hospitals, and graduate medical education programs located in a State are eligible to apply for a grant under this subpart. Each eligible applicant desiring a grant under this subpart shall submit an application in the form and at such time as the Secretary may prescribe.

(Approved by the Office of Management and Budget under control number 0915–0060)

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992]

§ 57.4104 For what projects may grant funds be requested?

Each eligible applicant must propose a fellowship program or a retraining program.

[54 FR 5617, Feb. 6, 1989, as amended at 57 FR 45746, Oct. 5, 1992]

§ 57.4105 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project must have a project director who is employed full time by the grantee institution;

(b) Projects must have an appropriate administrative and organizational plan, and adequate faculty, physical, and administrative resources for the achievement of stated objectives;

(c) Projects must systematically evaluate the training program, including the performance and competence of trainees and faculty, the administration of the program, and the degree to which program and educational objectives are met;

(d) The project must be under the programmatic control of a graduate medical education program in internal medicine or family medicine (including osteopathic general practice) or in a department of geriatrics or psychiatry;

(e) The project must be staffed by at least two physicians in full-time teaching positions who have experience or training in geriatric medicine or geriatric psychiatry and be staffed, or enter into an agreement with an institution staffed, by at least one dentist who is employed in a full- or part-time teaching position and has experience or training in geriatrics;

(f) The project must provide fellows with training in geriatrics and exposure to the physical and mental disabilities of a diverse population of elderly individuals. The population must include:

(1) Elderly in various levels of wellness from fully independent and well, to patients confined to bed with serious illness; and

(2) Elderly from a range of socioeconomic, racial and ethnic backgrounds;

(g) The project must provide medical and dental training experiences in:

(1) An ambulatory care setting;
(2) An inpatient service; and
(3) An extended care facility,

During the course of the training, each fellow must receive experience in primary care, consultation, and longitudinal care;

(h) Fellowship programs must have a curriculum which includes training in clinical geriatrics, teaching skills, administrative skills, and research skills for physicians and dentists;

(i) Retraining programs must provide 1 year of full-time training suited to the individual needs of each fellow. To assure that the needs of all fellows can be met, each retraining program must have the resources available to provide clinical, research, administrative, and teacher-training experience; and

(j) Effective in the second year of grant support, a minimum of three entering fellows, including at least one physician and one dentist, must be enrolled in each training program for which grant support is received. The Secretary may suspend this requirement if the Secretary determines that a grantee has made a good faith effort to comply with this requirement through the various recruitment means available in its institution and at the national level, and has met the other requirements stated in this section but is unable to have the required number of fellows in the program due to circumstances beyond its control.

[55 FR 37481, Sept. 12, 1990, as amended at 56 FR 29194, June 26, 1991; 57 FR 45746, Oct. 5, 1992; 59 FR 63902, Dec. 12, 1994]

§ 57.4106 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval. The Secretary will award grants to applicants whose projects will best promote the purposes of section 777(b) of the Act and these regulations. The Secretary will consider, among other factors:

(1) The extent to which the proposed training program will prepare physicians and dentists to perform the research, teaching, administrative and clinical duties of a faculty member specializing in geriatrics;

(2) The degree to which the project plan adequately provides for meeting the requirements set forth in § 57.4105;

(3) The administrative, management and resource capability of the applicant to carry out the proposed project in a cost-effective manner;

(4) The potential for the applicant to continue the program without Federal support after completion of the requested project period; and

(5) The extent to which the project will increase the number of geriatric fellowship and retraining positions available for individuals who want to prepare for academic careers in geriatric medicine, psychiatry, or dentistry.

(b) In determining the funding of applications approved under paragraph (a) of this section, the Secretary will consider any special factors relating to national needs as the Secretary may from time to time announce in the FEDERAL REGISTER.

[55 FR 37481, Sept. 12, 1990, as amended at 59 FR 63902, Dec. 12, 1994]

§ 57.4107 How long does grant support last?

(a) The notice of grant award specifies the length of time the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed 5 years.

(b) Generally, the grant will initially be funded for 1 year, and subsequent continuation awards will also be for 1 year at a time. Decisions regarding continuation awards and the funding levels of these awards will be made after consideration of such factors as the grantee's progress and management practices, existence of legislative authority, 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.

(c) Neither the approval of any application nor the award of any grant shall

commit or obligate 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. For continuation support, grantees must make separate application at such time and in such a form as the Secretary may prescribe.

[55 FR 37481, Sept. 12, 1990, as amended at 57 FR 45746, Oct. 5, 1992]

§ 57.4108 What financial support is available to fellows?

Expenditures from funds are limited to:

(a) Tuition and fees, in accordance with the established rates of the institution, except as limited by the Secretary;

(b) Stipend support, in accordance with established Public Health Service postdoctoral stipend levels; and

(c) Travel to field training if the site is beyond a reasonable commuting distance and requires the fellow to establish a temporary new residence. However, fellowship funds may not be used for daily commuting from the new place of residence to the field training headquarters.

§ 57.4109 Who is eligible for financial assistance as a fellow?

To be eligible for a fellowship an individual must:

(a) Be a resident 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;

(b) Be a physician or a dentist enrolled in a ''fellowship program'' or a ''retraining program'' as defined in § 57.4102; and

(c) Not be receiving concurrent support for the same training from another Federal education award which provides a stipend or otherwise duplicates financial provisions except education benefits under the Veteran's Readjustment Benefits Act, and loans from Federal sources.

[55 FR 37481, Sept. 12, 1990, as amended at 61 FR 6129, Feb. 16, 1996]

§ 57.4110 What are the requirements for fellowships and the appointment of fellows?

(a) The grantee must complete a statement which documents the appointment of each fellow. To complete this statement the grantee must require the provision of information and documentation of eligibility by each fellow. The statement of appointment must be completed by the beginning of the training period or as soon thereafter as possible if the fellow receives notice of his or her fellowship appointment after the training period has begun. The statement of appointment must include information to document the eligibility of the fellow and certify that there will be compliance with all applicable Public Health Service terms and conditions governing the appointment. The program director must sign the statement on behalf of the grantee, and the fellow must sign it thus certifying the statements are true and complete. The original copy of the statement must be retained by the grantee to be available for program review and financial audit. A copy shall be provided to the fellow for his or her records.

(b) The grantee may not require fellows to perform work which is not an integral part of the geriatric training program, or to perform services which detract from or prolong their training.

(Approved by the Office of Management and Budget under control number 0915–0060)

[55 FR 37481, Sept. 12, 1990, as amended at 56 FR 29194, June 26, 1991]

§ 57.4111 Termination of fellowships.

(a) The grantee must terminate a fellowship:

(1) Upon request of the fellow;

(2) If the fellow withdraws from the grantee institution; or

(3) If the grantee determines that:

(i) The fellow is no longer an active participant in the training program; or

(ii) The fellow is not eligible or able to continue in accordance with its standards and practices.

(b) The grantee must deposit any Federal portion of the tuition refund owed to a fellow into the grant account and provide written notice to the fellow that it is doing so.

(Approved by the Office of Management and Budget under control number 0915–0060)

[55 FR 37481, Sept. 12, 1990, as amended at 56 FR 29194, June 26, 1991. Redesignated at 59 FR 63902, Dec. 12, 1994]

§ 57.4112 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and this subpart.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

(c) Any balance of federally-obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward provided specific approval is granted by the Secretary. If at any time during a budget period, it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by withdrawing the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

[55 FR 37481, Sept. 12, 1990, as amended at 57 FR 45746, Oct. 5, 1992. Redesignated at 59 FR 63903, Dec. 12, 1994]

§ 57.4113 What additional Department regulations apply to grantees?

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 46—Protection of human subjects
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 83—Regulation for the administration and enforcement of sections 794 and 855 of the Public Health Services 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[55 FR 37481, Sept. 12, 1990, as amended at 57 FR 45746, Oct. 5, 1992. Redesignated at 59 FR 63903, Dec. 12, 1994; 61 FR 6129, Feb. 16, 1996]

§ 57.4114 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[59 FR 63903, Dec. 12, 1994]

§ 57.4115 Additional conditions.

The Secretary may impose additional conditions on any grant award before or at the time of any award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[55 FR 37481, Sept. 12, 1990. Redesignated at 59 FR 63903, Dec. 12, 1994]

PART 58—GRANTS FOR TRAINING OF PUBLIC HEALTH AND ALLIED HEALTH PERSONNEL

Subparts A–B [Reserved]

Subpart C—Grants for Public Health Traineeships for Students in Schools of Public Health and in Other Graduate Public Health Programs

Sec.
58.201 To what grant program do these regulations apply?
58.202 Definitions.
58.203 Who is eligible to apply for a grant?
58.204 How will applications be evaluated?
58.205 How is the amount of the award determined?
58.206 How long does grant support last?
58.207 For what purposes may grant funds be spent?
58.208 What are the requirements for appointment of trainees?
58.209 Who is eligible for financial assistance as a trainee?
58.210 What financial support is available to trainees?
58.211 Duration of traineeships.
58.212 Termination of traineeship.
58.213 What additional Department regulations apply to grantees?
58.214 What other audit and inspection requirements apply to grantees?
58.215 Additional conditions.

Subpart D—Grants for Health Administration Traineeships and Special Projects Program

58.221 To what grant program do these regulations apply?
58.222 Definitions.
58.223 Who is eligible to apply for a grant?
58.224 How will applications be evaluated?
58.225 How is the amount of the award determined?
58.226 How long does grant support last?
58.227 For what purposes may grant funds be spent?
58.228 Who is eligible for financial assistance as a trainee?
58.229 What financial support is available to trainees?
58.230 Duration of traineeships.
58.231 Termination of traineeships.
58.232 What additional Department regulations apply to grantees?
58.233 What other audit and inspection requirements apply to grantees?
58.234 Additional conditions.

Subparts E–F [Reserved]

Subparts A–B [Reserved]

Subpart C—Grants for Public Health Traineeships for Students in Schools of Public Health and in Other Graduate Public Health Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended by 63 Stat. 35 (42 U.S.C. 216); sec. 748 of the Public Health Service Act, 90 Stat. 2279, as amended by 91 Stat. 1505; as amended and redesignated as sec. 792 of the Public Health Service Act by 95 Stat. 927 (42 U.S.C. 295h–1b); renumbered as sec. 761, as amended by Pub. L. 102–408, 106 Stat. 2045 (42 U.S.C. 294).

SOURCE: 45 FR 73661, Nov. 6, 1980, unless otherwise noted.

§ 58.201 To what grant program do these regulations apply?

These regulations apply to the award of grants to eligible educational entities under section 761 of the Public Health Service Act (42 U.S.C. 294) to provide funds for traineeships for students enrolled in graduate or specialized training in public health.

[47 FR 54439, Dec. 3, 1982, as amended by 61 FR 6129, Feb. 16, 1996]

§ 58.202 Definitions.

Act means the Public Health Service Act, as amended.

Educational entity means a school, college, or university which is accredited by a body or bodies recognized for this purpose by the Secretary of Education or an institution which provides specialized training in public health.

Fiscal year means the Federal fiscal year, beginning October 1 and ending the following September 30.

Full-time student means a student who is either (1) in a residency program in preventive medicine or dentistry or (2) is enrolled on a full-time basis in a graduate program in public health and who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters of other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

Graduate program or *graduate training* means a program of education leading to a master's degree or equivalent or doctoral degree or equivalent.

National of the United States means (as defined in the Immigration and Nationality Act at 8 U.S.C. 1101(a)(22)) (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.

Nonprofit refers to the status of an entity 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 insure, to the benefit of any private shareholder or individual.

School of Public Health means a public or non-profit private school which provides training leading to a graduate degree in public health or equivalent degree and is accredited according to section 799(1)(E) of the Public Health Service Act.

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

Specialized training in public health or *specialized training in preventive medicine or denistry* means a residency training program approved by the Liaison Committee on Graduate Medical Education or by the Commission on Dental Accreditation leading to board eligibility in a specialty in preventive medicine or dental public health respectively.

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.

Trainee means a student who is receiving traineeship funds from a grant made under these regulations.

[45 FR 73661, Nov. 6, 1980, as amended at 47 FR 54439, Dec. 3, 1982; 61 FR 6129, Feb. 16, 1996]

§ 58.203 Who is eligible to apply for a grant?

The following are eligible for grants:

(a) Any accredited school of public health which is located in a State; and

(b) Any other public or nonprofit private eduational entity which is located in a State and provides graduate or specialized training in public health. However, no entity of this type may obtain an award under this subpart to support traineeships in health administration, hospital administration, or health policy analysis and planning.[1]

[45 FR 73661, Nov. 6, 1980, as amended at 47 FR 54439, Dec. 3, 1982; 61 FR 6130, Feb. 16, 1996]

§ 58.204 How will applications be evaluated?

(a) The Secretary will award a grant to each eligible school of public health which submits an application containing all the information and assurances requested in the required form and time.

(b) For public and nonprofit educational entities other than schools of public health, the Secretary will decide which applications to approve by considering, among other factors:

(1) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner;

(2) The degree of need for the professionals to be trained; and

(3) The adequacy of the staff and faculty; and

(4) Whether the applicant's graduate programs in environmental or occupational health or dietetics and nutrition, or both, meet the requirements in paragraphs § 58.208 (c) and (d).

Within the limits of funds available for competing awards the Secretary will award grants to those approved applicants whose traineeship programs will best promote the purposes of section 761 of the Act.

[45 FR 73661, Nov. 6, 1980, as amended at 47 FR 54439, Dec. 3, 1982; 61 FR 6130, Feb. 16, 1996]

[1] For traineeships in health administration, hospital administration, or health policy analysis and planning, eduational entities which are *not* accredited schools of public health may only apply under section 771 of the Act.

§ 58.205 How is the amount of the award determined?

(a) *Grants to schools of public health.* The Secretary will use a formula to determine the amount of the grant to be awarded to each school of public health with an approved application.

This formula is

$$G = \frac{SS}{TS} \times AF$$

G is the amount of the grant award; SS is the number of eligible full-time and full-time equivalent students of each applicant enrolled in severe shortage occupations targeted for support (epidemiology, environmental health, biostatistics, toxicology, public health nutrition, and maternal and child health); TS is the total number of students enrolled in graduate and specialized training in all schools of public health with approved applications; and AF is the amount of traineeship funds under this program that the Secretary has designated for award to schools of public health for that fiscal year. The Secretary will determine the number of students enrolled in graduate and specialized training in public health at the school (SS) with the formula

$$SS = FTS + \frac{PTC}{9}$$

FTS is the number of full-time students, and PTC is the total number of credit hours in which part-time students are enrolled. If necessary, the figure for

$$\frac{PTC}{9}$$

will be rounded to the next highest number. Students will be counted as of October 15 of the fiscal year in which application is made. The amount of a grant will never exceed the amount requested by the applicant.

(b) *Grants to public and nonprofit private educational entities.* The remaining funds will be available to meet continuation commitments and to award on a competitive basis to eligible public or nonprofit private educational entities other than schools of public health. The Secretary will determine the amount of these awards by estimating the sum necessary during the budget period to cover the tuition, fees, stipends, and allowances (including travel costs approved by the Secretary) for full-time students, and the tuition and fees for part-time students which the applicant proposes to provide to its trainees.

[45 FR 73661, Nov. 6, 1980, as amended at 47 FR 54440, Dec. 3, 1982; 61 FR 6130, Feb. 16, 1996]

§ 58.206 How long does grant support last?

(a) The written notice of grant award specifies the period during which formula grant funds are available for obligation by the grantee, or the period during which the recipient of a competitive grant award need not recompete for funds. This period will not exceed one year for formula grants and 3 years for competitve grants. The period during which recompetition is not necessary is called the project period.

(b) Generally a competitive grant will initially be funded 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 levels 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.

(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.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for the period, the Secretary may adjust the amounts awarded by

withholding the excess. A budget period is an interval of time (usually 12 months) into which the project period is divided for funding and reporting purposes.

§ 58.207 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles specified in subpart Q of 45 CFR part 74, and these regulations. Use of grant funds to meet the direct or indirect administrative costs of the training institution is not authorized.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 58.208 What are the requirements for appointment of trainees?

(a) The grantee must require each trainee to complete a statement of appointment by the beginning of the training period, or as soon as possible if the trainee receives notice of his or her traineeship appointment after the training period has begun. The program director must sign the statement on behalf of the grantee and the original copy of the statement must be retained by the grantee to be available for program review and financial audit. The grantee must also send a copy of the statement to the Secretary upon request.

(b) The grantee must require full-time trainees to sign a statement that they will not undertake employment during their traineeships which would interfere with their ability to satisfactorily complete the training program in a timely fashion.

(c) The grantee may not require trainees to perform any work which is not an integral part of their training program and required of all students in the program, or to perform services which detract from or prolong their training.

(d) The grantee must advise each trainee who is enrolled in a course of study which requires more than twelve months that continued support under this program is contingent upon the continued availability of grant funds.

(Approved by the Office of Management and Budget under control number 0915–0060)

[45 FR 73661, Nov. 6, 1980, as amended at 47 FR 54440, Dec. 3, 1982; 61 FR 6130, Feb. 16, 1996]

§ 58.209 Who is eligible for financial assistance as a trainee?

(a) To be eligible for a traineeship, an individual must meet the following conditions:

(1) Trainees must be United States citizens, non-citizen nationals, or foreign nationals having in their possession a visa permitting permanent residence in the United States.

(2) New trainees must be pursuing a graduate degree in a health professions field in which there is a severe shortage of health professionals (including the fields of epidemiology, environmental health, biostatistics, toxicology, public health nutrition, and maternal and child health). Ongoing traineeship commitment will be continued.

(3) All trainees must meet the school's admission requirements specified in the approved grant application.

(b) Traineeship support may not be provided to:

(1) Individuals who do not meet the qualifications for admission as specified in the approved application;

(2) Full-time Federal employees unless they are on Leave Without Pay status;

(3) Students pursuing training at the undergraduate level;

(4) Students in programs designed to prepare them for careers in research;

(5) Preventive medicine and dental public health residents (section 763 of the Act may be used for these students); or

(6) Individuals on temporary or student visas.

[61 FR 6130, Feb. 16, 1996]

§ 58.210 What financial support is available to trainees?

(a) Expenditures are limited to:

(1) Tuition and fees, in accordance with the established rates of the institution except as limited by the Secretary.

(2) Stipends, for full time students, in whatever amount the grantee determines that each trainee needs to pursue the training program, as long as that amount does not exceed the limits established by the Secretary.

(3) Transportation allowances on an individual basis when prior approval has been obtained from the Secretary in the following circumstances:

(i) In cases of extreme need, the grantee may pay a trainee an allowance from grant funds for travel from his or her residence to the training site.

(ii) The grantee may pay a trainee an allowance from grant funds for travel to field training if the site is beyond a reasonable commuting distance and requires the trainee to establish a temporary new residence. However, the grantee may not pay an allowance for daily commuting from the new place of residence to the field training headquarters.

(iii) The grantee may pay a trainee an allowance from grant funds for domestic travel to conduct research to meet dissertation requirements.

(b) The grantee may not give a stipend or allowance to a part-time trainee, but may give a traineeship award to pay a part-time trainee's tuition and fees.

§ 58.211 Duration of traineeships.

Traineeships must be for a full academic year, except an appointment for less than a full academic year may be made when the student will complete the program of study at the termination of the appointment, or when joint-degree programs require enrollment at another unit of the grantee institution for part of the academic year. A traineeship may not exceed 12 months in duration. However, consecutive or subsequent traineeship appointments may be made if a student's required program of study exceeds 12 months. Training for which the student receives a traineeship must begin during the period for which funds are made available, but may extend beyond the end of this period.

§ 58.212 Termination of traineeship.

The grantee must terminate a traineeship:

(a) Upon request of the trainee;

(b) If the trainee withdraws from the grantee institution; or

(c) If the grantee determines that

(1) The trainee is no longer an enrolled student; or

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

§ 58.213 What additional Department regulations apply to grantees?

Several other regulations apply to grantees. They 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 80—Nondiscrimination under programs receiving Federal financial 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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[49 FR 38116, Sept. 27, 1984, as amended at 61 FR 6130, Feb. 16, 1996]

§ 58.214 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6130, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.215 Additional conditions.

The Secretary may impose additional conditions in the grant award before or

at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

Subpart D—Grants for Health Administration Traineeships and Special Projects Program

AUTHORITY: Sec. 215 of the Public Health Service Act. 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); sec. 749 of the Public Health Service Act, 90 Stat. 2280, Pub. L. 94–484 (42 U.S.C. 294s); redesignated as sec. 791A, amended by 95 Stat. 927, Pub. L. 97–35 and 96 Stat. 2061, Pub. L. 97–414 (42 U.S.C. 295h–1a); renumbered as sec. 771, amended by 106 Stat. 2049, Pub. L. 102–408 (42 U.S.C. 294i).

SOURCE: 45 FR 73658, Nov. 6, 1980, unless otherwise noted.

§ 58.221 To what grant program do these regulations apply?

These regulations apply to the award of grants to eligible educational entities under section 771 of the Public Health Service Act (42 U.S.C. 294i) to provide funds for traineeships for students enrolled in graduate programs in health administration, hospital administration, or health policy analysis and planning.

[45 FR 73658, Nov. 6, 1980, as amended at 49 FR 21535, May 22, 1984; 61 FR 6130, Feb. 16, 1996]

§ 58.222 Definitions.

Act means the Public Health Service Act, as amended.

Educational entity means a school, college, or university which is accredited by a body or bodies recognized for this purpose by the Secretary of Education.

Fiscal year means the Federal fiscal year, beginning October 1 and ending the following September 30.

Full-time student means a student who is enrolled on a full-time basis in a graduate program in health administration, hospital administration, or health policy analysis and planning, and who is enrolled for a sufficient number of credit hours in any semester or other academic term to enable him or her to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study at the school in which the student is enrolled.

Graduate program means a program of education leading to a master's degree or equivalent or a doctoral degree or equivalent.

National of the United States (as defined in 8 U.S.C. 110(a)(22), the Immigration and Nationality Act) 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.

Nonprofit refers to the status of an entity 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.

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

School of public health means a public or private school in a State providing education leading to a graduate degree in public health or an equivalent degree, including advanced training related to public health, which is accredited as provided for in section 799(1)(E) of the Act.

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.

Trainee means a student who is receiving traineeship funds from a grant made under these regulations.

[45 FR 73658, Nov. 6, 1980, as amended at 49 FR 21535, May 22, 1984; 61 FR 6130, Feb. 16, 1996]

§ 58.223 Who is eligible to apply for a grant?

Any public or nonprofit private educational entity (excluding schools of public health) located in a State is eligible to apply for a grant to support traineeships in its graduate program in

health administration, hospital administration, or health policy analysis and planning which has been accredited, or is about to be accredited, according to section 799(1)(E) of the Act.

[49 FR 21535, May 22, 1984, as amended at 61 FR 6130, Feb. 16, 1996]

§ 58.224 How will applications be evaluated?

(a) As required by section 798(a) of the Act, each application for a grant under this subpart shall be submitted to a peer review group, composed principally of non-Federal experts, for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval.

(b) The following criteria will be used for review of applications:

(1) The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner;

(2) The adequacy of the staff and faculty;

(3) The adequacy of institutional resources available to conduct graduate level education, to include the adequacy of teaching facilities;

(4) The adequacy of recruitment and placement assistance for students in accord with the legislative purpose and intent; and

(5) The extent to which the application justifies the purpose, scope, and need for traineeship and or special project grant.

(Approved by the Office of Management and Budget under control number 0915–0060)

[61 FR 6130, Feb. 16, 1996]

§ 58.225 How is the amount of the award determined?

The Secretary will use a formula to determine the amount of the grant award for each entity with an approved application. This formula is:

$$G = \frac{SS}{TS} \times AF$$

G is the amount of the grant award; SS is the number of students enrolled in approved graduate programs in health administration, hospital administration, or health policy analysis and planning at the school; TS is the total number of students in these programs at all schools with approved applications, and AF is the amount of available funds authorized under section 771 for traineeships in a given fiscal year. The Secretary will determine the number of students enrolled in these programs at the school (SS) with the formula:

$$SS = FTS + \frac{PTC}{9}$$

FTS is the number of full-time students enrolled in these programs and PTC is the total number of credit hours in which part-time students are enrolled. If necessary, the figure for PTC/9 will be rounded to the next highest number. Students will be counted as of October 15 of the fiscal year in which application is made. The amount of a grant will never exceed the amount requested by the applicant.

[45 FR 73658, Nov. 6, 1980, as amended at 49 FR 21536, May 22, 1984; 61 FR 6131, Feb. 16, 1996]

§ 58.226 How long does grant support last?

(a) The notice of grant award specifies the period during which funds are available for obligation by the grantee. This period will not exceed one year. If at any time during the period of the grant it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

(b) 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.

§ 58.227 For what purposes may grant funds be spent?

(a) A grantee shall only spend funds it receives under this subpart according to the approved application and budget, the authorizing legislation, terms and conditions of the grant award, applicable cost principles in subpart Q of 45 CFR part 74, and these regulations. Use of traineeship funds to

meet the direct or indirect administrative costs of the training institution is not authorized.

(b) Grantees may not spend grant funds for sectarian instruction or for any religious purpose.

§ 58.228 Who is eligible for financial assistance as a trainee?

To be eligible for a traineeship, an individual must meet the following conditions:

(a) The individual must be a resident 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.

(b) The individual must be accepted for enrollment, or be enrolled in a grantee's accredited graduate program in health administration, hospital administration, or health policy analysis and planning;

(c) The individual may not be receiving concurrent support for the same training from another Federal source except education benefits under the Veteran's Readjustment Benefits Act.

[45 FR 73658, Nov. 6, 1980, as amended at 49 FR 21536, May 22, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.229 What financial support is available to trainees?

(a) The grantee may use grant funds to pay for:

(1) Tuition and fees, in accordance with the established rates of the institution except as limited by the Secretary;

(2) Stipends, for full time trainees in whatever amount the grantee determines that each trainee needs to pursue the training program, as long as that amount does not exceed the limits established by the Secretary;

(3) Transportation allowances on an individual basis when prior approval has been obtained from the Secretary in the following circumstances:

(i) In cases of extreme need, the grantee may pay a trainee an allowance from grant funds for travel from his or her residence to the training site.

(ii) The grantee may pay a trainee an allowance from grant funds for travel to field training if the site is beyond a reasonable commuting distance and requires the trainee to establish a temporary new residence. However, the grantee may not pay an allowance for daily commuting from the new place of residence to the field training headquarters.

(iii) The grantee may pay a trainee an allowance from grant funds for domestic travel to conduct research to meet dissertation requirements.

(b) The grantee may not give a stipend or allowance to a part-time trainee, but may give a traineeship award to pay a part-time trainee's tuition and fees.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.230 Duration of traineeships.

A traineeship must be for a full academic year except that an appointment for less than a full academic year may be made to a student who will complete his or her program of study in a lesser time or when joint-degree programs require enrollment at another unit of the grantee institution for part of the academic year. A traineeship may not exceed 12 months in duration. However a grantee may make consecutive or subsequent traineeship appointments to students whose required program of study exceeds 12 months. The training for which a student receives a traineeship must begin during the period for which funds are made available, but may extend beyond that period.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.231 Termination of traineeships.

The grantee must terminate a traineeship:

(a) Upon request of the trainee;

(b) If the trainee withdraws from the grantee institution; or

(c) If the grantee determines that:

(1) The trainee is no longer an enrolled student; or

(2) The trainee is not eligible or able to continue in attendance in accordance with its standards and practices.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

§ 58.232 What additional Department regulations apply to grantees?

Several other Department regulations apply to grantees. They 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 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 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 HHS programs or activities receiving Federal financial assistance
45 CFR part 93—New restrictions on lobbying

[49 FR 38116, Sept. 27, 1984. Redesignated and amended at 61 FR 6131, Feb. 16, 1996]

§ 58.233 What other audit and inspection requirements apply to grantees?

Each entity which receives a grant under this subpart must meet the requirements of 45 CFR part 74 concerning audit and inspection.

[61 FR 6131, Feb. 16, 1996; 61 FR 51020, Sept. 30, 1996]

§ 58.234 Additional conditions.

The Secretary may impose additional conditions in the grant award before or at the time of the award if he or she determines that these conditions are necessary to assure or protect the advancement of the approved activity, the interest of the public health, or the conservation of grant funds.

[45 FR 73658, Nov. 6, 1980. Redesignated at 61 FR 6131, Feb. 16, 1996]

Subparts E–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 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]

§ 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 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 accordance 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

[1] Section 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.''

to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(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 community 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 nonfederal 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 recompete 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 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.

(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
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 programs 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.

(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

[1] Applications 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.

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 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 impelmenting 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, nonexclusive, 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;

(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]

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 recompete 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 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 (nonprocurement) 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 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

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.

Underfined 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 recompete 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 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 (nonprocurement) 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 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.
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. 294–294*l*–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;

(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.

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[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.

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[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 administration, 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, ostepathic 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. 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.

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§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 reasearch or reserch 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 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 associated 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 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]

§ 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.

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[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 indication 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.

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[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 communications 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

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 forbearance 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.

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[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.

(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.

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[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 of 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 bankrupty 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.

(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 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 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

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 approvable, 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

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 temporary 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

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 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 52 752, 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.

(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 defaulted 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.

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[52 FR 752, Jan. 8, 1987, as amended at 57 FR 28799, June 29, 1992; 58 FR 67350, Dec. 21, 1993]