

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]

Subpart E—F [Reserved]

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

Subpart A—Project Grants for Family Planning Services

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Subpart A—Project Grants for Family Planning Services

AUTHORITY: 42 U.S.C. 300a-4.

SOURCE: 45 FR 37436, June 3, 1980, unless otherwise noted.

EDITORIAL NOTE: At 58 FR 7462–7463, Feb. 5, 1993, the Secretary of Health and Human Services (HHS) suspended the effectiveness of the provisions of Subpart A issued at 53 FR 2922, Feb. 2, 1988. The actions taken on Feb. 2, 1988, were:

1. The authority citation for subpart A of 42 CFR part 59 is revised.
2. In 42 CFR 59.2, the following definitions are added:

- Family planning*
- Grantee*
- Prenatal care*
- Program and project*
- Title X*
- Title X program and Title X project*

3. In 42 CFR 59.5(a), paragraph (a)(5) is removed and paragraphs (a)(6) through (a)(11) are redesignated as paragraphs (a)(5) through (a)(10), respectively.

4. 42 CFR 59.5(b)(3)(i) is revised.

5. In 42 CFR part 59, §59.7 through §59.13 are redesignated as §59.11 through §59.17 respectively, and new §59.7 through §59.10 are added.

6. In addition to the amendments set forth above, in 42 CFR part 59 remove the words “project” or “projects” or “project’s” and add in their place, the words “Title X project” or “Title X projects” or “Title X project’s” respectively, in the following places:

- (a) Section 59.2 definition of “low income family”;
- (b) Section 59.5(a)(1);
- (c) Section 59.5(b) introductory text;
- (d) Section 59.5(b)(3)(iii);
- (e) Section 59.5(b)(4);
- (f) Section 59.5(b)(7);
- (g) Section 59.5(b)(10);
- (h) Section 59.6(a);
- (i) Newly redesignated §59.11(a);
- (k) Newly redesignated §59.11(a)(7);
- (l) Newly redesignated §59.11(b);
- (m) Newly redesignated §59.11(c);
- (n) Newly redesignated §59.12(a), the first time it appears;
- (o) Newly redesignated §59.15;
- (p) Newly redesignated §59.16(a).

§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.

§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.

Family planning means the process of establishing objectives for the number and spacing of one’s children and selecting the means by which those objectives may be achieved. These means include a broad range of acceptable and effective methods and services to limit or enhance fertility, including contraceptive methods (including natural family planning and abstinence) and the management of infertility (including adoption). Family planning services includes preconceptional counseling, education, and general reproductive health care (including diagnosis and treatment of infections which threaten reproductive capability). Family planning does not include pregnancy care (including obstetric or prenatal care). As required by section 1008 of the Act, abortion may not be included as a method of family planning

in the title X project. Family planning, as supported under this subpart, should reduce the incidence of abortion.

Grantee means the organization to which a grant is awarded under section 1001 of the Act.

Low income family means a family whose total annual income does not exceed 100 percent of the most recent Community Services Administration Income Poverty Guidelines (45 CFR 1060.2). *Low-income family* also includes members of families whose annual family income exceeds this amount, but who, as determined by the title X 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.

Prenatal care means medical services provided to a pregnant woman to promote maternal and fetal health.

Program and *project* are used interchangeably and mean a coherent assembly of plans, activities and supporting resources contained within an administrative framework.

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

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

Title X means title X of the Act, 42 U.S.C. 300, *et seq.*

Title X program and *title X project* are used interchangeably and mean the identified program which is approved by the Secretary for support under section 1001 of the Act, as the context may require. Title X project funds include all funds allocated to the title X program, including but not limited to

grant funds, grant-related income or matching funds.

[45 FR 37436, June 3, 1980, as amended at 48 FR 3614, Jan. 26, 1983; 49 FR 38118, Sept. 27, 1984; 53 FR 2944, 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.2 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§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, such as natural family planning, it may participate as part of a title X project as long as the entire title X 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 service, 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) Provide that priority in the provision of services will be given to persons from low-income families.

(6) Provide that no charge will be made for services provided to any person 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.

(7) 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 CSA Income Poverty Guidelines (45 CFR 1060.2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

¹Section 205 of Pub. L. 94-63 states: “Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.”

(8) 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 or title XX of the Social Security Act, a written agreement with the title XIX or title XX agency is required.

(9)(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.

(10) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each title X project must meet each of the following requirements unless the Secretary determines that the title X project has established good cause for its omission. Each title X project must:

(1) Provide for medical services related to family planning (including physician’s consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service 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 title X program,

(ii) inform the community of the availability of services, and (iii) promote continued participation in the title X project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all title X 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 title X project participants will be authorized by the title X project director or his designee on the title X 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 methods 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 title X 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.

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

sec. 931(b)(1) of Pub. L. 97-35, 95 Stat. 570, 42 U.S.C. 300(a))

[45 FR 37436, June 3, 1980, as amended at 49 FR 38118, Sept. 27, 1984; 53 FR 2944, 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.5 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§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 assurances satisfactory to the Secretary that the title X project shall provide for the review and approval of informational and educational materials developed or made available under the title X 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 title X 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 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 it is to be made available; and

(v) Establish a written record of its determinations.

[45 FR 37436, June 3, 1980, as amended at 53 FR 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.6 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§59.7 Standards of compliance with prohibition on abortion.

A project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that it does not include abortion as a method of family planning. Such assurance must include, as a minimum, representations (supported by such documentation as the Secretary may request) as to compliance with each of the requirements in §59.8 through §59.10. A project must comply with such requirements at all times during the period for which support under title X is provided.

[53 FR 2944, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.7 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§59.8 Prohibition on counseling and referral for abortion services; limitation of program services to family planning.

(a)(1) A title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning.

(2) Because title X funds are intended only for family planning, once a client served by a title X project is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services by furnishing a list of available providers that promote the welfare of mother and unborn child. She must also be provided with information necessary to protect the health of mother and unborn child until such time as the referral appointment is kept. In cases in which emergency care is required, however, the title X project shall be required only to refer the client immediately to an appropriate provider of emergency medical services.

(3) A title X project may not use prenatal, social service or emergency med-

ical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning, such as by weighing the list of referrals in favor of health care providers which perform abortions, by including on the list of referral providers health care providers whose principal business is the provision of abortions, by excluding available providers who do not provide abortions, or by "steering" clients to providers who offer abortion as a method of family planning.

(4) Nothing in this subpart shall be construed as prohibiting the provision of information to a project client which is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method; *provided*, that the provision of this information does not include counseling with respect to or otherwise promote abortion as a method of family planning.

(b) *Examples.* (1) A pregnant client of a title X project requests prenatal care services, which project personnel are qualified to provide. Because the provision of such services is outside the scope of family planning supported by title X, the client must be referred to appropriate providers of prenatal care.

(2) A title X project discovers an ectopic pregnancy in the course of conducting a physical examination of a client. Referral arrangements for emergency medical care are immediately provided. Such action is in compliance with the requirements of paragraph (a)(2) of this section.

(3) A pregnant woman asks the title X project to provide her with a list of abortion providers in the area. The title X project tells her that it does not refer for abortion but provides her a list which includes, among other health care providers, a local clinic which principally provides abortions. Inclusion of the clinic on the list is inconsistent with paragraph (a)(3) of this section.

(4) A pregnant woman asks the title X project to provide her with a list of abortion providers in the area. The project tells her that it does not refer for abortion and provides her a list which consists of hospitals and clinics and other providers which provide prenatal care and also provide abortions.

None of the entries on the list are providers that principally provide abortions. Although there are several appropriate providers of prenatal care in the area which do not provide or refer for abortions, none of these providers are included on the list. Provision of the list is inconsistent with paragraph (a)(3) of this section.

(5) A pregnant woman requests information on abortion and asks the title X project to refer her to an abortion provider. The project counselor tells her that the project does not consider abortion an appropriate method of family planning and therefore does not counsel or refer for abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services, and provides her with a list of such providers from which the client may choose. Such actions are consistent with paragraph (a) of this section.

(6) Title X project staff provide contraceptive counseling to a client in order to assist her in selecting a contraceptive method. In discussing oral contraceptives, the project counselor provides the client with information contained in the patient package insert accompanying a brand of oral contraceptives, referring to abortion only in the context of a discussion of the relative safety of various contraceptive methods and in no way promoting abortion as a method of family planning. The provision of this information does not constitute abortion counseling or referral.

[53 FR 2945, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of § 59.8 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§ 59.9 Maintenance of program integrity.

A title X project must be organized so that it is physically and financially separate, as determined in accordance with the review established in this section, from activities which are prohibited under section 1008 of the Act and § 59.8 and § 59.10 of these regulations from inclusion in the title X program. In order to be physically and financially separate, a title X project must have an objective integrity and inde-

pendence from prohibited activities. Mere bookkeeping separation of title X funds from other monies is not sufficient. The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances. Factors relevant to this determination shall include (but are not limited to):

(a) The existence of separate accounting records;

(b) The degree of separation from facilities (*e.g.*, treatment, consultation, examination, and waiting rooms) in which prohibited activities occur and the extent of such prohibited activities;

(c) The existence of separate personnel;

(d) The extent to which signs and other forms of identification of the title X project are present and signs and material promoting abortion are absent.

[53 FR 2945, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of § 59.9 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§ 59.10 Prohibition on activities that encourage, promote or advocate abortion.

(a) A title X project may not encourage, promote or advocate abortion as a method of family planning. This requirement prohibits actions to assist women to obtain abortions or increase the availability or accessibility of abortion for family planning purposes. Prohibited actions include the use of title X project funds for the following:

(1) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning;

(2) Providing speakers to promote the use of abortion as a method of family planning;

(3) Paying dues to any group that as a significant part of its activities advocates abortion as a method of family planning;

(4) Using legal action to make abortion available in any way as a method of family planning; and

(5) Developing or disseminating in any way materials (including printed

matter and audiovisual materials) advocating abortion as a method of family planning.

(b) *Examples.* (1) Clients at a title X project are given brochures advertising an abortion clinic. Provision of the brochure violates paragraph (a) of this section.

(2) A title X project makes an appointment for a pregnant client with an abortion clinic. The title X project has violated paragraph (a) of this section.

(3) A title X project pays dues to a state association which, among other activities, lobbies at state and local levels for the passage of legislation to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity. Payment of dues to the association violates paragraph (a)(3) of this section.

(4) An organization conducts a number of activities, including operating a title X project. The organization uses non-project funds to pay dues to an association which, among other activities, engages in lobbying to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity. Payment of dues to the association by the organization does not violate paragraph (a)(3) of this section.

(5) An organization that operates a title X project engages in lobbying to increase the legal availability of abortion as a method of family planning. The project itself engages in no such activities and the facilities and funds of the project are kept separate from prohibited activities. The project is not in violation of paragraph (a)(1) of this section.

(6) Employees of a title X project write their legislative representatives in support of legislation seeking to expand the legal availability of abortion, using no project funds to do so. The title X project has not violated paragraph (a)(1) of this section.

(7) On her own time and at her own expense, a title X project employee speaks before a legislative body in support of abortion as a method of family

planning. The title X project has not violated paragraph (a) of this section.

[53 FR 2945, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of § 59.10 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§ 59.11 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 title X projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the title X 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 title X project. No grant may be made for less than 90 percent of the title X project's costs, as so estimated, unless the grant is to be made for a title X 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 of the title X project's estimated costs.

[45 FR 37436, June 3, 1980. Redesignated and amended at 53 FR 2944, 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.11 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§59.12 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the title X project without requiring the project to recompute for funds. This period, called the project period, will usually be for 3 to 5 years.

(b) Generally the grant will initially be for 1 year and subsequent continuation awards will also be for 1 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.

[45 FR 37436, June 3, 1980. Redesignated and amended at 53 FR 2944, 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.12 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§59.13 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 prin-

ciples prescribed in subpart Q of 45 CFR part 74.

[45 FR 37436, June 3, 1980. Redesignated at 53 FR 2944, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.13 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§59.14 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:

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

42 CFR part 122, subpart E—Health Systems Agency review of certain proposed uses of Federal health funds

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

[49 FR 38116, Sept. 27, 1984. Redesignated at 53 FR 2944, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of §59.14 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§59.15 Confidentiality.

All information as to personal facts and circumstances obtained by the title X project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information

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may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

[45 FR 37436, June 3, 1980. Redesignated and amended at 53 FR 2944, 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of § 59.15 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§ 59.16 Inventions or discoveries.

(a) A title X project grant award is subject to the regulations of HHS as set forth in 45 CFR parts 6 and 8, as amended. These regulations shall apply to any activity of the title X project for which grant funds are used, whether the activity is part of an approved title X project or is an unexpected by-product of that title X project.

(b) The grantee and the Secretary shall take appropriate measures 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 grant activity are aware of and comply with such obligations.

[45 FR 37436, June 3, 1980. Redesignated and amended at 53 FR 2944, 2946, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of § 59.16 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

§ 59.17 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.

[45 FR 37436, June 3, 1980. Redesignated at 53 FR 2944, Feb. 2, 1988]

EDITORIAL NOTE: For provisions of § 59.17 which have been suspended, see the EDITORIAL NOTE following the SOURCE of Subpart A.

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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]

¹Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

§ 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 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 implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

§ 59.210 Inventions or discoveries.

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 59.211 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publica-

tions, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, non-exclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 59.212 Grantee accountability.

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

(b) [Reserved]

(c) *Accounting for grant-related income—(1) Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) *Grant closeout—(1) Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the

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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.

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- 59a.11 Programs to which these regulations apply.
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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: