

**Public Health Service, HHS**

**§ 59.1**

and other educational costs the Secretary determines to be allowable.

[45 FR 71568, Oct. 29, 1980]

**Subparts HH–PP [Reserved]**

**PART 58—GRANTS FOR TRAINING OF PUBLIC HEALTH AND ALLIED HEALTH PERSONNEL**

**Subparts A–F [Reserved]**

**PART 59—GRANTS FOR FAMILY PLANNING SERVICES**

**Subpart A—Project Grants for Family Planning Services**

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**Subpart A—Project Grants for Family Planning Services**

AUTHORITY: 42 U.S.C. 300 through 300a-6.

SOURCE: 65 FR 41278, July 3, 2000, unless otherwise noted.

**§ 59.1 To what programs do these regulations apply?**

(a) 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. Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and subrecipients, and grantees shall require and ensure that subrecipients (and the subrecipients of subrecipients) comply with the requirements contained in these regulations pursuant to their written contracts with such subrecipients.

(b) Except for §§ 59.4, 59.8, and 59.10, the regulations of this subpart are also applicable to the execution of contracts 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, and will be applied in accordance with the applicable statutes, procedures and regulations that generally govern Federal contracts. To this extent, the use of the terms “grant”, “award”, “grantee”, and “subrecipient” in applicable regulations of this subpart will apply similarly to contracts, contractors and subcontractors, and the use of the term “project” or “program” will

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also apply to a project or program established by means of a contract.

[84 FR 7786, Mar. 4, 2019, as amended at 84 FR 14313, Apr. 10, 2019]

### § 59.2 Definitions.

As used in this subpart:

*Act* means the Public Health Service Act, as amended.

*Advanced Practice Provider* means a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM).

*Family* means a social unit composed of one person, or two or more persons living together, as a household.

*Family planning* means the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. These means include a broad range of acceptable and effective family planning methods and services, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility, including information about or referrals for adoption. Family planning services include preconception counseling, education, and general reproductive and fertility health care, in order to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. Family planning methods and services are never to be coercive and must always be strictly vol-

untary. Family planning does not include postconception care (including obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.

*Grantee* means the entity that receives Federal financial assistance by means of a grant, and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.

*Low income family* means a family whose total income does not exceed 100% of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). The project director may find that low income family also includes members of families whose annual 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:

(1) Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:

(i) That it suspects the minor to be the victim of child abuse or incest; and  
(ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

(2) For the purpose of considering payment for contraceptive services only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage, the project director may consider her insurance coverage

status as a good reason why she is unable to pay for contraceptive services. In making that determination, the project director must also consider other circumstances affecting her ability to pay, such as her total income. The project director may, for the purpose of considering whether the woman is from a low income family or is eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5, consider her annual income as being reduced by the total annual out-of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs, or estimate them at \$600.

*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.

*Program* and *project* are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by, a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.

*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.

*Subrecipient* means any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be

referred to as “delegates” or “contract agencies.”

[65 FR 41278, July 3, 2000; 65 FR 49057, Aug. 10, 2000; 84 FR 7787, Mar. 4, 2019; 84 FR 14313, Apr. 10, 2019]

**§ 59.3 Who is eligible to apply for a family planning services grant or contract?**

Any public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.

[84 FR 7787, Mar. 4, 2019]

**§ 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 family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents). Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range

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of such family planning methods and 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.<sup>1</sup>

(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, promote, refer for, or support abortion as a method of family planning.

(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) 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.

(12) Should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:

(i) Subrecipients and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided;

(ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and

(iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(14) Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).

(b) In addition to the requirements of paragraph (a) of this section, each

<sup>1</sup>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.”

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 referral to other medical facilities when medically necessary, consistent with § 59.14(a), 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) Except as provided in § 59.14(a), 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 41273, July 3, 2000; 65 FR 49057, Aug. 10, 2000; 84 FR 7787, Mar. 4, 2019]

**§ 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:

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(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 statutory provisions applicable to the Title X program, and ensure that no Title X funds are used where abortion is a method of family planning.

(b) Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process, but shall be deemed ineligible for funding. The Department will explicitly summarize each requirement of the Title X regulations or include the Title X regulations in their entirety within the Funding Announcement, and shall require each applicant to describe its plans for affirmative compliance with each requirement.

(c) If the proposal is deemed compliant with this regulation, then applicants will be subject to criteria for selection within the competitive grant review process, including:

(1) The degree to which the applicant's project plan adheres to the Title X statutory purpose and goals for the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents), while

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meeting all of the statutory and regulatory requirements and restrictions, including that none of the funds shall be used in programs where abortion is a method of family planning.

(2) The degree to which the relative need of the applicant for Federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.

(3) The degree to which the applicant takes into account the number of patients, particularly low-income patients, to be served while also targeting areas that are more sparsely populated and/or places in which there are not adequate family planning services available.

(4) The extent to which family planning services are needed locally and the applicant proposes innovative ways to provide services to unserved or underserved communities.

(d) 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.

(e) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

[65 FR 41278, July 3, 2000, as amended at 84 FR 7788, Mar. 4, 2019]

### **§ 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 75, subpart E.

[65 FR 41278, July 3, 2000, as amended at 81 FR 3009, Jan. 20, 2016]

**§ 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 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards
- 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 activi-

ties 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

[65 FR 41278, July 3, 2000, as amended at 81 FR 3009, Jan. 20, 2016]

**§ 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 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; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

[84 FR 7788, Mar. 4, 2019]

**§ 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 as amended at 65 FR 49057, Aug. 10, 2000]

**§ 59.13 Standards of compliance with prohibition on abortion.**

A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through

59.16. A project supported under this subpart must comply with such requirements at all times during the project period.

[84 FR 7788, Mar. 4, 2019]

**§ 59.14 Requirements and limitations with respect to post-conception activities.**

(a) *Prohibition on referral for abortion.* A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.

(b) *Information about prenatal care.* (1) Because Title X funds are intended only for family planning, once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care. The Title X provider may also choose to provide the following counseling and/or information to her:

(i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;

(ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);

(iii) Referral to social services or adoption agencies; and/or

(iv) Information about maintaining the health of the mother and unborn child during pregnancy.

(2) In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency.

(c) *Use of permitted lists or referrals to encourage abortion.* (1) A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

(2) The list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in paragraph (b)(1)(ii) of this section may be limited to those that do not provide abortion, or may

include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortion.

(d) *Provision of medically necessary information.* Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that 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 such information does not promote abortion as a method of family planning.

(e) *Examples.* (1) A pregnant client of a Title X project requests prenatal health care services. Because the provision of such services is outside the scope of family planning supported by Title X, the client is referred for prenatal care and may be provided a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). Provision of a referral for prenatal health care is consistent with this part because prenatal care is a medically necessary service.

(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 complies with the requirements of paragraph (b) of this section.

(3) After receiving nondirective counseling at a Title X provider, a pregnant woman decides to have an abortion, is concerned about her safety during the procedure, and asks the Title X project to provide her with a referral to an abortion provider. The Title X project tells her that it does not refer for abortion, but provides the following: A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), which is not presented as a referral for abortion, but as a list of comprehensive primary care and prenatal care providers that does not identify which providers perform abortion, and the project staff

member does not identify such providers on the list; and information about maintaining her health and the health of her unborn child during pregnancy. Such actions comply with paragraphs (a) through (c) 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 that consists of hospitals and clinics and other providers, all of which provide comprehensive primary health care (including prenatal care), as well as abortion as a method of family planning. Although there are several licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in the area that do not provide abortion as a method of family planning, none of these providers is included on the list. Provision of the list is inconsistent with paragraphs (a) and (c) of this section.

(5) A pregnant woman requests information on abortion and asks the Title X project to refer her for an abortion. The counselor tells her that the project does not consider abortion a method of family planning and, therefore, does not refer for abortion. The counselor offers her nondirective pregnancy counseling, which may discuss abortion, but the counselor neither refers for, nor encourages, abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services and offers her the list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), assistance, and information for pregnant women described in paragraph (b) of this section. None of the providers on the list provide abortions. Such actions are consistent with paragraphs (a) through (c) 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 rel-

ative safety of various contraceptive methods and in no way promoting abortion as a method of family planning. The provision of this information is consistent with paragraph (d) of this section and this section generally and does not constitute an abortion referral.

[84 FR 7788, Mar. 4, 2019]

**§ 59.15 Maintenance of physical and financial separation.**

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 Public Health Service Act and §§ 59.13, 59.14, and 59.16 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 independence 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:

(a) The existence of separate, accurate accounting records;

(b) The degree of separation from facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;

(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

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

[84 FR 7788, Mar. 4, 2019, as amended at 84 FR 14313, Apr. 10, 2019]

**§ 59.16 Prohibition on activities that encourage, promote, or advocate for abortion.**

(a) *Prohibition on activities that encourage abortion.* (1) A Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions in the funded project that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion for family planning purposes.

(2) Prohibited actions include the use of Title X project funds for the following:

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

(ii) Providing speakers or educators who promote the use of abortion as a method of family planning;

(iii) Attending events or conferences during which the grantee or sub-recipient engages in lobbying;

(iv) Paying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes;

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

(vi) Developing or disseminating in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning.

(b) *Examples.* (1) Clients at a Title X project are given brochures advertising a clinic that provides abortions, or such brochures are available in any fashion at a Title X clinic (sitting on a table or available or visible within the same space where Title X services are provided). Provision or availability of the brochure violates paragraph (a)(2)(vi) of this section.

(2) A Title X project makes an appointment for a pregnant client for an abortion for family planning purposes. The Title X project has violated paragraph (a)(1) of this section.

(3) A Title X project pays dues with project funds to a State association that, 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 and does not separately collect and segregate the funds for such purposes. Payment of dues to the association violates paragraph (a)(2)(iv) 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 that, 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)(2)(iv) 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)(2)(i) 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, in their personal capacities and using no project funds to do so. The Title X project has not violated paragraph (a)(2)(i) 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)(2)(i) of this section.

(8) A Title X project uses Title X funds for sex education classes in a local high school. During the course of the class, information is distributed to students that includes abortion as a method of family planning. The Title X project has violated paragraph (a)(2)(vi) of this section.

[84 FR 7788, Mar. 4, 2019]

**§ 59.17 Compliance with reporting requirements.**

(a) Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, “State notification laws”).

(b) A project may not receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:

(1) Has in place and implements a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:

(i) A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client’s sexual partner(s);

(ii) Timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or provider with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws.

(iii) Protocols to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and

(iv) Commitment to conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STDs.

(2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section, including which:

(i) Indicate the age of minor clients;

(ii) Indicate the age of the minor client’s sexual partners if such age is an element of a State notification law under which a report is required; and

(iii) Document each notification or report made pursuant to such State notification laws.

(c) Continuation of grantee or sub-recipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.

(d) The Secretary may review records maintained by a grantee or sub-recipient for the purpose of ensuring compliance with the requirements of this section, the requirement to encourage family participation in family planning decisions, or any other section of this rule.

[84 FR 7788, Mar. 4, 2019]

**§ 59.18 Appropriate use of funds.**

(a) Title X funds shall not be used to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient. Funds shall only be used for the purposes, and in direct implementation of, the funded project, expressly permitted by this regulation and authorized within section 1001 of the Public Health Service Act, that is, to offer family planning methods and services. Grantees must use the majority of grant funds to provide direct services to clients, and each grantee shall provide a detailed plan or accounting for the use of grant dollars, both in their applications for funding, and in any annually required reporting. Any significant change in the use of grant funds within the grant cycle shall not be undertaken without the approval of the Office of Population Affairs.

(b) Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for office.

(c) Each project supported under Title X shall fully account for, and justify, charges against the Title X grant. The Department shall put additional protections in place to prevent possible misuse of Title X funds through

## § 59.19

misbilling or overbilling, or any other unallowable expense.

[84 FR 7788, Mar. 4, 2019]

### § 59.19 Transition provisions; compliance.

(a) *Compliance date concerning physical and financial separation.* The date by which covered entities must comply with the physical separation requirements contained in § 59.15 is March 4, 2020. The date by which covered entities must comply with the financial separation requirements contained in § 59.15 is July 2, 2019.

(b) *Compliance date concerning applications.* The date by which covered entities must comply with § 59.7 and 59.5(a)(13) (as it applies to grant applications) is the date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.

(c) *Compliance date concerning reporting, assurance, and provision of service requirements.* The date by which covered entities must comply with §§ 59.5(a)(12), 59.5(a)(13) (as it applies to all required reports), 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18 is July 2, 2019.

[84 FR 7788, Mar. 4, 2019, as amended at 84 FR 14313, Apr. 10, 2019]

## 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).

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### § 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.<sup>1</sup> 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 program planning and deployment of resources;

(3) The capacity of the applicant to make rapid and effective use of such assistance;

<sup>1</sup> 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.

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(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 45 CFR part 75, subpart E.

(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; 81 FR 3009, Jan. 20, 2016]

### § 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all

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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 45 CFR part 75, subpart E.

(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; 81 FR 3009, Jan. 20, 2016]

### § 59.209 Civil rights.

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d *et seq.*) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

**§ 59.210 Inventions or discoveries.**

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

**§ 59.211 Publications and copyright.**

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, non-exclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

**§ 59.212 Grantee accountability.**

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for in-

direct 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 45 CFR 75.307, 75.371 through 75.385, and 75.316–75.325.

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; 81 FR 3009, Jan. 20, 2016]

**§ 59.213**

**§ 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 75.**

The provisions of 45 CFR part 75, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part.

[81 FR 3009, Jan. 20, 2016]

**PART 59a—NATIONAL LIBRARY OF MEDICINE GRANTS**

**Subpart A—Grants for Establishing, Expanding, and Improving Basic Resources**

Sec.

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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:

*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