

**Title X Regulations – Comparison of Current Regulations and 2018 Notice of Proposed Rulemaking**  
(May 30, 2018)

\*New language in RED; proposed deletions are struck through

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

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Current Regulations (42 CFR Part 59; <a href="https://www.hhs.gov/opa/sites/default/files/final-rules-42-cfr-59.pdf">https://www.hhs.gov/opa/sites/default/files/final-rules-42-cfr-59.pdf</a> )	2018 Notice of Proposed Rulemaking ( <a href="https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-11673.pdf">https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-11673.pdf</a> )
<p><b>§59.1 To what programs do these regulations apply?</b> 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.</p>	<p><b>§ 59.1 To what programs do these regulations apply?</b> (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. <b>Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and subrecipients, grantees shall require subrecipients (and the subrecipients of subrecipients) to comply with the requirements contained in such regulations pursuant to their written contracts with such subrecipients, and shall be required to ensure that their subrecipients (and the subrecipients of subrecipients) comply with such requirements.</b> (b) Except for §§ 59.3, 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</p>

	<p>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 also apply to a project or program established by means of a contract.</p>
<p><b>§59.2 Definitions.</b>  As used in this subpart:  <i>Act</i> means the Public Health Service Act, as amended.  <i>Family</i> means a social unit composed of one person, or two or more persons living together, as a household.  <i>Low income family</i> means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.  <i>Nonprofit</i>, 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.  <i>Secretary</i> 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.  <i>State</i> 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.</p>	<p><b>§ 59.2 Definitions.</b>  As used in this subpart:  <i>Act</i> means the Public Health Service Act, as amended.  <i>Family</i> means a social unit composed of one person, or two or more persons living together, as a household.  <i>Family planning</i> 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 choices, 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 adoption). Family planning services include preconceptional counseling, education, and general reproductive and fertility health care 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 and family planning services are never coercive and are strictly voluntary. 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.  <i>Grantee</i> 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.  <i>Low income family</i> means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example:  (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</p>

	<p>guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not be required if the Title X provider has documented in the medical record:</p> <p>(i) That it suspects the minor to be the victim of child abuse or incest; and</p> <p>(ii) That it has, consistent with and if permitted or required by applicable State or local law, reported the situation to the relevant authorities.</p> <p>(2) With respect to contraceptive services, a woman can be considered from a "low-income family" if she has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage.</p> <p><i>Nonprofit</i>, 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.</p> <p><i>Program and project</i> are used interchangeably and mean a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement and 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.</p> <p><i>Secretary</i> 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.</p> <p><i>State</i> 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, <i>et al.</i>), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.</p> <p><i>Subrecipient</i> 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."</p>
<p><b>§59.3 Who is eligible to apply for a family planning services grant?</b> Any public or nonprofit private entity in a State may apply for a grant under this subpart.</p>	<p>NO ACTUAL CHANGE (change referenced in proposal is to 2016 version of the regulation that was rescinded in 2017 through the Congressional Review Act)</p>
<p><b>§59.4 How does one apply for a family planning services grant?</b> (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;</p>	<p>NO CHANGE</p>

<p>(2) A budget and justification of the amount of grant funds requested;</p> <p>(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</p> <p>(4) Such other pertinent information as the Secretary may require.</p>	
<p><b>§59.5 What requirements must be met by a family planning project?</b></p> <p>(a) Each project supported under this part must:</p> <p>(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.</p> <p>(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.</p> <p>(3) Provide services in a manner which protects the dignity of the individual.</p> <p>(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.</p> <p>(5) Not provide abortion as a method of family planning. A project must:</p> <p>(i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:</p> <p>(A) Prenatal care and delivery;</p> <p>(B) Infant care, foster care, or adoption; and</p> <p>(C) Pregnancy termination.</p> <p>(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.</p> <p>(6) Provide that priority in the provision of services will be given to persons from low-income families.</p> <p>(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.</p> <p>(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</p>	<p><b>§ 59.5 What requirements must be met by a family planning project?</b></p> <p>(a) Each project supported under this part must:</p> <p>(1) Provide a broad range of acceptable and effective <del>medically approved</del> family planning methods (including <del>contraceptives</del>, natural family planning <del>and other fertility-awareness based</del> methods) and services (including infertility services, <del>including adoption</del>, and services for adolescents). <del>If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services. 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 of such family planning methods and services.</del></p> <p>(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.</p> <p>(3) Provide services in a manner which protects the dignity of the individual.</p> <p>(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.</p> <p>(5) Not provide, <del>promote, refer for, support, or present</del> abortion as a method of family planning. A <del>project must:</del></p> <p>(i) <del>Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options:</del></p> <p><del>(A) Prenatal care and delivery;</del></p> <p><del>(B) Infant care, foster care, or adoption; and</del></p> <p><del>(C) Pregnancy termination.</del></p> <p>(ii) <del>If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.</del></p> <p>(6) Provide that priority in the provision of services will be given to persons from low-income families.</p> <p>(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.</p>

<p>schedule of fees designed to recover the reasonable cost of providing services.</p> <p>(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.</p> <p>(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.</p> <p>(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.</p> <p>(11) Provide for an Advisory Committee as required by §59.6.</p> <p>(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:</p> <p>(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.</p> <p>(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.</p> <p>(3) Provide for informational and educational programs designed to—</p> <p>(i) Achieve community understanding of the objectives of the program;</p> <p>(ii) Inform the community of the availability of services; and</p> <p>(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.</p> <p>(4) Provide for orientation and in-service training for all project personnel.</p> <p>(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.</p> <p>(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.</p>	<p>(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.</p> <p>(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.</p> <p><del>(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.</del></p> <p><del>(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.</del></p> <p>(11) Provide for an Advisory Committee as required by §59.6.</p> <p><b>(12) In order to promote holistic health and provide seamless care, Title X service providers 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.</b></p> <p><b>(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:</b></p> <p><b>(i) Subrecipients and referral agencies and individuals by name, location, expertise and services provided or to be provided;</b></p> <p><b>(ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, as well as less formal partners within the community, in order to demonstrate a seamless continuum of care for clients; and</b></p> <p><b>(iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services.</b></p> <p><b>(14) Encourage family participation in the decision of minors to seek family planning services and ensure that the records maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).</b></p>
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<p>(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>	<p>(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:</p> <p>(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, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.</p> <p>(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.</p> <p>(3) Provide for informational and educational programs designed to—</p> <p>(i) Achieve community understanding of the objectives of the program;</p> <p>(ii) Inform the community of the availability of services; and</p> <p>(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.</p> <p>(4) Provide for orientation and in-service training for all project personnel.</p> <p>(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.</p> <p>(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.</p> <p>(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>
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<p><b>§59.6 What procedures apply to assure the suitability of informational and educational material?</b></p> <p>(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.</p> <p>(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:</p> <p>(1) <i>Size.</i> 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.</p> <p>(2) <i>Composition.</i> 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.</p> <p>(3) <i>Function.</i> In reviewing materials, the Advisory Committee shall:</p> <p>(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;</p> <p>(ii) Consider the standards of the population or community to be served with respect to such materials;</p> <p>(iii) Review the content of the material to assure that the information is factually correct;</p> <p>(iv) Determine whether the material is suitable for the population or community to which is to be made available; and</p> <p>(v) Establish a written record of its determinations.</p>	<p>NO CHANGE</p>
<p><b>§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?</b></p> <p>(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:</p> <p>(1) The number of patients, and, in particular, the number of low-income patients to be served;</p> <p>(2) The extent to which family planning services are needed locally;</p> <p>(3) The relative need of the applicant;</p> <p>(4) The capacity of the applicant to make rapid and effective use of the federal assistance;</p> <p>(5) The adequacy of the applicant's facilities and staff;</p> <p>(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</p> <p>(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.</p> <p>(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the</p>	<p><b>§ 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 amounts?</b></p> <p>(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 <b>statutory provisions applicable to the Title X program.</b> <del>section 1001 of the Act, taking into account:</del></p> <p>(1) <del>The number of patients, and, in particular, the number of low-income patients to be served;</del></p> <p>(2) <del>The extent to which family planning services are needed locally;</del></p> <p>(3) <del>The relative need of the applicant;</del></p> <p>(4) <del>The capacity of the applicant to make rapid and effective use of the federal assistance;</del></p> <p>(5) <del>The adequacy of the applicant's facilities and staff;</del></p> <p>(6) <del>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</del></p> <p>(7) <del>The degree to which the project plan adequately provides for the requirements set forth in these regulations.</del></p>

<p>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.</p> <p>(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.</p>	<p>(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 provision of the regulation (or include the entire regulation) within the Funding Announcement, and shall require each applicant to describe their plans for affirmative compliance with each provision.</p> <p>(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:</p> <p>(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), which meet all of the statutory and regulatory requirements and restrictions, and where none of the funds...shall be used in programs where abortion is a method of family planning.</p> <p>(2) The degree to which the relative need of the applicant is demonstrated in the proposal and the applicant shows capacity to make rapid and effective use of grant funds, including and especially among a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations.</p> <p>(3) The degree to which the applicant takes into account the number of 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.</p> <p>(4) The extent to which family planning services are needed locally and the applicant proposes innovative ways to provide services to unserved or underserved patients.</p> <p><del>(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.</del></p> <p><del>(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.</del></p>
<p><b>§59.8 How is a grant awarded?</b></p> <p>(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompet for funds. This period, called the project period, will usually be for three to five years.</p> <p>(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.</p>	<p>NO CHANGE</p>

**Commented [RS1]:** In the draft document, these two paragraphs were proposed as a redesignation: "Amend § 59.7 by a. Redesignating paragraphs (b) and (c) as (d) and (e); b. Adding new paragraphs (a), (b), and (c) as follows..."

In the NPRM, the up front language simply reads: "Revise § 59.7 to read as follows" and does not include a redesignation of current paragraphs (b) and (c), thereby deleting those paragraphs from the NPRM.



<p>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.</p>	
<p><b>§59.9 For what purpose may grant funds be used?</b> 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.</p>	NO CHANGE
<p><b>§59.10 What other HHS regulations apply to grants under this subpart?</b> Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include: <i>(note: citations omitted in this document)</i></p>	NO CHANGE
<p><b>§59.11 Confidentiality.</b> All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.</p>	<p><b>§ 59.11 Confidentiality.</b> All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and <del>must</del> 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; <b>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.</b> Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.</p>
<p><b>§59.12 Additional conditions.</b> 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.</p>	NO CHANGE
	<p><b>§ 59.13 Standards of compliance with prohibition on abortion.</b> A project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that, as a Title X grantee, it 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</p>

	with such requirements at all times during the project period.
	<p><b>§ 59.14 Prohibition on referral for abortion.</b></p> <p>(a) <i>Prohibition on referral for abortion.</i> 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. If asked, a medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is currently pregnant clearly states that she has already decided to have an abortion. This list is only to be provided to a woman who, of her own accord, makes such a request. The list shall not identify the providers who perform abortion as such. All other patients will be provided, upon request, a list of licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services.</p> <p>(b) <i>Referral for prenatal services.</i> 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 must be referred for appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption), and shall be given assistance with setting up a referral appointment to optimize the health of the mother and unborn child. She must also be provided with information necessary to protect her health and the health of the unborn child until such a time as the referral appointment is kept. 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 emergency medical services.</p> <p>(c) <i>Use of permitted referrals to encourage abortion.</i> A Title X project may not use prenatal, social service, emergency medical, or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning. Recognizing, however, the duty of a physician to promote patient safety, a doctor may, if asked, provide a list of licensed, qualified, comprehensive health service providers (some of which also provide abortion, in addition to comprehensive prenatal care). Such information related to abortion is permitted only if a woman who is currently pregnant clearly states that she has already decided to have an abortion.</p> <p>(d) <i>Provision of medically necessary information.</i> 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 otherwise promote abortion as a method of family planning.</p> <p>(e) <i>Examples.</i> (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</p>

services is outside the scope of family planning supported by Title X, the client must be referred to appropriate providers of prenatal care. Provision of prenatal services within the Title X project is inconsistent with this part.

(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 comprehensive care 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 her a list of licensed, qualified health care professionals in the area (some of whom provide abortion as part of their primary health care services). The list includes, among other licensed, qualified, comprehensive health care providers, a local health care professional who provides abortions in addition to comprehensive prenatal care. Inclusion of this provider/clinic on the list is consistent with paragraph (a) 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 that provide prenatal care and abortions. None of the entries on the list are providers that principally provide abortions. Although there are several appropriate licensed, qualified providers of prenatal care in the area that do not provide or refer for abortions, none of these providers are 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 project counselor tells her that the project does not consider abortion a method of family planning and therefore does not 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 referral.

**§ 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

	<p>the review established in this section, from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 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:</p> <ul style="list-style-type: none"> <li>(a) The existence of separate, accurate accounting records;</li> <li>(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;</li> <li>(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and</li> <li>(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.</li> </ul>
	<p><b>§ 59.16 Prohibition on activities that encourage, promote or advocate for abortion.</b></p> <p>(a) <i>Prohibition on activities that encourage abortion.</i> A Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions to assist women to obtain abortions or to increase the availability or accessibility of abortion for family planning purposes. Prohibited actions include the use of Title X project funds for the following:</p> <ul style="list-style-type: none"> <li>(1) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning;</li> <li>(2) Providing speakers or educators who, in the Title X project or the use of Title X project funds, promote the use of abortion as a method of family planning;</li> <li>(3) Attending events or conferences during which the grantee or subrecipient engages in lobbying;</li> <li>(4) 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;</li> <li>(5) Using legal action to make abortion available in any way as a method of family planning; and</li> <li>(6) Developing or disseminating in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning or otherwise promoting a favorable attitude toward abortion.</li> </ul> <p>(b) <i>Examples.</i> (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</p>

	<p>or availability of the brochure violates paragraph (a)(6) of this section.</p> <p>(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.</p> <p>(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. Payment of dues to the association violates paragraph (a)(4) of this section.</p> <p>(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)(4) of this section.</p> <p>(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.</p> <p>(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)(1) of this section.</p> <p>(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.</p> <p>(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) of this section.</p>
	<p><b>§ 59.17 Compliance with reporting requirements.</b></p> <p>(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").</p> <p>(b) A project may not receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:</p> <p>(1) Has in place and implemented a plan to comply with State laws Such plan shall include, at a minimum, policies and procedures with respect to such notification and reporting that include:</p>

	<p>(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 or determine the age of a minor client or of a minor client's sexual partner(s);</p> <p>(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; and compliance with State notification laws.</p> <p>(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</p> <p>(iv) Commitment to conduct a preliminary screening of any teen who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Such screening would be required with respect to any individual who is under the age of consent in the state of the proposed service area. Projects are permitted to diagnose, test for, and treat STDs.</p> <p>(2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section, including which:</p> <p>(i) Indicate the age of minor clients;</p> <p>(ii) Indicate the age of the minor client's sexual partners where required by law, and</p> <p>(iii) Document each notification or report made pursuant to such State notification laws.</p> <p>(c) Continuation of grantee or subrecipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.</p> <p>(d) The Secretary may review records maintained by a grantee or subrecipient for the sole purpose of ensuring compliance with the requirements of this section.</p>
	<p><b>§ 59.18 Appropriate use of funds.</b></p> <p>(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 with 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 give a detailed accounting for the use of grant dollars, both in their applications for funding, and within any annually required reporting. Further, any significant change in the usage of grant funds within the grant cycle shall not be undertaken without the approval of the Office of Population Affairs.</p> <p>(b) Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in</p>

	<p>any way tends to promote public support or opposition to any legislative proposal or candidate for office.</p> <p>(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 any possible misuse of Title X funds through misbilling or overbilling, or any other unallowable expense.</p>
	<p><b>§ 59.19 Transition Provisions.</b></p> <p>(a) In accordance with § 59.15, with respect to the requirement for physical separation that is effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], covered entities must comply with the applicable new requirements [DATE 1 year after the publication of the final rule].</p> <p>(b) In accordance with § 59.15, with respect to the requirement for financial separation is effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], covered entities must comply with the applicable new requirements no later than [DATE 60 days AFTER PUBLICATION OF THE FINAL RULE].</p> <p>(c) In regards to all other requirements are effective after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], covered entities must comply no later than 60 days following publication of the final rule.</p>