

PART 59—GRANTS FOR FAMILY PLANNING SERVICES
Subpart A—Project Grants for Family Planning Services

- Sec.
 59.1 To what programs do these regulations apply?
 59.2 Definitions.
 59.3 Who is eligible to apply for a family planning services grant?
 59.4 How does one apply for a family planning services grant?
 59.5 What requirements must be met by a family planning project?
 59.6 What procedures apply to assure the suitability of informational and educational material?
 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?
 59.8 How is a grant awarded?
 59.9 For what purposes may grant funds be used?
 59.10 What other HHS regulations apply to grants under this subpart?
 59.11 Confidentiality.
 59.12 Additional conditions.

Subpart A—Project Grants for Family Planning Services

Commented [RS1]: Some items in the left-hand column are spaced in this document to make comparison with the proposed changes easier.

2000 Regulations	2021 NPRM
<p>§ 59.1 To what programs do these regulations apply?</p> <p>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>§ 59.1 To what programs do these regulations apply?</p> <p>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. 3200) 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>§ 59.2 Definitions.</p> <p>As used in this subpart: Act means the Public Health Service Act, as amended.</p> <p><i>Family</i> means a social unit composed of one person, or two or more persons living together, as a household.</p>	<p>§ 59.2 Definitions.</p> <p>As used in this subpart: Act means the Public Health Service Act, as amended.</p> <p><i>Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents. Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions. Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.</i></p> <p><i>Family</i> means a social unit composed of one person, or two or more persons living together, as a household.</p>

Commented [RS2]: NPRM lists 42 U.S.C. 3200 here, which is a typo; should read 42 U.S.C. 300.

<p><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.</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>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><u><i>Family planning services include a broad range of medically approved contraceptive services, which includes Food and Drug Administration (FDA)-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.</i></u></p> <p><u><i>Health equity is when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.</i></u></p> <p><u><i>Inclusivity ensures that all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.</i></u></p> <p><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.</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><u><i>Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.</i></u></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><u><i>Service site is a clinic or other location where Title X services (under the Act) are provided to clients.</i></u></p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Commented [RS3]: Note: This change in italics appears to be a typo; there appear to be several such italics mistakes in this section.

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<p>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.</p>	<p><u>Title X recipients and/or their subrecipients may have service sites.</u></p> <p>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.</p> <p><u>Trauma-informed means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.</u></p>
<p>§ 59.3 Who is eligible to apply for a family planning services grant?</p> <p>Any public or nonprofit private entity in a State may apply for a grant under this subpart.</p>	<p>NO CHANGE</p>
<p>§ 59.4 How does one apply for a family planning services grant?</p> <p>(a) Application for a grant under this subpart shall be made on an authorized form.</p> <p>(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.</p> <p>(c) The application shall contain—</p> <p>(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;</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>NO CHANGE</p>
<p>§ 59.5 What requirements must be met by a family planning project?</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</p>	<p>§ 59.5 What requirements must be met by a family planning project?</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 <u>pregnancy</u></p>

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<p>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.¹</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>testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health 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 acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a referral to the client's method of choice and the referral must not unduly limit the client's access to their method of choice.</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.²</p> <p>(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed, which protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.</p> <p>(4) Provide services without regard ofto religion, race, color, national origin, disabilityhandicapping 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 clientswomen the opportunity to be provided information and counseling regarding each of the following options:</p> <p>(A) Prenatal care and delivery;</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Commented [RS4]: This is footnote 1 in the NPRM, but appears here as footnote 2 simply to differentiate from the 2000 rule text.

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

² 42 U.S.C. 300a-8 (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."

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<p>(B) Infant care, foster care, or adoption; and (C) Pregnancy termination. (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling. (6) Provide that priority in the provision of services will be given to persons from low-income families. (7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge. (8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.</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</p>	<p>(B) Infant care, foster care, or adoption; and (C) Pregnancy termination. (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant clientwoman indicates theyshe does not wish to receive such information and counseling. (6) Provide that priority in the provision of services will be given to clientspersons from low-income families. (7) Provide that no charge will be made for services provided to any clientspersons from a low-income family except to the extent that payment will be made by a third party (including a Ggovernment agency) which is authorized to or is under legal obligation to pay this charge. (8) Provide that charges will be made for services to clientspersons 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. <u>(i) Family income should be assessed before determining whether copayments or additional fees are charged.</u> <u>(ii) With regard to insured clients, clients whose family income is at or below 250% Federal poverty line (FPL) should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.</u> <u>(9) Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.</u> (10) 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</p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<p>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>XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.</p> <p>(119)(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 subrecipientsgrantees 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 subrecipientsgrantees in the ongoing policy decision making of the project.</p> <p>(121) Provide for an Advisory Committee as required by § 59.6. 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"). Title X projects must provide appropriate documentation or other assurance satisfactory to the Secretary that it:</p> <p>(i) Has in place and implements a plan to comply with State notification laws.</p> <p>(ii) Provides 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 for providers 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.</p> <p>(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:</p> <p>(i) Subrecipients and agencies or individuals providing referral services and the services to be provided;</p> <p>(ii) 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</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>(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><u>(iii) Explanation of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.</u></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 <u>physician’s consultation by a healthcare provider</u>, 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 <u>opportunities for community education, participation, and engagement informational and educational programs designed to:—</u></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 <u>diverse</u> persons to whom family planning services may be beneficial <u>to ensure access to equitable, affordable, client-centered, quality family planning services.</u></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) Provide for coordination and use of referrals <u>and linkages arrangements</u> with <u>primary healthcare</u> other providers, <u>other providers</u> of health-care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other</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><u>Federal programs, who are in close proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.</u></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 <u>recipientgrantee</u>. The <u>recipientgrantee</u> 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>§ 59.6 What procedures apply to assure the suitability of informational and educational material?</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>§ 59.6 What procedures apply to assure the suitability of informational and educational material?</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 (<u>print and electronic</u>) 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 <u>T</u>itle 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 <u>but not more than nine</u> members <u>and up to as many members the recipient determines</u>, 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 <u>of the population or community for which the materials are intended</u> (in terms of demographic factors such as race, <u>ethnicity</u>, color, national origin, <u>handicapped condition</u>disability, sex, <u>sexual</u></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;</p> <p>and</p> <p>(v) Establish a written record of its determinations.</p>	<p><u>orientation, gender identity, and age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.) of the population or community for which the materials are intended.</u></p> <p>(3) <i>Function.</i> In reviewing materials, the Advisory Committee shall:</p> <p>(i) Consider the educational, <u>and cultural, and diverse</u> 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, <u>medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;</u></p> <p>(iiiiv) Determine whether the material is suitable for the population or community to which is to be made available;</p> <p>and</p> <p>(iv) Establish a written record of its determinations.</p>
<p>§ 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?</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>§ 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?</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 <u>clientspatients</u>, and, in particular, the number of low-income <u>clientspatients</u> to be served;</p> <p>(2) The extent to which family planning services are needed locally;</p> <p>(3) <u>The ability of the applicant to advance health equity;</u></p> <p>(4) The relative need of the applicant;</p> <p>(54) The capacity of the applicant to make rapid and effective use of the <u>F</u>federal assistance;</p>

Commented [RS5]: These are listed as (ii), (iii), and (iv) in the NPRM, but the numbering is incorrect; they should be (iii), (iv), and (v).

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<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 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>(5) The adequacy of the applicant's facilities and staff;</p> <p>(76) 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>(87) 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 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>§ 59.8 How is a grant awarded?</p> <p>(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.</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. 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.</p> <p>(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>§ 59.8 How is a grant awarded?</p> <p>(a) The notice of grant award specifies how long <u>Department of Health and Human Services (HHS)</u> intends to support the project without requiring the project to recompete for funds. This <u>anticipated period</u>, 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 <u>recipientgrantee</u> 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 <u>recipientgrantee's</u> 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 <u>G</u>government.</p> <p>(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>§ 59.9 For what purpose may grant funds be used?</p> <p>Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the</p>	<p>§ 59.9 For what purpose may grant funds be used?</p> <p>Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the</p>

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<p>approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.</p>	<p>approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.</p>
<p>§ 59.11 Confidentiality.</p> <p>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>§ 59.10 Confidentiality.</p> <p>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. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.</p>
<p>§ 59.12 Additional conditions.</p> <p>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>	<p>§ 59.11 Additional conditions.</p> <p>The Secretary may, with respect to any grant, impose additional conditions prior to, or at the time of, or during 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>
<p>§ 59.10 What other HHS regulations apply to grants under this subpart?</p> <p>Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include: 37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements 42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure 45 CFR Part 16—Procedures of the Departmental Grant Appeals Board 45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements</p>	<p>§ 59.12 What other HHS regulations apply to grants under this subpart?</p> <p>Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include: 37 CFR pPart 401—Rights to inventions made by nonprofit organizations and small business firms under Government grants, contracts, and cooperative agreements 42 CFR Ppart 50, Subpart D—Public Health Service grant appeals procedure 45 CFR pPart 16—Procedures of the Departmental Grant Appeals Board 45 CFR pPart 754—Uniform Aadministrative Rrequirements, Cost Principles, and Audit Requirements for HHS Awards for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and</p>

Commented [RS6]: The NPRM reorders the content of sections 59.10, 59.11, and 59.12 from the 2000 regulations, along with making substantive text changes within each section.

To make it easier to understand the substantive changes in these sections and compare to the text of the 2000 regulations, please note that the 2000 regulation sections 59.10, 59.11, and 59.12 appear out of order in the left-hand column, so they match the NPRM order.

- 2000 reg 59.10 (What other HHS regulations apply to grants under this subpart?) is 59.12 in NPRM
- 2000 reg 59.11 (Confidentiality) is 59.10 in NPRM
- 2000 reg 59.12 (Additional conditions) is 59.11 in NPRM

COMPARISON OF 2000 TITLE X REGULATION AND 2021 TITLE X NPRM, 42 CFR PART 59
 NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION
 APRIL 14, 2021

<p>with states, local governments and Indian tribal governments</p> <p>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</p> <p>45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title</p> <p>45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance</p> <p>45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance</p> <p>45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments</p>	<p>agreements with states, local governments and Indian tribal governments</p> <p>45 CFR pPart 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</p> <p>45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title</p> <p>45 CFR pPart 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance</p> <p>45 CFR part 87—Equal treatment for faith-based organizations</p> <p>45 CFR pPart 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance</p> <p>45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------