2021 Title X NPRM Overview

Ensuring access to equitable, affordable, client-centered, quality family planning services

April 2021



2021 Title X NPRM in the Federal Register

- Ensuring access to equitable, affordable, client-centered, quality family planning services (86 FR 19812)
 - ✓ CFR: 42 CFR 59
 - ✓ Regulatory Information Number: 0937-AA11
 - ✓ Document Number: 2021-07762
 - ✓ Available at https://www.federalregister.gov/documents/2021/04/15/2021-07762/ensuring-access-to-equitable-affordable-client-centered-quality-family-planning-services
- Proposes to revise the 2019 Title X rule (84 FR 7714) by readopting the 2000 regulations (65 FR 41270), with several modifications needed to strengthen the program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients

2021 Title X NPRM Public Comment Period

- Public Comment Period Open from 4/15/2021 5/17/2021
- You may submit comments, identified by RIN 0937-AA11, by any of the following methods:
 - Federal eRulemaking Portal: http://www.regulations.gov.
 - ✓ Enter the above docket ID number in the "Enter Keyword or ID" field and click on "Search."
 - ✓On the next web page, click on "Submit a Comment" and follow the instructions.

Mail or Hand Delivery to:

- ✓ Attn: Title X Rulemaking, Office of Population Affairs, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201
- ✓ Comments, including any personally identifiable or confidential businesses information, received prior to the close of the comment period will be posted without change to http://www.regulations.gov.

What's Included in the 2021 Title X NPRM

- Statutory Background
- Regulatory and Litigation Background
- Public Health Impact as a Result of the 2019 Rules and Reason for this Proposal
- Proposed Rules
- Regulatory Impact Analyses
- Environmental Impact
- Paperwork Reduction Act
- Proposed Regulatory Text

§ 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 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.

§ 59.2 Definitions.

As used in this subpart:

- Act means the Public Health Service Act, as amended.
- Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents. (WHO)
- Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions. (QFP)
- Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients. (OMH)
- Family means a social unit composed of one person, or two or more persons living together, as a household.

§ 59.2 Definitions.

- Family planning services include a broad range of medically approved contraceptive services, which includes 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.
- 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. (CDC)
- 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. (White House Executive Order)

§ 59.2 Definitions.

- Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.
- Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.
- Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable. (IOM)
- Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.
- Service site is a clinic or other location where Title X services are provided to clients. Title X recipients and/or their subrecipients may have service sites.

§ 59.2 Definitions.

- **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. Outlaying Islands (Midway, Wage, et al.), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.
- Trauma-informed: 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. (SAMHSA)

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

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

§ 59.4 How does one apply for a family planning services grant?

- (a) Application for a grant under this subpart shall be made on an authorized form.
- (b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.
- (c) The application shall contain—
 - (1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;
 - (2) A budget and justification of the amount of grant funds requested;
 - (3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and
 - (4) Such other pertinent information as the Secretary may require.

- (a) Each project supported under this part must:
- (1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services and, STI services, preconception health services, and adolescent-friendly health services). 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.

§ 59.5 What requirements must be met by a family planning project?

(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

¹42 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."

§ 59.5 What requirements must be met by a family planning project?

(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

- (4) Provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.
- (5) Not provide abortion as a method of family planning. A project must:
- (i) Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:
 - (A) Prenatal care and delivery;
 - (B) Infant care, foster care, or adoption; and
 - (C) Pregnancy termination.
- (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

- (6) Provide that priority in the provision of services will be given to clients from low-income families.
- (7) Provide that no charge will be made for services provided to any clients 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 clients 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.
 - (i) Family income should be assessed before determining whether copayments or additional fees are charged.
 - (ii) With regard to insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

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

§ 59.5 What requirements must be met by a family planning project?

(11)(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 subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

- (12) 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:
- (i) Has in place and implements a plan to comply with State notification laws.
- (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.

- (13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:
- (i) Subrecipients and agencies or individuals providing referral services and the services to be provided;
- (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
- (iii) Explanation of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

- (b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:
- (1) Provide for medical services related to family planning (including consultation by a healthcare provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

- (2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.
- (3) Provide for opportunities for community education, participation, and engagement to—:
- (i) Achieve community understanding of the objectives of the program;
- (ii) Inform the community of the availability of services; and
- (iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.

- (4) Provide for orientation and in-service training for all project personnel.
- (5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.
- (6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.
- (7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

- (8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.
- (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 recipient. The recipient must be prepared to substantiate, that these rates are reasonable and necessary.

§ 59.5 What requirements must be met by a family planning project?

(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.

§ 59.6 What procedures apply to assure the suitability of informational and educational material? (print and electronic)?

(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 (print and electronic) 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.

§ 59.6 What procedures apply to assure the suitability of informational and educational material? (print and electronic)?

- (a) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:
 - (1) Size. The Committee shall consist of no fewer than five members and up to as many members the recipient determines, except that this provision may be waived by the Secretary for good cause shown.
 - (2) Composition. The Committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, 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).

§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

- (a) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:
 - (3) Function. In reviewing materials, the Advisory Committee shall:
 - (i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;
 - (ii) Consider the standards of the population or community to be served with respect to such materials;
 - (iii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;
 - (iv) Determine whether the material is suitable for the population or community to which is to be made available; and
 - (v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

- (a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:
- (1) The number of clients, and, in particular, the number of low-income clients to be served;
- (2) The extent to which family planning services are needed locally;
- (3) The ability of the applicant to advance health equity;
- (4) The relative need of the applicant;
- (5) The capacity of the applicant to make rapid and effective use of the federal assistance;
- (6) The adequacy of the applicant's facilities and staff;
- (7) 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
- (8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

§ 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) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.
- (c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

- (a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This anticipated period will usually be for three to five years.
- (b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient 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 recipient's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.
- (c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 75.

§59.10 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

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.

§59.11 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to, 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.

§59.12 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following the HHS Department-wide regulations which apply to grants under this subpart. These include:

- 37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
- 42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure
- 45 CFR Part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards
- 45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

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Attention is drawn to the following the HHS Department-wide regulations which apply to grants under this subpart. These include:

- 45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title
- 45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance
- 45 CFR Part 87--Equal treatment for faith-based organizations
- 45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

Telemedicine (86 FR 19818)

The Department proposes revising the 2019 Title X
Final Rule through notice and comment rulemaking,
by readopting the 2000 regulations with revisions that
will enhance the Title X program and its family
planning services, including family planning services
provided using telemedicine, for the future. (86 FR
19818)

Restricting Subrecipients (86 FR 19817)

- The Department is also concerned that some state policies restricting eligible subrecipients unnecessarily interfere with beneficiaries' access to the most accessible and qualified providers. These state restrictions are not always related to the subrecipients' ability to effectively deliver Title X services, but rather are sometimes based either on the non-Title X activities of the providers or because they are a certain type of provider.
- The Department believes that these state restrictions on subrecipient eligibility unrelated to the ability to deliver Title X services undermine the mission of the program to ensure widely available access to services by the most qualified providers. Therefore, the Department invites comment on ways in which it can ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients. (86 FR 19817)

Regulatory Impact Analysis (86 FR 19820-19828)

- Provides a summary of estimated costs, benefits, and transfers of the 2021 Title X NPRM
- Benefits include:
 - Increase in number of grantees
 - Increase in number of clients served
 - Additional clients receive access to contraceptives, public health screenings, and STI testing resulting in significant cost savings from earlier treatment and other interventions
 - Increase in diversity of grantees receiving funds, including geographic diversity
- HHS requests comments that might facilitate refinement of the analysis

Paperwork Reduction Act (86 FR 19828)

- Proposed rule contains information collection requirements (ICRs) that are subject to review by OMB under the Paperwork Reduction Act of 1995
- HHS solicits comment on the following issues:
 - The need for the information collection and its usefulness in carrying out the proper functions of our agency.
 - The accuracy of our estimate of the information collection burden.
 - The quality, utility, and clarity of the information to be collected.
 - Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.



Thank you!