2021 Title X Notice of Federal Rulemaking Overview

Moderator: Office of Population Affairs
April 28, 2021
12:30 pm CT

Woman: Thank you for joining the Office of Population Affairs to learn more about our 2021 Title X Notice of Public Rulemaking which is titled Ensuring Access to Equitable, Affordable Client-Centered Quality Family Planning Services.

2021 Title X NPRM in the Federal Register

The 2021 Title X NPRM has been published in the federal register. And you can see on this slide, some information to help you find where it's located, including the link, the CFR number, regulatory information number, document number.

You can use all of that information to search on the Federal Register to locate the document. OPA is proposing to revise the 2019 Title X Rule by readopting the 2000 regulations with several modifications that are 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

The public comment period for the 2021 Title X NPRM is open starting from April 15 through May 17. There are two ways that you can submit comments - one through the Federal eRulemaking Portal and a second, by mail or hand delivery. If possible, we encourage you to please submit comments through the Federal eRulemaking Portal and you can locate the document again, using information on the previous slide, including the RAN number which is 0937-AA11.
What’s Included in the 2021 Title X NPRM

What's included in the 2021 Title X NPRM, includes a discussion on the statutory background for the Title X program, the regulation and litigation background, the public health impact as a result of the 2019 rules and reasons for this proposal, the proposed rules itself, regulatory impact analysis, environmental impact, Paperwork Reduction Act, and proposed regulatory text.

And what we are going to do in the webinar today is walk through the proposed regulatory text. There's a lot more in the NPRM. Again, in addition to the proposed regulatory text, we encourage you to go to the Federal Register Web site and read the document in its entirety. But we will walk through the proposed regulatory text now.

2021 Proposed Regulatory Text – §59.1

So, for the 2021 Title X NPRM Section 59.1, covers what programs these regulations apply. The regulations of this subpart are applicable to the award of grants under Section 1001 of the Public Health Service Act, to assist in the establishment and operation of voluntary family planning projects.

2021 Proposed Regulatory Text – §59.2

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. Section 59.2 covers the definitions that are included in the NPRM. And there are many definitions, including definition of Act which means the Public Health Service Act as amended; definition for adolescent-friendly health services, which are services that are accessible, acceptable, equitable, appropriate, and affective for adolescents.
This comes from the definition used by the WHO and the full citation for these definitions is included in the NPRM document itself. There's a definition for client-centered care which is respectful of and responsive to individual client preferences, needs and values. Client values guide all clinical decisions. That definition comes from CDC and OPA's quality family planning document.

This is the definition for cultural and linguistically appropriate services, which are respectful of and responsive to the health, beliefs, practices and needs of diverse patients. That comes from the Office of Minority Health. There is a definition for family which means a social unit composed of one person or two or more persons living together as a household.

There's also a definition for family planning services which include a broad range of medically approved contraceptive services including FDA approved contraceptive services and natural family planning methods for clients who want to prevent pregnancy and space birth; pregnancy testing and counseling; assistance to achieve pregnancy; basic infertility services; SCI services; and other preconception health services.

There's also a definition for health equity which 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.

There's a definition for inclusivity which 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, 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 persons, persons with disabilities, persons who live in rural areas, and persons otherwise adversely affected by persistent poverty or inequality.

There is also a definition for a low-income family which means a family whose total annual income does not exceed 100% of the most recent poverty guidelines. Low-income family also includes members of families whose annual exceeds this amount but who as determined by the project director, are unable for good reason, 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. There is a definition for nonprofit. As applied to any private institution or organization. Means that no part of the entity has net earnings benefit or may lawfully benefit any private shareholder or individual.

There is a definition for quality healthcare which is safe, effective, client-centered, timely, efficient, and equitable. There's a definition for Secretary which 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.

And a definition for service sites, which 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. Lastly, there's a definition for state which includes in addition to several - several states, the District of Columbia, Guam, Commonwealth of Puerto Rico, Northern Marianna Islands, the US Virgin Islands, American Samoa, and the US outlying islands - the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.
And lastly, there's a definition for trauma informed which is a program, organization, or system that is trauma informed, realizes the widespread impact of trauma and understands potential paths to recovery, recognizes the signs and symptoms of trauma in clients, families and 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.

2021 Proposed Regulatory Text – §59.3

Those are all of the definitions included in the 2021 proposed regulatory text. Moving onto Section 59.3, this covers who's eligible to apply for family planning services grants, and that is any public or nonprofit private entity in a state, may apply for a grant under the subpart.

2021 Proposed Regulatory Text – §59.4

Section 59.4 covers how one applies for a family planning services grant. So, it includes several things - the application for a grant shall be made on an authorized form. An individual authorized to act for the applicant and assume on behalf of the applicant, the obligations imposed by the terms and condition, must sign the application.

And the application shall contain a description satisfactory to the Secretary of the project and how it will meet the requirements of the subpart, a budget and justification of the amount of grant funds requested, 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 other pertinent information as the Secretary may require.

2021 Proposed Regulatory Text – §59.5(a)

Section 59.5(a) talks about the requirements that must be met by a family planning project and is quite long, so there are several slides on this subpart.
So, each project supported under this part, must one, provide a broad range of acceptable and effective medically approved family planning methods, including natural family planning method and services including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services.

If an organization offers 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 accessible 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.

Moving on, 59.5(a) continued, number 2 - requirements under - that must be met under a family planning project includes providing 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 program of the applicant.

Number 3, must 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.
Number 4 - provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status. And number 5, not provide abortion as a method of family planning. A project must offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options - prenatal care and delivery, infant care, foster care, or adoption, and pregnancy termination.

If requested to provide such information in counseling, provides neutral and factual information, and nondirective counseling on each of the options and referral upon request, except with respect to any options or option about which the pregnant client indicates they do not wish to receive such information in counseling.

Continuing with 59.5(a) number 6 - provide that priority and provision of services will be given to clients from low income families. And number 7 provides that no charges will be made for services provided to any clients form 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 the charge.

Continuing again, 59.5(a), number 8 - provides that charges will be made for services to clients other than those from low income families in accordance with the schedule of discounts based on ability to pay. Except that charges to persons or families whose annual income exceeds 250% of the level set forth in the most recent poverty guidelines, will be made in accordance with the schedule of fees designed to recover the reasonable costs of providing services.
That family income should be assessed before determining whether copayments or additional fees are charged and with regard to insured clients, clients whose family income is at or below 250% of the federal poverty level, should not pay more in copayments or additional fees than what they would otherwise pay when the scheduled discount is applied.

Continuing again, 59.5(a) number 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 reverify income or rely solely on client 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.

And 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. When the cost of service is to be reimbursed under titles of the Social Security Act, a written agreement with that agency is required.

Number 11, 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 including existing or potential subrecipients which have previously provided or proposed to provide family planning services to the area that's supposed to be served by the applicant. And provide an
opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

Twelve, 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.

Title X projects must provide appropriate documentation or other assurance satisfactory to the Secretary, that it has in place and implements a plan to comply with state notification laws and provide 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 intervention, strategies and referrals to improve the safety and current situation of the patient and compliance with state notification laws.

And continuing still, 59.5(a) number 13 - ensure transparency in the delivery of services by reporting the following information in grant applications in all required reports. One, subrecipients and agencies or individuals providing referral services and the services to be provided.

Two, a 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 three, explanation of how the recipient will ensure adequate oversight and accountability for services and effectiveness of outcomes among subrecipients.
And that concludes Section 59.5(a), what requirements must be met by the family planning project.

2021 Proposed Regulatory Text – §59.5(b)

Moving now to 59.5(b), additional requirements that must be made in addition to Part A. Each project must meet the following requirements unless the Secretary determines that the product has established good cause for a submission.

These include one, providing for medical services related to family planning including consultation via healthcare provider, examination, prescription, continuing supervision, laboratory examination, contraceptive supplies, and necessary referrals to other medical facilities when medically indicated, and provide for the effective use of contraceptive devices and practices.

Still in 59.5(b) number 2, provide for social services related to family planning including counseling, referral to and from other social and medical service agencies, any ancillary services which may be necessary to facilitate clinic attendance.

And three, provide for opportunities for community education, participation, and engagement; two, achieve community understanding of the objectives of the program, inform the community of availability of services, and promote continued participating in a project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered quality family planning services.

Continuing still with 59.5(b) number 4, provides for orientation and in service training for all project personnel. Number 5, provide services without the imposition of any duration of residency requirement or requirement that the
patient be referred by a physician. Number 6, provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

And number 7, provide that all services purchased for the project participants will be authorized by the project director or his designee on the project staff. 59.5(b) continued, number 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 of 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.

And number 9, provide that if family planning services are provided by contract or other similar arrangement with actual providers of services, services will be provided in accordance with the plan that establishes rates and methods of payment for medical care. These payments must be made under agreement with the schedule of rates and payment procedures maintained by the recipient.

The recipient must be prepared to substantiate that these rates are reasonable and necessary. And 59.5(b) continued still, number 10, provide to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of a 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.
2021 Proposed Regulatory Text – §59.6

Moving to 59.6, what procedures apply to assure the suitability of informational and educational materials both print and electronic? Part A states that a grant under this section maybe made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials, both 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 the Title X of the Act.

The project shall not disseminate any such materials which are not approved by the advisory committee. The advisory committee referred to on the previous slide in Paragraph A of this section, shall be established as follows - the size, specific committee, shall consist of no fewer than five members and up to as many members as the recipient determines. Except that this provision may be waived by the Secretary for good cause shown.

The composition of the committee - 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, indigenous, Native American persons, Asian Americans and Pacific Islanders and other persons of color, members of religious minorities, lesbian, gay, bisexual, transgender, and queer persons, persons with disabilities, persons who live in rural areas, and persons otherwise adversely affected by persistent poverty or inequality.
And finally, the functions of the advisory committee. In reviewing material, the advisory committee shall consider the educational, cultural and diverse backgrounds of individuals to whom the materials are addressed; shall consider the standards of the population or community to be served with respect to such materials; shall review the content of the materials to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive and trauma informed.

Shall determine whether the material is suitable for the population or community to which it is to be made available. And shall establish a written record of its determination.

2021 Proposed Regulatory Text – §59.7

Moving to 59.7, what criteria the Department of Health and Human Services will use to decide which family planning service project to fund and in what amount.

Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of projects which will in the department's judgment best promote the purposes of Section 1001 of the Act.

Taking into account one, the number of clients and in particular the number of low income clients to be served; two, the extent to which family planning services are needed locally; three, the ability of the applicant to advance health equity; four, the relative need of the applicant; five, the capacity of the applicant to make rapid and effective use of federal assistance; six, the adequacy of the applicant's facilities and staff; seven, the relative availability of nonfederal resources within the community to be served and the degree to which those resources are committed to the project; and eight, the degree to
which the project may adequately provide for the requirements set forth in these regulations.

59.7 continued, the criteria the department will use to decide which family planning projects to fund, and in which amounts. The Secretary shall determine the amount of any award on the basis of its estimate of the sum necessary for the performance of the project. No grant may be made for less than 90% of the project's cost as so estimated, unless the grant is to be made for a project which was supported under Section 1001 for less than 90% of its cost 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. And no grant may be made for an amount equal to 100% for the project's estimated costs.

2021 Proposed Regulatory Text – §59.8

Moving to 59.8, how a grant is awarded - one, the Notice of Grant Award specifies for 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 initial 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 factors such as the recipient's progress and management practices, and the availability of funds.

In all cases, continuation awards require determination by HHS that continued funding is in the best interest of the government. And C, neither the approval
of any application nor the award of any grant submits or obligates the United States in any way to make additional, supplemental, continuation or other awards, with respect to any approved application or portion of an approved application.

**2021 Proposed Regulatory Text – §59.9**

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.

**2021 Proposed Regulatory Text – §59.10**

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 is required by law with appropriate safeguards to 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. Recipients 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.

**2021 Proposed Regulatory Text – §59.11**

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 interest of public health or the proper use of grant funds.

**2021 Proposed Regulatory Text – §59.12**

And lastly, 59.12, talks about what other HHS regulations apply to grants under this subpart and whose attention is drawn to the following HHS departmentwide regulations which apply to grants under this subpart and include 37 CFR Part 401, Rights to Invention, made by nonprofit organizations and small business firms under government grants, contracts and cooperative agreements - 42 CFR Part 50(d), Public Health Service Grant Appeals Procedure; 45 CFR Part 16, Procedures of the Department both Grant Appealed For; 45 CFR Part 17, 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 VII, Title VI of (unintelligible) the Civil Rights Act of 1964.

And in addition, 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 Programs and Activities Receiving or Benefiting 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.

That concludes the review of the proposed regulatory text.

**Telemedicine (86 FR 19818)**

Two other points that we wanted to make sure to point out to all of you listening to this recording - one is around telemedicine and you can find the information on this in the Federal Register Notice on page 19818.
And what's pointed out on page 19818 is that 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.

**Restricting Subrecipients (86 FR 19817)**

One additional point that we wanted to point out is around restricting subrecipients. This can be found in the Federal Register Notice on page 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 the 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 most qualified providers.

Therefore, the Department invites comments on ways in which it can ensure the Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients.

**Regulatory Impact Analysis (86 FR 19820-19828)**

The 2021 Title X NPRM also includes a discussion of regulatory impact analysis which can be found on pages 19820 through 19828 in the Federal Register. And this provides a summary of estimated costs, benefits, and transfers of the 2021 Title X NPRM. Benefits include increasing the number of grantees, increasing the number of clients served.
Additional clients receive access to contraceptives, public health screenings, STI testing resulting in significant cost savings from earlier treatment and other interventions, and an increase in the diversity of grantees receiving grant funds including geographic diversity. HHS requests comments that might facilitate refinement of this analysis.

**Paperwork Reduction Act (86 FR 19828)**

The Federal Register, the 2021 Title X NPRM also includes a discussion of the Paperwork Reduction Act which can be found in the Federal Register on page 19828. The proposed rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act.

HHS solicits comments on the need for the information collection and its usefulness in carrying out the proper functions of our agencies; the accuracy of our estates of the information collection burden; the quality, utility, and clarity of the information to be collected; and recommendations to minimize the information collection burden on the affected public including automated question techniques.

**Thank You**

That concludes our review of the 2021 Title X NPRM. We hope that this has been helpful for you to review the contents of the 2021 Title X NPRM. We thank you for joining us today.

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