July 31, 2018

Diane Foley, Deputy Assistant Secretary for Population Affairs
Office of the Assistant Secretary of Health
Office of Population Affairs
US Department of Health and Human Services
Attn: Family Planning
Hubert H. Humphrey Building, Rm 716G
200 Independence Avenue SW
Washington DC 20201

Re: Proposal to Revise Title X Regulations, Compliance with Statutory Program Integrity Requirements, Docket ID: HHS-OS-2018-0008

On behalf of the National Association of County and City Health Officials (NACCHO) and the nearly 3,000 local health departments across the United States, we write to provide comment on the Office of Population Affairs (OPA) notice of proposed rulemaking (NPRM), “Compliance with Statutory Program Requirements,” RIN 0937-ZA00.

Local health departments are the governmental agencies that work every day in their communities to prevent disease, promote wellness, and protect health. They convene community partnerships and facilitate important conversations with diverse stakeholders on how to create the conditions in which all people can be healthy. NACCHO and local health departments are partners with HHS and agencies like the Centers for Disease Control and Prevention (CDC) to enhance the health and well-being of Americans. Over half of Title X grantees are state and local health departments that play a critical role in ensuring access to a broad range of family planning and complete preventive health services to communities. State and local health departments that are not Title X grantees work alongside the funded entities to ensure services such as family planning and STI and HIV testing are available to communities across the United States.

NACCHO is deeply concerned that the NPRM will have devastating effects on the Title X family planning program and the low-income patients for whom Title X provides critical healthcare. Title X is the only federal program exclusively dedicated to providing low-income and adolescent patients with essential preventative reproductive healthcare and comprehensive reproductive health information, and it has received bipartisan support for decades. The program is designed to ensure that people—regardless of geography, income, background, and insurance status—have access to basic, preventative reproductive healthcare including birth control, STI testing, and cancer screenings. The program serves approximately 4 million individuals each year, many of whom identify as members of ethnic or racial minority communities that often face disproportionate barriers to accessing healthcare. A significant number of women in the United States still lack health insurance, and Title X plays an essential part in allowing those women to access reproductive
healthcare that they would otherwise not be able to attain. The rule would: move Title X away from its proper focus on making modern family planning tools available to all, regardless of income; create unworkable and unclear physical and financial separation and compliance requirements; prevent highly qualified, trusted family planning providers from continuing in their long-standing Title X roles; and destabilize the enormously effective network of Title X providers, in essence destroying the program.

Proposed 42 C.F.R. §59.14 eliminates the long-standing requirement that pregnancy counseling be nondirective and bars any referrals to abortion providers.

The revisions to Title X would impose new rules limiting the ability of millions of patients to get birth control and preventative care from healthcare providers, including Planned Parenthood. The Title X legislative and current regulatory requirement for nondirective pregnancy options counseling puts patients’ own stated needs at the heart of their care, their reproductive choices, and their requested referrals. It does not mandate the type of counseling, information, or referral that pregnant people receive. Currently Title X providers that also offer abortion services serve more than 40 percent of the patients who receive care through Title X; in many cases and for many reasons, including financial and geographical, these patients do not have anywhere else to turn.

When individuals have access to care, decisions regarding their healthcare choices should be made privately between them and their provider. Providers have an ethical responsibility to provide patients with accurate and complete information about their full array of healthcare options. The proposed rule forbids any Title X project from presenting the option of abortion. Although the preamble suggests that some form of abortion discussion might be able to take place, the text of the proposed rule suggests that all nondirective counseling regarding abortion may be barred while requiring all pregnant people be referred for prenatal care and/or social services regardless of their wishes. These new rules would limit what providers across the country could discuss with their patients by explicitly banning discussion of referral to safe, legal abortion services. The NPRM would also sanction the creation of confusing lists consisting only of comprehensive health care providers that may or may not offer abortion to be available to some women, but tie the hands of clinicians in actually making those lists useful or identifying the specific care patients might find at providers outside of Title X.

Proposed §59.5(a)(1) makes it explicit that a Title X project is not required to provide a broad range of acceptable and effective family planning methods and services.¹

Under the proposed rule, a participating entity may offer only a single method or a limited number of family planning methods as long as the entire project offers a broad range. This rule allows grantees to exclude contraceptive options due to “staffing limitations, technological capacity, economics (including costs and demand), and conscience concerns.”² Proposed §59.2 removes “medically approved” from the definition for family planning, allowing Title X clinics to provide contraceptive and fertility awareness methods (i.e. calendar-based methods relying on abstinence during fertile windows) that have not been regulated, approved, or certified by any particular

¹ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530, 25515.
² Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25516.
agency or accreditation body.³ This proposal threatens Title X’s mission to ensure access to a full range of contraceptive methods and dilutes an essential feature of quality family planning by no longer requiring provision of Federal Food and Drug Administration (FDA)-approved contraceptive methods.⁴ The proposed rule, instead, emphasizes that projects are not required to provide “every acceptable and effective family planning method or service,” allowing Title X projects to exclude methods of their choosing.⁵

Withholding information about pregnancy options and disrupting the existing requirement that Title X programs provide every effective and acceptable mode of birth control is a serious departure from the way the program has been operating with an emphasis on ensuring access to all 18 FDA-approved contraceptive methods. When providers deny access to information about all healthcare options, they compromise the health of the more than four million people annually who rely on Title X services to meet their reproductive health needs.

**Proposed §59.15 and 59.16 create vague and confusing standards related to separating finances, space, and activities related to abortion, which are already regulated, that will constrain Title X-funded entities and improperly limit their activities.**

The incredibly broad, often vague changes proposed in the NPRM will cause confusion and disruption among Title X-funded health centers. Title X providers will find it extremely difficult and burdensome to comply with the new requirements if they are adopted, and many organizations will determine that they cannot do so. Some of the most challenging and counterproductive requirements include physical separation from a long and nebulous list of “activities related to abortion” that might be undertaken outside Title X projects and with non-Title X funds.

Sites that provide Title X-funded services have long been permitted to provide abortions and abortion referrals using separate, non-federal funds.⁶ Section 1008 of the Public Health Service Act enacted in 1970 still holds: “None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.”⁷ However, the Act does not further extend funding prohibitions. Now requiring Title X recipients to physically and financially separate Title X activities from any abortion-related activities, including abortion referrals, ignores the crucial role that specialized providers have played in the Title X program for decades.⁸ This rule would

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³ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25515.
⁵ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25515.
⁷ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25502.
⁸ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532.
directly impact more than ten percent of Title X sites, which offer abortions using non-federal funds, including health centers operated by hospitals and independent agencies.\(^9\)

Proposed §59.16(a) further defines activities that build abortion infrastructure to include a host of lobbying, educational, and legal activities.\(^10\) The precise phrasing prohibiting activities that may “encourage, promote or advocate abortion as a method of family planning” is left intentionally vague and open for greater inclusion. As such, the proposed rule makes it impossible for Title X providers to continue to effectively serve and comprehensively inform patients of their full range of options by incapacitating them physically, financially, and geographically.

Without reason, these factors reverse HHS’ longstanding interpretation that “[i]f a Title X grantee can demonstrate [separation] by its financial records, counseling and service protocols, administrative procedures, and other means...then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for ‘physical’ separation.”\(^11\) In 2000, HHS further issued a notice to clarify that Title X service sites could use common waiting rooms, staff, and filing systems for abortion-related activities and Title X project activities.\(^12\)

It is unreasonable to expect Title X-funded entities to be able to comply with these requirements, which will have the ultimate impact of excluding many highly qualified and trusted providers from being able to participate in the Title X program, thus significantly reducing access to care for a considerable number of patients who rely on Title X.

**Proposed §59.2 redefines “low-income family” to fill the contraceptive coverage gap created by the administration’s own actions.**

The Affordable Care Act requires that all non-grandfathered health plans cover an HHS-designated list of women’s preventive services, which includes contraceptive services. The administration created a significant gap in that coverage in its interim final rules of October 13, 2017, regarding religious\(^13\) and moral\(^14\) objections to contraceptive coverage, which, if permitted to take effect, would allow virtually any employer to claim an exemption from the contraceptive coverage requirement.

The NPRM proposes that Title X, an already underfunded and overstretched government program, fill that gap, by explicitly enabling, and possibly requiring, Title X-funded entities to provide free contraceptive services to women, regardless of income, whose employers claim a religious or moral

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\(^10\) Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532.


\(^13\) “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act.” 82 Federal Register 197 (October 13, 2017), p. 47792.

exemption. Title X was not designed to, nor is it able to, meet the needs of insured individuals who have incomes above 250% of the federal poverty level; however, the NPRM proposes to change the definition of “low-income family” so that any woman who has employer-sponsored health insurance coverage “which does not provide the contraceptive services sought by the woman because [the employer] has a sincerely held religious or moral objection to providing such coverage” “can be considered” to be low-income.\textsuperscript{15}

**HHS has drastically underestimated the costs associated with implementation of the NPRM, which financially cripple the Title X network.**

The estimated costs included in the NPRM’s economic impact analysis are drastically underestimated, and many provisions of the NPRM that would require organizations to incur significant cost are not considered in the analysis at all.

The proposed rule’s extensive new reporting requirements—from subrecipients to patient medical records—would be far more economically and administratively burdensome than HHS suggests. It would require changes in electronic health record systems and additional time in training and management that far exceed the limited costs estimated in the NPRM. The physical separation requirements would impact all Title X providers and seek to require wholly separate second sites to be opened in order for Title X-funded organizations to continue separate, non-Title X activities. The economic analysis that seems to relate to this provision in the NPRM claims that it would cost between $10,000 and $30,000 in the first year to comply (i.e. to open a separate site).

But HHS fails to consider the long-term cyclical impacts of this rule. Restricting patient access and the provision of comprehensive, quality care leads to: (1) the possible closure of Title X centers, (2) patients delaying or forgoing care and developing a range of negative health outcomes as previously discussed, and (3) overburdened state and local health systems facing additional emergency care demands from low-income vulnerable patients. Moreover, because the rule would redefine eligibility for free family planning services to include individuals whose employer-based insurance does not cover contraception without cost sharing, due to the Affordable Care Act’s contraceptive coverage exclusion for employers with religious or moral opposition, already-limited Title X funds would be redirected to cover privately-insured patients’ costs.\textsuperscript{16} Ultimately, increased taxpayer contributions will be required to shoulder Title X and the health system’s costs. Currently, $1 invested in Title X saves more than $7 in Medicaid-related costs, thereby saving taxpayer contributions towards Medicaid.\textsuperscript{17} Thus, implementing the rule would not achieve HHS’ stated goals.

\textsuperscript{15} 2018 NPRM, § 59.2. The definitional change specifies that this change in definition is “[w]ith respect to contraceptive services,” which would presumably include the contraceptive coverage required under the Affordable Care Act. It is unclear whether other Title X services would be included and, if not, how such differences would be operationalized.


\textsuperscript{17} Letter to HHS from United States Senators and Congress people, \url{https://www.warren.senate.gov/imo/media/doc/2018.05.14%20Letter%20to%20HHS%20Opposing%20Domestic%20Gag%20on%20Title%20X.pdf}.
These and other costs will be more than many Title X projects can bear on top of the NPRM’s apparent new restrictions on spending for infrastructure and will undoubtedly lead to providers leaving Title X for economic reasons alone and, as a result, lay off staff, reduce hours, or close their doors altogether. The NPRM does not account for any costs associated with such consequences, such as unemployment for laid off staff or the cost to patients in trying to find a new, trusted provider. Further, many displaced patients will likely not be able to find a new, affordable, high-quality provider, resulting in patients delaying care or not receiving it at all. The costs in public health outcomes and taxpayer dollars resulting from the loss of access to Title X-funded family planning in communities will be significant. If there are just 10,000 more Medicaid-funded family planning births resulting from the loss of access—an incredibly low estimate out of 4 million current Title X patients, 90% of whom have incomes under 200% of the federal poverty level and likely qualify for Medicaid if pregnant—the cost to taxpayers would be nearly $80 million a year.\footnote{The average Medicaid-funded birth costs $7,950. Frost JJ et al., “Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program,” Milbank Quarterly, 92(4):696–749, \url{https://www.guttmacher.org/article/2014/10/return-investment-fuller-assessment-benefits-and-cost-savings-us-publicly-funded}.}

**Title X family planning providers are critical partners in combating rising, crisis rates of STIs, testing and diagnosing individuals living with HIV, and maintaining gains in unintended pregnancy rates, especially among adolescents.**

All Title X family planning providers are essential to screening for, diagnosing, and treating STIs and HIV and providing comprehensive family planning options to all people. They offer a broad range of safety-net healthcare that is pivotal to addressing rising crisis rates of STIs, improving health disparities in current rates of newly diagnosed HIV, and maintaining the nation’s decreasing rates of unintended pregnancy, especially in young people. At a minimum, all Title X-funded sites are required to provide HIV prevention education and testing, either on-site or by referral,\footnote{Vanessa White and Christine Brazell, *Family Planning Providers Key in Fight Against HIV,* HIV.GOV, \url{https://www.hiv.gov/blog/family-planning-providers-key-in-fight-against-hiv}.} in addition to cancer and sexually transmitted infection (STI) screenings, a range of contraceptives, pregnancy testing, well-woman exams, and other relevant counseling and referrals. Title X was envisioned to provide “educational, comprehensive medical, and social services necessary to aid individuals to freely determine the number and spacing of their children.”\footnote{42 C.F.R. § 59.1} This language is inclusive of all individuals, regardless of their financial or social background and access to health insurance, and inclusive of all services. The proposed rule, however, would restrict access to these critical services, including prevention and treatment for HIV and other STDs. Individuals relying on Title X for care cannot afford policy that could dismantle this critical network of providers.

The assumption that other health care providers would and could absorb clients and provide similar services if these Title X providers were barred from serving these patients is a falsehood. The existing local public health system relies on the infrastructure that is currently in place to provide reproductive health services to the poor and marginalized, and this proposed rule would destabilize community health systems. Local health departments and community health centers may not provide the same full range of reproductive health services or have the capacity or expertise to take
on such a large patient population. If participation in Title X was limited, patients would simply receive inadequate reproductive health care, or no reproductive health care at all, including critical HIV and STI testing and treatment services, as care options are already limited, particularly for low income and rural individuals.

Seekers of healthcare deserve evidence-based care and the autonomy to make the decisions that are right for their health and themselves with the help and support of their provider. All patients, no matter their service mechanism, expect and deserve medically accurate, comprehensive information from their providers and it is unethical and dangerous for a governmental body to compromise patient health by interfering with the provision of that evidence-based care and information. Local health departments who participate in Title X and other providers with whom they partner with must be allowed to provide the broad range of contraceptive methods with nondirective options counseling, not withhold full and accurate medical information from patients, and provide confidential care.

As such, NACCHO stands with our partners across the public health and healthcare landscape in firm opposition to these regulatory proposals. If you require additional information about the issues raised in these comments, please contact Eli Briggs, Senior Director of Government Relations, at ebriggs@naccho.org.

Sincerely,

Lori Tremmel Freeman, MBA
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