Dr. Diane Foley  
Deputy Assistant Secretary for Population Affairs  
Office of the Assistant Secretary for Health, Office of Population Affairs  
U.S. Department of Health and Human Services  
Attention: Family Planning  
Hubert H. Humphrey Building, Room 716G  
200 Independence Ave., SW  
Washington, DC 20201

July 31, 2018

Re: RIN 0937-ZA00, Compliance with Statutory Program Integrity Requirements

Dear Dr. Foley,

The National Women’s Law Center (the “Center”) is writing in response to the notice of proposed rulemaking (NPRM) entitled “Compliance with Statutory Program Integrity Requirements.” Since 1972, the Center has worked to protect and advance the progress of women and their families in core aspects of their lives, including employment, income security, education, and reproductive rights and health, with an emphasis on the needs of low-income women and those who face multiple and intersecting forms of discrimination. The Center has long worked to ensure that health care and health insurance meet women’s needs, and that all people have equal access to a full range of health care regardless of income, age, race, sex, sexual orientation, gender identity, health status, geographic location, or type of insurance coverage. This includes access to affordable family planning.

The NPRM would fundamentally change the nation’s only federally-funded family planning program into something completely unrecognizable and harmful to individuals across the country. Not only are these changes outside the bounds of the intent of the Title X statute, but they also violate federal law.

The Department of Health and Human Services (the Department) cannot and should not proceed with this rulemaking. The Department should withdraw the NPRM immediately.

The bipartisan Title X program is a critical source of non-directive information and family planning services to those who do not have other sources of this care.

Following approval of the first contraceptive pill by the FDA in 1960, research showed that low-income women had more children than they desired because they had inequitable access

1 Office of the Assistant Secretary for Health, Office of the Secretary, Human and Health Services; Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25502 (June 1, 2018) hereafter Office of the Assistant Secretary for Health.
to contraceptives. Five years later, the Supreme Court held in *Griswold v. Connecticut* that the right to privacy includes the right to use birth control.\(^2\) It was against this backdrop of medical innovation, disparities in contraceptive access, and the legal right to use contraception that President Richard M. Nixon called on Congress to “establish as a national goal the provision of adequate family planning services within the next five years to all those who want them but cannot afford them.”\(^3\) Congress responded by passing the Title X statute with overwhelming support from both Republicans and Democrats.\(^4\)

As originally enacted in 1970, the Title X statute authorized the Secretary of HHS to make grants to public or nonprofit private entities to establish and operate “voluntary family planning projects.”\(^5\) Congress has amended the statute over the last 48 years, and the current Title X statute requires that projects “offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).”\(^6\) To this day, the Title X family planning program is the nation’s only dedicated source of federal funding for family planning. It supports high-quality, culturally sensitive family planning services and other preventive health care for low-income, under-insured and uninsured individuals who may otherwise lack access to health care. And Title X–funded centers adhere to high standards of clinical care and patient confidentiality.

Specifically, current Title X regulations require neutral, factual information and non-directive counseling on all pregnancy options. This has been a long-standing requirement of the program which puts patients’ own stated needs at the heart of their care, their reproductive choices, and their requested referrals. It ensures that pregnant people are provided the opportunity to receive counseling on all of their options, have their questions answered, and actually receive information relevant to whatever options they might choose, as well as receiving any referral they request. The American College of Obstetricians and Gynecologists,\(^7\) the American Academy of Family Physicians,\(^8\) and the American Academy of Pediatrics\(^9\) endorse this approach in their practice recommendations.

The requirements currently in place ensure that a person visiting a Title X clinic will receive the care that he or she needs – from contraceptive counseling and the range of methods, including the most effective ones available, to non-directive counseling about her options if

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\(^2\) *Griswold v. Connecticut*, 381 U.S. 479 (1965). In *Griswold*, the Court recognized the importance of privacy to marriage and invalidated Connecticut’s attempt to prohibit married couples from using birth control. In 1972, in *Eisenstadt v Baird*, the Court extended to unmarried couples the right to birth control. 405 U.S. 438 (1972).


\(^8\) David A. Moss, Matthew J. Snyder, and Lin Lu, Options for Women with Unintended Pregnancy, 91(8) American Family Physician S44-9 (April 15, 2015).

\(^9\) Laurie L. Hornberger and AAP Committee on Adolescents, Diagnosis of Pregnancy and Providing Options Counseling for the Adolescent Patient, 140(3) Pediatrics e20172273 (September 2017).
she is pregnant. And all of these services are provided on a sliding scale to those most in need and who are economically unable to afford the care otherwise. Over four million people rely on this care every year,\textsuperscript{10} with Black women, Latina women, and members of the LGBTQ community disproportionately relying on Title X-funded clinics for their care.\textsuperscript{11} In many cases, the Title X program is the only source of health care women use. Six in ten women who obtain health care from a publicly funded family planning center consider it to be their usual source of health care.\textsuperscript{12}

Yet the NPRM would fundamentally change this critical program, in direct contravention of the statute and other legal requirements, and to the detriment of the health and economic security of those who need the Title X program the most.

**The proposed changes in the NPRM would gag providers, take away critical care, and fundamentally alter the program, in violation of the Title X statute.**

The NPRM would completely change key aspects of the current Title X program, including:

- Eliminating the longstanding requirement for nondirective options counseling for pregnant patients;
- Prohibiting referral to abortion providers;
- Requiring referral for prenatal care and/or social services for all pregnant people, regardless of their wishes;
- Directing Title X-funded entities to withhold full and accurate medical information from patients;
- Prohibiting more than a dozen activities related to abortion, including that a Title X project may not “present,” “support,” or even “promote a favorable attitude toward” abortion as a method of family planning;
- Requiring onerous physical and financial separation of Title X-funded entities that would have a significant chilling effect on and prevent a wide variety of otherwise-permissible activities paid for with non-Title X funds;
- Permitting Title X projects to refuse to provide the broad range of contraceptive methods and preferencing abstinence, natural family planning, and fertility awareness-based methods;
- Forcing new harmful requirements on Title X providers who provide services to young people;


\textsuperscript{11} Patients seen at Title X-funded clinics are disproportionately Black and Hispanic or Latino/a, with 21% of Title X patients self-identifying as Black or African American and 32% as Hispanic or Latino/a, as compared to 12% and 18% of the nation, respectively. Nat’l Family Planning and Reproductive Health Assn, Title X: An Introduction to the Nation’s Family Planning Program (Nov. 2017) available at https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

• Redefining “low-income” to include women whose employers refuse to provide insurance coverage of birth control pursuant to the Administration’s own unlawful rules.

These changes will effectively destroy the program, undermining the high-quality family planning care provided to patients across the country. Each of these changes violates the Title X statute. It allows entities to participate even if they refuse to provide the broad range of contraceptive methods that have been a core part of Title X-funded services since the program’s inception nearly 50 years ago. It removes the requirements that ensure patients’ own health needs are at the center of Title X-funded care. It violates the essential legal and ethical principle of voluntary, non-coercive counseling in all Title X services. It undermines trust in the program and jeopardizes the provider-patient relationship. It threatens patient confidentiality, particularly for minors, in ways that could cause many patients to avoid seeking care.

Although the NPRM in many ways is designed to target abortion-related activities and entities that provide abortion care, its impact is not limited to such activities and providers. The NRPM would have far-reaching implications for all Title X-funded entities, the services they provide, and the ability of patients to seek and receive high-quality, confidential family planning and sexual health care.

These comments focus specifically on a few of the harmful and unlawful proposals mentioned above, and the legal requirements not met by the Department in promulgating the NPRM. The Center supports other comments that have been submitted by current Title X grantees and other organizations that provide additional commentary about other problematic aspects of the NPRM.

The NPRM unlawfully redefines “low-income” to solve a problem that the Administration itself created.

The NPRM proposes to redefine “low-income family” to include an individual who does not have health insurance coverage of contraceptives because she receives her coverage through an employer that has a religious or moral objection to providing such coverage.\textsuperscript{13} The reason the Department is doing this is to respond to a problem of its own making. Because it is facing litigation over its October 2017 rules that exempt virtually any employer that objects to covering birth control from complying with the Affordable Care Act’s birth control benefit, the Department in this NPRM is trying to provide itself cover from legal challenges.\textsuperscript{14} But the Department cannot simply redefine a word to mean something it does not mean. And, in fact, the Secretary is required by statute to define “low-income family” by considering economic

\textsuperscript{13} Office of the Assistant Secretary for Health, § 59.2.

status. While an employer taking insurance coverage of birth control away from an individual will undoubtedly have an economic impact, it does not mean someone is automatically “low-income.” The Title X program is not a back-up plan to enable employer discrimination.

Moreover, the Department’s proposals do not acknowledge that redefining “low-income” individuals in this way would completely overwhelm the Title X program. The Title X program was not designed to, nor can it, absorb the unmet needs of insured individuals who have incomes above 250% of the FPL. Title X is designed to subsidize a program of care, not pay all of the cost of any service or activity; the Title X statute and regulations contemplate how Title X and third-party payers will work together to pay for care. The system is not designed to provide free contraceptive services to people whose employers object to insurance coverage of contraception, regardless of their income. And Title X is already underfunded and overburdened. Requiring Title X projects to prioritize and pay for these patients leaves fewer already-scarce dollars to serve the low-income patients who are meant to be served by the Title X program. Efforts to expand the requirements on the Title X program would require an act of Congress, as well as significant increases in appropriated funds.

The Department’s new definition of “low-income family” promotes, advances, and endorses one set of religious beliefs – those of the employers that object to covering birth control – and excessively entangles the government in those religious beliefs through the Title X program. This violates the Establishment Clause of the Constitution.

The NPRM threatens patient confidentiality and privacy, particularly critical to ensuring that young people seek out care.

Family planning services address some of the most sensitive and personal issues in health care and therefore require strong confidentiality protections. Patients seeking family planning services encompass a broad spectrum of patient populations. Certain groups, including adolescents and young adults, and people at risk of domestic or intimate partner violence, have special privacy concerns that additionally require strong protections.

The NPRM undermines patient confidentiality and access to care in two primary ways: by exerting increased and inappropriate pressure on adolescent patients and their Title X providers to involve family members including parents or guardians in virtually all cases; and by inserting the Secretary improperly into the enforcement of state reporting laws, impacting all Title X patients. The Department has not adequately considered the impact these additional

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15 42 USC § 300a-4(c) (2016).
17 U.S. Const. amend. I.
reporting requirements could have on patient confidentiality and the provider-patient relationship.

The proposed rule adds specific information Title X providers are required to collect and document in records, the collection of which could cause significant harm to the provider/patient relationship. Whether the counseling and care that patients receive would remain confidential could be at risk under the proposed rule, particularly given the reporting and family involvement requirements for care provided to minors. The Center is particularly concerned about the threat to patient confidentiality for young people, and the potential that people will not seek care at all rather than have confidential information shared without their consent.

The proposed rule requires that Title X projects must include in their compliance plans a commitment to “conduct a preliminary screening of any teen who presents with [an STD], pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor.”20 This requirement would apply to every individual under the age of consent in a state, and turns health care providers into interrogators of their patients, even when there is no sign of abuse. The chilling effect on care for young people – who may otherwise be seeking care urgently for a sexually transmitted disease or unintended pregnancy – would be devastating on both their physical and mental health, as well as their long-term well-being.

Additionally, the Center echoes concerns raise by organizations that represent health care providers in regards to the counseling and reporting requirements in the NPRM that may violate providers’ legal duty of care to their patients and endanger their eligibility for liability insurance.

The NPRM would be harmful to individuals’ health and economic well-being, and especially for those who already face barriers to care. The Department did not adequately take account of those harms, as it is required to do by Public Law 105-277.

The Department is required by law to assess the impact of the NPRM on families’ health and well-being yet it failed to adequately do so.

Under Public Law 105-277, the Department must present adequate rationale for the implementation of any rulemaking that may negatively affect family well-being, and the Office of Management and Budget must certify the assessment.21 The kinds of fundamental changes to the Title X program proposed in the NPRM warrant an in-depth and substantive

20 Office of the Assistant Secretary for Health, § 59.17(b)(1)(iv).
21 Family Assessments Under Section 654 of P.L. 105-277, The well-being analysis must consider: 1) Does this action by government strengthen or erode the stability of the family and, particularly, the marital commitment? 2) Does this action strengthen or erode the authority and rights of parents in the education, nurture, and supervision of their children? 3) Does this action help the family perform its functions, or does it substitute governmental activity for the function? 4) Does this action by government increase or decrease family earnings? Do the proposed benefits of this action justify the impact on the family budget? 5) Can this activity be carried out by a lower level of government or by the family itself? 6) What message, intended or otherwise, does this program send to the public concerning the status of the family? 7) What message does it send to young people concerning the relationship between their behavior, their personal responsibility, and the norms of our society?
impact assessment. However, the Department gives no details of its assessment in the NPRM, merely stating that it would not negatively impact family well-being.

This family well-being assessment is crucial for the Department to understand the population the Title X program serves and the long-term impact of the proposed changes to the program, not only to health but also to economic security. Upon properly conducting the analysis, the Department will find that the NPRM will have a negative impact on family well-being that necessitates rescinding it. The Center requests particular attention to the following data that point to the NPRM’s negative impact on family well-being:

- **Restricting access to family planning information and services has an economic impact.** Birth control access is directly linked to a dramatic increase both in women’s participation in the workforce and families’ reliance on women’s earnings.\(^{22}\) Indeed, delaying the birth of one’s first child has been widely found to contribute to a family’s strengthened economic stability.\(^ {23}\) That is because having a child tends to decrease a woman’s earnings in both the short and long term, known as the family gap.\(^ {24}\) More specifically, research on recent generations of women has found that having a child creates both an immediate drop in women’s earnings and a long-term decrease in their earnings trajectories.\(^ {25}\) Decreasing access to birth control— which will be a result of the proposed changes in the NPRM — will make it more difficult for women to access the health care they need that will help them achieve and maintain economic stability.

- **The family planning methods being prioritized by the Department are not appropriate for many people.** All individuals should have access to the family planning method of their choice that fits their lifestyle and needs without coercion. Expert agencies within the Department recommend this standard of care.\(^ {26}\) Yet the Department seeks to prioritize birth control methods that are not medically approved— such as fertility awareness-based methods (FABM) and natural family planning. But these methods are not an appropriate contraceptive option for many individuals. For example, for FABM to be used effectively, a woman must have a menstrual cycle between 26 and 32 days, but a significant number of women have menstrual cycles

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23 *Id.*

24 *Id.*

25 *Id.*

26 Federal guidelines such as the CDC’s and the Office of Population Affairs’ Providing Quality Family Planning Services (QFP) and HRSA’s recommendations for preventive services for women clearly state that offering women the full range of FDA-approved contraceptive methods is a critical element of quality family planning. Gavin L, Pazol K., 63(RR04), Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs (2015). And the Women’s Preventive Services Initiative recommends counseling that emphasizes patient-centered decision-making and allows for discussion of the full range of contraceptive options. Women’s Preventive Services Initiative, Recommendations for Preventive Services for Women: Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration (2016).
that are shorter or longer than that length and are ineligible for FABMs.\textsuperscript{27} Furthermore, transgender men often use contraception to control their reproductive health and natural family planning methods cannot provide the same medical results.\textsuperscript{28} Similarly, women who experience domestic and interpersonal violence often prefer certain medically-approved family planning methods, like the copper IUD, that are not detectable by and/or cannot be interfered with by partners.\textsuperscript{29} These individuals are at particular risk of having no viable family planning option if the NPRM is finalized, but the Departments provide no analysis to show the impact on them or their families.

- **Unintended pregnancies can place additional financial stress and strains on marriages and co-habiting relationships.** Among female Title X contraceptive clients, 20\% currently live with a partner.\textsuperscript{30} And 16\% of all women of reproductive age who are eligible for no cost care at Title X clinics are married.\textsuperscript{31} Despite this, there is no indication that the Department has reviewed the evidence showing that the timing and spacing of children may affect the formation and stability of romantic unions.\textsuperscript{32} Unplanned births are tied to increased conflict and decrease satisfaction in relations and with elevated odds that a relationship will fail.\textsuperscript{33} Ultimately, a family that is not financially stable with an unintended pregnancy is likely to have a negative impact on the child’s future educational and health outcomes.\textsuperscript{34}

- **Delayed or denied access to abortion negatively impacts women’s financial well-being.** Restricting Title X clinics from referring for abortion, and only referring for prenatal counseling and social services as proposed in the NPRM, would leave women on their own to find abortion care, inevitably delaying that care. In so doing, the NPRM seeks to undermine access to abortion care beyond the bounds of what this rule regulates. Yet, abortion is a health care service that people need, and, like any other health care service, one for which people need unbiased counseling and referral. The NPRM does not acknowledge that abortion is an essential part of comprehensive

\textsuperscript{27} American College of Obstetricians and Gynecologists, FAQ: Fertility Awareness-Based Methods of Family Planning (April 2015) available at https://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning.

\textsuperscript{28} Juno Obedin-Maliver & Harvey J. Makadon, Transgender Men and Pregnancy, 9 Obstetric Med. 4, 6 (2015).


\textsuperscript{31} NWLC calculations based on American Community Survey, 2012-2016 5-year averages using Steven Ruggles, Katie Genadek, Ronald Goeken, Josiah Grover, and Matthew Sobek, Integrated Public Use Microdata Series: Version 6.0 [Machine-readable database]. Minneapolis: University of Minnesota, 2017, available at https://usa.ipums.org/usa/. Data are for 2012-2016. Women eligible for no cost of care at Title X clinics are defined as women living under 100\% FPL. Women of reproductive age can be defined as women between the ages of 15-49.

\textsuperscript{32} Adam Sonfield et al., Guttmacher Inst., The Social and Economic Benefits of Women’s Ability to Determine Whether and When to Have Children, (2013).

\textsuperscript{33} Id.

\textsuperscript{34} Id.
reproductive health care for women. By willfully ignoring this fact, the Department seeks to create a system that isolates and stigmatizes abortion care and undermines health care providers that provide both contraceptive and abortion care. Ultimately, the Department clearly has failed to consider the impact of full and accurate information during time sensitive decisions about whether to continue a pregnancy. The delays that would result from the NPRM could increase the cost of an abortion, which ultimately can make it inaccessible for some women.\textsuperscript{35} Research has shown that one year after being denied an abortion, women were worse off financially than women who terminated a pregnancy.\textsuperscript{36} Further, women who were unable to obtain an abortion were less likely to be employed in a full-time job and more likely to be living below the federal poverty line.\textsuperscript{37}

- \textit{The “sexual risk avoidance” framework and extreme parental involvement efforts required by the NPRM are demeaning to young people and deny their ability to make decisions independently.} The NPRM sends a negative message to young people about their sexual activity, what preventive options they should access, and the value of confidentiality as a minor. As described above, the Department sends a clear signal that Title X providers should preference a young person’s parents’ opinions and beliefs over the person seeking care. But evidence shows that providers should always maintain a level of confidentiality so minors feel comfortable to fully disclose and receive the proper counseling and services for their visit. The NPRM’s proposals would discourage minors from seeking services like STI testing, pregnancy tests, and contraceptive counseling if they believe they would be judged or their parents would be contacted about the details of their visit. The Department ignores the health risks associated with unprotected sex or maintaining unhealthy relationships, and the inherent costs to young people and their families if they do not receive the care they need.

- \textit{The impact of these negative changes will be especially harsh on communities that are already marginalized from the health care system and disproportionately rely on Title X-funded clinics.} The Center is particularly concerned about the impact of the NPRM on Black women, Latina women, and the LGBTQ community. The Title X program provides critical services to people in these communities. For example, LGBTQ people already face negative economic impacts because of discrimination, including in health care, failure to recognize LGBTQ families, and failures to protect LGBTQ students.\textsuperscript{38} Under the current regulations, clinics that receive Title X funds provide high-quality, medically-accurate, confidential care that puts patients’ own stated needs at the center of care, all of which combats the inherent challenges


\textsuperscript{36} Adam Sonfield et al., Guttmacher Inst., The Social and Economic Benefits of Women’s Ability to Determine Whether and When to Have Children (2013).


LGBTQ people can face in the health care system. Should the Title X program no longer provide this kind of care to the people that rely on it most, the health and economic well-being of these communities face the greatest harm.

Given the overwhelming weight of evidence that shows this NPRM would have a negative impact on family well-being, the Center questions the depth of the Department’s assessment and calls on the Office of Management and Budget to further inquire about it.

**The Administration issued the NPRM without complying with Executive Order 12866.**

The Department cannot proceed with the NPRM because both the Department and the Office of Information and Regulatory Affairs (OIRA) did not comply with Executive Order 12866. Executive Order 12866 states: “Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need.”\(^{39}\) To that end, the Center reiterates its comments above that the NPRM is not allowed under the Title X statute or Public Law 105-277.

Moreover, the Department has not provided legitimate justification that the NPRM is made necessary by a legitimate compelling public need. The Department provides little credible justification for these proposals. It abruptly abandons the core principles of the Title X program to adopt a viewpoint of family planning and reproductive health care that de-prioritizes evidence-based health care, limits care, and violates medical ethics. All of the rule’s harmful changes are proposed without any evidence of need or rational—much less persuasive—justification in the NPRM. The Department seems to have consulted neither family planning providers, their patients, nor experts in the field. Indeed, the proposal is contradicted by the Department’s own standards of care for family planning. The well-documented successes of the Title X program to date show just how misguided these changes are.

One justification provided by the NPRM provides an illustration of the Department’s fake justifications. It claims an inconsistency between certain federal religious exemption laws and the current requirement that Title X providers offer “abortion referral and counseling” to pregnant women. In response, the Department decides to actively prohibit those activities altogether. In other words, even if a provider wants to provide that service, under the NPRM, the health care provider would be prohibited from doing so. This overreach – and discrimination against providers that want to provide abortion care – demonstrates how its so-called justification is based on nothing more than an ideological goal of stopping abortion. The Department is not justified in overreaching as it has in the NPRM.

Moreover, one of the express purposes of Executive Order 12866 is “to make the [regulatory] process more accessible and open to the public.”\(^{40}\) Executive Order 12866 does this through several requirements on agencies and OIRA to make their plans for regulatory action public and open to comment. Executive Order 12866 requires that all regulations under

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\(^{40}\) Id.
development or review be included in the relevant agency’s Regulatory Plan and that such plan be published in the Unified Regulatory Agenda and available to the public. The NPRM did not appear in the Spring 2018 Unified Agenda which the Administration itself describes as “actions likely to occur in the next 12 months” and that those not on the list were either “withdrawn or delayed.” The Administration’s failure to list the NPRM in the Unified Regulatory Agenda violates Executive Order 12866. In skipping this step, the Administration deprived the public of information that could significantly impact its ability to access health care. Furthermore, once OIRA made public on its website that it was reviewing the NPRM, on May 18, 2018, it appears that OIRA did not allow public input before finalizing its review. On May 21 and 23, 2018, the Center requested a meeting with OIRA about the NPRM. But on May 23, 2018, OIRA pulled the listing of the NPRM from its website, and on May 24, 2018, OIRA replied to the Center that it had completed its review of the NPRM and would not meet on it.

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This NPRM violates federal law, was issued in violation of federal requirements, and would have devastating effects on women’s health and their economic security. The Department should rescind the NPRM immediately.

Sincerely,

Fatima Goss Graves
President and Chief Executive Officer
National Women’s Law Center

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41 Id.
43 All correspondence on file with the Center.