

Considerations for Drafting Comments on the Title X NPRM

On June 1, 2018, the US Department of Health and Human Services (HHS) officially published a notice of proposed rulemaking ("2018 NPRM")¹ for the Title X family planning program.² The 2018 NPRM not only reintroduces the majority of a Reagan-era Title X rule known as the "domestic gag" rule, but it expands those provisions and introduces numerous new and harmful requirements and restrictions.

Collectively, the provisions of the 2018 NPRM would undermine the high-quality standards of care in Title X and discourage and prevent highly qualified, trusted family planning providers from participating in the Title X program. Although the rule in many ways is designed to target abortion-related activities and entities that provide abortion care, it is not limited to such activities and/or providers, and 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.

The information below can be used to inform comment letters.

- Undermines the standard of care: The 2018 NPRM appears to permit entities to participate the Title X program which 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.
 - The proposal appears to blur the lines between "choices," "methods," and "services" to diminish the range of each (and especially the range of any contraception) provided under the Title X family planning program. (Section 59.2)
 - It also eliminates "medically approved" from the longstanding regulatory requirement that projects provide "a broad range of acceptable and effective medically approved family planning methods." (Section 59.5)
 - o The NPRM replaces the cautionary, caveat language of the current regulations (that organizations that only provide a single method of family planning can still participate in a Title X project as long as the entire project offers a broad range of family planning services) with a more permissive directive that "projects are not required to provide every acceptable and effective family planning method or service." (Section 59.5)
- Eliminates nondirective options counseling: The 2018 NPRM eliminates the long-standing requirement for nondirective options counseling and prohibits abortion referral in the event a patient has a positive pregnancy test. However, the proposal requires all pregnant people to be referred for prenatal care and/or social services, regardless of their wishes.
 - While HHS refrains from explicitly prohibiting counseling on abortion by a Title X project, the 2018 NPRM, at a minimum, creates significant confusion about whether abortion counseling is still permitted, and likely makes it difficult, if not impossible, for Title X projects to provide such counseling—particularly in light of the ban on "present[ing]" abortion as an option.³ (Section 59.5)
 - The proposed rule requires that Title X projects must refer pregnant patients for "appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption)" regardless of the patient's wishes or interest in such referrals. (Section 59.14)

¹ The 2018 NPRM was released May 29, and formally published in the *Federal Register* on June 1. The proposed rule has a comment period open through July 31, 2018. https://www.gpo.gov/fdsys/pkg/FR-2018-06-01/pdf/2018-11673.pdf.

[&]quot;Compliance With Statutory Program Integrity Requirements." 83 Federal Register 106 (June 1, 2018), p. 25502.

² Title X of the Public Health Service Act, Sections 1001 to 1008 (42 U.S.C. §§300 to 300a-6).

³ For more on abortion counseling, see Section III(i) of this analysis.

⁴ 2018 NPRM, § 59.14.

- **Undermines trust:** The 2018 NPRM directs Title X-funded entities to withhold full and accurate medical information from patients.
 - The Title X NPRM would require Title X projects to heavily favor an entity's possible religious and/or moral objection to abortion over the needs and wishes of patients. In additional to eliminating nondirective options counseling, the NPRM provides that, if specifically asked by a person who is already pregnant and who "clearly states that she has already decided to have an abortion," a "medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)." The list, if provided, "shall not identify the providers who perform abortion as such." (Section 59.14)
- Attempts to give HHS unchecked discretion to disqualify applicants: The 2018 NPRM changes the criteria for awarding Title X grants and attempts to give HHS broad, seemingly unchecked discretion to disqualify applicants before the competitive review process even begins if the agency deems them to not have sufficiently described how they will satisfy every requirement of "the regulation."
 - o The proposed rule includes no details for how HHS purports to determine whether an application has clearly addressed how it will satisfy the regulatory requirements to HHS's satisfaction, nor any mechanism for oversight of HHS' peremptory compliance review. Without such guidance or oversight, this new authority seems designed to be used to reshape the Title X network as HHS sees fit by allowing only favored applications to even reach the review panels. (Section 59.7)
- **Undermines confidentiality**: The 2018 NPRM threatens patient confidentiality, particularly for minors, in ways that could cause many patients to avoid seeking care in Title X settings.
 - o The NPRM undermines Title X's historically strong confidentiality protections requiring providers to put reporting and notification laws ahead of patient needs. It provides that "concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws." (Section 59.11)
 - o The NPRM requires every Title X project to "[e]ncourage family participation in the decision of minors to seek family planning services and ensure that the records maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged). (Section 59.14)
 - The proposed rule also changes the definition of "low-income family" to require that Title X providers document in the medical records of unemancipated minors "the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services," and adds this requirement as a condition of allowing unemancipated minors to receive confidential services based on their own resources (as opposed to their family's income). (Section 59.2)
- Adds costly and misguided reporting requirements: The 2018 NPRM adds extensive new reporting requirements by grantees about their networks, and by health centers about the actions they take with their patients and about the patients themselves.
 - By law, Title X projects are required to comply with state law requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, and incest. The 2018 NPRM, however, expands these reporting requirements to include intimate partner violence and sex trafficking, and similar reporting

⁶ 2018 NPRM, §§ 59.17 and 59.11.

⁵ See e.g. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, Div. H, Title II, Sec. 208 (2018) ("Notwithstanding any other provision of law, no provider of services under title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.").

- laws,"⁷ and extends the requirements to local law as well as state law.⁸ These changes exceed HHS authority.⁹
- o If finalized, the NPRM would require Title X projects to have in place an implemented plan for compliance with state reporting laws that, at minimum, include: a summary of obligations of the project (or organizations and individuals) to comply with state notification laws; "[t]imely and adequate" annual training of all individuals serving patients (including volunteers and other non-employees); policies and procedures with respect to state notification and reporting laws; and protocols to ensure that every minor seeking services is provided coercion counseling. The section also requires that Title X projects must commit 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."¹⁰ This requirement would apply to every individual under the age of consent and turns health care providers into interrogators of their patients, even when there is no sign of abuse. (Section 59.17)
- Prohibits activities related to abortion: The 2018 NPRM creates vague and confusing standards prohibiting more than a dozen activities associated with abortion, such as that a Title X project may not "present," "support," or even "promote a favorable attitude toward" abortion as a method of family planning.
 - According to the regulatory text of the NPRM, a Title X project cannot perform, provide, include, refer for, encourage, support, promote, present, advocate, indirectly encourage or promote, promote a favorable attitude toward, take any affirmative action to assist a patient to secure or obtain, or take actions to increase the availability or accessibility of abortion as a method of family planning.¹¹ These vague and broad prohibitions are certain to create confusion among Title X projects and providers, and would limit their willingness and ability to conduct otherwise-permissible activities. (Sections 59.13, 59.14., and 59.16)
- Requires physical and financial separation: The 2018 NPRM imposes onerous physical separation requirements on 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.
 - o The NPRM seems to give wide latitude to HHS to determine how the physical and financial separation requirement would be applied to activities and/or Title X-funded entities. The NPRM requires Title X projects to have "objective integrity and independence" from prohibited activities as determined by the Secretary of HHS based on a review of facts and circumstances.¹²
 - o The 2018 NPRM sets more stringent standards for Title X projects to meet than did the 1988 gag rule. It prohibits specific activities, including referral for abortion and activities associated with abortion, and would require that "Title X projects be physically and financially separate from programs in which abortion is provided or presented as a method of family planning, including programs that refer for abortions and programs that encourage, promote or advocate abortion as a method of family planning." (Section(s) 59.15)

⁷ 2018 NPRM, § 59.11.

^{8 2018} NPRM, §§ 59.17 and 59.11.

⁹ See e.g. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, Div. H, Title II, Sec. 208 (2018) ("Notwithstanding any other provision of law, no provider of services under title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.").

¹⁰ 2018 NPRM, § 59.17(b)(1)(iv).

¹¹ These prohibitions appear collectively in §§ 59.2, 59.5, 59.13, 59.14, and 59.16. By contrast, the current Title X regulation provides that a Title X project cannot provide abortion as a method of family planning (42 C.F.R. § 59.5), which is in line with the statutory prohibition, "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." 42 U.S.C. §300a-6.

¹² 2018 NPRM, § 59.15.

¹³ 2018 NPRM, 25519.

- Makes counseling on abortion difficult, if not impossible: The broad prohibitions and vague standards created by the 2018 NPRM related to abortion, combined with the proposed rule's physical separation requirements, would make it difficult, if not impossible, for Title X providers to counsel on abortion.
 - Unlike in the 1988 rule, the 2018 NPRM does not explicitly prohibit counseling on abortion, though the
 proposed regulation forbids "present[ing]" the option of abortion. However, the proposed rule would
 prohibit a much broader category of activities associated with abortion, and the preamble does not
 address whether abortion counseling would be violative of other prohibitions. (Section 59.14)
 - Even where the preamble suggests that nondirective counseling on abortion would be permitted, it confines this permission to physicians/doctors. Since the vast majority of medical services and counseling in Title X is provided by non-physician clinicians, such as nurse practitioners, few Title X projects could engage in the even limited opportunity for counseling seemingly contemplated by the proposed rule.
- Redefines "low-income": The 2018 NPRM would explicitly enable and may require Title X-funded entities to
 provide free or low-cost contraceptive services to women, regardless of income, whose employers provide
 insurance coverage but object, contrary to the Affordable Care Act, to that coverage including
 contraception.
 - o Title X was not designed to, nor can it, absorb the unmet 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.¹⁴
 - This proposal is using an already underfunded and overstretched government program to fill a while created by the administration in its interim final rules of October 13, 2017 regarding religious 15 and moral 6 objections to contraceptive coverage.
- Attempts to give HHS expanded oversight powers and grantees expanded responsibilities for the actions of subrecipients and referral providers: The 2018 NPRM seeks to give HHS unprecedented information and regulatory authority regarding Title X subrecipients and other care partners and asserts new control over how Title X grantees contract with their subrecipients and health centers.
 - o HHS's Title X relationship has been and is with the Title X grantees concerning the projects they operate, and not with the subrecipients or health centers that the grantee may subcontract with to provide family planning methods and services through a Title X project. The NPRM, however, seeks to change that relationship, by explicitly imposing the requirements of the Title X regulations equally on grantees and subrecipients.¹⁷ (Section 59.1)
- Places an inappropriate emphasis on comprehensive primary care: The 2018 NPRM unnecessarily and
 inappropriately seems to require that Title X providers prioritize comprehensive primary health care either
 by providing such services onsite or by having robust referral linkages with primary care providers in close
 physical proximity to the Title X-funded health center. HHS is pursuing this requirement even though
 primary care is not a permissible use of Title X funds and the best referrals for Title X patients are not
 necessarily defined merely by physical proximity.

¹⁷ 2018 NPRM, § 59.1(a).

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¹⁴ 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.

¹⁵ "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act." 82 Federal Register 197 (October 13, 2017), p. 47792.

¹⁶ "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act." 82 *Federal Register* 197 (October 13, 2017), p. 47838.

o The NPRM prioritizes "holistic health and seamless care" by seemingly requiring Title X providers to "offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site." The preference for Title X projects to be co-located with primary care is an unnecessary and impermissible change unsupported by evidence.

A more detailed analysis of the 2018 NPRM is available at www.nationalfamilyplanning.org.

 $^{^{18}}$ 2018 NPRM § 59.5, entitled, "What requirements must be met by a family planning project" (emphasis added), sets out the primary requirements each Title X project must meet. As such, § 59.5(a)(12) seems to be a requirement for **either** onsite primary care **or** robust referral linkages in close physical proximity. 2018 NPRM, § 59.5(a)(12).