National
Family Planning
& Reproductive Health Association

TO: Interested Parties
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SUBJECT: Analysis of 2018 Proposed Title X Regulation
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I. Introduction

On June 1, 2018, the US Department of Health and Human Services (HHS) officially published a notice of proposed rulemaking ("2018 NPRM" or "proposed rule")[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[3] ("1988 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.

Specifically, the 2018 NPRM, at a minimum:

a. Undermines the standard of care: The 2018 NPRM appears to permit Title X projects to 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.

b. Eliminates nondirective options counseling: The 2018 NPRM eliminates the long-standing requirement for nondirective options counseling and prohibits abortion referral, but requires all pregnant people to be referred for prenatal care and/or social services, regardless of their wishes.

c. Undermines trust: The 2018 NPRM directs Title X-funded entities to withhold full and accurate medical information from patients.

d. 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 any

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[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. "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] More information on the 1988 gag rule is provided in the next Section II of this analysis, "Background: The 1988 Domestic Gag Rule."

objective merits panel review if the agency deems them to not have sufficiently described how they will satisfy every requirement of "the regulation."

e. 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.

f. 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.

g. 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.

h. 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.

i. 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.

j. Redefines "low-income": The 2018 NPRM would explicitly enable and may require Title X-funded entities to provide free 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.

k. 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.

l. 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.

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.

This analysis examines key provisions of the 2018 NPRM, as well as provides background and comparison to the core provisions of the 1988 domestic gag rule.

It is important to note that while the preamble text[4] of a rule provides guidance[5] in interpreting a regulation's meaning and application, it is only the regulatory text of a rule that has the force of law. Simply put, the preamble of a rule, while providing some insight into an agency's thinking, does not govern: the regulatory text does. Thus, this analysis focuses primarily on the regulatory text of the 2018 NPRM, but notes where preamble language is of particular relevance.

II. Background: The 1988 Domestic Gag Rule

The Title X statute itself bars Title X projects from offering "abortion as a method of family planning."[6] Despite this statutory prohibition, in 1988, President Ronald Reagan's administration promulgated a final rule designed to "set specific standards for compliance with the statutory requirement" prohibiting abortion.[7] This regulation became commonly known as the "domestic gag rule."

The 1988 gag rule did three key things:

- Prohibited referral for and counseling on abortion: Title X projects were prohibited under the 1988 gag rule from providing "counseling concerning the use of abortion as a method of family planning" or providing "referral for abortion as a method of family planning."[8]

  Title X-funded sites were further mandated to refer all pregnant patients for prenatal care and/or social services, regardless of what options the patient wanted to pursue, and to provide them with information "necessary to protect the

[4] A proposed rule is comprised of a preamble and regulatory text. The preamble is the language at the beginning of a *Federal Register* publication that contains a summary of the issues and actions under consideration, date and contact information, and supplementary information about the rationale and intentions of the proposed rule. The regulatory text details the exact changes the agency proposes to make to the standing body of law in the Code of Federal Regulations (CFR).
[5] Further, it is the preamble of a final rule – as opposed to the preamble of a proposed regulation – that has this guidance effect. The 2018 NPRM is a proposed rule; therefore, both the preamble and the regulatory text may change by the time the rule is published as a final rule. In particular, the preamble of the final rule will certainly change from the 2018 NPRM version, since the final rule will need to address comments submitted during the open comment period.
[6] 42 U.S.C. 300a-6. "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."
[7] "Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects, Final Rule." 53 *Federal Register* 21 (February 2, 1988), p. 2922.
[8] 1988 gag rule, § 59.8(a)(1).

health of mother and unborn child until such time as the referral appointment is kept."[9]

- Prohibited activities related to abortion: Title X projects were not allowed to "encourage, promote or advocate abortion as a method of family planning."[10] This prohibition extended to "actions to assist women to obtain abortions or increase the availability or accessibility of abortion for family planning purposes."[11]

  The 1988 gag rule specifically prohibited "use of Title X project funds" for lobbying for legislation that increased the availability of, providing speakers to promote the use of, paying dues to any group that as a significant part of its activities advocated, using legal action to make available, and developing or disseminating materials advocating abortion as a method of family planning.[12]

- Required physical and financial separation: The 1988 gag rule required strict physical and financial separation between Title X projects and activities associated with abortion that were prohibited under the rule.[13] The rule required Title X projects to have "objective integrity and independence" from prohibited activities – namely, abortion itself, referral for and counseling on abortion as a method of family planning as prohibited by § 59.8 of the rule, and the activities of encouraging, promoting, or advocating abortion prohibited in § 59.10.

  Whether Title X projects had the requisite objective integrity and independence would be determined by the Secretary of HHS based on a review of facts and circumstances, including: the "existence of separate accounting records";[14] the "degree of separation from facilities (e.g., treatment, consultation, examination, and waiting rooms) in which prohibited activities occur and the extent of such prohibited activities";[15] the "existence of separate personnel";[16] and "the extent to which signs and other forms of identification of the Title X project are present and signs and material promoting abortion are absent."[17]

Several organizations, including NFPRHA, sued to keep the rule from going into effect. The court cases took several years, culminating in a hearing before the US Supreme Court in 1990. In 1991, the Supreme Court ruled in *Rust v. Sullivan* that the gag rule was an appropriate use of executive power.[18] In response to that ruling, Congress passed an appropriations bill to explicitly allow for abortion counseling within Title X (as part of

[9] 1988 gag rule, § 59.8(a)(2).
[10] 1988 gag rule, § 59.10(a).
[11] Ibid.
[12] 1988 gag rule, § 59.10(a)(1)-(5).
[13] 1988 gag rule, § 59.9.
[14] 1988 gag rule, § 59.9(a).
[15] 1988 gag rule, § 59.9(b).
[16] 1988 gag rule, § 59.9(c).
[17] 1988 gag rule, § 59.9(d).
[18] *Rust v. Sullivan*, 500 U.S. 173 (1991).

overall nondirective counseling), but it was unable to override President George HW Bush's veto.[19]

In 1992, HHS issued a memo stating that the regulations would thereafter be interpreted to permit doctors to counsel on abortion within the context of the doctor-patient relationship. NFPRHA and the National Association of Nurse Practitioners in Reproductive Health successfully sued under the Administrative Procedures Act, given that there was not proper rulemaking for the new policy.[20]

In January 1993, President Bill Clinton issued a presidential memorandum[21] compelling HHS to rescind the gag rule and promulgate new rules. The new rules, which were issued in February 1993[22] and finalized in July 2000,[23] required financial, but not physical, separation of Title X and non-Title X activities and reinstated the practice of nondirective options counseling and referral upon patient request.

The regulation finalized in 2000, which governs the Title X program today, clarified that Title X funds cannot used for abortion care, to support advocacy for abortion access, or to facilitate a patient obtaining such care (i.e. making an appointment).[24]

Although the 1988 gag rule was on the books for more than a decade, the rule was never implemented on a nationwide basis.[25]

III. The 2018 Proposed Rule

The 2018 NPRM not only resurrects much of the 1988 gag rule and expands upon it, but proposes a number of harmful new requirements and restrictions.

a. The 2018 NPRM appears to permit Title X projects to 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.

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."[26] Over the years, Congress added to the

[19] "Family Planning Amendments Act of 1992," S. 323, 102nd Cong. (1992).
[20] *National Family Planning and Reproductive Health Association v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992).
[21] Memorandum of January 22, 1993, for the Secretary of Health and Human Services on the Title X "Gag Rule," 58 Federal Register 23 (Feb. 5, 1993), p. 7455.
[22] "Standards of Compliance for Abortion-Related Services in Family Planning Service Projects" (Proposed Rule). 58 Federal Register 23 (Feb. 5, 1993), p. 7464.
[23] "Office of Public Health and Science; Standards of Compliance for and Provision of Abortion-Related Services in Family Planning Services Projects, Final Rule." 65 Federal Register 128 (July 3, 2000), p. 41270.
[24] 2000 Title X final rule.
[25] Ibid.
[26] "Family Planning Services and Population Research Act of 1970," Pub. L. No. 91-572, 84 Stat. 1504 (1970). Following approval of the first contraceptive pill by the Food and Drug Administration in 1960, research showed that low-income women had more children than they desired because they had inequitable access to contraceptives. In a Special Message to Congress on the Problems of Population

statute, 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)."[27]

The earliest Title X regulations made clear that under Congress' directive, Title X projects were required to provide "medical services related to family planning including physician's consultation, examination, prescription, continuing supervision, laboratory examination, contraceptive supplies" and "for use of a broad range of medically approved methods of family planning including the rhythm method" (emphasis added).[28]

Nearly identical regulatory language continues to govern Title X today, nearly 50 years later, with the current regulations requiring Title X projects to provide "medical services related to family planning (including physician's consultation, examination[,] prescription, and continuing supervision, laboratory examination, contraceptive supplies" and "a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)" (emphasis added).[29]

Section 59.2 of the 2018 NPRM proposes to define "family planning" to mean "the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved." In this definition, "the means" of achieving family planning goals would:

> "include a broad range of acceptable and effective choices, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility (including adoption)" (emphasis added).[30]

The 2018 NPRM appears to be watering down these long-standing requirements, and blurring the lines between "choices," "methods," and "services" to diminish the range of each (and especially the range of any contraception) to be provided.

Section 59.5 of the proposed rule, which details the requirements that must be met by a Title X project, makes further changes concerning methods and services. In sum, these changes:

Growth on July 18, 1969, 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." Congress responded by creating Title X.

[27] 42 U.S.C. §300.

[28] "Part 59—Grants for Family Planning Services," 36 *Federal Register* 179 (September 15, 1971), p. 18465, § 59.5.

[29] 42 C.F.R. § 59.5.

[30] 2018 NPRM, 25513.

- Eliminate "medically approved" from the longstanding regulatory requirement that projects provide "a broad range of acceptable and effective medically approved family planning methods";

- Add adoption (note: not referral for adoption, but adoption itself) as a type of service that can be offered, along with the existing offerings required by the Title X statute of basic infertility services and services for adolescents); and

- Replace 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. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services."

These changes seem designed to do two key things. First, the changes attempt to broaden the types of methods and services to which the "broad range" requirement applies. Second, the changes seem to encourage more single-method/service or limited method/service providers within a Title X project.[31]

When put together, the changes in the 2018 NPRM seem to contemplate a Title X project that, for example, provides only natural family planning and other fertility awareness-based methods (and perhaps a single type of contraception, such as condoms), along with abstinence-only-unless-married education for adolescents and adoption services. Under the 2018 NPRM, such a project might be considered to be providing a broad range of methods and services, even though the Title X statute and regulations as they have existed and been understood since 1971, it would not be providing a broad range.

b. The 2018 NPRM eliminates the long-standing requirement for nondirective options counseling and prohibits abortion referral, but requires all pregnant people to be referred for prenatal care and/or social services, regardless of their wishes.

The current § 59.5(a)(5) requires Title X projects to offer "pregnant women the opportunity to be provided information and counseling regarding . . . prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination." It further requires that such information and counseling "provide neutral, factual information and nondirective options counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling."

[31] *See e.g.* 2018 NPRM, 25516.

This current standard puts patients' own stated needs at the heart of options counseling and referral. It does not mandate the type of counseling or referral pregnant people receive; rather, it ensures that pregnant people are provided the opportunity to receive counseling on all of their options, and actually receive counseling on whatever options they choose, as well as receiving any referral they request.

The 2018 NPRM eliminates this long-standing and medically ethical requirement that Title X projects provide neutral, factual, nondirective options counseling and referral regarding all of a pregnant patient's options—including abortion—upon request.

Instead, the proposed rule deletes all reference in § 59.5 to nondirective options counseling and expands the prohibition on providing abortion as a method of family planning (which begins § 59.5(a)(5))[32] and adds that Title X projects shall not "promote, refer for, support, or present" abortion as a method of family planning. While HHS refrains from explicitly prohibiting counseling on abortion by a Title X project, the 2018 NPRM at 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.[33]

The proposed then further **requires** (in § 59.14) 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. Title X projects would be further required to give patients "assistance with setting up a referral appointment to optimize the health of the mother and unborn child."[34]

HHS states as justification for these changes that the current requirement that Title X projects offer pregnant patients counseling on and referrals for abortion is inconsistent with Title X's statutory prohibition on providing abortion as a method of family planning.[35] HHS states that "[r]eferrals for abortion are, by definition, directive," and so Title X projects cannot provide abortion referral and be in compliance with the federal law requiring that "all pregnancy counseling" in Title X projects "shall be nondirective."[36] HHS does not, however, find that referrals for prenatal and/or social services—which would now be mandated for every pregnant person, regardless of whether she wants such a referral—are similarly directive and violative of federal law.

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[32] The fact that the current § 59.5(a)(5) restates the Title X statute's prohibition on providing abortion as a method of family planning provides important context for the nondirective options counseling requirement, making clear that providing information and counseling on, and referral for, any service is not the same as actually providing that service to patients.

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

[34] 2018 NPRM, § 59.14.

[35] 2018 NPRM, 25506.

[36] *See e.g.* Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, Div. H, Title II, 716–717 (2018).

HHS further argues that requiring Title X projects to offer pregnant people the opportunity to be provided information and counseling on abortion or referrals for abortion "is inconsistent with the conscience protections embodied in the Church, Coats-Snowe, and Weldon Amendment."[37]

c. The 2018 NPRM directs Title X-funded entities to withhold full and accurate medical information from patients.

Along with the elimination of Title X's nondirective options counseling requirement, the changes discussed in the preceding section require Title X projects to put their thumb on the scale in favor of carrying a pregnancy to term. They also weigh heavily in favor of furthering an entity's possible religious and/or moral objection to abortion over the needs and wishes of patients.

Yet while the elimination of counseling and referral requirements permit Title X projects to withhold information from patients, the 2018 NPRM goes a step further and seemingly encourages Title X projects to withhold full and accurate medical information from a patient. Section 59.14(a) of the proposed rule 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." All other patients, if they ask, are to be provided a similar list but which excludes abortion providers.

In other words:

1. A list that includes abortion providers can only be provided a) by a medical doctor b) to a woman who clearly states that she has already decided to have an abortion;

2. Such a list does not have to include abortion providers—that seems to be a decision left to the project—and the proposed rule forbids a Title X project from telling the patient whether or not the provided list includes any abortion providers; and

3. If the list does include abortion providers, those providers a) cannot be noted as such in any way, b) can only be "comprehensive health service providers," and c) must provide comprehensive prenatal care in addition to abortion.

Altogether, these changes at best will lead to inconsistency in what information different Title X projects offer with regard to abortion, and at worst, direct Title X projects to mislead patients. They also harm all patients by limiting these lists of

[37] 2018 NPRM, 25506. Note: HHS is currently working to finalize regulations proposed in early 2018 concerning health care refusal law. The proposed refusal regulations overstep statutory authority and would seek to dramatically expand the reach of current refusal laws.

referrals to comprehensive health care providers, and eliminating inclusion of any kind of specialist.

d. **The 2018 NPRM changes the criteria for awarding Title X grants and attempts to give HHS broad, seemingly unchecked discretion to disqualify applicants before any objective merits panel review if the agency deems them to not have sufficiently described how they will satisfy every requirement of "the regulation."**

HHS claims that, with the new proposed application review crieria in the 2018 NPRM, it seeks to "[i]ncrease competition and rigor among applicants, [and] encourage[e] broader and more diverse applicants,"[38] despite no evidence that such change is needed, would be beneficial to patients, or is actually accomplished by the changes. If anything, the evidence shows that Title X patients would be harmed by the change-for-the-sake-of-change that HHS appears to be seeking.

Over time, the existing network of Title X primary grantees and subrecipients have been relatively stable, and as such have developed deep expertise and decades of experience in family planning that profoundly benefit the communities they serve. Many service sites are specialized family planning centers, whether run by nonprofit providers or within government health departments, with clinicians spending their full time on family planning care. Compared with non-Title X-funded health care providers, Title X sites provide higher quality care and are better able to help patients start and effectively use their chosen method of family planning.[39] These providers are more likely to provide the full range of FDA-approved contraceptives, including IUDs and contraceptive implants, onsite.[40] In addition, many patients prefer accessing care through a specialized Title X provider.[41]

Since 1971, the Title X regulations have specified the following seven criteria be used as the criteria for selecting Title X grantees:

1. The number of patients, and, in particular, the number of low-income patients to be served;

2. The extent to which family planning services are needed locally;

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[38] 2018 NPRM, 25517.

[39] *See, e.g.*, Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, 20 Guttmacher Policy Review 20, 21-22 (May 17, 2017); Hasstedt, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net*, 20 Guttmacher Policy Review 12, 12-13 (2017), https://www.guttmacher.org/gpr/2017/01/understandingplanned-parenthoods-critical-role-nations-family-planning-safety-net.

[40] *See, e.g.*, Bocanegra, et al., *Onsite Provision of Specialized Contraceptive Services: Does Title X Funding Enhance Access?*, J. Women's Health (May 2014), *abstract available at* https://www.liebertpub.com/doi/full/10.1089/jwh.2013.4511; *see also* Zolna & Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, Guttmacher Institute (2016), http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[41] Frost, et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22 *Women's Health Issues* 519, 525 (2012), https://doi.org/10.1016/j.whi.2012.09.002.

3. The relative need of the applicant;

4. The capacity of the applicant to make rapid and effective use of the federal assistance;

5. The adequacy of the applicant's facilities and staff;

6. The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

7. The degree to which the project plan adequately provides for the requirements set forth in these [Title X] regulations.[42]

When Title X competitive grantmaking occurs, objective merits review panels of experts score each of these seven criteria to determine the best applications. The 2018 NPRM eliminates these historic seven criteria, replacing them with four broad criteria that in some ways appear internally inconsistent, make any meaningful merits review scoring exceedingly difficult, and seem to give HHS great flexibility in how it assesses applications and makes decisions. Completely removed are the current criteria concerning the adequacy of the applicant's facilities and staff and the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project.

The proposed rule sets out adherence to Title X's statutory purpose and goals and meeting "all of the statutory and regulatory requirements and restrictions," and the statute's prohibition on providing abortion as a method of family planning, as the first criteria for selection through the competitive grant review process.[43]

The remaining three new criteria relate in some ways to aspects of the current regulations: the relative need of the applicant and the capacity to make rapid and effective use of grant funds;[44] the number of patients to be served;[45] and the extent to which family planning services are needed locally.[46]

However, these criteria are modified and made more vague, apparently to prioritize HHS's clear goal of reshaping the Title X program and network. These altered criteria prioritize new and non-traditional efforts and entities over proven techniques and experienced providers. Capacity to make rapid and effective use of grant funds is newly linked to applicants that make use of such funds "among a broad range of partners and diverse subrecipients and referral individuals and

[42] 42 C.F.R. § 59.7(a)(1-7).
[43] 2018 NPRM, § 59.7(c)(1).
[44] 2018 NPRM, § 59.7(c)(2).
[45] 2018 NPRM, § 59.7(c)(3).
[46] 2018 NPRM, § 59.7(c)(4).

organizations, and among non-traditional Title X partnering organizations."[47] The number of patients to be served is modified so that the grant application should also target "areas that are more sparsely populated and/or places in which there are not adequate family planning services available."[48] The extent to which family planning services are needed locally is combined with criteria assessing how "the applicant proposes innovative ways to provide services to unserved or underserved patients."[49]

Further, and even more concerning, is the unchecked discretion HHS seeks to give itself to prevent applications from even reaching the objective review process that governs the awarding of grant. The proposed section 59.7(b) states:

> "Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process, but shall be deemed ineligible for funding. The Department will explicitly summarize each provision of the regulation (or include the entire regulation) within the Funding Announcement, and shall require each applicant to describe their plans for affirmative compliance with each provision."

If, and only if, HHS deems an application has sufficiently described how the applicant will satisfy every requirement of "the regulation," will the application be assessed by objective reviewers under the new grantmaking criteria. 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.

e. The 2018 NPRM threatens patient confidentiality, particularly for minors, in ways that could cause many patients to avoid seeking care in Title X settings.

One of the hallmarks of Title X has been the program's strong protections for patient confidentiality. Since the 1970s, federal law has required that both adolescents and adults be able to receive confidential family planning services in Title X projects. The strong confidentiality protections for adolescents are derived from the Title X statute, regulations, and relevant case law. They have been

[47] 2018 NPRM, § 59.7(c)(2).
[48] 2018 NPRM, § 59.7(c)(3).
[49] 2018 NPRM, § 59.7(c)(4).

modified only to encourage, but not mandate, family involvement,[50] and to require Title X providers to comply with state child abuse reporting laws.[51]

Family planning services, which address some of the most sensitive and personal issues in health care, are among those that require the strongest protections. The Title X confidentiality regulations[52] are among the strongest in current law, and these confidentiality protections are one of the reasons individuals choose to seek care at Title X sites.[53]

The regulations contain exceptions that allow health providers to disclose patient information without documented consent if necessary to provide services to the patient or if the disclosure is required by law; but even then appropriate safeguards for confidentiality must be in place. These regulatory requirements have been incorporated into Title X program guidance,[54] and combined with the current regulations, can be viewed as a gold standard in confidentiality protections across the nation's health system.[55]

Patients seeking family planning services, and therefore generally requiring strong confidentiality protections, encompass a broad spectrum of patient populations.[56] Research has documented the special privacy concerns of certain populations,

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[50] Congress amended the Title X statute in 1981 to encourage family involvement, but did not require it. Pub. L. No. 97-35, § 931 (1981). "The conferees believe that, while family involvement is not mandated, it is important that families participate in the activities authorized by this title as much as possible." H.R.Conf.Rep. No. 208, 97th Cong., 1st Sess. 799 (1981). *See also* Abigail English and Carol Ford, "The HIPAA Privacy Rule and Adolescents: Legal Questions and Clinical Challenges," *Perspectives on Sexual and Reproductive Health*, Volume 36, Number 2, March/April 2004, Guttmacher Institute, http://www.guttmacher.org/pubs/journals/3608004.html.

[51] Rebecca Gudeman and Sarah Madge, "The Federal Title X Family Planning Program: Privacy and Access Rules for Adolescents," *Youth Law News*, Volume XXX, Number 1, January-March 2011, National Center for Youth Law, https://youthlaw.org/publication/the-federal-title-x-family-planning-program-privacy-and-access-rules-for-adolescents1/.

[52] 42 C.F.R. § 59.11.

[53] Jennifer J. Frost, Rachel Benson Gold, and Amelia Bucek, "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs," *Women's Health Issues* 22 (November 2012): e519-e525.

[54] Office of Population Affairs, Program Requirements for Title X Funded Family Planning Projects, (April 2014), Sec. 10. http://www.hhs.gov/opa/pdfs/ogc-cleared-final-april.pdf.

[55] Abigail English, Center for Adolescent Health & the Law, and National Family Planning & Reproductive Health Association, Adolescent Confidentiality Protections in Title X, June 5, 2014. http://www.nationalfamilyplanning.org/document.doc?id=1559.

[56] Rachel B. Gold, "A New Frontier in the Era of Health Reform: Protecting Confidentiality for Individuals Insured as Dependents," *Guttmacher Policy Review* 16, no. 4 (2013): 2. https://www.guttmacher.org/pubs/gpr/16/4/gpr160402.pdf.

including adolescents and young adults,[57] and victims of domestic or intimate partner violence.[58]

The 2018 NPRM threatens Title X's longstanding and critical protections for patient confidentiality, particularly for minors, in ways that could undermine the trust Title X patients have in their providers and cause many patients to avoid seeking care in Title X settings. In particular, the proposed rule undermines patient confidentiality in two primary ways:

1. *Greater pressure for family involvement*
   Although the Title X statute encourages, but does not mandate, family involvement in the family planning decisionmaking of minors, the 2018 NPRM attempts to make such involvement mandatory for all adolescents in several ways.

   Section 59.2 of the proposed rule 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."

   The 2018 NPRM 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). In other words, if a Title X provider does not encourage such minors to involve their parents or guardian in their decision to seek family planning services **and** does not document the specific actions taken to encourage such involvement, the

[57] Research findings have shown that privacy concerns influence the behavior of adolescents and young adults with respect to whether they seek care, where they do so, which services they accept, and how candid they are with their health care providers. Carol A. Ford, Abigail English, and Garry Sigman, "Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine," *Journal of Adolescent Health* 35, no. 2 (2004): 160-167. http://www.jahonline.org/article/S1054-139X%2804%2900086-2/fulltext; Alina Salganicoff, Usha Ranji, Adara Beamesderfer, and Nisha Kuran, *Women and Health Care in the Early Years of the ACA: Key Findings from the 2013 Kaiser Women's Health Survey* (Menlo Park, CA: Henry J. Kaiser Family Foundation, May 2014): 28, 38-39. https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8590-women-and-health-care-in-the-early-years-of-the-affordable-care-act.pdf. Adolescents are especially concerned about disclosures to their parents of their use of family planning services, but young adults have similar concerns. Diane M. Reddy, Raymond Fleming, and Carolyne Swain, "Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services," *JAMA* 288, no. 6 (2002): 710–714; Rachel K. Jones, et al., "Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception," *JAMA* 293, no. 3 (2005): 340–348; Carol A. Ford, et al., "Young Adults' Attitudes, Beliefs, and Feelings About Testing for Curable STDs Outside of Clinic Settings," *Journal of Adolescent Health* 34, no.4 (2004): 266-269.

[58] *National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings*. (San Francisco: Family Violence Prevention Fund, 2004). http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf.

2018 NPRM would seek to prevent unemancipated minors from receiving confidential services for free.

Section 59.2 provides that the only exception to the family involvement documentation requirement is if the provider has documented in the medical record 1) that it suspects the minor is the victim of child abuse or incest, **and** 2) that the provider has reported the situation to the relevant authorities, consistent with and if permitted or required by applicable state or local law (more on mandatory reporting in the next subsection of this document).

Section 59.5(a)(14) similarly pushes toward family involvement as a requirement for all minors, whether they seek free care or not.[59] This section 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).

Taken together, these provisions of the proposed rule seek to insert HHS into the provider/patient relationship, increasing family involvement beyond the language of the Title X statute and subverting the judgment and expertise of Title X providers as to whether encouraging family participation is practical (i.e. a realistic, appropriate option and not harmful) based on the specific circumstances of the individual minor patient.

2. *Compliance with reporting requirements*

The 2018 NPRM dramatically expands the scope and HHS's oversight of compliance with reporting requirements, and institutes harsh penalties for perceived failures of Title X projects to comply. The proposed rule also 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.

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.[60] The 2018 NPRM, however, expands these reporting requirements to include intimate partner violence and sex trafficking,[61] and

[59] 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.
[60] *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.").
[61] 2018 NPRM, §§ 59.17 and 59.11.

"similar reporting laws,"[62] and extends the requirements to local law as well as state law.[63] These changes exceed HHS authority.[64]

The proposed rule prescribes a number of steps Title X projects must take to demonstrate compliance with the reporting requirements. Under § 59.17 of the 2018 NPRM, Title X projects must have in place and implemented a 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 proposed rule further 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."[65] 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.

Yet even if a Title X project seemingly satisfies these compliance requirements, a project could be at risk of not being funded and/or losing funding. The 2018 NPRM seeks to prohibit projects from receiving Title X funds unless the project provides "appropriate documentation or other assurance satisfactory to the Secretary" of HHS that it has met the compliance requirements.[66] It also states that continuation of "grantee or subrecipient funding . . . is contingent upon demonstrating to the satisfaction of the Secretary" that the requirements have been met.[67] This vague language could translate into a subjective and coercive standard that could be used to force Title X projects to take actions that violate established medical ethics or risk losing funding.

This language also opens up the potential for HHS to seek patient medical records as a means of providing "appropriate documentation . . . satisfactory to the Secretary." Section 59.17(d) expressly seeks to provide HHS with this authority, stating, "The Secretary may review records

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[62] 2018 NPRM, § 59.11.
[63] 2018 NPRM, §§ 59.17 and 59.11.
[64] *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.").
[65] 2018 NPRM, § 59.17(b)(1)(iv).
[66] 2018 NPRM, § 59.17(b).
[67] 2018 NPRM, § 59.17(c).

maintained by a grantee or subrecipient for the sole purpose of ensuring compliance with the requirements of this section."

This potential for harm is exacerbated by the specific information the proposed rule requires Title X providers to collect and document in records in order to demonstrate compliance with § 59.17(b)(1). Section 59.17(b)(2) requires providers to document the age of minor patients as well as the age of the minor patients' sexual partners where required by law. Not only does this require Title X projects to maintain records that include this highly personal information, but it would require providers to collect the information in the first place no matter what the surrounding circumstances—meaning providers would be required to ask minor patients for this information, the very act of which could scare away or at a minimum disturb minor patients and cause them to no longer seek care in a Title X setting. Section 59.17(b)(2) also requires providers to document "each notification or report made pursuant to" state notification laws.

The 2018 NPRM further undermines Title X's historically strong confidentiality protections by adding language to § 59.11 that seeks to overrule the professional medical judgment of Title X providers and require them to put reporting and notification laws ahead of patient needs. Section 59.11 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."

Putting notification and reporting laws ahead of patients' needs and confidentiality concerns risks the health and safety of Title X patients and could lead to many patients to withhold important information from providers or even seek care at all in Title X settings. Moreover, the potential invasion of patient privacy by the government contemplated in the 2018 NPRM could have a major chilling effect on individuals' willingness to seek Title X-funded services, and the interests of patients, public health, and privacy law weigh strongly against such an invasion.

f. 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.

As discussed in the preceding subsection, the 2018 NPRM adds numerous provisions requiring Title X-funded providers to document actions they take with their patients, and about the patients themselves, in patient medical records.[68] In addition to threatening patient privacy and individuals' willingness to seek services in Title X settings, these requirements would have a significant cost to current Title X projects in changes that would need to be made to electronic health record

[68] 2018 NPRM, § 59.2 and 59.17.

templates in order to capture such information.[69] These, and other costs,[70] are not reflected in the proposed rule's Analysis of Economic Impacts.[71]

The proposed rule also seeks unprecedented oversight of Title X grantees' subrecipients, referral agencies, and other partners. Section 59.5(a)(13) would require in all grant applications and required reports:

- The name, location, expertise, and services provided or to be provided of every subrecipient, referral agency, and individual;
- A detailed description of the extent of collaboration with subrecipients, referral agencies, and individuals, as well as with less formal partners in the community; and
- A clear explanation of how a grantee "will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services." This new requirement is imposed despite the fact that there is nothing else in the Title X legal scheme that actually makes grantees responsible for the "quality and effectiveness of outcomes among subrecipients" and referrals, or that explains the nature of "effective" outcomes, as purportedly addressed here.

Additionally, § 59.18 requires grantees to "use the majority of grant funds to provide direct services to clients" and to "give a detailed accounting for the use of grant dollars, both in their applications for funding and within any annually required reporting."

These reporting requirements are intended, according to HHS, to "ensure accountability for, and wise use of, taxpayers' money."[72] However, these new requirements would be costly and administratively problematic,[73] and detract from Title X's primary mission, which is providing care.

g. 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.

[69] Electronic health record (EHR) template changes cost approximately $10,000 for development and installation, depending on the extent of the changes and the number of sites across which updates need to be installed. This amount does not include staff time to implement changes, which would be substantial and require coordinating with EHR vendors and implementing the new templates with IT staff and clinicians.
[70] More information on HHS's underestimation of the economic impact of the 2018 NPRM will be provided in NFPRHA's comments to the proposed rule.
[71] 2018 NPRM, 25522.
[72] 2018 NPRM, 25508.
[73] For example, describing with specificity an entire Title X project's network would take up significant pages of a grant application, leaving fewer pages to detail the actual Title X project, let alone "clearly address how the proposal will satisfy the requirements of this regulation" as required by § 59.7(b).

The 2018 NPRM takes broad aim at any activities HHS considers associated with abortion, and includes prohibitions on more than a dozen such activities by Title X projects. According to the regulatory text of the 2018 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.*[74]

As discussed elsewhere in this analysis, 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.

The 2018 NPRM also includes a specific list of prohibited activities that includes and expands upon the prohibitions of the 1988 gag rule. For example:

- Whereas the 1988 gag rule prohibited paying dues to any group that as a significant part of its activities advocated abortion as a method of family planning, the 2018 NPRM would change the standard to "any group that, as a more than insignificant part of its activities" advocates abortion as a method of family planning "and does not separately collect and segregate funds used for lobbying purposes";

- Whereas the 1988 gag rule prohibited developing or disseminating materials that advocated abortion as a method of family planning, the 2018 NPRM would also prohibit developing or disseminating materials (including web-based materials) that "otherwise promot[e] a favorable attitude toward abortion."

Additionally, the 2018 NPRM would add new provisions that prohibit the use of Title X project funds for attending events or conferences during which the grantee or subrecipient engages in lobbying.[75]

h. 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.

As written, it is clear that the 2018 NPRM includes a specific list of activities that would be subject to the proposed rule's separation requirements, but it is unclear exactly what those standards would require a Title X-funded entity to do to be in

[74] 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.

[75] The 1988 gag rule prohibited the "use of Title X project funds" for lobbying for legislation that increased the availability of, providing speakers to promote the use of, paying dues to any group that as a significant part of its activities advocated, using legal action to make available, and developing or disseminating materials advocating abortion as a method of family planning.

compliance. Further, the 2018 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.

Similar to the 1988 gag rule, the 2018 NPRM requires strict physical and financial separation between Title X projects and activities associated with abortion that are prohibited under the proposed rule.[76] The separation requirements detailed in § 59.15 of the 2018 NPRM apply to all activities prohibited under §§ 59.13, 59.14, and 59.16. These sections prohibit 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."[77]

The separation requirement would also apply to some of the broader and more vague prohibitions (including that Title X projects may not promote, support, or encourage abortion as a method of family planning). Thus, while physical separation does not seem to be required for a Title X project to use non-Title X funds to "present" abortion as a method of family planning (because the prohibition on "present[ing" abortion as a method of family planning does not appear in §§ 59.13, 59.14, or 59.16), physical separation would be required for activities that "promote" or "encourage" abortion as a method of family planning (because they appear in § 59.16).

The 2018 NPRM further 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.[78] The 2018 NPRM sets more stringent standards for Title X projects to meet than did the 1988 gag rule. Under § 59.15 of the 2018 NPRM, the factors relevant to the Secretary's determination will include:

a. The existence of separate, <u>accurate</u> accounting records;

b. The degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, <u>office entrances and exits, shared phone numbers, email addresses, educational services, and websites</u>) in which prohibited activities occur and the extent of such prohibited activities;

c. The existence of separate personnel, <u>electronic or paper-based health care records, and workstations</u>; and

[76] 2018 NPRM, § 59.15.
[77] 2018 NPRM, 25519.
[78] 2018 NPRM, § 59.15.

d. The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.[79]

HHS is particularly concerned over what it terms "Infrastructure Building That Creates Fungibility Concerns Related to Abortion Services."[80] Thus, in addition to the physical and financial separation requirements of § 59.15, the 2018 NPRM adds a new section (§59.18) prohibiting the use of Title X funds "to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient." HHS includes infrastructure as including "securing physical space, developing or acquiring health information technology systems (including electronic health records), bulk purchasing of contraceptives or other clinic supplies, clinical training for staff, and community outreach and recruiting."[81]

Title X projects are likely to have a difficult, if not impossible, task in ascertaining what activities would run afoul of these separation requirements. The proposed rule is therefore likely to have a significant chilling or prohibitory effect on a wide variety of otherwise-permissible activities paid for with non-Title X funds. To undertake those activities the only safe course would be complete physical separation, an exceedingly costly step that is not rational or achievable in order simply to pay membership dues or engage in a lawsuit.

Despite these onerous requirements and the negative impact they are likely to have, HHS seeks comment on whether additional separation requirements, such as complete organizational separation or requiring a Title X health center to operate under a distinct name different from a facility that provides abortion care, are required.[82]

i. 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. Indeed, the preamble of the 2018 NPRM states that "a doctor would be permitted to provide nondirective counseling on abortion," and such counseling "would not be considered encouragement, promotion, or advocacy of abortion as a method of family planning" as prohibited under § 59.16 of the proposed rule, but does not explain how the proposed rule actually authorizes it.[83]

However, as explained in previous sections, the proposed rule would prohibit a much broader category of activities associated with abortion than what is

[79] Emphasis added to denote additions to 1988 gag rule.
[80] 2018 NPRM, 25508.
[81] 2018 NPRM, 25508.
[82] 2018 NPRM, 25519.
[83] 2018 NPRM, 25507.

prohibited in § 59.16, and the preamble does not address whether abortion counseling would be violative of other prohibitions in §§ 59.2, 59.5, 59.13, and 59.14. Further, 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.

Collectively, the 2018 NPRM's broad prohibitions on activities associated with abortion, the elimination of Title X's longstanding nondirective options counseling requirement, the onerous physical separation requirements for activities provided with non-Title X funds, and the extremely limited (if at all available) permission in the preamble for abortion counseling by doctors would make it difficult, if not impossible, for Title X-funded providers to feel comfortable counseling on abortion in a Title X setting, even when a patient explicitly asks for such counseling.

j. The 2018 NPRM would explicitly enable and may require Title X-funded entities to provide free 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.

The current Title X regulations require that "no charge will be made for services provided to any person from a low-income family" except to the extent that payment can be made by a third-party payer (like commercial insurance or Medicaid).[84] Individuals with incomes above 100% of the federal poverty level (FPL) are charged on a schedule of discounts based on their ability to pay or full fee, depending on their income level.[85] These requirements are based in the Title X statute, which requires any person from a low-income family receive services from a Title X project at no charge and authorizes the Secretary of HHS to define low-income "so as to [e]nsure that economic status shall not be a deterrent to participation in the programs assisted under this title."[86]

The 2018 NPRM, however, 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.[87]

This definitional change would, when read in the context of the current regulations at §§ 59.5(a)(7) and (a)(8), would explicitly enable and may require Title X-funded

[84] 42 C.F.R. § 59.5(a)(7).
[85] 42 C.F.R. § 59.5(a)(8).
[86] 42 U.S.C. § 300a-4(c).
[87] 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.

entities to provide free contraceptive services to women whose employers object to them having insurance coverage of contraception, regardless of their income.

Although the 2018 NPRM states that such women "can be considered" low income for the purposes of contraceptive services, and HHS states in the preamble that this change would allow such women to receive "free or low-cost" family planning services, the preamble also states that the proposed rule "would amend the definition . . . to include women who are unable to obtain certain family planning services" under their employer-sponsored coverage due to their employers' religious beliefs or moral convictions.[88] This language suggests that this definitional change would be a requirement and not merely permissive.

Title X was not designed to, nor can it, absorb the unmet needs of insured individuals who have incomes above 250% of the FPL. Furthermore, 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, directing Title X-funded agencies to seek payment from such third party payers. Even more, 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 at the heart of Title X's purpose.

k. 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.

Historically, the Title X regulations applied to Title X projects (a program of educational, comprehensive medical, and social service activities funded by a Title X service grant to aid individuals in freely determining the number and spacing of their children) and grantees (the entity that is awarded a service grant under section 1001 of the Public Health Service Act to establish and operate a Title X project). In practical terms, this has meant that 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 2018 NPRM seeks to change that relationship, by explicitly imposing the requirements of the Title X regulations equally on grantees and subrecipients.[89] The proposed rule would also require grantees to require subrecipients (and the subrecipients of subrecipients) to ensure compliance with the regulations by incorporating compliance measures into their contracts with subrecipients.[90]

Although federal law generally requires subrecipients of federal funds to comply with the same requirements (when applicable) as apply to the grantee, HHS has

[88] 2018 NPRM, 25514.
[89] 2018 NPRM, § 59.1(a).
[90] Ibid.

consistently operated with the understanding that it is the grantee – and the grantee alone – with which HHS has a relationship. As such, any directives from HHS must flow through the grantee to the subrecipients and health centers. Similarly, as the grantee is responsible for ensuring the project's compliance with Title X's regulations, HHS's oversight of Title X (including program review) is through the Title X grantee; HHS currently has no direct oversight authority of subrecipients or health centers.

I. 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.

Title X funding cannot be used to provide comprehensive primary care services, nor is co-location with primary care contemplated by or present in the Title X statute. Further, many women actively choose reproductive health-focused providers for contraceptive care, even when there is a primary care-focused site available nearby, because family planning patients feel more respected by staff, know they are able to obtain confidential services there, and recognize that staff at specialized providers are especially well-versed in family planning and sexual health.

The 2018 NPRM prioritizes "holistic health and seamless care" by seemingly requiring Title X providers to either "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."[91]

As with the FY 2018 FOA, the preference for Title X projects to be co-located with primary care is an unnecessary and impermissible change unsupported by evidence. As we know, Title X providers have robust referral relationships of all kinds that they can use to benefit their patients, but a unique focus on physically close primary care will not improve or otherwise assist Title X care—to the contrary, it will tend to diminish specialists' direct participation in the Title X program, to the detriment of patients.

IV. Conclusion

The 2018 NPRM contains a number of deeply concerning, harmful, and potentially impermissible requirements and restrictions that, if finalized, would reshape not only the Title X provider network but the Title X program itself. However, it should again be noted that this proposed rule is still that—a proposal—and has a number of procedural stages to go through before it could go into effect.

[91] 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).

The public comment period, which ends July 31, is a critical opportunity to detail the concerns Title X grantees, subrecipients, and health centers have about the proposed rule and its potential impact on their programs and patients.