National
Family Planning
& Reproductive Health Association

May 17, 2021

Office of Population Affairs
Office of the Assistant Secretary for Health
US Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Attn: Title X Rulemaking

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments to the US Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," RIN 0937-AA11.

NFPRHA is a non-partisan, nonprofit membership association whose mission is to advance and elevate the importance of family planning in the nation's health care system. NFPRHA membership includes more than 1,000 members that operate or fund more than 3,500 health centers that deliver high-quality family planning education and preventive care to millions of people every year. NFPRHA represents the broad spectrum of publicly funded family planning providers, including state and local health departments, hospitals, family planning councils, federally qualified health centers, Planned Parenthood affiliates, and other private non-profit agencies. As a leading expert in publicly funded family planning, NFPRHA conducts and participates in research; provides educational subject matter expertise to policymakers, health care providers, and the public; and offers its members capacity-building support aimed at maximizing their effectiveness and financial sustainability as providers of essential health care.

NFPRHA's members include the majority of current Title X grantees, those that withdrew from Title X due to the 2019 Title X rule and a large segment of Title X subrecipients.

NFPRHA greatly appreciates HHS' NPRM revoking the 2019 Title X regulations. Once finalized, the proposed rule would return Title X to its essential purpose of "making comprehensive voluntary family planning services readily available to all persons desiring such services."[1]

As a result of the 2019 rule, more than 1,200 family planning providers in 34 states left the Title X program.[2] Numerous states were left either with no Title X-funded programs or, because of the loss of subrecipients, with programs unable to serve the entirety of the service areas they were funded to serve.[3] Despite assertions that the 2019 regulations would cause new applicants to apply for Title X funding and result in "more clients being

[1] The Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, 84 Stat.1504, § 2(1) (1970).

[2] Forty Title X projects across 34 states had service sites withdraw or have withdrawn completely from the Title X program due to the 2019 rule. Nat'l Family Planning & Reproductive Health Ass'n, *State of the Title X Network*, (July 2020), https://www.nationalfamilyplanning.org/file/2020-state-one-pagers-new/Impact-of-the-Title-X-Rule-in-California.pdf.

[3] Mia Zolna et al., *Estimating the impact of changes in the Title X network on patient capacity*, Guttmacher Inst., 2 (2020), https://www.guttmacher.org/sites/default/files/article_files/estimating_the_impact_of_changes_in_the_title_x_network_on_patient_capacity_2.pdf.

served,"[4] the Trump administration was unable to find new grantees to fill the gaps the regulations created, and large numbers of clients lost access to Title X services. According to federal data, 2.5 million people lost access to Title X-funded services in less than two years.[5]

The 2019 rule forced Title X-funded providers that offered a full range of reproductive health services to choose between continuing to receive Title X funding and providing comprehensive, high-quality care consistent with professional and ethical duties. In addition, providers were forced either to forego Title X funding because they were financially or otherwise unable to comply with the 2019 rule's "physical separation" requirements, or to waste large sums attempting to comply with a sweeping, subjective mandate. The organizations that remained in the program are being required to provide incomplete care and counseling, and many have struggled to replace providers in areas that are underserved.

The NPRM will help repair damage the 2019 regulations caused to the Title X program, its providers, and the patients they serve. NFPRHA supports finalization of the proposed rule as quickly as possible and offers these comments to help clarify and improve the proposed rule.

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The 2019 Title X rule has caused great harm to the nation's public health.

NFPRHA agrees with HHS' statement in the NPRM that "the 2019 rule was a solution in search of a problem, a solution whose severe public health consequences caused much greater problems."[6] The 2019 rule caused nearly half of all Title X projects to lose providers from the program.[7] The results of these losses, compounded by the impact of the COVID-19 pandemic, have been devastating: the government's preliminary data "indicate that only about 1.5 million clients were served" in FY 2020, down from 3.1 million in FY 2019 (in which the 2019 rule was in effect for about half of the year), and down from an annual average of 4 million patients served before the 2019 rule.[8]

The 2019 rule also undermined the effectiveness of the Title X services grants, contradicted standards of care, and wasted regulatory and health care resources. The rule articulated unworkable, illusory approaches; nowhere is this more evident than with the rule's "physical separation" requirement.

To start, the premises of the physical separation scheme do not fit with the most basic characteristics of Title X. Title X projects are defined by the family planning-related *activities* that take place in a variety of ordinary educational and health care settings. Projects are not standalone, brick-and-mortar "Title X" physical spaces. Instead, the projects have always operated in *thousands* of different physical settings, including a variety of multi-purpose health care centers, government offices, schools and universities, hospitals, and mobile sites. Before the 2019 rule, there were Title X projects in all 50 states, DC, and most of the territories. There were more than 3,800 sites where Title X services were being provided and even with the large gaps created by the 2019 rule, that number still exceeded 2,800. Thus, a regulatory scheme requiring physical separation and under which the Secretary would make case-by-case, individualized determinations of whether there was sufficient separation "based on a review of facts and circumstances" at each of the thousands of places where Title X

[4] Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7,714, 7,723 (Mar. 4, 2019).

[5] *See* Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 Fed. Reg. 19,812 (Apr. 15, 2021).

[6] *Id.* at 19,817.

[7] *State of the Title X Network*, Nat'l Family Planning & Reproductive Health Ass'n (July 2020), https://www.nationalfamilyplanning.org/file/2020-state-one-pagers-new/Impact-of-the-Title-X-Rule-in-California.pdf. *State of the Title X Network*, *supra* note 2.

[8] 86 Fed. Reg. at 19,822–23.

project administration or services occur was unrealistic and unworkable from the beginning. To the extent that any Title X sites could be reviewed, such comprehensive, individualized assessments of myriad factors identified in the 2019 rule would involve exorbitant regulatory costs.

HHS did not issue guidance that might have helped with compliance or enforcement. Thus, those charged with implementation—both inside and outside HHS—had no clear, discernable standard that could be readily summarized, consistently applied, and objectively enforced. Indeed, when grantees inquired of HHS, they were sometimes given different answers to the same implementation questions, even when the facts and circumstances presented to HHS were the same. For example, different grantees were given different answers as to whether and how their service sites had to physically and administratively separate from non-Title X provision of pregnancy counseling that included referrals for abortion at patients' request.

Most harmfully, continued implementation of a physical separation scheme would conflict with medical best practices and the realities of modern health care and stigmatize Title X patients. The Title X program has always urged its family planning service providers to help patients access health care and social services needs, and the 2019 rule's physical separation requirements are inconsistent with that goal.

HHS spent years encouraging and providing resources for Title X grantees and subrecipients to acquire and maintain up-to-date, integrated electronic health records systems, but section 59.15 pushed in the opposite direction, calling for duplicate, Title X-only systems that could leave vital information out of a patient's general medical records. The harmful physical separation factors in section 59.15 even included signs identifying Title X projects, which would flag Title X care as separate from ordinary health care and contribute to stigma about patients who use Title X-funded services.

Rescinding section 59.15 and its "physical separation" enforcement scheme is essential. Title X's purpose and all of its statutory requirements, including the limitation on the use of Title X funds set forth in 42 U.S.C. § 300a-6, can be fully served by finalizing the NPRM. HHS' notice at 65 FR 41281 (July 3, 2000), which has clearly, successfully, and efficiently implemented 42 U.S.C. section 300a-6 for decades, will further inform implementation of the finalized rule for both the Department and grantees.

NFPRHA further appreciates the NPRM's recognition of the 2019 rule's excessive "infrastructure costs" and "micro-level monitoring and reporting,"[9] and its proposal in section 59.5(a)(13) to reduce these burdens. However, NFPRHA believes that requiring grantees to provide details on the "extent of collaboration with referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients"[10] is too onerous. Proposed section 59.5(a)(13) does not adequately differentiate between reporting related to subrecipients, which provide Title X-funded services under the oversight of a grantee, and referral agencies or individuals who are outside a Title X project. Gathering information from health and social services providers that receive no funding from Title X on a regular basis is time- and resource-intensive for grantees, compounded by the need to include such information in "all required reports."[11] For that reason, NFPRHA asks that the proposed section 59.5(a)(13)(ii) end after the word "subrecipients."

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[9] *Id.* at 19,817.

[10] *Id.*

[11] *Id.*

NFPRHA strongly supports the NPRM's focus on health equity.

As noted above, NFPRHA strongly supports the administration's emphasis on health equity in the proposed rule. Acknowledging economic and social obstacles to health is a core part of the Title X statute, which emphasizes removing or lessening financial barriers to access to contraception and sexual health care. Title X-funded health centers prioritize people with low incomes and provide care regardless of ability to pay. Financial barriers are just one expression of inequity, however; US public health policy now acknowledges that it is racism, not race, that drives health disparities. Public awareness of this persistent reality has been heightened by the COVID-19 pandemic, which has mercilessly demonstrated how systemic racism and other forms of oppression result in disproportionately poor health outcomes for people of color.

It is urgent that the US dismantle the many inequities in our nation's health care system. Because of this, the ongoing effect of systemic racism on people accessing Title X care must be explicitly included and addressed as part of the final rule. The Title X family planning program and today's provision of family planning services arose out of a history in our country that includes reproductive coercion and a fundamental devaluing of the bodily autonomy of people of color and people with low incomes. This history[12] has contributed to a justifiable mistrust of the health care system, particularly with respect to family planning.[13] NFPRHA urges HHS to explicitly acknowledge and reckon with that history as a part of the final rule.

NFPRHA strongly supports the proposed additions to the definitions in the Title X regulations, including definitions for health equity and inclusivity. In particular, the transition from using the word "women" to the more inclusive "client" is greatly appreciated. Gender identity should never be a barrier to receiving the care one needs. The proposed rule's definitions help to illustrate key aspects of quality care including the importance of client-centeredness; cultural and linguistic appropriateness; and recognition of how trauma affects people. Defining how services should be provided is an important step toward a more equitable Title X program.

However, the language in section 59.5(a)(4), which states that Title X projects must "provide services ***without regard for*** [emphasis added] religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status," seems contrary to this focus on health equity and cultural competence. If Title X providers are intended, as stated in the proposed rule, to work towards advancing health equity, it is imperative that care is delivered in a way that intentionally centers and considers the identity and needs of the patient. NFPRHA encourages HHS to revise section 59.5(a)(4) to read as follows: "Each project supported under this part must provide services in a manner that does not discriminate against any patient based on religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status."

Another provision that strengthens equity is the returned focus on Title X's priority population—low-income patients—and removal of the 2019 rule's change to the definition of "low income" to include any people—regardless of income—whose employers refuse to include coverage for such services in their employer sponsored insurance due to religious or moral objections. The NPRM defines "low income" consistent with its plain meaning and a statutory aim of Title X—to "[e]nsure that economic status shall not be a deterrent to participation" in family planning.[14]

The proposed rule creates a new criterion for scoring applications for Title X service grants to take into account "the ability of the applicant to advance health equity." NFPRHA believes that this eighth standard is consistent

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[12] *See* Dorothy Roberts, *Killing the Black Body: Race, Reproduction, and the Meaning of Liberty* (1997).

[13] *See, e.g.*, Rachel G. Logan et al., *"When Is Health Care Actually Going to Be Care?" The Lived Experience of Family Planning Care Among Young Black Women*, 31(6) Qualitative Health Research 1169 (2021), https://doi.org/10.1177/1049732321993094; Biftu Mengesha, *Racial Injustice and Family Planning: An Open Letter to Our Community*, 96(4) Contraception 217 (2017), https://doi.org/10.1016/j.contraception.2017.05.009.

[14] 42 U.S.C. § 300a-4(c).

with the core mission of Title X to make high-quality "family planning services readily available to all persons desiring such services,"[15] and complements the criteria that have successfully governed grantmaking in this program since 1971. However, it would be helpful for the Department to provide in funding announcements and supporting materials more information or examples of how such ability would be successfully demonstrated in an application, just as the Department commonly elaborates on other matters in funding announcements. Explanatory information would also provide valuable context to the independent, expert review panels that participate in the review, evaluation, and scoring of Title X applications.

The Title X program has a significant role to play in combating racism and other systemic barriers to care and in ensuring that all people, regardless of their race, ethnicity, age, sexual orientation, gender identity, immigration status, employer, insurance status, or any other demographic, have timely access to comprehensive, high-quality family planning and sexual health care services. The 2019 rule's onerous requirements diverted attention and resources from this important work. In contrast, the proposed rule's emphasis on health equity is consistent with Title X's mission to provide equitable, affordable, client-centered, quality family planning and sexual health care services.

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NFPRHA strongly supports ensuring that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients.

Despite mounting evidence that expelling well-qualified, trusted family planning providers from publicly funded health programs like Title X has adverse effects on patients' access to critical family planning and sexual health care, states in recent years have increasingly targeted specialized reproductive health care providers for exclusion from key federal health programs, including Title X. At least 17 states currently have laws on the books that could impact the Title X service delivery network should Title X funding flow through the state government.[16] State policies putting restrictions on how state funds are allocated, called "tiering," make it difficult or impossible for privately operated reproductive health–focused providers to receive funding. Tiering and other prohibitions against abortion providers often exclude the very specialist providers that are the most qualified and best-equipped to help Title X patients achieve their family planning goals. As noted in the NPRM, "[P]roviders with a reproductive health focus often provide a broader range of contraceptive methods on-site and therefore may reduce additional barriers to accessing services."[17]

The NPRM rightfully recognizes that "state policies restricting eligible subrecipients unnecessarily interfere with beneficiaries' access to the most accessible and qualified providers," and that "denying participation by family planning providers that can provide effective services has resulted in populations in certain geographic areas being left without Title X providers for an extended period of time."[18] NFPRHA strongly agrees with HHS that "state restrictions on subrecipient eligibility unrelated to the ability to deliver Title X services undermine the mission of the program to ensure widely available access to services by the most qualified providers."[19]

To best achieve the program's goals, Title X has historically funded a diverse network of service delivery providers—including state, county, and local health departments, as well as hospitals, family planning councils,

[15] *Planned Parenthood Federation of America, Inc. v. Heckler*, 712 F.2d 650, 651 (D.C. Cir. 1983) (quoting S. Rep. No. 91-1004, at 2 (1970)).

[16] Guttmacher Institute, *State Family Planning Funding Restrictions* (updated May 1, 2021), https://www.guttmacher.org/state-policy/explore/state-family-planning-funding-restrictions#.

[17] 86 Fed. Reg. at 19,817.

[18] *Id.* (citing Marion W. Carter, et al., *Four aspects of the scope and quality of family planning services in U.S. publicly funded health centers: Results from a survey of health center administrators*, 94(4) Contraception 340 (2016), https://doi.org/10.1016/j.contraception.2016.04.009).

[19] *Id.*

Planned Parenthood affiliates, federally qualified health centers, and other private non-profit organizations. These networks vary widely across communities because they are specifically established to provide the most effective care to their specific patient populations. It is therefore imperative that HHS "ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients."[20] Final Title X rule protections should fully enforce the statutory intent of the Title X program, which means making grant awards based on the applicant's ability to effectively implement the program and its governing regulations, including through subrecipients (if any). Also fundamental is the ability of any public or private nonprofit entity to apply for Title X funds, including entities that provide and/or fund entities that provide abortions outside of Title X with non-Title X funds.[21]

In December 2016, HHS under President Obama finalized a rule that added language to section 59.3 of the Title X regulations to clarify that entities could not be prohibited from participating in Title X based on anything other than the entity's ability to provide services effectively.[22] The 2016 language (bolded below) is as follows:

> § 59.3 Who is eligible to apply for a family planning services grant **or to participate as a subrecipient as part of a family planning project**?
> **(a)** Any public or nonprofit private entity in a State may apply for a grant under this subpart.
> **(b) No recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons unrelated to its ability to provide services effectively.**[23]

This language was the only issue addressed by the final 2016 rule.

In early 2017, Congress used its authority under the Congressional Review Act (CRA)[24] to overturn the rule.[25] Some may argue that, in the current rulemaking, HHS cannot include language seeking to achieve a similar goal to the 2016 rule because Congress used the CRA to overturn it. This is incorrect.

Although it is correct that the statute prohibits an agency from issuing a rule that is "substantially the same" or in "substantially the same form" as one Congress has used the CRA to overturn, the prohibition does not prevent an agency from seeking a different regulatory solution to the same issue the agency previously sought to address in the disapproved rule.[26]

By their own terms, the current NPRM and the 2016 Title X rule are not "substantially the same," and there are approaches HHS can and should take in the current rulemaking to "ensure that Title X projects do not undermine

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[20] *Id.*

[21] 42 U.S.C. § 300(a) ("The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)."); *see also* 42 C.F.R. § 59.3 ("*Any* public or nonprofit private entity in a State may apply for a grant under this subpart.") (emphasis added).

[22] *See* Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients, 81 Fed. Reg. 91,852, 91,860 (Dec. 19, 2016).

[23] *Id.*

[24] 5 U.S.C. §§ 801–808.

[25] *See* Joint Resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the final rule submitted by Secretary of Health and Human Services relating to compliance with title X requirements by project recipients in selecting subrecipients, Pub. L. No. 115-23, 131 Stat. 89 (Apr. 13, 2017).

[26] *See* 5 U.S.C. § 801(b)(2).

the program's mission by excluding otherwise qualified providers as subrecipients"[27] without running afoul of the CRA.

For example, whereas the 2016 rule in its entirety was focused on addressing the exclusion of otherwise qualified providers and was thus limited only to adding language to section 59.3 (prohibiting Title X recipients "making subawards for the provision of services as part of its Title X project [from barring] an entity from participating for reasons unrelated to its ability to provide services effectively"[28]), the current rulemaking encompasses many regulatory changes, revokes the 2019 Title X rule, and restores the 2000 regulations with modifications. Thus, if HHS incorporates language in the final rule to address the Department's concern over state restrictions on subrecipient eligibility unrelated to the ability to deliver Title X services, the 2016 and 2021 rules would still be vastly different in purpose and scope and should not trigger the CRA prohibition.

NFPRHA proposes making the following additional changes as part of the finalized version of the NPRM:

1. Add a new subsection (14) to section 59.5(a), requiring that Title X projects "Provide that, if family planning services are provided by contract or other similar arrangements with actual providers of services, no provider that would otherwise be eligible to apply for a grant or subgrant under this subpart is discriminated against, or excluded, limited, or otherwise restricted from participation in the project, based on any factor unrelated to its qualifications to provide the required services and effectively serve individuals in need throughout the service area."

2. Add language to section 59.7(a) to clarify that "Funding decisions will be made based solely on the ability of a project applicant, whether the applicant proposes to provide the project's services through its own entity or in reliance upon other entities, to provide the required services and best serve individuals in need throughout the anticipated service area."

3. Add section 59.7(d) to require that "(d) If an applicant proposes to rely on other entities to provide services under the project, no grant shall be made unless the applicant provides assurance satisfactory to the Secretary that it will meet the requirement established in 59.5(a)(12) of this subpart."

4. Add section 59.301 to a new Subpart D of 42 CFR Part 59 ("Additional Requirements"): "Prohibition on the use of certain criteria in the selection process for Federal awards and subawards. (a) No Federal agency, grantee, subrecipient, or other entity shall, in the course of administering or carrying out any program or activity under title X of the Act, discriminate against, or act in a manner which has the effect of excluding, limiting, or restricting the participation of any entity that would otherwise be eligible to apply for funds under title X of the Act, on the basis of any factor unrelated to its qualifications to effectively carry out the program or activity. (b) The Secretary shall monitor and enforce the requirements in this section, including but not limited to requiring recipients of Federal funds under title X of the Act to maintain and submit records regarding the criteria used in the decisions of the recipient or any subrecipients to recruit and retain qualified entities, including providers of health care or other services. Within thirty days of identifying noncompliance by any recipient or subrecipient, the Secretary shall take appropriate action to remedy the noncompliance, including immediate redirection of project funds from the recipient or subrecipient to a suitable, qualified alternative entity that will

[27] 86 Fed. Reg. at 19,817.

[28] 81 Fed. Reg. at 91,860.

> administer the grant funds consistent with this section while minimizing the impact of any interruption of services in the affected service area. In the event that a recipient or subrecipient relinquishes its grant funding, whether in part or in full, for noncompliance, the Secretary shall take appropriate action within sixty days of notice of relinquishment to redirect or otherwise administer the grant funds consistent with this section while minimizing the impact of any interruption of services in the affected service area, including through the approval of a sole source replacement grant to a suitable, qualified alternative entity."

Additionally, based on the experience of HHS and Title X's network of providers over the last several years, it seems clear that HHS' specific regulatory approach to addressing exclusions of qualified providers would be significantly different in its operative provisions and cost-benefit analysis, further distinguishing the 2021 rule from the disapproved 2016 rule.

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NFPRHA supports restoring and strengthening Title X's confidentiality protections.

Two interrelated hallmarks of Title X have been the program's historically strong protections for patient confidentiality and its commitment to serving adolescents. Since the 1970s, federal law has required that both adolescents and adults be able to receive confidential family planning services in Title X projects. Research shows these confidentiality protections are one of the reasons individuals choose to seek care at Title X sites.[29]

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 populations.[30] Certain groups, including adolescents and young adults, and people at risk of domestic or intimate partner violence, have special privacy concerns that require particularly strong protections.[31]

The 2019 Title X rule weakened these protections by requiring providers to encourage family involvement even when it could be harmful; by giving the Secretary oversight authority in the enforcement of complex and nuanced state reporting laws; and by imposing new inappropriate reporting and documentation obligations on providers. In doing so, the 2019 rule undermined the provider-patient relationship to the detriment of public health.

The NPRM would reinstate the Title X confidentiality regulations in place prior to the 2019 rule[32] while making important improvements. First, the NPRM eliminates the 2019 rule's unnecessary and harmful requirements to

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[29] Jennifer J. Frost et al., *Specialized Family Planning Clinics in the United States*, 22(6) J. Women's Health Issues E519–E525 (2012), https://www.whijournal.com/article/S1049-3867(12)00073-4/fulltext.

[30] Rachel B. Gold, *A New Frontier in the Era of Health Reform: Protecting Confidentiality for Individuals Insured as Dependents*, 16(4) Guttmacher Pol'y Rev. 2, 2 (2013), https://www.guttmacher.org/sites/default/files/article_files/gpr160402.pdf.

[31] Pamela J. Burke et al., *Sexual and Reproductive Health Care: A Position Paper of the Society for Adolescent Health and Medicine*, 54 J. Adolescent Health 491, 491–96, (2014), https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf; Diane M. Reddy et al., *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services*, 288(6) J. Am. Med. Ass'n 710, 710–14 (2002), https://jamanetwork.com/journals/jama/fullarticle/195185; 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*, 293(3) J. Am. Med. Ass'n 340, 340–48 (2005), https://jamanetwork.com/journals/jama/fullarticle/200191; Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 J. Adolescent Health 36, 36–43 (2017), https://pubmed.ncbi.nlm.nih.gov/29157859/; , Family Violence Prevention Fund, *National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings* (2004), http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf.

[32] Title X's confidentiality requirements are currently largely codified at 42 C.F.R. § 59.11; the NPRM proposes reorganizing the Title X regulations so that the confidentiality section would now be section 59.10

take and document specific actions to encourage family involvement in the family planning decision-making of all adolescents, without including the statutory limitation "[t]o the extent practicable."[33] Those requirements completely disregarded the expertise, training, and experience Title X providers already use in assisting adolescents to involve their families in decisions about family planning services and other key health care matters when realistic and appropriate.

Second, the NPRM eliminates the 2019 rule's requirement giving HHS substantial oversight over compliance with complex state reporting requirements concerning child abuse, child molestation, sexual abuse, rape, incest, or human trafficking. Combined with the 2019 rule's requirements to collect and document specific information in Title X records, as well as giving HHS the authority to impose harsh penalties if HHS—not the state—believes a Title X project is out of compliance with state requirements, the 2019 rule pushed providers toward inappropriate screening and over-reporting that would harm patients and undermine the provider-patient relationship, ultimately resulting in fewer patients seeking critical health services.

Determinations regarding compliance with state reporting laws properly rest with state authorities. State reporting laws are complex and vary widely from state to state.[34] They seek a nuanced balance between the need to protect those who experience abuse and ensure that law enforcement can bring victimizers to justice with the need to ensure that patients are able to seek critical health care services they might avoid if they do not trust their health care provider. Thus, many state laws include both specific requirements that trigger an obligation to make a report and others that allow for the exercise of discretion by health care professionals.

The 2019 rule purports to solve a problem that does not exist. Professionals providing services in Title X-funded sites are aware of their reporting obligations, already receive training on them, and make reports in compliance with these requirements. Title X providers take seriously their reporting obligations and their responsibility to protect their patients from real risks of exploitation and abuse.[35]

Third, the NPRM adds important clarification to how Title X-funded entities are to balance client confidentiality with the program's statutory requirement that "no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge."[36] In that regard, NFPRHA welcomes the NPRM's addition of language codifying a longstanding practice that had been included in the 2014 Title X Program Requirements that reasonable efforts must be made to "collect charges without jeopardizing client confidentiality," along with a new requirement that clients be informed of "any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client."[37] The Department is right to recognize the potential for harm from varied state and local laws regarding the accessibility of patient information to insurance policyholders who are not the patient. As more and more patients have access to insurance, the potential risks of disclosure of sensitive information have increased. These proposed additions to the Title X regulations will help to ensure that confidentiality remains paramount in Title X.

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[33] 42 U.S.C. § 300.

[34] *See, e.g.*, Rebecca Gudeman & Erica Monasterio, *Mandated Child Abuse Reporting Law: Developing and Implementing Policies and Training*, Nat'l Ctr. for Youth L. & Fam. Plan. Nat'l Training Ctr. for Service Delivery (2014), http://www.cardeaservices.org/documents/resources/Mandated-Child-Abuse-Reporting-Law-GUIDE-20140619.pdf.

[35] Position Paper of the American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists & Society for Adolescent Health and Medicine, *Protecting Adolescents: Ensuring Access to Care and Reporting Sexual Activity and Abuse*, 35 (5) J. Adolescent Health 420–23 (2004).

[36] 42 U.S.C. § 300a-4.

[37] 86 Fed. Reg. at 19,820.

The NPRM proactively addresses the potential within the Title X regulations themselves for harm related to disclosure of a patient's sensitive information to third parties such as policyholders who are not the patient. In addition, HHS should evaluate Title X's interaction with other laws and regulations for possible conflicts that could undermine Title X clients' confidentiality and potentially subject them to harm. For example, the final rule, "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program"[38] (ONC rule), contains information-blocking provisions that went into effect April 5, 2021. The ONC rule requires that a broad range of electronic health information (EHI) be made immediately available to patients and bans the withholding of EHI as "information blocking." Title X clients could be harmed if third parties gain access to EHI containing sensitive information that is disclosed pursuant to the information-blocking ban. However, the information-blocking ban contains several exceptions, including a "privacy exception" that allows information to be withheld to comply with state or federal privacy laws. NFPRHA presumes that if sensitive information were withheld in compliance with Title X's confidentiality protections, that would fall within the ONC rule's privacy exception and would not constitute information blocking.[39] To avoid any confusion, however, it would be helpful for HHS to make this presumption explicit in the final version of this NPRM or through another regulatory vehicle.

Additionally, NFPRHA urges HHS to include language clarifying that longstanding prohibitions on requiring parental notice and consent in Title X remain in effect. Efforts to require parental consent or notification for Title X-funded family planning services have been consistently rejected by the courts. Consistent with the Title X statute, regulations governing the program at that time, and case law, the 2001 Title X Guidelines,[40] which combined program requirements and clinical program guidelines, contained a section specifically on adolescent confidentiality and explicit statements regarding parental notice and consent. When the 2001 Title X Guidelines were replaced by the 2014 Title X Program Requirements,[41] that explicit language was removed, even though the principles articulated in the 2001 Title X Guidelines were then and are still valid. To assuage widespread concerns about whether the protections remained in effect following removal of the language, on June 5, 2014, OPA released an "OPA Program Policy Notice" (PPN)[42] clarifying that Title X's protections remain unchanged in the 2014 Program Requirements. While these protections thus exist in that subregulatory guidance, they are absent from the actual Title X regulation.

To alleviate any confusion**,** NFPRHA recommends the following language—which is identical to PPN 2014-1 and the 2001 program guidance—be added to the end of section 59.10 as follows:

> "Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services."

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[38] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25,642 (May 1, 2020).

[39] A Title X provider's actions in compliance with Title X's confidentiality protections would almost certainly meet the ONC rule's privacy exception. In the alternative, given the importance of Title X's confidentiality protections in preventing physical and/or emotional harm to clients, the withholding of EHI might also not be considered information blocking because it would fall under the ONC rule's "preventing harm" exception.

[40] Office of Population Affairs, *Program Guidelines for Project Grants for Family Planning Services*, § 8.7 (Jan. 2001), https://www.ncbi.nlm.nih.gov/books/NBK215204/.

[41] Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects*, Version 1.0 (Apr. 2014), https://opa.hhs.gov/sites/default/files/2021-03/title-x-program-requirements-april-2014.pdf.

[42] Office of Population Affairs, *OPA Program Policy Notice 2014-01—Confidential Services to Adolescents* (June 5, 2014), https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/program-policy-notices/opa-program-policy-notice-2014-01-confidential-services-to-adolescents.

NFPRHA strongly supports the NPRM's return to the core mission of Title X and adherence to nationally recognized standards of care.

Title X was enacted in 1970 expressly to make "'comprehensive family planning services readily available to all persons desiring such services."[43] Specifically, many people with low-incomes had more children than they desired because both the pill and the other most effective contraceptive method at the time, the copper intrauterine device (IUD), were available only through medical professionals and at a high cost, both for the contraceptive itself and for medical visits. President Richard M. Nixon therefore called on Congress to "establish as a national goal the provision of adequate family planning services . . . to all those who want them but cannot afford them," stressing that "no American woman should be denied access to family planning assistance because of her economic condition."[44]

Congress responded with overwhelming bipartisan support, enacting Title X to help people living with low incomes who desired but could not access the contraceptive methods that more affluent members of society could access. Congress noted that these individuals were "forced to do without, or to rely heavily on the least effective nonmedical techniques for fertility control unless they happen to reside in an area where family planning services are made readily available by public health services or voluntary agencies."[45] Congress stressed that it sought to establish a comprehensive family planning program and to make quality services readily available to those with low incomes—not simply expand the number of individuals served.[46] Congress also recognized that, in this area of individuals' reproductive decision-making, Title X required "explicit safeguards to [e]nsure that the acceptance of family planning services and information relating thereto must be on a purely voluntary basis by the individuals involved."[47]

Thus, through Title X, Congress sought to provide people with low incomes with biomedical contraceptives, with equal access to high-quality family planning medical care, and with the true freedom to make their own decisions about whether and when to have children. The statute requires Title X projects to "offer a broad range of acceptable and effective family planning methods and services," and that persons from low-income families be given priority in the Title X program and that no charge may be made for the services and supplies provided for those persons. In the decades since it first began, and prior to the 2019 rule, Title X projects provided high-quality, up-to-date services that were considered the gold standard of family planning care.

The 2019 rule undermined this longstanding standard of care in a variety of ways: It eliminated the term "medically approved" from the longstanding regulatory requirement that projects provide "a broad range of acceptable and effective medically approved family planning methods;"[48] included overly permissive language that opened the door to participation in the program by providers who object to fundamental tenets of the Title X program, and diverged from the nationally recognized clinical standards, the Quality Family Planning guidelines (QFP), published by the CDC and OPA in 2014. Furthermore, the 2019 rule made drastic changes to pregnancy counseling by Title X providers that contradicted Congress' explicit, repeated mandates; ignored central principles of medical ethics; and, attempted to enlist clinicians in deceiving and delaying patients who seek information about or access to abortion providers.

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[43] *Heckler*, 712 F.2d at 651 (quoting S. Rep. No. 91-1004, at 2 (1970)).

[44] Richard Nixon, *Special Message to the Congress on Problems of Population Growth* (July 18, 1969), https://www.presidency.ucsb.edu/documents/special-message-the-congress-problems-population-growth.

[45] S. Rep. No. 91-1004, at 9 (1970).

[46] *See id.* at 10; 84 Stat. 1504.

[47] S. Rep. No. 91-1004, at 12.

[48] *See* 84 Fed. Reg. at 7,787; Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502, 25,515 (June 1, 2018).

NFPRHA applauds HHS for the proposed rule's return to the core mission of the Title X program—a program that will once again match patients' expectations that they will receive high-quality, client-centered care that provides comprehensive, medically accurate counseling and information, and referrals for any other services sought.

In particular, NFPRHA supports the following changes and urges HHS to swiftly finalize them:

- The inclusion of "FDA-approved contraceptive services" and reinstatement of the term "medically approved" to the proposed definition of family planning services;
- The restoration of adherence to and explicit reference in the rulemaking to nationally recognized standards of care (including the QFP, as periodically updated), standards by which OPA can once again monitor and evaluate Title X project performance in furtherance of the core mission of Title X;
- The recognition that "offering only a single method of family planning could unduly limit Title X clients, especially low-income clients, by reducing access to a client's method of choice," and the new requirement that sites that do not offer "the broad range of methods on-site" provide clients with a client-centered referral to a provider that does offer the client's method of choice;[49]
- The focus on providing services "in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with national recognized standards of care";[50]
- The reinstatement of the requirement to offer nondirective options counseling to pregnant patients upon request on all options relating to their pregnancy, including abortion referral;
- The revocations of the prohibition on referrals for abortion; the requirement that providers refer pregnant patients for prenatal care, regardless of their expressed wishes; the erroneous declaration that prenatal care is "medically necessary" for all pregnant persons; the requirement that Title X providers maintain physical, staff, and administrative system separation from locations that provide abortion as a method of family planning and from other abortion-related activities; and the requirement that counseling be provided only by physicians or "advanced practice providers," meaning "medical professional[s] who receive[] at least a graduate level degree in the relevant medical field"; and
- The restoration of statutorily based criteria for awarding Title X grants and the elimination of the discretion the 2019 rule gave to HHS to disqualify Title X grant applicants even before the competitive review process begins if the agency deems an applicant to have insufficiently described how it will satisfy all regulatory requirements.

NFPRHA strongly supports the proposed rule's emphasis on relying on nationally recognized standards of care when providing Title X-funded clinical care. As the proposed rule states, revocation of the 2019 rule is necessary to undo "the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations with fewer opportunities for care are relegated to inferior access."[51] One way the 2019 rule perpetuates such a two-tiered system is by deliberately shunning nationally recognized clinical standards.

Clinical standard-setting is well-established and routinely undertaken by federal agencies, medical specialty groups, and professional societies. According to the American Medical Association, "[m]edical professional associations, specialty societies, and voluntary health organizations became involved in developing standards of care in an increasingly rigorous fashion"[52] by the late 1980s. By the early 2000s, the American Medical Association stated that "[t]here is now little debate about [standards of care's] validity and importance for the

[49] 86 Fed. Reg. at 19,819.

[50] *Id.* at 19,830.

[51] *Id.* at 19,817.

[52] Eleanor D. Kinney, *The Origins and Promise of Medical Standards Of Care*, 6(12) AMA J. of Ethics 574–76 (2004), https://journalofethics.ama-assn.org/article/origins-and-promise-medical-standards-care/2004-12

delivery of high quality medical care."[53] Health care providers determine what care is appropriate and inappropriate based on medical standards of care and best-available evidence. This is critically important for both quality of care and health equity.

The 2019 rule ignored this fact, and the NPRM rightfully restores that focus. Of utmost importance in the NPRM is its reinstatement of the requirement on nondirective options counseling. The proposed rule, reflecting both federal law and clinical standards of care, puts patients' own stated needs at the heart of pregnancy counseling. It does not mandate the type of counseling, information, or referral pregnant people receive; rather, it ensures that pregnant people are provided the opportunity to receive counseling on all of their options, have their questions answered, and receive information relevant to whatever options they might choose, as well as receiving any referral they request. The American College of Obstetricians and Gynecologists,[54] the American Academy of Family Physicians,[55] and the American Academy of Pediatrics[56] endorse this approach in their practice recommendations. By reinstating the requirement that Title X projects provide nondirective pregnancy counseling, including referrals upon patient request, the NPRM adheres to medical ethics and congressional mandates.[57]

Standards of care related to family planning care develop over time, as acknowledged in the QFP.[58] First released in 2014, the QFP has been periodically updated, and as new evidence emerges, that will continue. To ensure quality and equity, Title X health centers rely on protocols that reflect the QFP and other federal and professional medical associations' recommendations for clinical care. The NPRM recognizes that the use of evidence-based medicine is essential to achieving quality of care and health equity.

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Modernizing the Title X regulations is important to the program's future success.

Despite the Title X program's success over the course of its history, including the nearly two decades spent operating under the 2000 regulations that serve as the basis of this NPRM, changes in the health care delivery landscape necessitate updates to the Title X regulations to account for the context in which services currently are delivered in the family planning safety net. As initially enacted and still today, the Title X program's essential purpose is to ensure access to comprehensive, high-quality family planning care for all, without Title X patients being subject to outdated or cost-based limits on their health care. Medical care continues to evolve in important ways, and Title X patients should not be left out of care advances now or in the future.

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53 *Id.*

54 American College of Obstetricians & Gynecologists (ACOG), Committee Opinion No. 819, 137(2) *Obstetrics & Gynecology* e34–e41 (2009), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2021/02/informed-consent-and-shared-decision-making-in-obstetrics-and-gynecology.pdf.

55 David A. Moss et al., *Options for Women with Unintended Pregnancy*, 91(8) Am. Fam. Physician 544–49 (2015), https://www.aafp.org/afp/2015/0415/afp20150415p544.pdf.

56 Laurie L. Hornberger et al., *Diagnosis of Pregnancy and Providing Options Counseling for the Adolescent Patient*, 140(3) Pediatrics (2017), https://pediatrics.aappublications.org/content/pediatrics/140/3/e20172273.full.pdf.

57 *Consolidated Appropriations Act, 2021*. Pub. L. No. 116-260. *U.S. Statutes at Large* 133 (2019). U.S. Congress. House. Committee on Energy and Commerce. *Title X Pregnancy Counseling Act of 1991: Report (to accompany H. 3090).* 102nd Congress, 1st session, 1991. H. Rep. 102-204. U.S. Congress. Senate. Committee on Labor and Human Resources. *Title X Pregnancy Counseling Act of 1991: Report (to accompany S. 323).* 102nd Congress, 1st session, 1991. S. Rep. 102-86.

58 *See* CDC, Proving Quality Family Planning Services: Recommendations of CDC and the US Office of Population Affairs, 63 Morbidity & Mortality Weekly Report No. 4 (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf; Loretta Gavin et al., Update: Providing Quality Family Planning Services—Recommendations from CDC and the US Office of Population Affairs, 2015, 65 Morbidity & Mortality Weekly Report No. 9, 231–234 (Mar. 11, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf; Loretta Gavin et al., Update: Providing Quality Family Planning Services—Recommendations from CDC and the US Office of Population Affairs, 2017, 66 Morbidity & Mortality Weekly Report No. 50, 1383–1385 (Dec. 22, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6650a4-H.pdf.

In section 59.5(a)(9), the Department proposes a requirement that each project must take "reasonable measures to verify client income, without burdening clients from low-income families." This requirement is consistent with Title X's mission and supportive of the NPRM's emphasis on health equity, including the impact that cost-sharing has on access to health care. NFPRHA supports this requirement and asks that the final rule confirm that Title X projects *may* rely solely on patient self-reporting in assessing income, as is consistent with past practice in Title X projects.

The NPRM makes an important update in section 59.5(b)(1) in recognition that medical services in many Title X-funded health centers can be and are provided by health care providers who are not physicians. In fact, the NPRM preamble specifically mentions physician assistants and nurse practitioners as the types of health care providers that provide consultation in Title X settings. Indeed, nurse practitioners, certified nurse midwives, and physician assistants accounted for 67% of the Title X program's full-time equivalent (FTE) Clinical Services Providers (CSPs) in 2019; physicians and registered nurses with an expanded scope of practice accounted for 24% and 9% of all CSP FTEs, respectively.

However, it is important to note that "consultation by a [health care] provider" is not and should not be limited only to the examples cited by HHS, as these CSPs represent only one type of health care providers in Title X settings.[59] In 2019, 23%—or more than 1.07 million—of family planning encounters fell under the primary responsibility of other service providers, including registered nurses practicing within a standard scope of practice, licensed practical nurses, health educators, and social workers.[60] These professionals not only account for a substantial number of Title X encounters on their own, but also provide critical support to CSPs in team-based care models typical in modern health care delivery. They are more likely to be Black, Indigenous, and people of color (BIPOC)—racial and ethnic groups that are both persistently underrepresented in health care professions and more reflective of people served through the Title X program.[61] NFPRHA encourages HHS to elevate the critical role these health care professionals play in the Title X program.

Among the enhancements it proposes to the program, HHS also specifically highlights "telemedicine." The importance of telehealth, more broadly, has been growing in recent years and has become particularly clear in the context of the COVID-19 public health emergency. Since spring 2020, use of telehealth modalities has allowed tens–if not hundreds–of thousands of Title X users to remotely access many Title X services without placing themselves at increased risk for potential COVID-19 exposure. That said, the Department's use of the term "telemedicine" in the NPRM instead of "telehealth" is of concern. "Telehealth" refers to a broader scope of remote health care services than telemedicine and includes health services such as counseling and education. Accordingly, in addition to its change from "physician" to "[health care] provider" in section 59.5(b)(1), HHS can further improve the Title X regulations by explicitly naming and defining "telehealth" in that same section as follows:

> 59.5(b)(1): Provide for clinical and other qualifying services related to family planning (including consultation by a healthcare provider, family planning counseling and education, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, including audio-only modalities, regardless of the patient's or provider's setting, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

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[59] C. Fowler et al., *Family Planning Annual Report: 2019 National Summary* (2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.

[60] *Id.*

[61] Edward Salsberg et al., *Estimation and Comparison of Current and Future Racial/Ethnic Representation in the US Health Care Workforce*, 4(3) JAMA Network Opene213789, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2777977.

In section 59.5(b)(6), the rule maintains a requirement that "family planning medical services will be performed under the direction of a physician with special training or experience in family planning." However, there are many states where some of these non-physician clinicians are permitted to practice without the supervision of physician. For instance, 23 states, the District of Columbia, Guam, and the Northern Mariana Islands permit a nurse practitioner to practice independently without the supervision of a physician.[62] NFPRHA recommends that the word "physician" in section 59.5(b)(6) be replaced by "licensed health care provider."

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***The NPRM's overstatement of certain refusal provisions should be corrected*.**

Citing subsection (d) of the Church Amendment[63] and the Weldon Amendment,[64] the proposed rule's preamble indicates that objecting grantees "will not be required to follow the proposed rule's requirements regarding abortion counseling and referral."[65] Elsewhere, it states that, "[u]nder these [refusals] statutes, objecting providers or Title X grantees are not required to counsel or refer for abortions."[66] 86 FR 19818; *see also* 86 FR 19817. In doing so, the NPRM assumes broad refusal allowances that are not authorized by the federal laws on which the Department purports to rely (the "refusal statutes") and that would perpetuate the very harms the NPRM professes to address by impairing patients' ability to obtain comprehensive medical information and care. The Department should correct the NPRM's misstatements of these refusal statutes' scope as it finalizes the new Title X regulations.

Other than to correct the NPRM's misstatements, there is no need to address the refusal statutes at all in the context of this rulemaking; those provisions of federal law speak for themselves and cannot be altered by rulemaking under Title X.[67] To the extent the Department refers to these statutes in the final rule, however, it should modify the preamble's language to match what is actually required under the statutes. The proposed rule's preamble currently elides key distinctions between the refusal statutes' application to grantees (entities) and employees (individuals), and it both misstates and overstates the scope of those laws.

Subsection (d) of the Church Amendment, upon which the proposed rule relies, refers only to *individuals*; it states that "[n]o individual shall be required" to perform or assist in the performance of certain activities.[68] As the Supreme Court has stated, where a statute "does not define the term 'individual,'" the word is presumed to refer only to natural persons, not "organization[s]" or entities.[69] Therefore, by its terms—
=and underscored by its title—this provision does not grant any right of refusal to entities whatsoever, regardless of whether they are a Title X grantee or a subrecipient. Consequently, this cited section provides no authority for the preamble's statement that objecting "Title X *grantees* are not required to counsel or refer for abortions."[70]

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[62] https://www.aanp.org/advocacy/state/state-practice-environment.

63 42 U.S.C. § 300a–7(d).

64 Consolidated Appropriations Act, 2021, Pub. L. No. 116–260, Div. H, § 507(d) (2020) (emphasis added).

65 86 Fed. Reg. at 19,818. The Proposed Rule does not mention the Coats-Snowe Amendment, 42 U.S.C. § 238n, another refusal statute that does not implicate Title X.

66 *Id.* at 19817.

67 *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9,968, 9,973 (Feb. 23, 2011) (recognizing both that "[h]ealth care entities must continue to comply with the long-established requirements of the statutes . . . governing Departmental programs" and that the refusal "laws and the other federal statutes have operated side by side often for many decades").

68 Indeed, that section is titled "Individual rights respecting certain requirements contrary to religious beliefs or moral convictions."

69 *Mohamad v. Palestinian Auth.*, 566 U.S. 449, 454–55 (2012).

70 86 Fed. Reg. at 19,817 (emphasis added).

Unlike subsection (d) of the Church Amendment, the Weldon Amendment covers entities as well as individuals. Its scope, however, is narrow. The Weldon Amendment provides:

> None of the funds made available in this Act may be made available to a Federal agency or program, or to a state or local government, if such agency, program, or government subjects any institutional or individual health care entity to *discrimination* on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.[71]

The amendment's scope is limited in three important ways.

First, the Weldon Amendment regulates the behavior of a limited group of actors: "Federal agenc[ies] or program[s], or . . . state or local government[s]." The Department of Justice has explained, on behalf of the United States, that the mere receipt of Federal funds does not mean that an organization, such as a recipient of Title X funds, is a Federal agency or program covered by the Amendment.[72] Therefore, the mere fact that a nongovernmental organization may accept Title X funds does not mean that the organization is subject to the Weldon Amendment.

Second, the Amendment's prohibition on discrimination does not prevent the limited group of governmental actors to which it applies from adopting and applying neutral program requirements. As an example, consider an entity that runs a nutritional education project. If that entity also provided pregnancy counseling that does not include abortion referral and applied for a grant under a nutritional education program, the Weldon Amendment might prohibit a state government from denying that grant based on the entity's refusal to refer for abortion—a service entirely separate from the funding and program at issue. But the Weldon Amendment does not prohibit the Department from neutrally applying Title X's program rules that beneficiaries of a family planning program are best served by receiving referral for all pregnancy options, upon request. That would not be "discrimination" against entities that do not refer for abortions; it would simply be identifying the scope of the program.[73]

Third, the Amendment prohibits only "discrimination on the basis that [a] health care entity does not provide, pay for, provide coverage of, or *refer for* abortions."[74] (emphasis added). Referral for abortions is but one part of options counseling. Accordingly, by providing that entities can refuse to refer for abortion, the text of the Amendment does not suggest that Title X grantees may refuse to provide all counseling, including discussion of factual information, related to abortion. But the preamble's language currently states, incorrectly, that "objecting . . . Title X grantees are not required to counsel . . . for abortions."[75]

Read properly in accordance with their text, as described above, the Church and Weldon Amendments do not conflict with the requirement that Title X providers offer pregnancy counseling and referrals. Title X aims to provide comprehensive, non-directive family planning services to people with low incomes. As the NPRM recognizes, one key aspect of these services is nondirective options counseling, including referrals. The QFP, for example, provides that "[r]eferral to appropriate providers of follow-up care should be made at the request of the client" receiving pregnancy counseling, and "[e]very effort should be made to expedite and follow through on all referrals."[76] Construing the Church and Weldon Amendments to require government bodies to fund entities that

71 Consolidated Appropriations Act, 2021, Pub. L. No. 116–260, Div. H, § 507(d) (2020) (emphasis added).

72 Gov't Br. at 2, 28–30, *NFPRHA v. Ashcroft*, No. 04-2148 (D.D.C. Dec. 24, 2004), ECF No. 9.

73 *See, e.g.*, *Agency for Int'l Dev. v. All. For Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213–14 (2013).

74 https://www.hhs.gov/sites/default/files/ocr/civilrights/understanding/ConscienceProtect/publaw111_117_123_stat_3034.pdf

75 86 Fed. Reg. at 19817.

76 Loretta Gavin & Karen Pazol, *Update: Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs*, 66(50) MMWR 1383–85 (2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6650a4-H.pdf; *see also* AMA Code of Medical Ethics Opinion 2.1.1, *Informed Consent*, (2016), https://www.ama-assn.org/delivering-care/informed-consent; *see also*

refuse to permit their staff to refer patients for abortions would decrease patients' access to information and provide them with substandard care.[77] Health care entities that refuse to refer for abortion serve as roadblocks in patients' time-sensitive searches for care.[78] The government is not required to fund entities that disregard the Department's program requirements for Title X by refusing to refer for abortion upon patient request.

For all these reasons, the Department should refrain from inaccurately discussing Federal refusal laws in finalizing the proposed rule. Those laws speak for themselves, and additional discussion in a Title X rulemaking is likely to create more confusion than clarity. Any reference to them should accurately reflect their limited scope.

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Two proposed "technical corrections" also require changes.

The NPRM also proposes making a "technical correction" to section 59.12 to include 45 CFR part 87, the "Equal Treatment for Faith-based Organizations" rule (faith-based organizations rule) in the list of regulations that apply to Title X. The previous administration, which finalized the faith-based organizations rule on December 17, 2020, explicitly declined to apply this rule to Title X. Furthermore, the faith-based organizations rule, insofar as it applies to HHS grant programs, only "applies to grants awarded in HHS social service programs." As Title X is a health service program, with grants made to entities "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services," 45 CFR Part 87 does not rightfully apply and should therefore not be included in the final Title X rule.

Currently, 45 CFR Part 92 does not apply to the Department, though it does apply to many or most Title X services sites that receive federal financial assistance (through the acceptance of Medicaid reimbursements, for example). In the final rule, the Department should clarify which entities within the Title X program are subject to 45 CFR Part 92 and section 1557 of the Affordable Care Act. If, in the future, 45 CFR Part 92 is modified in a manner that brings additional Title X entities within its scope, the Department should update Table 1 to section 59.12 at that time to again bring clarity as to the scope of 45 CFR Part 92's application.

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Rescinding the 2019 rule is an essential action necessary to restore the Title X program.

Congress created Title X because, without a national program, only a patchwork of family planning resources served some communities and those individuals with the least economic resources had the hardest time accessing quality, up-to-date family planning care.[79] The 2019 rule reinstituted the very patchwork system that Title X had been created to solve and had successfully addressed for nearly 50 years. The NPRM documents

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Farr A. Curlin et al., *Religion, Conscience, and Controversial Clinical Practices*, 356 N. Engl. J. Med. 593, 597 (2007) (most physicians surveyed believed that physicians with a moral or religious objection to a procedure are obligated to present patients with all options and refer a patient requesting that procedure to another physician who does not object to it). to present patients with all options and refer a patient requesting that procedure to another physician who does not object to it).

77 Megan L. Kavanaugh et al., *It's not something you talk about really": information barriers encountered by women who travel long distances for abortion care*, 100 Contraception 79–84 (2019) (finding that "health care providers play a crucial role in ensuring pregnant patients' right to informed consent within reproductive health care delivery").

78 *Id.* at 81–82 (some gynecologists and other providers acting as "gatekeepers" who steer patients away from abortion and refuse to provide information about how to obtain an abortion); *see also* Luciana E. Hebert et al., *Variation in Pregnancy Options Counseling and Referrals, And Reported Proximity to Abortion Services, Among Publicly Funded Family Planning Facilities*, 48(2) Persp. Sexual Reprod. Health 65–71 (2016) (providers were significantly more likely to refer for adoption than abortion, and health departments and community health centers were significantly less likely to refer to abortion and provide a list of abortion providers than comprehensive reproductive health centers).

79 *See* S. Rep. No. 91-1004, at 9.

well how the 2019 rule caused 19 Title X grantees, "231 subrecipients, and 945 service sites immediately" to withdraw from the program.[80] HHS, despite efforts to do so, "has been unable to secure new Title X grantees and service sites to meet the unmet need" with the 2019 rule in place.[81]

Providers that withdrew from Title X due to the 2019 rule have struggled to maintain health care options for vulnerable, low-income people—precisely the population that the Title X program was originally designed to help—without federal funds. Some providers have been able to access state funds, a temporary commitment that is subject to overall pressures on state budgets. Others have sought to maintain services through private fundraising and by drawing on organizational reserves. Reliance on other public monies is tenuous at best, and private fundraising is beyond the capacity of some agencies that provide family planning care. Spending down reserves is unsustainable, and in the end deeply destabilizing to non-profit organizations with missions to serve people in need year over year. The NPRM sets the foundation for re-building the nationwide network of Title X service sites.

The 2019 rule also has forced those Title X providers that have remained in the program to limit their services and waste resources on unnecessary compliance steps—resources that could otherwise go toward patient care. "Given the previous success" of the Title X program for decades under regulations finalized in 2000, "the large negative public health consequences of maintaining the 2019 rules, the substantial compliance costs for grantees, and the lack of tangible benefits," HHS correctly proposes to "revok[e] the 2019 Title X regulations."[82]

HHS should make explicit that its decision to revoke the 2019 rule is a distinct agency action from any modifications to the 2000 rule included in the final rule. That rescission decision can stand on its own, separate from the also well-supported decision to affirmatively promulgate a smaller set of regulations that updates those promulgated in 2000. Because the 2019 rule as a whole imposes such a disastrous impact on what should be a national public health service, accessible to all; destroys that essential aspect of the Title X program; and "was a solution in search of a problem," it is imperative that HHS immediately and completely rescind the 2019 rule.[83] HHS should specify that its decision to rescind the 2019 rule in full is severable from its new, affirmative promulgation of the 2021 regulations, so that if any disputes arise over the terms of the newly promulgated provisions, the agency avoids the danger of the disastrous 2019 rule rearing up again.

In particular, the 2019 rule added a lengthy set of harmful, often unclear restrictions at sections 59.13 through 59.19 that have no analogues in the original 2000 regulations and that the NPRM appropriately seeks to remove.[84] HHS should make plain that *none* of those provisions is needed for Title X's ongoing functioning and that the Department is rescinding each to avoid unnecessarily interfering with that functioning. While the NPRM discusses many of the most serious flaws in the major provisions, including the 2019 rule's counseling and physical separation requirements, a number of the confusing and overreaching restrictions being rescinded are not specifically mentioned. These restrictions are the opposite of the "bright line rules" that the 2019 rulemaking purported to impose.[85] They include vague references to "documentary evidence" of compliance (section 59.13; *see also* section 59.17(a)(2)) and to unclear metrics for the use of Title X funds (section 59.18) that go beyond the already-stringent requirements of federal grants management, Title X statutory and appropriations

[80] 86 Fed. Reg. at 19,815.

[81] *Id.* at 19,816.

[82] *Id.* at 19,817

[83] *Id.*

[84] Upon rescission of the 2019 rule, which amended but did not replace the 2000 regulations, the 2000 regulations (sections 59.1 through 59.12) that existed before those 2019 amendments would again govern. Upon promulgation of the updated set of affirmative regulations proposed in the NPRM, and their taking effect, the updated 2021 set of sections 59.1 through 59.12 would govern the program.

[85] 86 Fed. Reg. at 19,814.

requirements, and the budgets, audits, reviews, and other compliance mechanisms that have functioned well since at least 2000.

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For 50 years, the Title X family planning program has been a critical underpinning of the public health safety-net infrastructure that serves millions of people with low incomes each year.

NFPRHA appreciates the opportunity to comment on the NPRM, "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services." If you require additional information about the issues raised in these comments, please contact Robin Summers, Vice President and Senior Counsel, at rsummers@nfprha.org.

Sincerely,

Clare Coleman
President & CEO